Framework Contract SANCO/2008/01/055 Lot 1: Public Health – Contract N° SANCO/2008/01/055 Lot 1- Provision of Evaluation, Impact Assessment and Related Services to the Commission in the Areas of Public Health, Consumer Protection and Food Chain

Specific Contract: Study to measure the implementation of EU health policies at national, regional and local levels, assessing the utility of existing indicators for this task and developing new indicators as necessary

FINAL REPORT
VOLUME II – ANNEXES

submitted by

"Public Health Evaluation and Impact Assessment Consortium" (PHEIAC)

Including:

Economisti Associati srl (Lead Firm)

The Evaluation Partnership (Partner)

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CEMKA-EVAL (Partner)

30 August 2012

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Main Abbreviations and Acronyms

ITALY

AIFA	Italian Medicines Agency
Age.Na.S.	National Agency for Regional Health Services
AMR	Antimicrobial Resistance
ASL	Local Health Enterprise
CCM	National Centre for Disease Prevention and Control
CIO	Technical Commission on Healthcare Associated Infections
CNR	National Research Council
CS	Cancer Screening
CSS	National Health Council
ECDC	European Centre for Disease Prevention and Control
EIA	Environmental Impact Assessment
GISCi	Italian Working Group on Cervical Cancer Screening
GISCoR	Italian Working Group on Colorectal Cancer Screening
GISMa	Italian Working Group on Breast Cancer Screening
HAI/HCAI	Healthcare Associated Infection
HEIA	Health Equity Impact Assessment
HIA	Health Impact Assessment
HiAP	Health in All Policies
HSIA	Health Systems Impact Assessment
HTA	Health Technology Assessment
ICM	Intersectoral Coordination Mechanism
ISPESL	Institute for Prevention and Safety at Work
ISS	National Health Institute
JA	Joint Action
LEA	Essential Levels of Assistance
LILT	Italian League for the Fight Against Cancer
MS	Member State
OMC	Open Method of Coordination
ONDA	Women's Health Observatory
ONS	National Observatory of Screening
PASQ	European Union Network for Patient Safety and Quality of Care
PHP	Public Health Programme
PNP	National Prevention Plan
PRP	Regional Prevention Plan
PSN	National Health Plan
PSR	Regional Health Plan
PS	Patient Safety
RCA	Root Cause Analysis
RLS	Reporting and Learning Systems
SEA	Strategic Environmental Assessment
SIMES	Monitoring Information System on Health Mistakes
SSN	Italian National Health Service

FRANCE

ABM	Agence de la biomédecine
AFSSAPS	National Agency for the Safety of Drugs and Health Products
AMR	Antimicrobial Resistance
ANSES	National Food, Environmental and Occupational Health Agency
ANSM	National Security Agency of Medicines and Health Products
ARLIN	Antennes Régionales de Lutte contre les Infections Nosocomiales
ARS	Regional Health Agency
ATIH	Agency for Information on Hospital Care
CCEQA	Comité de coordination de l'évaluation clinique et de la qualité
CLS	Local Health Contract
CCLIN	Centres de coordination de la lutte contre les infections nosocomiales
CNIL	Commission nationale informatique et liberté
CNRS	National Centre for Scientific Research
CNS	National Health Conference
CNSP	National Committee on Public Health
CRSA	Regional Conference of Health and Autonomy
CS	Cancer Screening
CTINILS	Comité technique des infections nosocomiales et des infections liées aux soins
DGCS	General Directorate for Social Policy
DGOS	General Directorate of Health Care Supply
DGS	General Directorate of Health
DRASS	Decentralised State Services
DREES	Directorate of Research, Studies, Evaluation and Statistics
DSS	Directorate of Social Security
ECDC	European Centre for Disease Prevention and Control
EHESP	School of Higher Education in Public Health
EIA	Environmental Impact Assessment
ENEIS	Epidemiological Survey of Healthcare-associated Adverse Events
EPR	Evénements porteurs de risques
HAI/HCAI	Healthcare Associated Infections
HAS	National Health Authority
HCAAM	French High Council for the Future of Health Insurance
HCSP	High Council for Public Health
HEIA	Health Equity Impact Assessment
HIA	Health Impact Assessment
HiAP	Health in All Policies
HPST Law	Hospital, Patients, Health and Territories Act
HSIA	Health Systems Impact Assessment
INCa	National Institute for Cancer
Ineris	National Institute for Industrial Environment and Risks
INPES	National Institute for Prevention and Health Education
InVS	National Institute for Public Health Surveillance
IPAQSS	Indicateurs Pour l'Amélioration de la Qualité et de la Sécurité

	des Soins
JA	Joint Action
MS	Member State
MoH	Ministry in charge of Health
OMC	Open Method of Coordination
ORS	Regional Health Observatory
PASQ	European Union Network for Patient Safety and Quality of Care
PC	Action Plan on Cancer
PHP	Public Health Programme
PHP Law	Law on Public Health Policy
PMSI	Programme de Médicalisation des Systèmes d'Information
PRS	Regional Health Projects
PS	Patient Safety
PSI	Patient Safety Indicators
PSRS	Regional Strategic Health Plans
PST	Health at Work Plan
RAISIN	Réseau d'alerte, d'investigation et de surveillance des infections nosocomiales
RPS	Regional prevention scheme
SEA	Strategic Environmental Assessment
SHI	Statutory Health Insurance

SWEDEN

AMR	Antimicrobial Resistance
CAP	Common Agricultural Policy
CS	Cancer Screening
ECDC	European Centre for Disease Prevention and Control
EIA	Environmental Impact Assessment
FAS	Swedish Council for Working Life and Social Research
FHI	Swedish National Institute of Public Health
HAI/HCAI	Healthcare Associated Infections
HIA	Health Impact Assessment
HiAP	Health in All Policies
HSIA	Health Systems Impact Assessment
ICM	Intersectoral Coordination Mechanism
JA	Joint Action
KBF	Municipal Basic Facts for Public Health Planning
MS	Member State
OMC	Open Method of Coordination
PASQ	European Union Network for Patient Safety and Quality of Care
PH	Public Health
PHP	Public Health Programme
PS	Patient Safety
RAF	Reference Group for Antibiotic Questions
RCC	Regional Cancer Centre
SBU	Swedish Council on Health Technology Assessment
SE	Sweden

SEA	Strategic Environmental Assessment
SKL	Swedish Association of Local Authorities and Regions
SOSSEG	Swedish Organised Service Screening Evaluation Group
SOU	Official Government Inquiries
VBF	Local Welfare Accounts

POLAND

AMR	Antimicrobial Resistance
CS	Cancer Screening
ECDC	European Centre for Disease Prevention and Control
EIA	Environmental Impact Assessment
HAI/HCAI	Healthcare Associated Infections
HIA	Health Impact Assessment
HiAP	Health in All Policies
HSIA	Health Systems Impact Assessment
JA	Joint Action
MS	Member State
OMC	Open Method of Coordination
PASQ	European Union Network for Patient Safety and Quality of Care
PHP	Public Health Programme
PS	Patient Safety
SEA	Strategic Environmental Assessment

ANNEX A – MAPPING OF POLICY ACTIONS REQUESTED OF MEMBER STATES AND INDICATORS PROPOSED

Introduction

The mapping factsheets below provide lists of actions requested of the MS by EU soft-law instruments in the twenty-one policy areas identified in the context of the Study. In the case of specific 'verticals' the corresponding objective of the Health Strategy is indicated. Requested actions are classified on the basis of the taxonomy elaborated in this Report.

The mapping includes also indicators that were previously proposed, classified again on the basis of the proposed taxonomy. The list reports further relevant indicators that are found to be missing and can be usefully considered, based on a review of the policy actions and the information available on the possible causes of success or failure in implementation. An initial review of the possible factors impacting on implementation is also provided. Finally, a paragraph of preliminary comments highlights notable features of the proposed indicators, identifies possible sources of data and outlines issues to be eventually addressed in the implementation of the system of indicators.

Each factsheet is structured as follows. First policy actions requested to MS are classified, based on the classification framework proposed in Volume I. Then the indicators already proposed by the various sources consulted are listed and classified in a similar way. Then a summary review is made of the most likely factors impacting on policy uptake which eventually leads to the section on proposed missing indicators. The combination of proposed and missing indicators is finally used as a basis for the policy matrix of Table 2.1 in Volume I. Whenever possible, information is also provided on whether there is consensus on the way health outcomes and impacts can be measured by means of indicators.

The template of the factsheet is structured according to the following format:

<table>
<tr><td colspan="4">Relevant actions directly envisaged in the strategy</td></tr>
<tr><td colspan="2">Other relevant EU Policy documents</td><td colspan="2">Actions envisaged therein</td></tr>
<tr><td>Availability of relevant preparatory study with proposed indicators</td><td>Availability of impact assessment report with proposed indicators</td><td>Availability of implementation report with proposed indicators</td><td>Reporting requirement on Member States</td></tr>
<tr><td colspan="2">Already proposed indicators from various sources</td><td colspan="2">Already proposed indicators from various sources</td></tr>
<tr><td colspan="2">Likely factors impacting on implementation and level of uptake</td><td colspan="2">Missing indicators i.e. actions envisaged not covered by already proposed indicators</td></tr>
</table>

Principle 1. Shared Health Values: universality, access to good quality care, equity and solidarity of healthcare systems, citizens' empowerment, reduction of health inequalities

<table>
<tr><td colspan="4">

- Member States Actions Stated in the Strategy
- PRI. Adopt a statement on fundamental health values
- HAR. Improve collection, compatibility and comparability of health data
- EXC. Exchange best practices

</td></tr>
<tr><td colspan="2">

Linked Communications/Recommendations

- CONC. Common values and principles in European Union Health Systems (2006)
- COM. Solidarity in health: reducing health inequalities in the EU (2009)
- COMM. An EU Framework for National Roma Integration Strategies up to 2020 (2011)

</td><td colspan="2">

More Detailed Member States' Actions

- OBJ. Reduce health inequalities. Create more equitable access to high quality health care and prevention. Improve access to health services to migrants, ethnic minorities and other vulnerable groups.
- HAR. Establish a common set of indicators to monitor health inequalities in order to prioritize areas of improvement. Improve data collection. Provide the Commission with detailed information in relation to particular population groups and determinants.
- ANA. Establish a methodology to audit the health situation
- EXC Improve the exchange of information, knowledge and coordination of policies.
- AWA Promote initiatives aimed to raise awareness
- PRI. Place policy emphasis on reducing health inequalities.
- STR.FUND Increase the use of the funding opportunities offered by the Cohesion Policy to address health inequalities. Use the existing option under the CAP rural development facility.
- OBJ. Reduce the gap in health status between the Roma and the rest of the population
- OBJ. Provide access to quality healthcare especially for children and women, as well as preventive care and social services at a similar level and under the same conditions to the Roma as to the rest of the population.

</td></tr>
<tr><td>Preparatory Study YES</td><td>Impact Assessment YES</td><td>Implementation Report NO</td><td>Reporting Requirement NO</td></tr>
<tr><td colspan="2">

Already Proposed Process Indicators (source)

- PRI1. Number of MS whose national health strategy documents explicitly recognise the shared principles (interim evaluation)
- PRI. Number of Member States with comprehensive policy approach which can be analysed in the social OMC NSR (impact assessment)

</td><td colspan="2">

Already Proposed Process Indicators (source)

- HAR2. Eurostat working group subjective expert opinion (impact assessment)
- ANA2/ANA.4. Number and quality of studies, and access to distribution platforms (internet portal) and publications (impact assessment)
- STR.FUND Number of MS SF Programming Documents with indicators of Health Inequalities and related Committed Financing (adapted from impact assessment)

</td></tr>
<tr><td colspan="2">

Likely Factors Impacting on Implementation

- HAR. European framework methodology to analyze data on health inequality only recently proposed (2011)
- ANA. Health status audit methodology developed in the UK but apparently never transposed to other systems.
- LEG. Privacy issues in collecting data (e.g. France)
- PROG. Need for a more structured policy implementation framework in certain MS

</td><td colspan="2">

Missing Indicators

A link with mortality and morbidity indicators can be established through data on:

- OUT1. population not receiving care for financial reasons and related socioeconomic breakdown;
- IMP1. socioeconomic breakdowns of data on premature mortality, life expectancy, life expectancy in good health, etc.

A very quick proxy of the level of uptake of initiatives in MS can be given by:

- EXC.2 number of pilot projects/ best practices contributed to the EU Health Inequalities portal.
- AWA1. Number of awareness raising campaigns

</td></tr>
</table>

Preliminary Comment. Health inequalities is a policy area at a relatively early stage of development with still poorly defined analytical methodologies also at the European level. PRI remains the indicator of choice, although possibly currently formulated in too rigid terms. Given the stage of policy development, bibliographic indicators (ANA2/ANA4) can be particularly appropriate to measure the uptake in the broader policy debate at the national level. In the coming years, the number of MS implementing specific programmes targeting the Roma can represent a concrete though rough proxy for the degree of prioritisation attached to health inequities; EU policy has been too recently introduced to serve as a reference for the 2005-2011 period. It is unclear whether the social OMC national strategy reports can represent a sustainable source for comparison over time. The portal www. health-inequalities.eu is a source of information and a repository of programmes. Previous surveys carried out at the regional level by other PHP projects (www.air-healthinequalities.eu) are also available. Ostensibly, there is need for further bibliographic research. A preparatory study was drafted for the UK Presidency, however it was of limited use to draw process indicators[1].

Principle 2. Health is the Greatest Wealth

<table>
<tr><td colspan="4">Member States' Actions

• FUND. Invest in prevention, protection and improvement of the population's overall physical and mental health
• EXC. Share best practice in health prevention investment.
• RES. Development of a programme of analytical studies of the economic relationships between health status, health investment and economic growth and development</td></tr>
<tr><td colspan="2">Linked Communications/Recommendations

• CONC On the EPC- Commission Joint Report on health systems in the EU (2010)</td><td colspan="2">• FUND ensure a sustainable financing basis, a high degree of pooling of funds and a good resource allocation
• EVALencourage a cost-effective use of care,;
• PRO encourage the provision and access to primary health care services to reduce unnecessary use of specialist and hospital care.;
• PRI curb supply-induced demand by considering the interaction between demand side factors and supply side factors, etc.;
• EVAL ensuring the cost-effective use of medicines through better effectiveness assessment;
• EVAL improving data collection and information channels to increase overall system performance
• EVAL deploying health-technology assessment of the effectiveness, costs and broader impact of healthcare treatments more systematically in decision-making processes;
• PRI improving health promotion and disease prevention also outside the health sector</td></tr>
<tr><td>Preparatory Study NO</td><td>Impact Assessment NO</td><td>Implementation Report NO</td><td>Reporting Requirement NO</td></tr>
<tr><td colspan="2">Already Proposed Process Indicator (source)
FUND. Number of MS for which the investment in prevention, protection and improvement of health status has increased year-on-year (in absolute terms and as a % of healthcare spending) since 2008 (interim evaluation)</td><td colspan="2"></td></tr>
<tr><td colspan="2">Likely Factors Impacting on Implementation

• HAR. Difficulties in collecting homogenous data and item classification issues. Availability of a common classification methodology
• HAR. Delays in reporting and availability of data.
• EVAL. Tradition of evaluating programmes/ Availablity of cost assessment reports</td><td colspan="2">Missing Indicators
A link with mortality and morbidity indicators could be established through data on:
• OUT1. The cost-effectiveness of various prevention interventions;
• IMP1. The cost of not implementing health prevention best practice in terms of quality life years lost.
A very quick proxy of the level of knowledge reached in health prevention investment can be given by
• EVAL.1 Number of Cost-effectiveness evaluations /health technology assessments commissioned by the MS in the</td></tr>
</table>

[1] http://ec.europa.eu/health/ph_determinants/socio_economics/documents/ev_060302_rd06_en.pdf

	areas covered by the strategy • EXC. Number of MS contributing cost effectiveness / evaluation studies in the prevention field. • RES. Number of studies produced on the subject

Preliminary Comments. Data on expenditure in prevention (FUND) and on the effectiveness / heatlh technology assessment studies carried out (EVAL) would appear the indicator of choice to measure political commitment, although fraught with practical implementation and comparability difficulties OECD reported as the source of reference. A research indicator (RES) is best placed to capture cultural cross-contamination in the policy debate and can be complemented by very simple proxies of EU added value (EXC). PRI indicator substantially overlap with HIAP.

Principle 3. Health in All Policies

<table>
<tr><td colspan="4">Member States' Actions

• PRI Strengthen integration of health concerns into all policies at Member State and regional levels,
• ANA. Use HIAP in Impact Assessment and evaluation tools
• PRO. Support increased intersectoral cooperation in the field of health.
• ANA. Support the use of HIA and HSIA
• ANA Disseminate the online Health Systems Impact Assessment Tool
• EVAL Explore opportunities for using post-hoc evaluation to support the integration of health into other policies.</td></tr>
<tr><td colspan="2">CONC. Health in All Policies -HiAP – (2006)</td><td colspan="2">• RES. Develop the knowledge base on health and its determinants, trends in them, and in health inequalities;
• PRO/PART. Consider in the national policymaking the added value offered by cooperation between government sectors social partners, the private sector and the NGOs for public health;
• ANA undertake, where appropriate, HIA assessment of major policy initiatives with a potential bearing on health with a special attention to the impact on equity in health, including mental health, and health inequalities;
• ORG. focus on capacity building in policy analysis and development for improved intersectoral policies;</td></tr>
<tr><td>Preparatory Study
YES</td><td>Impact Assessment
NO</td><td>Implementation Report NO</td><td>Reporting Requirement NO</td></tr>
<tr><td colspan="2">Already Proposed Process Indicator (source)
• PRI.1: Number of MS with an overarching national health strategy / policy plan that includes an explicit reference to HiAP (interim evaluation)
• ANA.2. Number of MS that are referred to in publications in relation to the HiAP principle (interim evaluation)
• ANA.3. Number of MS that have developed specific tools / guidelines for health IA (interim evaluation)</td><td colspan="2"></td></tr>
<tr><td colspan="2">Likely Factors Impacting on Implementation

• LEG. Lack of a clear framework for HIA use in the public administration.
• HAR. Availability of a sufficient number of registries as a precondition.
• TRAI. Availability of professionals trained in HIA/HSIA
• ORG. Existence of a centre of expertise to play the lighthouse in HIA implementation
• ORG. Secretariat for intersectoral coordination
• AWActive dissemination of HIA principles and methodologies at all Government levels
• FUND. Resource constraints
• EVAL. Lack of convincing evidence from other</td><td colspan="2">Missing Indicators
• PRI.1. Number of MS stating commitment to HIAP in their Health strategy documents.
A very quick proxy of implementation of health in all policies in a given MS can be given by the
• PRO.1 Number of procedures established al co-ordination mechanisms have been established to consider the viewpoint of health authorities.
• EVAL.1 Number of MS with Ex Post Evaluation Reports inclusive of Health Considerations (in selected areas)
• ORG. Number of MS in which a leading centre of expertise for HIA can be identified
• ANA3 Circulation reached by HSIA in the given MS
• ORG.1 Number of MS that have established secretariats for intersectoral cooperation</td></tr>
</table>

Countries' evaluations of HIAP effectiveness	• ORG. Number of MS that have appointed centres of expertise to disseminate best practice in HiAP • PART. Number of MS that have involved NGO in HIAP policymaking • RES Number of MS with research projects on the health dimension of other policies

Preliminary Comments. The bibliographical indicator (ANA.2) is particularly relevant to capture dissemination of this relatively new policy concept. Assessment of institutional preconditions (ANA.3, PRO.1) can be a first proxy of actual implementation. There are little consolidated sources for comparison. A 2010 study for DG EMPL on Social IA reviewed the many conceptual and practical difficulties of trying to determine whether specific countries have IA systems. Commitment to the WHO Health for All and the WHO Healthy Cities programmes used as proxy indicators in the preparatory study. Baseline data available in the preparatory study are not always consistent. Need for further substantial bibliographic research. Unstructured information on local/regional developments in the HiAP field is also available in the blogsphere, see e.g. http://healthimpactassessment.blogspot.it/

Principle 4. Strengthening the EU Voice in Global Health

• PRI. Ensure in-depth analysis and dialogue between national and global health policies. • OBJ. Address challenges in coordination	
Linked Communications/Recommendations • COM. The EU Role in Global Health (2010) • COM. A European Programme for Action to tackle the critical shortage of health workers in developing countries (2006)	Member States' Actions • OBJ1. The EU should endeavour to defend a single position within the UN agencies. • OBJ.2. Ensure that their migration policies do not undermine the availability of health professionals in third countries • OBJ.3. Step up efforts to ensure that migrants have access to quality health services without discrimination. • ORG. Designate a coordinator on global health • EXC. Contribute to a platform to exchange information • FUND. Increase the proportion of financing provided for the achievement of MDG to improve the HRH situation
Already Proposed Process Indicator (source) • FUND.2. HRH Actions funded by Bilateral Means (2006 Communication)	Already Proposed Outcome/Impact Indicators (source) • OBJ.1 Number of coordinated EU statements in the WHO (World Health Assembly / WHO Europe Region Committee) vs. number of individual MS statements in the WHO (in absence of a coordinated EU statement) (interim evaluation) • OBJ.2. Number of resolutions in the WHO (World Health Assembly / WHO Europe Region Committee) cosponsored by EU MS acting together vs. number of resolutions cosponsored by EU MS acting individually (interim evaluation)
Likely Factors Impacting on Implementation • ORG. Allocation of responsibilities between Ministries at the MS level. • LEG. Legal status of migrants	Missing Indicators A link with mortality and morbidity indicators can be established through data on: • OUT.1. Number of health professionals drawn from developing countries; A very quick proxy of the level of compliance with the global coordination effort can be given by the • PRI.2 Number of MS Committed to the WHO Global Code of Practice on International Recruitment of Health Personnel.

	• ORG.2 Number of MS that have actually appointed a global health coordinator liaising with the EU one. • PRO. Number of MS that have established procedures to avoid overlapping in their global healh programmes

Preliminary Comments. Data on coordinated statements and resolutions is limited to the WHO level and therefore can provide only a partial coverage of political commitment to reduce fragmentation of initiatives. This can be complemented by data on organizational compliance (ORG.1) with appointing a global health coordinator. All actions about avoiding health discrimination of migrants are basically a subset of health inequality policies and could be monitored with the indicators envisaged under Principle 1 above. In several cases, Member States already report policies on migrants among their active policies to reduce health inequalities. Indicators on the brain drain phenomenon have been hindered so far by limited availability of data[2]. Member States formally collecting information under the provisions of the 2010 WHO Global Code of Practice on the International Recruitment of Health Personnel could also serve as a source of information in the future.

Objective 1. Fostering Good Health in Ageing Europe – Health of Older People

Linked Communications/Recommendations	Member States' Actions
• CONC. Public health strategies to combat neurodegenerative diseases associated with ageing and in particular Alzheimer's disease (2008) • COM. On a European initiative on Alzheimer's disease and other dementias (2009). • CONC. On a Research Joint Programming Initiative on Combating Neurodegenerative Diseases (2009)	• PROG. Establish a national strategy, action plan or other providing for assessable implementation arrangements aimed at improving the quality of life of patients and carers; • AWAmprove the distribution of useful information to make aware of the care principles and best practices. • LEG. Consider measures for simplifying administrative procedures for patients and carers; • TRAI improve the skills of professionals by means of training and professional and vocational development. • PROG.RES Develop a Strategic Research Agenda (SRA) and implementation plan and specify the actions, instruments and resources required for its implementation. • RES. Implement the SRA also through their national research programmes or other national research activities and disseminate research findings. • EXC. Exchange information resources and best practices • PART Involve representatives of patient and care organisations and healthcare providers including stakeholders from the private sector.
Preparatory Studies NO | Impact Assessment YES	Implementation Report NO | Reporting Requirement NO
Already Proposed Process Indicators (source) • HAR.1? Develop indicators for monitoring prevalence, incidence, and risk factors on a comparable basis between the Member States (impact assessment);	Already Proposed Process Indicators (source) • PROG.1 To monitor the coverage and content of strategies or plans established by the Member States on dementias (impact assessment); • PHP.FUND of actions in the planned Joint Action funded through the Health Programme (impact assessment, but this is actually a PHP indicator)
Likely Factors Impacting on Implementation • ORG. Availability of centres of excellence in a given MS • FUND. Resource constraints	Missing Indicators All indicators related to the AWA; PART; RES, LEG, TRAI and EXC components above. See note below for links with the related Joint Action

Preliminary Comments. In the IA progress indicators were left to subsequent identification and their monitoring is the responsibility of the European Union Health Information Committee (EHIC). To implement the Communication a Joint

[2] See Commission Green Paper on the European Workforce for Health COM (2008) 725.

Action[3] has been launched, led by the Haute Autorité de Santé (France), building also on the results of the EuroCode (European Collaboration on Dementia) Project. The JA is financed through an operating grant to Alzheimer's Europe that has a database of all the national plans produced so far . The research part envisages a body mandated to establish common conditions, rules and procedures for cooperation and coordination and to monitor the implementation of the strategic research agenda. So far no fully validated link between prevention and diminished morbidity is reported in the scientific literature, but the mater remains controversial.

Objective 1. Fostering Good Health in Ageing Europe – Tobacco

<table>
<tr><td colspan="2">Linked Communications/Recommendations</td><td colspan="2">• REC. Smoke-free Environments (2009)</td></tr>
<tr><td colspan="2">Member States' Actions

• LEG. Provide effective protection from exposure to tobacco smoke in indoor workplaces, indoor public places, public transport and, as appropriate, other public places as stipulated by Article 8 of the WHO Framework Convention on Tobacco Control
• PROG. Develop national tobacco control strategies addressing the issue of protection from tobacco smoke in both public and private settings and reduce exposure to second hand tobacco smoke of children and adolescents.
• POL Complement smoke-free policies with supporting measures and ensure adequate instruments to implement national strategies, tobacco control policies and programmes in order to ensure effective protection from exposure to tobacco smoke.</td><td colspan="2">Member States' Actions

• OBJ. Promote cessation of tobacco use, deter initiation and provide adequate treatment for tobacco dependence.
• AWA. Inform on services supporting the cessation of tobacco use on the packages of smoking tobacco products in order to raise awareness about the risks .
• ORG/EXC. Establish national focal points for tobacco control with a view to exchanging information and best practices as well as policy coordination with other Member States.
• HAR. Co-operate on a coherent framework of definitions, benchmarks and indicators
• EVAL. Monitor and evaluate the effectiveness of policy measures.
• REP. Inform the Commission of legislative and other action taken and of the results of monitoring and evaluation.</td></tr>
<tr><td>Preparatory Study YES</td><td>Impact Assessment YES</td><td>Implementation Report PART</td><td>Reporting Requirement YES</td></tr>
<tr><td colspan="2">Already Proposed Outcome/Impact Indicators (source)

• OUT.1 Changes in exposure to SHS in particular settings or for particular groups (impact assessment study)
• OUT.2 Per capita sales of tobacco products (impact assessment)
• OUT.3 Number of cigarettes smoked per smokers (impact assessment)
• IMP.1 Proportion of the population who are smokers (impact assessment)
• OUT.4 Rate of quit attempts (impact assessment)
• OUT.5 Intentions to quit smoking (impact assessment)
• IMP.2 Changes in incidence and mortality from tobacco-related diseases (impact assessment)</td><td colspan="2">Proposed Indicator (source)

• LEG.1 Number of MS that have introduced comprehensive smoke-free laws in line with their international obligations under the WHO FCTC (interim evaluation)
• ANA.2 Studies published in the peer reviewed (and grey) literature (preparatory study then dropped)
• LEG.1. Number of MS that have introduced flanking tobacco control measures including: pictorial warnings on tobacco packs; subsidised support for smokers to quit (interim evaluation)
• AWA.2 Proportion of the population that thinks secondhand smoke is harmful (impact assessment)
• POL.3 Attitudes about the acceptability of exposing others to second-hand smoke (impact assessment)
• POL.3 Level of support for smoke-free policies in public places and workplace (impact assessment);
• POL.1 Data on enforcement of and compliance with</td></tr>
</table>

[3] The JA is (i) to incorporate the 'dementia dimension' into the EU ongoing and future actions; (ii) to produce a citizen's summary of dementia prevention measures under a 'Healthy brain lifestyle' set of recommendations. (iii) to map the existing and emerging good practices related to treatment and care for persons suffering from Alzheimer's disease and other forms of dementia and to improve the dissemination and application of such practices (using, when possible, the Structural Funds); (iv) to improve epidemiological data on Alzheimer's disease and other dementias, implementing the conclusions of the EuroCoDe Project using also the planned European Health Examination Survey; (v) To map the existing and emerging good practices and improve the dissemination and application of such practices, and (vi) To establish, using the facilities provided by the Health Programme, a European Network for rights and dignity of people with dementia, which should formulate recommendations on dignity, autonomy and social inclusion, and to share best practices on respecting the rights of vulnerable adults and tackling patient abuse.

	smoke free policies (recommendation).
Likely Factors Impacting on Implementation • POL. Difficulties in enforcing policy at the workplace or in certain venues • LEG. Individual rights consideration • AWA. Cultural / lifestyle trends among certain groups • FUND. Lack of resources • LEG. Lobbying from concerned stakeholders	Missing Indicators No indicator has been proposed on: • PROG. the existence of comprehensive strategies / programmes • ORG. the establishment of focal points to act as liaison offices • EVAL. availability of monitoring and evaluation reports on smoking cessation / prevention programmes • EXC. contribution to exchange of best practices • HAR.2 Degree of harmonisation reached in indicators on tobacco policies

Preliminary Comments. The relevance of the bibliographic indicator proposed in the preparatory study is of dubious relevance. Comprehensive information over time on most indicators in available in the WHO surveys on the degree of implementation of the Framework Convention on Tobacco Control. To be verified whether comparable data are available on outcome and impact indicators and the information that can be retrieved from the relevant PHP projects. Eurobarometers on Tobacco available as sources of information on awareness.

Objective 1. Fostering Good Health in Ageing Europe – Nutrition

Linked Communications/Recommendations	• CONC. Council Conclusions on Obesity Nutrition and Physical Activity (2005) • White Paper on a Strategy for Europe on Nutrition, Overweight and Obesity related health issues (2007)
Member States' Actions • OBJ. Enable citizens to make healthy dietary choices. Address the decline in physical activity levels in recent decades. • AWA. Fostering citizens´ knowledge on diet and health; • LEG. Ensure that consumers are not misled by advertising, and that especially the credulity of children is not exploited. Encourage the development of codes of conduct regarding commercial communication targeted at children; • AWA/PRO. Enable health professionals to give on a routine basis practical advice on the benefits of optimal diets and increased levels of physical activity; • EXC. Contribute to the exchange of best practices in this field; • PART/LEG.VOL. Encourage stakeholders to take initiatives voluntary action or agreements;	Member States' Actions • PRI.ORG. Mainstream nutrition and physical activity into all relevant policies at local, regional, national levels (employers, urban environments, etc); • RES. Further develop research and the scientific basis for actions in the field • AWA Foster education on healthy dietary choices at schools • OBJ. Encourage children and adolescents to exercise on a regular daily basis; • AWA Develop nutrition and physical education activities for children as an integrated part of health education in general • AWA. Encourage the involvement of the media sector in order to develop common messages and campaigns. • HAR.EVAL Develop comparative indicators for monitoring. • PART. Develop partnerships for local actions that can support voluntary initiatives such as responsible advertising.
Preparatory Study NO / Impact Assessment YES	Implementation Report YES / Reporting Requirement YES
Already Proposed Outcome /Impact Indicator (source) • OUT.1 BMI (impact assessment) • OUT.2 Waist circumference (impact assessment) • OUT.3 Consumption of Fruit and Vegetables (impact assessement). • LEG/LEG.VOL Legislation / voluntary initiatives requiring nutritional labelling or signposting (ir) • LEG/LEG.VOL- Legislation / voluntary	Already Proposed Process Indicator (source) • DEL- Salt reduction initiatives (in line with the EU target of 16% reduction by 2013 (implementation report) • DEL Initiatives promoting better urban design to provide safe and attractive structures for everyday physical activity (ir) • PRO- Provision of guidelines for physical activity / education campaigns (implementation report) • LEG- Mandatory inclusion of physical education in schools

initiatives on the marketing of unhealthy food and beverages to children (implementation report) • AWA. Information and education campaigns (ir) • LEG. Existence of measures affecting food prices • DEL. Initiatives to increase availability of processed foods with reduced content of total fat and/or added sugar (implementation report)	• DEL - Provision of free or subsidized school meals / promotion of healthy food (implementation report) • TRAI - Role of health and education professionals (ir) • EVAL- Strengthening monitoring and evaluation (ir) • PART Engaging commitment from commercial stakeholders (implementation report) • PRI – Promoting and supporting community based interventions (ir)
Likely Factors Impacting on Implementation • ORG Need for a coordinating body to keep policy momentum • FUND Availability of resources	Missing Indicators • HAR. Number of MS that contribute harmonised data to the WHO database • PRI.1 Number of MS whose Health Strategies include a commitment to develop nutrition and obesity partnerships • PRO. Number of MS that have signed protocols with health professionals on advising patients of diets and physical activity • PRO Number of partnerships established • ORG.1 Existing of body coordinating national activities and partnerships • EXC.2 Number of MS that make available their pledges through a website. • REP.1 Number of items reported by MS in implementation reports

Preliminary Comments. The variance in diet across Member States, and the difference in policy approaches was a factor of paramount importance to have actions developed also at the regional and local levels. 2010 implementation report available at http://ec.europa.eu/health/nutrition_physical_activity/docs/implementation_report_a6_en.pdf. Availability of surveys on consumer behaviours for AWA indicators hindered by comparability issues. Eurobarometer data available as a baseline for 2005. WHO Europe maintains on behalf of the Commission a database monitoring policy implementation across Europe. Cfr. http://data.euro.who.int/nopa/

Objective 1. Fostering Good Health in Ageing Europe – Alcohol

Linked Communications/Recommendations	• COM. An EU strategy to support Member States in reducing alcohol-related harm (2006) • CONC. Alcohol and health (2009)
Member States' Actions • OBJ1. Protect young people, children and the unborn child (e.g through action on labeling, enforce age limits on selling alcohol). • OBJ2. Reduce injuries and death from alcohol-related road accidents (e.g. by introducing a zero BAC or young or unexperienced drivers, developing random breath testing for all drivers). • OBJ3. Prevent alcohol-related harm among adults and reduce the negative impact on the Workplace (e.g. through better information, primary health –care programmes and workplace-specific actions). • AWA/EDU. Inform, educate and raise awareness on the impact of harmful and hazardous alcohol consumption, and on appropriate consumption patterns (e.g. through information and educational programmes).	Member States' Actions • OBJ.4 Address the well-being of the ageing population in the EU, including the effects of harmful alcohol consumption • AWA Raise awareness among care professionals, carers, and older citizens of interactions between medication and alcohol • EVAL/AWA. Strengthen identification, dissemination and monitoring of effective policy measures in general and with particular reference to alcohol-related harm during pregnancy and while driving • OBJ.6. Recognise the reduction in inequalities in health as a policy priority and the need to reduce inequalities through both social and targeted alcohol preventive interventions • PART: Engage actors in the alcohol beverage chain to work proactively in enforcing regulatory measures • POL Improve the implementation of regulations on

• EVAL/RES. Develop and maintain a common evidence base at EU level (by funding research, monitoring and evaluation programmes) • PROG. Strengthen or develop, as appropriate, comprehensive national strategies or action plans tailored to national needs • REP. Report on developments and results to the Commission by 2011 • LEG/POL. Make use of the most effective measures to provide regulation and enforcement in the area of alcohol policy. • EVAL. Evaluate their impact	alcohol marketing to protect children and adolescents. Ensure that self-regulatory standards are monitored, • HAR. include in existing information systems scientific data on alcohol consumption and harm caused by harmful use of alcohol in the age group of 60 and above, • RES. Increase research on links between harmful use of alcohol and infectious diseases such as HIV/AIDS and TB, • PRO. Develop and implement early identification and brief intervention procedures in primary and elderly healthcare and in school health settings, • AWA. Encourage initiatives to raise awareness of the impact of harmful use of alcohol on health and social welfare, • RES. Consider how best to inform and educate consumers, including research on how alcohol labels may play a part in helping consumers estimate their own consumption, or informing them of health risks
Preparatory Study YES | Impact Assessment YES	Implementation Report YES | Reporting Requirement YES
<u>Already Proposed Outcome/Impact Indicator (source)</u> • OUT1. Total adult per capita consumption per year (strategy) • OUT.2 Binge drinking defined as 60g of alcohol on one occasion (strategy) • IMP.1 Alcohol attributable years of life lost (strategy). • IMP.2 Value of property damage (e.g. car repairs and purchases) due to drink driving (preparatory study) • IMP.3 Total cost of alcohol related road fatalities and injuries or accidents (preparatory study) • OUT.3 Amount spent on alcoholic beverages by under-age drinkers (preparatory study) • IMP.4 Value of alcohol-related insurance claims (preparatory study) • IMP.5 Increase in insurance premiums attributable to alcohol (preparatory study) • OUT.4 Cost of alcohol-related work absenteeism and unemployment, or alcohol-related accidents at work, and lost productivity from loss of life (preparatory study) • IMP.6 Value of lives lost/saved due to alcohol drinking (preparatory study) • IMP.7 Sickness and pension insurance costs due to alcohol related diseases (preparatory study) • OUT.5 Weekly household expenditure on alcohol drink (preparatory study) • IMP.7 Expenditure and cost of crime prevention, detection, processing, and imprisonment (i.e. law enforcement) for alcohol related crimes (preparatory study) • OUT.6 Revenues and expenditure by alcohol industry on advertising, promotion and sponsorship (preparatory study) • OUT.7 Market share (revenues) by alcoholic drink (preparatory study) • OUT.8 Alcoholic industry sales revenue by market share (preparatory study) • IMP.8 Level of employment and unemployment	<u>Already Proposed Process Indicator (source)</u> • PROG.1 Number of MS that have developed or revised their alcohol policy /strategies (interim evaluation and progress report) • LEG.1 Number of MS that have implemented new measures to protect young people, children and the unborn child from harm from alcohol (interim evaluation) • LEG.1 Trends in restrictions to selling and serving alcohol to minors (progress report) • LEG.1.Statutory or self-restrictions to advertising implemented in the MS (progress report) • AWA.1 Number of nation-wide awareness campaigns by topic (progress report) • DEL.2 Availability of counseling programmes to children and pregnant women (progress report) • LEG.1 BAC levels for drivers / inexperienced drivers (progress report) • LEG1. Number of MS implementing statutory / voluntary restrictions on alcohol consumption in public environments (progress report) • POL.2 Total value of fines/penalties related to drink-driving (preparatory study) • FUND.2 Law enforcement costs (police, processing offenders) (preparatory study) • FUND.2 Government expenditure on drink-driving Campaigns (preparatory study) • POL.2 Fines related to under-age drinking (preparatory study) • FUND.1. Cost of enforcement on-premise regulations (preparatory study) • POL.2. Server liability fines (preparatory study) • FUND.2 Advertising controls enforcement costs (preparatory study) • FUND.2 Cost of alcohol-related advice programmes (preparatory study)

in alcohol industry • IMP.9 Health care costs and expenditure (e.g. ambulances and treatment) related to alcohol-related morbidity and mortality. • OUT. 9 Additional cost to manufacturers as a result of information labelling. • Cost of compliance with member state and self-regulation	
Likely Factors Impacting on Implementation • PRO. Institutional coordination between levels of Government • ORG. Existence of a coordinating body • FUND. Availability of resources LEG. Lobbying from concerned stakeholders	Missing Indicators There is no proposed indicator on: • ORG. the establishment of a coordinating office with overall alcohol policy responsibility • POL. population breath-tested on a given year • EVAL. MS providing evaluation reports on their policies • PART. Number of partnership established with stakeholders • RES Number of MS with research projects on the itesm highlighted in the EU policy documents

Preliminary Comments. Most of the indicators proposed by the preparatory study appear rather theoretical, sometimes of dubious relevance, or at any rate would require a study on its own to elicit information and are very burdensome to implement. Also as a result of this the original impact assessment report restrained from proposing indicators and stated that these would be selected later in the policy implementation process and that the MS health and economic assessment of their own measures would serve as basis to monitor progress in implementation and level of uptake. As far as objectives are concerned the original impact assessment of the Alcohol Strategy made reference to a mix of impact indicators composed by a triangulation of results from the European Health Survey System, trends in consumption monitored through the Eurobarometer and The WHO European Alcohol Information System. The Committee on Data Collection, Indicators and Definition, responsible for the three indicators outlined in the strategy, has stated that developing an indicator for each of the five priority themes of the strategy is not always possible. There is plenty of information available from the WHO European Alcohol Information System, the Eurobarometers and the various PHP projects.

Objective 1. Fostering Good Health in Ageing Europe – Mental Health

Linked Communications/Recommendations	• CONC A Community Mental Health Action (2005) • COM. European Mental Health Pact (2008) • CONC. The European Pact for Mental Health and Well-being: results and future action (2011)
Member States' Actions • OBJ.1 Implement the Declaration and Action Plan endorsed by the WHO European Ministerial Conference on Mental Health; • HAR. Collect good quality and comparable data on mental health, and on the economic and social consequences of common mental health problems; • PRI. Design and implement comprehensive, integrated and efficient mental health systems that cover promotion and prevention together with treatment and rehabilitation, care and recovery; • EVAL. Further develop appropriate monitoring and evaluation tools which allow for comparisons of the mental health status and of promotion and prevention practices within and between MS • STR.FUND Consider the use of funding instruments, such as Structural Funds, PHARE, and Twinning programmes, which can cover specific needs and challenges in the field of	Member States' Actions • PROG: Develop strategies and/or action plans on mental health including depression and suicide prevention; • PART. Carry out these strategies/action plans in partnership with the relevant stakeholders and other policy sectors; • OBJ.7 Improve social determinants and infrastructure which support mental well-being and improve access to this infrastructure for people suffering from mental disorders; • PRI. Promote, where possible and relevant, community-based, socially inclusive treatment and care models; • OBJ.6 Take measures against the stigmatisation and exclusion of and discrimination against people with mental health problems and to promote their social inclusion and their access to education, training, housing and work; • STR.FUND Make best use of the possibilities offered by the Structural Funds in the field of mental health in particular for the reform and further improvement of their mental health systems without prejudice to the future

mental health. With specific reference to the following objectives: OBJ.1 Prevent Depression and Suicide, OBJ.2 Ensure Mental Health in Youth and Education, OBJ.3 Ensure Mental Health In workplace Settings, OBJ.4 Ensure Mental Health of Older People, OBJ.5 Combating Stigma and Social Exclusion • EXC. Establish a mechanism for the exchange of information; • PROG.EVAL Identify good practices and success factors and develop recommendations and action plans; • AWA. Communicate the results of such work through a series of conferences on the Pact's priority themes over the coming years	financial framework; • OBJ.6 Use the potential offered by technology applications, including e-Health, for improving mental health systems and services, prevention of mental disorders and the promotion of well-being; • OBJ.3. Take steps towards greater involvement of the health and social sectors along with social partners in the field of mental health and well-being at the workplace, to support and complement employer-led programmes where appropriate; • TRAI Support activities (e.g. training programmes) that enable professionals and managers particularly in healthcare, social care, and workplaces to deal with matters concerning mental well-being and mental disorders; • OBJ.3 Strengthen mental health promotion of children and young people by supporting positive parenting skills, holistic school approaches to reduce bullying and to increase social and emotional competences as well as supporting families where a parent has a mental disorder.
Preparatory Study NO | Impact Assessment NO	Implementation Report PART | Reporting Requirement NO
<u>Likely Factors Impacting on Implementation</u> • ORG. Availability of a coordinating body/centre of expertise • FUND. Resource constraints	<u>Missing Indicators</u> Main relevant process indicators appear to be PRI, PART; AWA, PROG, EXC, STR.FUND and EVAL. HAR is a precondition for policy dialogue. A number of OBJ. indicators are possible, but is unclear whether agreement has been reached on them

Preliminary Comments. A policy area lacking any previous institutional attempt at identifying indicators. Information available from several sources on Mental Health policies implemented at the MS level including from PHP projects, Commission country factsheets and WHO sources. Availability of data on the degree of implementation of the partnership principle to be better checked. Eurobarometers eventually available.

Objective 1. Fostering Good Health in Ageing Europe – Illicit Drugs

<u>Linked Communications/Recommendations</u>	• CONC. EU Drugs Action Plan for 2009-2012 (2008)
<u>Member States Actions</u> • PROG. Make available prevention programmes and strategies to prevent or delay first use of drugs. • OBJ.1 Develop early detection and intervention techniques for vulnerable groups • DEL. Offer low-threshold access to counseling, problem behaviour management and outreach work where relevant to specific high risk groups • OBJ.2. Increase the effectiveness and spread of evidence based drug treatment options . • DEL. Deliver existing and develop innovative rehabilitation and social re-integration programmes • AWA. Publicise the existence of treatment and rehabilitation services for potential target audiences • DEL. To increase the use of, monitor implementation and further develop effective alternatives to prison for drug-using offenders	<u>Member States' Actions</u> • ANA/EXC. To develop, implement and exchange good practice guidelines/quality standards for prevention, treatment, harm reduction and rehabilitation interventions and services • EVAL. Survey the availability and effectiveness of prevention, treatment, harm reduction and rehabilitation services. • DEL. To develop, as appropriate, services for minorities, including, for example, migrants • DEL. To develop and implement prevention, treatment, harm reduction and rehabilitation services for people in prison. • HAR Implement in prison settings indicators to monitor drug use, drug-related health problems and drug services delivery. • DEL. To provide access to, and improve coverage of, harm reduction services. • HAR. Improve and fully implement the five EMCDDA key epidemiological indicators and the development of new indicators and measures in drug demand reduction

Preparatory Study NO	Impact Assessment NO	Implementation Report YES	Reporting Requirement YES
Already Proposed Outcome/Impact Indicators (source) • OUT.1 Prevalence of youth drug use & perception of peer drug use (action plan) • IMP.1 Trends in drug use (action plan) <u>Already Proposed Process Indicator (source)</u> • PROG. Availability of evidence-based evaluated programmes and comprehensive strategies in MS, including those targeting first use (action plan) • OUT.1. Existence of analysis of risk and protective factors in drug use (action plan) • DEL.1 Increased availability of outcome-evaluated, targeted prevention programmes in MS (action plan) • OUT.2 Trends in treatment demand outcome and retention (action plan) • DEL.1 Increased availability of diversified and evidence-based treatment in MS (action plan) • DEL.1 Increased availability of rehabilitation and reintegration programmes in MS (action plan) • PROG.AWA. Information strategies in place in MS (ap)		Already Proposed Process Indicators (source) • EVAL3 EXC.2. Public register of services available (e.g. internet portal) (action plan) • DEL. Increased availability of ATP (action plan) • ATP implementation monitored (COM) (action plan) • ANA. Existence of relevant guidelines and/or quality standards (action plan) • Level of implementation of guidelines and/or standards (ap) • ANA. Methodological framework for the survey developed (ap) • ANA. Number of Member States that complete the survey (ap) • DEL. Availability of relevant services for minorities/migrants (ap) • HAR. Increase compliance of MS with implementation criteria for key indicators (action plan) • HAR. Improvement in treatment demand and problem use indicators (action plan) • DEL.2 Measures for rehabilitation and reintegration (ap) • DEL.2 Measures in drug demand reduction (ap) • HAR. Number of MS that have fully implemented Treatment Demand Indicator (ap)	
<u>Likely Factors Impacting on Implementation</u> • FUND. Availability of resources • TRAI Trained Personnel.		<u>Missing Indicators</u> • None. There is one to one correspondence between proposed actions and indicators in the Action Plan, but possibly for a dedicated AWA indicator, as a PROG.AWA one only was originally envisaged	

Preliminary Comments. Some baseline data available from 2007 implementation report on 2003 Council Recommendation on Drug Reduction focusing on availability of specific services. EMCDDA publishes yearly reports with regular updates.

Objective 1. Fostering Good Health in Ageing Europe – Cancer

• ANA. Implement new guidelines on cancer screening.	
<u>Linked Communications/Recommendations</u>	• CONC. On reducing the burden of cancer (2008) • COMM. On Action against Cancer: European Partnership (2009) • CONC. Action Against Cancer (2010) • Guidelines on quality assurance in breast cancer screening (2006) • Guidelines on cervical cancer screening (2008) • Guidelines for colorectal cancer screening (2010)
<u>Member States' Actions</u> • PROG. Develop and implement comprehensive cancer strategies or plans by 2013; • PRI. Consider the possibilities offered by preventative alternatives against infectious agents that can cause cancer; • AWA. Promote the European Code Against Cancer and carry out information initiatives targeted at different groups; • DEL. Continue with the implementation of	<u>Member States' Actions</u> • HAR. Ensure population-based cancer registration • STR.FUND. Take advantage of existing European structural funds to prevent cancer • EXC.Exchange best practices in the field of cancer prevention and control. • EXC. Participate actively in the European partnership on cancer • DEL. Providing a total EU wide 125 million examinations to citizens per year.

population-based quality-assured screening programmes for breast, cervical and colorectal cancer. Achieve 100% population coverage of screening for breast, cervical and colorectal cancer by 2013; • TRAI. Ensure that there is a trained, multidisciplinary workforce • DEL. Improve the quality of life for cancer patients through support, rehabilitation and palliative care;	• AWA. Promote large scale information campaigns on cancer screening, directed at the general public and health-care providers. • PRO. Develop a voluntary European pilot accreditation scheme for breast cancer screening and follow-up • OBJ. Reduce inequalities in cancer mortality by 70% by 2020 • HAR. Ensure accurate and comparable data on cancer incidence, prevalence, morbidity, cure, survival and mortality in the EU by 2013 • REP. Report on implementation
Preparatory Study NO / Impact Assessment NO	Implementation Report YES / Reporting Requirement YES
Already Proposed Process Indicators (source) • OBJ. Reducing Cancer Mortality Inequalities (COMM) • PROG.1 No of MS implementing cancer screening programmes according to Council Recommendation (2003/878/EC) (interim evaluation) • DEL.1Number of persons receiving screening on targeted (implementation report)	Already Proposed Process Indicator (source) • DEL.1 Percentage of EU population receiving screening by programme implementation status of MS (implementation report) • DEL.2 Percentage of Member States reporting adherence to specific EU principles in their programmes (implementation report)
Likely Factors Impacting on Implementation • EVAL. Evidence of benefit from prevention • FUND. Resource issues: availability of trained staff and equipment • LEG. Privacy problems with cancer registries • AWA. Lack of adequate information among population • HAR. Integration of cancer registration and cancer registries	Missing Indicators • PROG. Number of MS with Cancer Strategies • LEG Number of MS with Fully legalised Cancer Registries • HAR.2 Number of Registries available • AWA. Number of dissemination initiatives • PRO. Protocols for accreditation established • NET Number of Facilities / Programmes accredited for quality control • ANA bibliographic impact of guidelines/Evidence of circulation of guidelines (download, citation) • DEL.2 Existence of non-screening based vaccination based prevention strategies and population covered .

Preliminary Comments. Most of the information available focuses on cancer screening. See section on cancer screening in the main text for more detail. 2010 WHO Country Capacity Survey covers national cancer policies strategies or action plans. Little baseline data available to assess situation back in 2005.

Objective 1. Fostering Good Health in Ageing Europe – Rare Diseases

OBJ.1 Implement Communication on European Action in the Field of Rare Diseases	
Linked Communications/Recommendations	• COM On Rare Diseases: Europe's Challenges (2008) • REC On an Action in the Field of Rare Diseases (2009)
Member States' Actions • PROG. Put in place preferably by the end of 2013 and implement plans or strategies for rare diseases. • FUND: Ensure provisions to grant their financial sustainability over time • ANA/HAR. Put in place adequate mechanisms for codification of rare diseases, based on the ICD. Establish registries and databases. • PROG.RES. Include in plans or strategies provisions aimed at fostering research in the field of rare diseases. • NET. Identify national and regional centres of	Member States' Actions • PART. Empower and involve patients and patients' Organisations. Promote their activities • NET. Facilitate the development of European reference networks (ERNs). • PRO. Organise healthcare pathways for patients suffering from rare diseases. Support the use of telemedicine. • PRO. Produce good practice guidelines. • TRAI Ensure adequate education and training for all health professionals. • EXC. Share best practices and assessment reports on the therapeutic or clinical added value of orphan drugs.

expertise by the end of 2013, consider their creation, support them financially and foster their participation in ERNs.	• REP. Provide all the necessary information not later than five years after the date of adoption of this Communication.
Preparatory Studies NO | Impact Assessment YES	Implementation Report NO | Reporting Requirement YES
<u>Already Proposed Output/Impact Indicators (source)</u> • DEL. Number of people identified as affected by disease, geographical distribution (impact assessment); • OUT.2 Average duration from first symptoms to diagnosis (impact assessment); • OUT.3 Average length of stay in hospitals due to rare diseases (impact assessment); • IMP.1 Registered deaths due to rare diseases (impact assessment); • IMP.2 Health expectancy indicators: PYLL (Potential Years of Life Lost), DALY (Disability-Adjusted Life Years), HLY (Healthy Life Years) (impact assessment) <u>Already Proposed Process Indicator (source)</u> • PROG.1 Number of MS that have adopted an action plan on rare diseases (interim evaluation and impact assessment).	<u>Already Proposed Process Indicator (source)</u> • ANA.1 Proportion of rare diseases identified in the ICD (impact assessment) • FUND.2 Health Care expenditure for rare diseases as a percentage of total health care expenditure (at national/regional level) (impact assessment); • RES.2 National research funds available for rare diseases (impact assessment). • NET. Number of laboratories certified for genetic testing (impact assessment); • HAR.3 Number of national registries and databases (impact assessment); • PART.1 Number of patients' associations (impact assessment). • NET.2 Number and list of databases and laboratory networks created to share knowledge and information on rare diseases (impact assessment); • NET.1 The number of reference networks on rare diseases approved at EU-level (impact assessment). • EVAL.1 HTA tools to measure efficacy of the treatments.
<u>Likely Factors Impacting on Implementation</u> • HAR Major difficulties with coding and complex management of patient migration • PRO. Difficulties in managing and reimbursing off-label prescriptions • PRO. Accreditation mechanisms between MS • ORG: Organizational complexity and very limited information basis	<u>Missing Indicators</u> • HAR. Degree of harmonisation and comparability of epidemiological data • DEL.2 Number of diseases covered by centres of expertise at the national / regional level • DEL.1 Population covered by the centres of expertise on potential population affected • EXC. Contribution given to exchange of best practices • ANA.3 Number of accesses to the rare diseases database

Preliminary Comments. Sources of information available from previous PHP projects to be checked. Possible need for bibliographic search of baseline data.

Objective 1. Fostering Good Health in Ageing Europe – Organ Donation – Transplantation

OBJ.1 Follow up of the Communication on organ donation and transplantation and implement the action plan to strengthen cooperation between MS in this field. EXC. Share experience and best practices with a view to increasing organ availability, enhancing the efficiency and accessibility of transplantation systems and complementing the Directive on quality and safety	
<u>Linked Communications/Recommendations</u>	• COM Organ Donation and Transplantation: Policy Actions at the EU Level (2007) • CONC. On Organ Donation and Transplantation (2007) • COM. Action plan on Organ Donation and Transplantation (2009-2015): Strengthened Cooperation between MS (2008)
<u>Member States' Actions</u> • PROG.1 Draft a Country-specific set of priorities that could serve as a platform for discussion in the framework of EU Action Plan. • DEL. Gradually appoint transplant donor coordinators in hospitals. • TRAI. Implement effective training programmes	<u>Member States' Actions</u> • HAR. Develop registers of living donors to guarantee their health & safety • AWA. Improve the information available to the public and address the role of mass media. Organize meetings with journalists and opinion leaders to manage adverse publicity.

<table>
<tr><td colspan="2">for transplant donor coordinators.
• PRO. Promote the establishment of accreditation schemes for transplant donor coordinators (in a second stage).
• PRO/DEL. Gradually put in place Quality Improvement Programmes for organ donation in hospitals.
• EVAL. Design indicators to monitor actions
• OBJ.2 Promote altruistic donation for living donors.</td><td colspan="2">• AWA. Disseminate information about citizens' rights.
• PRO. Develop mechanisms to facilitate cross-border donors and the interchange of organs between national authorities.
• ANA. Incorporate in the Set of National Priority Actions the recommendations of the committee of experts.
• PRO. Promote at the national level EU-wide agreements on specific aspects of transplantation medicine
• HAR. Develop a register to follow up organ recipients
• TRAI. Train on methodologies on Quality Improvement Programmes. Train health professionals and patient support groups on communication skills.</td></tr>
<tr><td>Preparatory Study
YES</td><td>Impact Assessment
YES</td><td>Implementation Report NO</td><td>Reporting Requirement YES</td></tr>
<tr><td colspan="2"><u>Already Proposed Outcome/Impact Indicators</u>
• OUT.1 National Donation rates (living and deceased) (donors per million population) (impact assessment).
• OUT.2 Refusals to donate (impact assessment)
• OUT.3 National multi-organ donation rates (impact assessment)
• OUT.4 Conversion rates of potential into actual donors (impact assessment)
• OUT.5 National number of transplant procedures per organ and per million population (impact assessment)
• IMP.1 National survival rates for different organs (impact assessment)
• IMP.2 Living and deceased donation (impact assessment)
• IMP.3 Numbers of adverse events related to organ quality: infections (impact assessment)
• IMP.4 Transmission of malignant diseases (impact assessment)
• OUT.6 Organ damage (impact assessment)
• OUT.7 Reports to and from the tissue and cell vigilance system (impact assessment)
• OUT.8 Number of organs interchanged within the Community and with third countries (ia)</td><td colspan="2">• OUT.9 Percentage of organs for difficult to treat patients exchanged across borders (impact assessment)
• IMP.5 Number of people on waiting lists (impact assessment)
• IMP.6 Mortality while on waiting list (impact assessment)
• IMP.7 Access to waiting lists (impact assessment)
• IMP.8 Inequality in access to transplantation services at all stages of the donation pathway (impact assessment)
• IMP.9 Gender/Ethnic or minority status/resident /non-resident status/low social (impact assessment)
• IMP.10 Economic status/Type of diseases (rare diseases) (impact assessment)

<u>Already Proposed Process Indicator (source)</u>

• PROG.1 Number of MS that have adopted / revised National Action Plans (interim evaluation)
• NET.1 Number of transplant procurement hospitals (impact assessment)
• DEL. Number of hospitals that have appointed a transplant donor coordinator (action plan).
• DEL. Number of transplant coordinators per million population (impact assessment)
• PRO.1 Existence of a national quality programme (impact assessment)
• NET.CAP Number of hospitals with quality assurance programs (impact assessment)
• HAR. Number of MS that have developed registries
• TRAI. Health professionals and patient support groups receiving training
•</td></tr>
<tr><td colspan="2"><u>Likely Factors Impacting on Implementation</u>

• FUND. Resource issues
• PART. Active nongovernmental organizations
• ANA. Lack of common terminology in Europe</td><td colspan="2"><u>Missing Indicators</u>
• HAR.3 Number of MS that have developed registries
• AWA.1 Number of awareness raising campaigns
• AWA.2 Surveys to test level of knowledge among the population
• EVAL. Number of MS that have developed indicators.</td></tr>
</table>

Preliminary Comments. The IA report includes a number of indicators drawn from the preparatory study. However, the text of the Recommendation states that the identification of key indicators that could be used for the monitoring of progress in uptake as well as the evaluation of policy implementation and outcomes are the responsibility of the Member States together with the establishment of a methodology to evaluate the potential in each Member State. Common definitions both of terms and methodology will have to be adopted in order to evaluate the results of transplant systems. Baseline information available from several sources extensively quoted in the preparatory study.

Objective 1. Fostering Good Health in Ageing Europe – Injuries

<table>
<tr><td colspan="2">Linked Communications/Recommendations</td><td colspan="2">• COM. On Actions for a Safer Europe (2006)
• REC. On the prevention of injury and the promotion of safety (2007)</td></tr>
<tr><td colspan="2">Member States' Actions

• PROG/PART. Create policies for injury prevention, i.e. a framework of actions that engages the relevant partners and stakeholders and defines institutional responsibilities.
• ORG.PRO. Take a coordinating role of different policy sectors
• HAR. Develop representative injury surveillance and reporting instruments to obtain comparable information.</td><td colspan="2">Member States' Actions

• EVAL. Monitor the evolution of injury risks and the effects of prevention measures over time and assess the needs for introducing additional initiatives on product and service safety and in other areas.
• PROG. PRO Set up national plans or equivalent measures, including the promotion of public awareness of safety issues, for preventing accidents and injuries by promoting interdepartmental and international cooperation
• TRAI Encourage the introduction of injury prevention and safety promotion, in schools and in training of health and other professionals.</td></tr>
<tr><td>Preparatory Study NO</td><td>Impact Assessment NO</td><td>Implementation Report YES</td><td>Reporting Requirement NO</td></tr>
<tr><td colspan="2">Likely Factors Impacting on Implementation

• PRI. Statement of the seriousness of the injury problem in the national health plan
• AWA. A well-informed public through research and mass media
• AWA. Willingness of the mass media to participate in positive preventive efforts
• TRAI. Well-trained and committed professions
• LEG Laws that mandate child protection for the health professions. Laws to ban firearms. Regulation of alcohol sales
• PART. Active nongovernmental organizations
• ORG. Lead agency ensuring uniformity in developing and implementing policy</td><td colspan="2">Missing Indicators

Main relevant process indicators appear to be PROG, PRO, ORG; TRAI and EVAL. HAR is a precondition for policy dialogue</td></tr>
</table>

Preliminary Comments. Fairly comprehensive information made available in WHO-EU 2010 survey on Preventing Injuries in Europe inclusive of Country factsheets and attribution assessment of the role played by the EU and a scoring of "effective interventions" based on own WHO methodology. Availability of baseline data to be checked in the literature and PHP project deliverables.

Objective 2. Protecting Citizens from Health Threats – HIV/AIDS

<table>
<tr><td colspan="4">• OBJ.1 Address communicable disease threats such as HIV/AIDS and tuberculosis</td></tr>
<tr><td colspan="2">Linked Communications/Recommendations</td><td colspan="2">• CONC. On Combating HIV/AIDS (2005)
• COM. Combating HIV/AIDS in the European Union and neighbouring countries, 2009 -2013 (2009)</td></tr>
<tr><td colspan="2">Member States' Actions

• OBJ.2 Promote the implementation of the Dublin, Bremen and Vilnius declarations
• PROG/FUND. Ensure that national multi-sectoral HIV/AIDS structures, strategies, and financing plans are implemented
• EXC. Exchange best practices and experiences at Community level.
• AWA. Improve general knowledge and raise awareness on the prevention of HIV infection
• DEL Promote condom use and access to drug dependence treatment and harm reduction services.</td><td colspan="2">Member States' Actions

• DEL. Pay special attention to the access to affordable anti-retro viral treatment, as well as other medical treatment, for all in need.
• STR.FUND Assess the possibilities of structural and social funds and other instruments to scale up HIV/AIDS related health services
• PART/EVAL Strengthen the capacity of governmental institutions and civil society organisations to develop, implement and evaluate effective national HIV/AIDS programmes
• HAR. Build on the surveillance carried out under Decision 2119/98 EC, to gather even more robust and</td></tr>
</table>

• DEL. Counsel and support people with HIV/AIDS, their families and their friend • RES. Strengthen the co-operation of clinical trials	comprehensive data on HIV/AIDS and STIs, including on co-infections
Preparatory Study NO / Impact Assessment YES	Implementation Report PART / Reporting Requirement YES
Already Proposed Outcome/Impact Indicator (source) • OUT.1 The progress made in most at risk populations in form of highly disaggregated data (impact assessment) • OUT.2 Progress made in particularly affected countries (impact assessment)	Proposed Indicator (source) • PROG. Mid-term planning established on countries most affected (impact assessment) • EVAL2 EVAL.3 Progress made on a political level, degree of the political influence on the implementation of measures against HIV/AIDS: indicators selected (impact assessment) • PART.2 Degree of involvement of civil society on a national and regional level (impact assessment). • HAR.1 Progress made towards a harmonised and meaningful epidemiology and surveillance, in support of policy and decision making (impact assessment). • RES.3 RES.4 Progress made towards research in identified fields where knowledge gaps persist (impact assessment). • FUND.1 National spending allocated to HIV/AIDS interventions (in particular with regard to the negative implications of the economic crisis) (impact assessment).
Likely Factors Impacting on Implementation • ORG Availability of a policy coordinating entity, centre of expertise • TRAI Sufficiently trained staff to implement policy • PART Existence of representative NGOs • EVAL. Availability of evaluation	Missing Indicators • DEL.3 Harm reduction and counselling services actually delivered • DEL.1 Population having access to ARV • AWA Level of awareness / Awareness campaigns • STR.FUND Recourse to structural funds

Preliminary Comments. Availability of indicators at the MS level considered as a proxy of political commitment. ECDC regularly reports on progress in meeting the commitments of the Dublin, Vilnius and Bremen Declarations. The HIV/AIDS Think Tank and the Civil Society Forum indicated as impartial and objective bodies to monitor the progress made on specific objectives. Monitoring report based on selected indicators and data compiled by ECDC to be published by the Commission in 2012 and 2014, respectively. Eurobarometer available for baseline.

Objective 2. Protecting Citizens from Health Threats – Vaccination

Linked Communications/Recommendations	REC. On seasonal influenza vaccination (2009)
Member States' Actions • PROG. Adopt and implement national, regional or local action plans or policies aimed at improving seasonal influenza vaccination coverage • DEL. Reach, as early as possible, and preferably by the 2014-2015 winter season, a vaccination coverage rate of 75 % for 'older age groups' and, if possible, for other risk groups • DEL. Improve vaccination coverage among healthcare workers. • RES.1 EVAL1. Analyse the reasons why certain target groups do not want to get vaccinated	Member States' Actions • AWA. Organise information action for healthcare workers and risk groups and their families and information action to remove obstacles to vaccination uptake • ANA. Take into account the definition of 'older age groups' and of 'risk groups' as contained in the guidance issued by the ECDC; • REP. Report on a voluntary basis to the Commission on the implementation of this Recommendation, in particular, on the coverage achieved among risk groups.
Preparatory Study NO / Impact Assessment NO	Implementation Report NO / Reporting Requirement YES
Likely Factors Impacting on Implementation • RES. Resources available • AWA. Level of awareness among the population	Missing indicators • DEL1. Share of the population at risk actually reached by vaccination appears to be the indicator of choice

	• ANA.1 Conformity with ECDC definition • EVAL.1 RES.1 Availability of analysis on reasons for poor coverage • AWA. Dissemination campaigns organized

Preliminary Comments. Fairly limited information available with substantial comparison problems. See http://ecdc.europa.eu/en/ESCAIDE/Materials/Presentations%202010/ESCAIDE2010_Late_Breakers_Mereckiene.pdf

Objective 2. Protecting Citizens from Health Threats – Preparedness Planning

Linked Communications/Recommendations		• COM On strengthening coordination on generic preparedness planning for public health emergencies at EU level (2005) • COM On Pandemic Influenza Preparedness Planning (2005)	
Member States' Actions • OBJ.1. Organise adequate health and/or medical surveillance to identify public health threats. • OBJ.2 Extend the international relevance of health threats at a very early stage and follow their evolution and changing circumstances. • CAP. Make available laboratory capacity • PRO. Enhance procedures for communication between authorities and with professionals and the public in clear and unambiguous terms.		Member States' Actions • ORG.1. Enhance coordination of the response and of communications, information analysis and management and simulation for event-analysis and training. • ORG.2 EXC. Establish good liaison systems with other Member States, the Commission and Community agencies as well as international organisations, in particular the WHO. • PROG.1 Prepare National Influenza Preparedness Plans dealing with: 1) planning and coordination; 2) monitoring and assessment, 3) prevention and containment, 5) health system response, 6) communication issues	
Preparatory Studies NO	Impact Assessment NO	Implementation Report YES	Reporting Requirement NO
Likely Factors Impacting on Implementation ORG. Leading organization FUND. Resource issues		Missing Indicators. All indicators related to the actions listed above, and namely: PROG; ORG, PRO, NET.CAP, and EXC	

Preliminary Comments. None of the EU MS plans listed in the WHO website of [4] general preparedness health plans seem to have the feature of a preparedness plan. Very detailed reviews available of the quality features of the influenza preparedness plans are available from the ECDC with reference to 2007 and from the WHO (2011). The two studies make reference to a similar set of quality indicators, the first limits itself to availability only of the given feature in the plan, while the second extends to a qualitative scoring mechanism.

Objective 2. Protecting Citizens from Health Threats – CBRN

Linked Communications/Recommendations	• CONC. On addressing Chemical, Biological, Radiological and Nuclear Risks and on Bio-preparedness (2007) • COM. On strengthening CBRN in the EU. An EU action plan (2009) • CONC. An EU CBRN action plan (2009)
Member States' Actions • PROG. Prepare National CBRN Plans . Assess the required amounts and types of medical countermeasures in case of an incident the availability of medical resources the possibility of sharing medical counter-measures across borders in case of an incident. • PRO. Develop guidelines for the industry, the medical sector and the research community containing criteria identifying the forms of	Member States' Actions • NET. Set cooperation among laboratories assigned to deal with unknown pathogens and toxins at national level • EXC. Identify and exchange good practice on robust management structures at commercial, industrial, health care and research facilities which hold high-risk CBRN materials, in order to ensure regular security appraisal and monitoring of staff • NET. Set a network among existing laboratories which are competent and have capacity specialising in high risk

[4] http://www.who.int/influenza/preparedness/general_plans/en/index.html

<table>
<tr><td colspan="2">behaviour, in relation to transactions, which may give rise to suspicion.
• PRO. Develop detection models for different biological pathogens and toxins, considering distribution, possible vectors, infectious dose and stability.
• CAP. Develop reference material of biological agents for both clinical and environmental samples (according to internationally accepted standards) in order to achieve quality assurance in detection.
• ANA. Set minimum requirements for sampling, detection, identification and monitoring of pathogens and toxins within a civilian context.</td><td colspan="2">biological agents and toxins.
• DEL/ORG.2.Perform measurements of biological background at specific areas, and enhance cooperation and information exchange among Member States on the procedures in such projects.
• DEL. Develop and conduct, on the basis of risk assessments, regular exercises at local, regional, and national level involving and testing the cooperation of all relevant organisations, particularly those dealing with healthcare.</td></tr>
<tr><td>Preparatory Studies NO</td><td>Impact Assessment YES</td><td>Implementation Report NO</td><td>Reporting Requirement YES</td></tr>
<tr><td colspan="2"><u>Likely Factors Impacting on Implementation</u>

ORG. Leading organization
FUND. Resource issues</td><td colspan="2"><u>Missing Indicators.</u>

All the indicators of the actions listed above, and in particular:
PROG.1 Availability of CBRN plans
DEL. Number of exercises actually carried out and personnel involved
ORG.2 existence of a body liaising at the EU level
as well as the other relevant indicators ANA, NET, EXC</td></tr>
</table>

Preliminary Comments. Identification of possible indicators not carried out in the impact assessment phase and left to subsequent Council discussion and the final evaluation. Tentatively proposed indicators do not speficially focus on health aspects and include: decrease in CBRN incidents, which could for example be verified by way of the IAEA, Interpol's and Europol's data on this topic, relate to the implementation of security plans at CBRN facilities, as well as measures adopted to increase the security of transport, the adoption of codes of conduct etc. Conceptually speaking, the subject lends itself to be evaluated through the same "scoreboard principle" applied by the ECDC and WHO or influenza preparedness planning. Due to sensitivity and security reasons there is a notable shortage of public information on the subject.

Objective 2. Protecting Citizens from Health Threats – Antimicrobial Resistance

<table>
<tr><td colspan="2"><u>Linked Communications/Recommendations</u></td><td colspan="2">CONC Antimicrobial Resistance (2008)
Action Plan against the Rising Threat of Antimicrobial Resistance (2011)</td></tr>
<tr><td colspan="2"><u>Member States' Actions</u>

• FUND/CAP. Ensure that structures and resources for the implementation of the Council recommendation on the prudent use of antimicrobial agents in human medicine are in place.
• PROG. Continue with the implementation of specific strategies targeted towards the containment of the antimicrobial resistance.
• PROG. Develop and implement strategy and its translation into an action plan composed of concrete cross-sectoral and other relevant actions.</td><td colspan="2"><u>Member States' Actions</u>

• ORG.1 EVAL.2. Establish inter-sectoral mechanism with an appropriate mandate to coordinate and monitor the implementation of the strategy and action plan.
• HAR. Strengthen surveillance systems and improve data quality on AMR and use of antimicrobial agents from both human health and veterinary sector.
• OBJ. Promote prudent use of antibiotics in both the human and veterinary sector.
• AWA. Raise awareness campaigns on the risk of inappropriate use of antibiotics in self- medication, aimed at the general public, practitioners and health professionals, including veterinary sector</td></tr>
<tr><td>Preliminary Study NO</td><td>Impact Assessment NO</td><td>Implementation Report YES</td><td>Reporting Requirement YES</td></tr>
<tr><td colspan="2"><u>Already Proposed Outcome/Impact Indicators (source)</u>

• OUT1. Antimicrobial resistance indicators
• OUT2. Antimicrobial use or prescription</td><td colspan="2"><u>Already Proposed Process Indicator (source)</u>

• PRO. Guidelines on the appropriate use of antimicrobials (implementation report)
• PRO. Guidelines for hand hygiene (implementation</td></tr>
</table>

indicators • OUT3. Antimicrobial use in the community • OUT4. Antimicrobial use in hospitals • OUT5. Healthcare associated infection indicators <u>Already Proposed Process Indicator (source)</u> • PROG.1 National strategies and action plans (implementation report) • PROG/ANA Content of the action plans (implementation report) • PRO. Implementation of ICMs (implementation report) • NET. Surveillance Systems for Antimicrobial Resistance (implementation report) • POL. Control and preventive measures (implementation report)	report) • PROG. National programme for hospital hygiene and infection control (implementation report) • NET. National or regional networks to survey healthcare associated infections (implementation report) • DEL. Infection control committee and infection control nurses (implementation report) • PRO. National guidelines for the prevention and control of healthcare associated infections (implementation report) • TRAI. Education and training of health professionals (ir) • AWA. Awareness raising campaigns on antimicrobial resistance for healthcare professional (implementation report) • DISS. Information for the public (implementation report) • RES. National research initiatives (implementation report)
<u>Likely Factors Impacting on Implementation</u> FUND. Resource Issues, information technology, resources, LEG. Data security. Ownership of data	<u>Missing Indicator</u> • HAR.2 Degree of real data comparability between MS • EVAL.3 Number of MS that have put in place a monitoring systems • ORG.1 Number of a MS with a body responsible for intersectoral cooperation • DEL. Share of health establishments with an infection control committees and infection control nurses

Preliminary Comments. Very extensive set of indicators available from implementation reports on the 2002 Recommendation. MS were left free to devise their own heterogeneous outcome and process indicators that include compliance with agreed activities, such as surveillance and standard operating procedures (hand hygiene for instance). Structure indicators refer to a resource, such as staff, infrastructure or committees. Twelve countries reported using the indicators to monitor the implementation of their action plan.

Objective 3. Supporting Dynamic Health Systems and New Technologies – Patient Safety

<u>Linked Communications/Recommendations</u>	• COM On Patient Safety Including the Prevention and Control of Healthcare-associated Infections (HCAI) (2008) • REC. On Patient Safety Including the Prevention and Control of Healthcare-associated Infections (HCAI) (2009)
<u>Member States' Actions</u> • PROG.FUND Support the establishment and development of national policies and programmes on patient safety in general terms. embed patient safety as a priority issue, support the development of safer and user-friendly systems. • ORG.1 Designate competent authorities • PART. Empower citizens by involving patient organizations in the development of policies and programmes on patient safety. • AWA. Inform patients of levels of safety and provide accessible and comprehensible information on safety standards, safety measures and complaints procedures. • DEL. Establish comprehensive blame-free	<u>Member States' Actions</u> • PROG. Adopt and implement a strategy on HCAIs. Implement prevention and control measures to support the containment of HCAIs. • PRO. Enhance infection prevention and control at the level of healthcare institutions through an ad hoc programme and appropriate organizational arrangements . • EVAL.3/HAR. Establish or strengthen active surveillance systems by organizing prevalence surveys and establishing national reference data. • TRAI Foster education and training of healthcare workers on infection prevention and control. • AWA Improve the information on HCAIs given to patients; • RES. Support research. • HAR. Classify and measure patient safety at Community

<table>
<tr><td colspan="2">reporting and learning systems by encouraging both health workers and patients to report.
• TRAI. Ensure that patient safety is embedded into the education and training of healthcare workers</td><td colspan="2">Level by building on the OECD patient safety indicators and the Community Health Indicators Project.
• EXC Promote the cooperation and share information with the other Member States</td></tr>
<tr><td>Preparatory Study NO</td><td>Impact Assessment YES</td><td>Implementation Report NO</td><td>Reporting Requirement YES</td></tr>
<tr><td colspan="2"><u>Already Proposed Outcome/Impact Indicators (Source)</u>
• OUT. Number of MS that have fully implemented the 2009 Council recommendation on patient safety (interim evaluation)
• OUT.Prevalence and incidence of HCAIs in Member States. (impact assessment)
• OUT. Number of accepted applications on patient safety

<u>Already Proposed Process Indicators (source)</u>
• AWA. Quality and harmonization of the level of awareness of MS (impact assessment)
• AWA. Patients' awareness of differences in safety levels</td><td colspan="2"><u>Already Proposed Process Indicators (source)</u>
• DEL Access and level of use of up-to-date and comprehensive information system (impact assessment).
• ANA. Unified terminology in use (impact assessment.
• ANA. Adoption of Commission Decision covering case definitions for HCAIs (impact assessment)
• PRO.Existence of functional surveillance systems (impact assessment)
• ANA/TRAI Availability of surveillance methods, indicators, guidance on best practices and minimum infrastructure requirements, as well as training curricula for healthcare staff agreed at EU level (impact assessment).</td></tr>
<tr><td colspan="2"><u>Likely Factors Impacting on Implementation</u>

• LEG Legal issues surrounding healthcare workers' liability and penal responsibility
• LEG. Disciplinary systems and procedures
• FUND. Resource issues and reference laboratories</td><td colspan="2"><u>Missing Indicators</u>
• ORG.1 Number of MS that have designated competent authorities
• PROG.1 Number of programmes / plans enacted
• PART. Number of patient organizations involved in policymaking
• DEL.1 Number of MS putting in place blemefree information systems
• RES Number of research projects
Other relevant indicators are NET, EVAL.3, EXC and HAR</td></tr>
</table>

Preliminary Comments. More detailed information on indicators available from ongoing survey in the main text. Process (e.g. standard operating procedures on hand hygiene) and structure (number of infection control personnel) indicators to be developed by ECDC, building on the work of the IPSE project (impact assessment). Availability of baseline information to be checked.

Objective 3. Supporting Dynamic Health Systems and New Technologies – Telemedicine

<table>
<tr><td><u>Linked Communications/Recommendations</u></td><td>• COM On telemedicine for the benefit of patients, healthcare systems and society (2008).</td></tr>
<tr><td><u>Member States' Actions</u>

• OBJ.1 Build confidence in and acceptance of telemedicine services.
• OBJ.2 Solve technical issues and facilitate market development.
• OBJ.3Achieve wider deployment of telemedicine.
• EXC. Collect evidence and share good practice on implementation of telemedicine services and reimbursement schemes.
• POL. Make sure the legislation on the protection of personal data is duly complied with.</td><td><u>Member States' Actions</u>

• PROG. Assess their needs and priorities in telemedicine by the end of 2009.
• LEG. Establish clear legal frameworks recognizing and enabling telemedicine.
• LEG. Assess and adapt their national regulations enabling wider access to telemedicine services by the end of 2011.
• LEG. Address issues such as accreditation, liability, reimbursement, privacy and data protection.
• OBJ.4 Integrate telemedicine into their health systems.</td></tr>
</table>

Preliminary Study YES[5]	Impact Assessment NO	Implementation Report NO	Reporting Requirement NO
Likely Factors Impacting on Implementation • PRI. Different interpretations of the right to health care by EU member states • FUND. Financial equilibria constraints • LEG. Prior authorization for hospital services • TRAI. Availability of trained staff		Missing Indicators • PROG. MS presenting their national health strategies • LEG. Countries reporting legal barriers to telemedicine • LEG. Initiatives taken to remove legal barriers in the period	

Preliminary Comments. The Swedish Presidency report on e-Health for an Healthier Europe http://www.sweden.gov.se/content/1/c6/12/98/15/5b63bacb.pdf extensively reviews possible outcome and impact indicators of more widespread adoption of telemedicine. A section on telemedicine is to be found in the WHO 2009 global survey on e-health that is however based on subjective expert assessment. Further sources focusing on actions taken to remove legal obstacles in the subsequent period to be identified yet. Member States were urged to assess their needs and priorities in telemedicine by the end of 2009 with a view to present and discuss their national e-health strategies at the 2010 eHealth Ministerial Conference. By the end of 2011, Member States should have assessed and adapted their national regulations enabling wider access to telemedicine services. Issues such as accreditation, liability, reimbursement, privacy and data protection should have been addressed. The Commission was to release a staff working document on the legal issues in 2010. None of these sources could be identified in the inception phase. In 2009, the Commission established a European platform to support Member States in sharing information on current national legislative frameworks relevant to telemedicine and proposals for new national regulations and this can be used as a possible source.

[5] http://ec.europa.eu/information_society/activities/health/docs/policy/ehealth-era-full-report.pdf

ANNEX B – CASE STUDY REPORT: ITALY

A – Overall Health Strategy (White Paper)

1. Legal, Policy and Institutional Framework[6]

Table 1.1 - Legal and Policy Framework

Year	Type	Authority	Title	Comment
2001	Law	Parliament	Constitutional Law No. 3, 18 October 2001	Confers the bulk of health policy responsibilities to the regional governments.
2001	Decree	Ministry of Health	Ministerial Decree of 29 November 2001	It defines the essential level of assistance indicators (*Livelli Essenziali di Assistenza*/LEA).
2003	National strategic document	Ministry of Health	National Health Plan 2003-2005 (*Piano Sanitario Nazionale* 2003-2005)	Cornerstone of health policy, the Plan encompasses the proposals set out by the regional health departments and objectives to be met within the three-year period.
2004	National strategic document	Ministry of Health	National Prevention Plan 2004-2006 (*Piano Nazionale di Prevenzione* 2004-2006)	The National Prevention Plan becomes a planning document in its own right (although still formally part of the National Health Plan) with a simplified autonomous approval procedure requiring the agreement of the Health Ministry and the Regions only.
2004	Law	Parliament	Law No. 138/2004 "Urgent interventions to meet public health hazards"	Involving, *inter alia*, the establishment of the National Centre for Disease Prevention and Control (*CentroNazionale per la Prevenzione e il Controllo delle Malattie*/CCM).
2004	National sectoral document	Ministry of Health	National Screening Plan (*Piano Nazionale Screening*)	Adopted with the Ministerial Decree of 2 December 2004. The Plan allocated funds to the regions to improve screening programmes' 'structure' (including capacity, personnel, training, information system and communication to the public). Regions are requested to submit specific projects.
2006	Institutional agreement	State and Regions	Health Pact (*Patto per la Salute*) between the State and the Regions	Regions are required to subscribe to annual 'Health Pacts' which make additional resources conditional upon the achievement of healthcare planning and expenditure goals.
2006	National strategic document	Ministry of Health	National Health Plan 2006-2008 (*Piano Sanitario Nazionale* 2006-2008)	Cornerstone of health policy, the Plan encompasses the proposals set out by the regional health departments and objectives to be met within the three-year period.
2009	Institutional agreement	State and Regions	Health Pact (*Patto per la Salute*) between the State and the Regions 2010-2012	Regions are required to subscribe to annual 'Health Pacts' which make additional resources conditional upon the achievement of healthcare planning and expenditure goals.
2011	National strategic document	Ministry of Health	National Health Plan 2011-2013 (*Piano Sanitario Nazionale* 2011-2013)	Cornerstone of health policy, the Plan encompasses the proposals set out by the regional health departments and objectives to be met within the three-year period.

[6] This section draws extensively from the contents of: The European Observatory on Health Systems and Policies, 'Italy – Health System Review', Health Systems in Transition, Vol. 11, n. 6, 2009

In a nutshell, Italy's healthcare system is a regionally based public health service (*Servizio Sanitario Nazionale*/SSN) that provides universal coverage free of charge at the point of service. The system is organised around three levels: ***national, regional and local***. The role of the National Government - ensuring the general objectives and the fundamental principles of the system – is made particularly complex by the responsibilities attributed to the Regions[7] on health policy by the Constitution[8]. This sometimes results in jurisdictional overlaps between the two on health policy matters ending in Constitutional Court cases. At any rate, especially after the 2001 Constitutional reform, the bulk of health policy responsibilities lies with the ***regional governments***, that through their regional health departments (*Dipartimenti di Sanità Pubblica*), are also responsible for ensuring the delivery of health services through a network of population-based healthcare facilities and hospitals. The actual delivery of these services takes place through a network of population-based ***Local Health Enterprises*** (*Aziende Sanitarie Locali*/ASLs) established at the County (*provincia*) or Sub-county level. ASLs retain certain public health rights on their own and are responsible for achieving the health objectives and targets established by the regional authorities.

This Constitutional arrangement is not without a number of practical consequences. First of all the planning and programming process can become particularly cumbersome from the procedural viewpoint, as it has to be enshrined in a law and therefore requires Government and Parliament approval, as well as the approval of all the Regions concerned. Problems arise as there can be concurrent pieces of policy/programming legislation on the same subject; to complicate things further, a National Programme is usually mirrored in 21 separate Regional Programmes[9] (one per region), and may even be replicated at ASL level. The Ministry sets out the targets for the SSN and the related strategic allocation of funds through a three-year National Health Plan *(Piano Sanitario Nazionale)* whose time-span, however, does not necessarily coincide with that of the parallel Regional Health Plans (*Piani Sanitari* or *Sociosanitari Regionali*) that remain stand-alone documents. That said, as of 2010 a number of Regions were still operating according to their 2000 or 2002 Health Plans, while at the National Plan in use was that of 2006. In fact, because of the long and complex approval process it frequently happens that the validity of these plans is prolonged as their end date is deferred (*prorogatio*).

Also to ensure better coordination of activities, since 2004 prevention activities have been separately programmed in a ***National Prevention Plan*** (*Piano Nazionale di Prevenzione*) which, although formally part of the National Health Plan, has become a planning document in its own right with a simplified autonomous approval procedure requiring the agreement of the Health Ministry and the Regions only. Originally conceived as a three-year document also the National Prevention Plan has frequently been prolonged beyond expiry and to date two such documents have been approved, respectively covering the 2004-2006 and the 2010-2012 periods. Needless to say, each region has its own ***Regional Prevention Plan*** whose time coverage is however synchronised with the national one. Although the product of a joint effort, the National Health Plan and the National Prevention Plan are respectively produced by two separate ministerial bodies, the ***Healthcare Planning, Essential Levels of Care and Health Systems Ethics Directorate*** and the ***Healthcare Prevention Directorate*** (spearheaded by the National Centre for Disease Prevention

[7] In addition to regions, the administrative articulation at sub-state level includes the two autonomous provinces of Trento and Bolzano which, as far as public health jurisdiction is concerned, can be broadly assimilated to the status of regions. Any reference to Italian regions in this document should therefore be interpreted as including also these autonomous provinces.

[8] According to Art.117 of the Italian Constitution, the State and the Regions concur in legislating on matters of public health (*legislazione concorrente*). The 1990s saw a move towards greater decentralisation and self-rule in favour of the Regions and lower levels of administration (*enti locali*). Accordingly, a gradual decentralisation process of the Italian National Health Service started in 2001 with *Constitutional Law No. 3, 18 October 2001, which modified the second part of the Italian Constitution (Title V), providing regions with more powers*.

[9] http://www.agenas.it/agenas_pdf/Psr_vigenti.pdf

and Control/CCM, see below). The two Directorates belong to separate Departments, namely the Directorate of Quality and that of Innovation. This peculiar architecture and division of responsibilities between units responsible for planning and units responsible for prevention is reportedly replicated in the Regions.

Over and above these general programming instruments, Italy knows also the instrument of ***sectoral plans***. One of the first such examples is the 2004 Cancer Screening Plan (*Piano Nazionale Screening*) and others are currently under discussion, for instance on Alzheimer[10] and Rare Diseases[11]. One of the advantages of these sectoral plans is that related provisions (budgetary allocations, implementation mechanisms, etc.) are directly binding on all the actors concerned. Their main drawback is that - being considered legal documents in their own right and not part of the broad National Health Plan - these sectoral documents need to undergo a full-fledged approval process, including parliamentary reviews, which can be very time- and resource-consuming. To by-pass these constraints, some Regions have enacted their own sectoral plans by means of regional laws before the national one was approved, at the cost of incurring in coordination problems later on. However, there are also cases of regional sectoral programmes whose implementation provisions vary to some extent from the national ones, even if approved after the national sectoral plans had been enacted.

Governance Bodies. At the national level, the ***Ministry of Health*** is responsible for five different policymaking functions: (i) healthcare planning; (ii) healthcare financing; (iii) framework regulation; (iv) monitoring; and (v) general governance of the National Institutes for Scientific Research. Within the framework of the Ministry operates the ***National Centre for Disease Prevention and Control*** (*Centro Nazionale per la Prevenzione e il Controllo delle Malattie*/CCM) – established in 2004[12] with the general mandate to prevent the outbreak of diseases and to curb public health emergencies, and more specifically to coordinate the implementation of the National Prevention Plan[13]. In carrying out its mission, the Ministry of Health relies on the expertise of a number of advisory and technical scientific bodies, including:

- The ***National Health Council*** (*Consiglio Superiore di Sanità*/CSS) - an expert advisory body providing important technical and consultative support to the SSN.

- The ***National Health Institute*** (*Istituto Superiore di Sanità*/ISS) - the main institution for scientific and technical research, control and advice in the field of public health[14].

[10] While a National Plan for Alzheimer is still under consideration, the first Regional Plan for Alzheimer has been approved in April 2012 in the Lazio Region following from the draft law of 30 June 2010 (proposta di legge n. 35 del 2010): "Piano regionale in favore di soggetti affetti da malattia di Alzheimer-Perusini ed altre forme di demenza". Art. 1 of the new law reads: "The Region […] *in compliance with the objectives set out by the European Union in the area of neurodegenerative diseases*, ensures that the necessary assistance and healthcare services are provided to patients affected by the Alzheimer's disease or by other forms of dementia".

[11] Although Italy has not yet adopted a National Plan for Rare Diseases, one is being drafted, in preparation for which a public consultation was launched and concluded in April 2012. Prevention of Rare Diseases has gained momentum after the European Communication 'On Rare Diseases: Europe's Challenges' – Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on Rare Diseases: Europe's challenges, COM(2008) 679 final.

[12] Law 138 of 26 May 2004

[13] http://www.ccm-network.it/documenti_Ccm/normativa/Intesa_23-3-2005.pdf

[14] Aluttis, C. et al., 'Review of Public Health Capacity in the EU - Supplementary document to the final technical report of Tender No. EAHC/2009/Health/05: Developing public health capacities in the EU', 2012

- The ***Institute for Prevention and Safety at Work*** (*Istituto Superiore per la Prevenzione e Sicurezza del Lavoro*/ISPESL) - responsible for providing information and research on health promotion and healthy conditions in the workplace.

- And the recently established ***National Agency for Regional Health Services*** (*Agenzia Nazionale per i Servizi Sanitari Regionali*/Age.Na.S) - jointly accountable to the Regions and the Ministry and carrying out comparative analysis of the costs and effectiveness of the services offered to the public. Its activities also include: (i) the development and dissemination of systems and methodologies for patient safety; (ii) the management of programmes for Health Technology Assessment (HTA); and (iii) the preparation of clinical as well as organisational guidelines.

At the regional level the Regions and their regional health departments bear full responsibility for planning healthcare activities, for monitoring the quality, appropriateness and efficiency of the services provided. In performing their *legislative function*, regions decide on: (i) the principles for organising healthcare providers and for providing healthcare services; (ii) the criteria for financing all healthcare organisations (public and private); and (iii) the technical and management guidelines for the provision of services in the regional health departments. Conversely, their *executive functions* involve the preparation of three-year ***regional health plans*** (*Piani Sanitari Regionali*), mirroring the overall National Health Plan (see above) based on specific regional healthcare needs. Finally, regional health departments provide technical support to local healthcare facilities. Ten regions have created ***regional health agencies***, whose tasks consist of assessing the quality of local healthcare, providing technical and scientific support to the regional health departments and to the Local Health Enterprises, as well as of defining the range of services to be supplied. Furthermore, the agencies follow the accreditation process at the regional level, assess the quality of local healthcare services, and liaise with Age.Na.S. accordingly. Levels of performance vary considerably between regions[15] also because of "*differences in contextual, political, economic and cultural factors as well as differences between regional health systems*[16]".

The main coordination mechanism where lines of action are jointly agreed and adopted by the National and Regional Governments is the ***Standing Conference on Relations between the State, the Regions and the Autonomous Provinces*** (*Conferenza permanente per i rapporti tra lo Stato, le regioni e le province autonome*[17]). The Conference is the main consultative body for all the legislative activities with a regional dimension. It can promote collaboration schemes across regions and the central government and propose its own legislation[18]. The Conference has also become the main channel to communicate EU policy orientations to all the actors involved in the management of health policy. In fact, at least two of the meetings of the Standing Conference each year are specifically devoted to discuss EU policy and its implications on the Regions. This separate session is known as ***sessione comunitaria***[19] and should ensure that national policy making issued in line with the Community's is adapted to the country's regional contexts. The Regions have yet another coordination platform where they are the only participants, without any central government involvement, the so-called Conference of the Presidents of the Regions and Autonomous Provinces (***Conferenza delle Regioni***), with the Presidents of the Regions as its members. This is the

[15] Aluttis, C. et al. 2012: Review of Public Health Capacity in the EU. Final Report. Maastricht/The Netherlands, March 2012.
[16] *Ibid.*
[17] The Conference (*Conferenza Stato-Regioni*) was established by Law 400/1988 to provide a platform where the Regions could be represented in the high-level decision-making process, particularly in matters with direct implications on the Regions. The Conference has become the prime line of communication and negotiation between the State and the Regions. It is through the Conference that State-Regions Agreements (*Intese Stato-Regioni*) are reached.
[18] http://www.statoregioni.it/
[19] Established by Law 9 March 1989, n. 86, art. 10.

institutional lieu where Regions prepare documents expressing their interests and stakes, including in the area of public health. Once agreed on a shared course of action, a delegation composed of regional representatives meets and communicates the agenda of Regions to the Government in the State-Regions Conference.

Policy Implementation, Monitoring and Evaluation. The Ministry of Health exercises its leverage in policy implementation mainly through the process of *resource allocation* to the Regions. As a rule, the Ministry has very limited discretion in allocating resources and on the contrary is called to manage a situation of chronic financial deficit among the regions. An attempt has been made to limit these deficits by requiring the regions to subscribe to annual 'Health Pacts' (*Patti per la Salute*), which make additional resources conditional upon the achievement of healthcare planning and expenditure goals. Since 1997 resources have been distributed through a weighted capitation rate. This takes into account the demand for healthcare services of each region, as well as the age structure and health condition of the population, given by the mortality rate and an indicator-based performance reporting and assessment mechanism: the essential level of assistance indicators (LEA). ***Essential level of assistance indicators*** describe the level of services that are to be guaranteed to the citizen through public financing[20]. Failure to achieve the minimum standards as per the indicators, results in a (limited) financial penalty[21]. The ascertainment of whether these minimum standards have been met by the Regions requires a complex certification. Responsibilities for the certification process are divided among the Regions themselves, the Health Ministry, Age.Na.S., AIFA (the Italian Medicines Agency) and the Permanent LEA Committee[22].

On the other hand, a separate system exists for performance assessment and funding of the National Prevention Plan, which falls under the supervision of the CCM. A share of funds (75%) is allocated to the Regions for the implementation of their PRP that also follows an indicator-based certification procedure. While the remaining share (25%) – the so-called ***central actions*** – are directly approved by the CCM Scientific Committee[23] following criteria and standards pre-defined in a yearly CCM programme[24]. Italy has also recently attempted to introduce a practice of evaluating programmes and plans with the aim of building on lessons learnt and inform the subsequent programming period. So, for instance, the current PNP will be evaluated. But although the evaluation practice is gaining some ground, experience in this field remains rather limited by EU standards.

2. Overall EU Health Policy Adoption/Implementation

It is recognised that the uptake of EU health polices would be easier if strategic policymaking could be concentrated on a smaller number of long-term priorities consistently pursued over time, otherwise there is the risk of dispersing resources by trying to operate in many areas. This may easily limit impacts. Ideally, there should be no more than a dozen strategic objectives with a clear European dimension; such should be the areas where Government should focus its attention. The

[20] In compliance with the Ministerial Decree of 29 November 2001 defining the LEA package.
[21] As per Ministerial Decree of 12 December 2001
[22] Certification of compliance is attributed to the Regions after the competent authorities analyse the documentation duly provided by the Regions, and following a cross-check of these forms with the Ministry's records. In this process, the LEA Committee establishes the methodology to be followed, while the actual data collection, assessment by means of LEA indicators and cross-check with Ministerial records is performed by the Health Ministry's offices.
[23] The CCM is composed of a Scientific and a Strategic Committee (*Comitato Scientifico*, *Comitato Strategico*). Besides assessing the overall CCM annual programme proposal, the former examines and approves individual projects, while the latter sets intervention priorities, adopts annual programmes of activities, approves the CCM's activities report for the previous year and sets out guidelines for training and the dissemination of information.
[24] The last meeting took place on 19 April 2012, to screen proposed projects and assess their consistency with the CCM programme for 2012.

risk is that too many Europan priorities are not perceived as real priorities. There should be continuity of action with few new items added to the agenda; meanwhile, consistency of intent should be ensured over time. Momentum on these priorities should be maintained, among others, by means of Recommendations to be released at intervals of three to five years. The Recommendations should update on progress and orient future action. Adding too many items to the European agenda is also a cause of possible administrative burden and overstretching of resources. The number of staff who can follow the ever-growing number of European initiatives is limited and it might not always be possible to follow all of them with an equal level of attention. Summary views of the role played by some factors in influencing uptake of EU policies are reported in Table 2.1 below.

Table 2.1 – Assessment of possible factors affecting the adoption and implementation of EU policy

Obstacles/drivers	Comments
Institutional architecture (since uptake might be more difficult in more decentralised systems)	This is clearly an obstacle, not only because of institutional arrangements but also because decentralised systems are usually found in larger States whose epidemiological background can be extremely diversified as is the case in Italy.
The different nature of the soft law instrument chosen by the EU, i.e. whether Recommendations, Council Conclusions, or Commission Communications (since MS may attribute a different level of priority or deal with them in a different way)	Council Conclusions are a quite weak instrument because they are voted almost as a matter of institutional courtesy rather than after adequate discussion of the subject matter. Similarly, Commission Communications are not necessarily endorsed by the Member States; therefore they are a tool of dubious relevance in an OMC policy area. Their value may be restricted to simply paving the way for a subsequent recommendation. The conclusion is that Council Recommendations are the only soft law instrument that really counts.
Prior adequate discussion / consultation period before the adoption of a EU Policy (since this may facilitate adoption)	Evidence shows that a three-year preparatory discussion period is often necessary to come to a policy document that MS truly share in. The duration of this period is sometimes not in line with the Commission's own internal work programme deadlines that unduly impose a conclusion to a process that is not complete in terms of content development. The operational efficiency that results from this process is only apparent because it impinges on the democratic functioning of decision-making, and casts doubts on effective uptake on the part of MS at the end of the process.
Other aspects of legislative techniques adopted to put pressure on recipients (such as the inclusion in the text of deadlines for compliance or explicit reporting requirements)	Stakeholders and lobbying groups favour this technique as a way to put pressure on Parliaments. It may work or it may not. Experiences and opinions can vary in this respect and probably it is too early to tell. Reporting requirements included in soft legislation documents are never really considered mandatory and in any event, they are not perceived as a very influential factor.
Issues of national ownership (since policy items put forward in the European agenda by individual MS may encounter resistance in other MS due to national experiences, cultural factors, traditions or technical obstacles to transposition)	This is part of the problem mentioned above, as it can happen that the various National Presidencies propose items based on their national background, administrative tradition and experiences that have not really been shared and discussed with others and are approved just as a matter of courtesy after a very short discussion in the Council.
Adequate maturity, i.e. existence of sufficient evidence ('pilot' experiences, evaluations, scientific studies) supporting the inclusion of a given policy approach in the European agenda	The issue is not so much the adequate maturity of a policy, but rather the existence of a clear European added value, as was for instance the case with rare diseases. EU added value on any one priority does not have to translate, in the minds of policy

Obstacles/drivers	Comments
	makers, simply into prospects for mutual learning and exchange of best practices, as this is possible in all policy areas and regardless of European involvement. Support from PHP studies has often been limited because they have mainly been drafted for academic purposes and with limited attention to the peculiar needs of policymaking. Circulation of PHP results remains also quite limited.
Programming capacity (since some MS could find it difficult to cope with the total number of programmes, action plans, strategies requested by the EU in a given period. Not only for internal capacity constraints, but also for the duration of the political approval process)	This is indeed a crucial factor. In the Italian context formal programming requires a relatively long and complex procedure and therefore requests for a sectoral plan have to be strictly prioritised. Much in the same vein, there can be staff shortages to follow all the initiatives discussed at the EU level.
Clear prioritisation of actions (since the inclusion of too many European items in the policy making agenda might ultimately be detrimental for most urgent priorities, particularly in times of financial crisis)	Too many fast-changing priorities have been released over time. Conversely, to avoid dispersing focus and resources, only a few items should be endorsed at once so as to ensure continuity in the release of policy documents and in the parallel financing of research programmes. The "Rare Diseases" priority has certainly benefited from the high level of attention that the Commission has managed to maintain over time by various means.
Existence of relevant OMC / JA mechanisms on the subject at the European level and the MS participation therein (since this may facilitate adoption)	This is not really a relevant factor. Participation in Joint Actions and OMC is often only a question of institutional etiquette and a mild attempt to keep oneself updated on the issue at hand. For these reasons, they are far from being reliable indicators of effective policy uptake.
Pressure from stakeholders' groups or lack thereof (since this may ultimately influence uptake)	This is certainly a major factor. Involvement of NGOs played a major role in the establishment of a national policy on cancer screening; their absence is seen as detrimental in those policy areas where these groups are less active or inexistent.

Summary of Main Conclusions

- The ad hoc preparation of *sectoral* programmes stemming directly from a piece of European soft legislation is a much more meaningful sign of EU added value than mere quotations of European legislation in *general* programming documents. Any indicator that equalled these two scenarios would be highly misleading in the country.

- Citation/quotation of European guidance in general national programming documents could be a poorly representative indicator of policy uptake. There can be cases (e.g. the National Prevention Plan) where a European item is not included simply for strategic reasons (i.e., to reach a consensus as soon as possible between the State and the Regions). After that, regions are free to decide whether to include the said item in their respective Regional Prevention Plans.

- Strengthening evaluation is area where EU contribution could be higher in the future.

- It is expected that the problem of the rotational presidencies and of their changing priorities will not be solved any time soon, but efforts should be made to find alternative mechanisms to ensure continuity in the EU focus on a limited set of clear objectives.

- It was noted that in Italy linking process indicators with financial incentives (e.g. in the PHP) can give some appreciable results in terms of policy uptake.

- Finally, the Commission should be very cautious before introducing bibliographic indicators, or indicators otherwise based on scientific literature, as they risk to provide unintended incentives to work for academic purposes only in projects disconnected from policymaking and on-the-ground implementation.

B – Health in All Policies (HIAP)

1. Legal, Policy and Institutional Framework

Table 1.1 - Legal and Policy Framework

Year	Type	Authority	Title	Comment
2007	Working paper	Turin Local Health Enterprise 3	"Health in All Policies" *("Salute in Tutte le Politiche")*	The document setting out the Italian HIAP strategy.
2007	Programming document	Health Ministry; the WHO European Observatory	"Gaining Health – Making healthy choices easier" *("Guadagnare salute – Rendere facili le scelte salutary")*	Inter-ministerial, multi-component programme involving communication activities and actions to reduce alcohol and tobacco consumption and to increase fruit and vegetables intake, among others, to reduce the long-term burden of chronic diseases on the healthcare system and society.
2007	Baseline study	Istituto d'Igiene dell'Università Cattolica nel Sacro Cuore	The effectiveness of Health Impact Assessment	This study: • Maps HIAs in all Italian regions in 2003-2004; • Identifies HIA activities performed and their features; • Analyses HIA processes and results; and • Disseminates and communicates HIA culture.
2008	Regional law	Abruzzo Regional Government	Abruzzo Regional Law 2/2008	Act explicitly requiring that HIA be incorporated in all EIAs or SEAs so as to gauge the health risks and benefits associated with any project, plan or programme of interest to the region.
2010	National strategic document	Ministry of Health	Draft 2011-2013 National Health Plan	The first national planning document including an explicit reference to HIAP. The strategy is articulated into four lines of actions with a clear focus on the regional and local Government level and an emphasis on grassroots participatory processes.
2010	National Strategic document	Ministry of Health/CCM	2010 National Prevention Plan	The first document to incorporate the *Guadagnare Salute* initiative in the national health strategy; the major example of national-level intersectoral cooperation
2010	Regional strategic documents	Piedmont, Lombardia, Veneto, Friuli Venezia Giulia, Marche, Tuscany and Emilia-Romagna Regions	2010-2012 Regional Prevention Plans	Earliest regional healthcare planning documents including explicitly the concept of HIAP.

Overall HIAP Strategy. The development of a ***national HIAP strategy*** has had a two-staged approach. It first materialised in ***2007*** when after the joint EU-WHO intergovernmental conference on "*Health in All Policies: achievements and challenges*" the Ministry of Health requested its CCM department to contribute to the establishment of a brand new Health in All Policies strategy that

would consist of the *elaboration of an evaluation document to assess the impact that each and every non-healthcare-related public policy might have on people's health. Such an assessment would then justify the agenda of priorities for future policy-making and would involve the appropriate national and sub-national administrations.* The local health prevention department entrusted with the task (ASL 3 Turin) drafted a ***working paper*** "*Salute in Tutte le Politiche*[25]", that although strictly speaking never officially endorsed, was long referred to as the Italian strategy on the subject and as such can be found quoted also in recent EU-funded studies[26]. While making specific reference to the EU-waged HIAP approach, as well as to HIAP understood in the WHO terms, the document outlines the possible terms of a HIAP strategy in Italy and incorporates considerations on the establishment of intersectoral cooperation and the institutionalisation and usage of Health Impact Assessments (HIA) with specific reference to five policy areas that were being investigated in parallel study commissioned by the CCM to the same institution.

Italy has then first included an explicit reference to the concept of HIAP in a national strategic document with its draft ***2011-2013 National Healthcare Plan*** (*Piano Sanitario Nazionale*/PSN[27]) currently being under approval[28] by the National Government and the Regions. The document includes a chapter on the need to promote the principles of Health in All Policies, and specifically also mentions compliance with the requirements of both the 2007 EU Health Strategy and the principles stated in 1997 WHO Conference on Intersectoral Cooperation on Health[29]. It has, however, a less ambitious scope than the 2007 working paper. In fact, the PSN-HIAP strategy is based on a twofold cautionary approach of preconditions to be met for any further institutional development: 1) the need to have in place a sounder basis of scientific evidence to demonstrate clear links between health and the various underlying policies; 2) the need to better develop processes and mechanisms (political leadership, public support, legal basis and technical assistance) to promote HIAP in the various communities. The strategy is articulated into four lines of actions with a clear focus on the regional and local Government level and an emphasis on grassroots participatory processes, and namely:

- increasing political awareness about the need to implement HIAP;
- creating intersectoral working groups to promote HIAP at regional and local levels;
- supporting empowerment projects at the community level to build capacity for participatory approaches and intersectoral cooperation; and
- training.

This twofold approach draws from two preparatory studies. The seminal 2007 € 200,000 project on ***Health in All Policies*** (*Salute in Tutte le Politiche*[30]) of which the working paper above was part, and that aimed to collect all the available information on the links between public policies and health. The project was articulated into five specific studies on mobility, work, lifestyles, cities, and income, of which only the first has been published[31] so far. The study, however, reportedly contributed to raising awareness about the paucity of sound or at least plausible scientific evidence available to support HIA in a number of policy areas and the need to invest much more in related research before the adoption of HIA as a full-fledged operational instrument. Still in 2007,

[25] ASL3 Torino, Salute in tutte le politiche, 2007

[26] Joint Action on Health Inequalities, 'Health Impact Assessment: Pre-meeting questionnaire summary report', reports as follows: the policy areas considered for HIAP policy in Italy include: the impact on equity in the processes of care and non-healthcare polices; occupation during recession, specific labour polices i.e. control of asbestos and prevention of work accidents in constructions.

[27] http://www.agenas.it/agenas_pdf/181110_per_PSN.pdf

[28] The approval process originally scheduled for the end of 2011 has reportedly been frozen by the change of Government first and the budgetary difficulties linked to the Eurozone crisis then.

[29] http://whqlibdoc.who.int/hq/1997/WHO_PPE_PAC_97.6.pdf

[30] http://www.ccm-network.it/prg_area4_salute_politiche_Asl3TO

[31] http://www.ccm-network.it/documenti_Ccm/pubblicazioni/salute-in-tutte-le-politiche/Mobilita-e-salute.pdf

Age.Na.S was commissioned to conduct an inquiry[32] on the participatory mechanisms to involve NGOs and citizens in the health-related aspects of policymaking at all levels. The study concluded that i) there was no such thing as a basis for a national plan to develop and coordinate institutional and capacity building in the field of intersectoral cooperation, and that ii) hardly any mechanism was available to promote a valuable and replicable model of community empowerment out of the few and far between examples that could be found at local level. Following the study, an interregional working group was created to provide a platform for the exchange of community empowerment experiences[33].

At the regional level specific references to HIA – although with a meaning that is quite detached from the spirit of the original EU HIAP policy initiative and without any explicit reference to it – have been included in seven ***2010-2012 Regional Prevention Plans*** (*Piani Regionali di Prevenzione*/PRP[34]), and namely. Piedmont, Lombardia, Veneto, Friuli Venezia Giulia, Marche, Tuscany and Emilia-Romagna all located either in the North or in the Centre of the Country.

Governance. Responsibility for promoting HIAP is generally entrusted with the Ministry of Health and the HIAP strategy has been *de facto* promoted at the national level by the CCM. But there is no unit at either the national or regional Government level specifically entrusted with promoting HIAP and nobody routinely collects data, monitors local developments or evaluates experiences on a regular basis accordingly. The last data available come from a baseline study commissioned to a network of Universities in 2004 in preparation of the Finnish presidency initiative and this was also used as a source of data for the related EU-level preparatory study[35]. Some of the regions above, e.g. Emilia-Romagna have proposed performance indicators for their PRP but these have not been necessarily monitored or reported back to the Ministry because these actions are considered of a pilot nature and therefore not relevant for national fund disbursement purposes and related certification of the progress reached in implementation. The *Conferenza delle Regioni*, also in the light of the divisive nature of HIA among the regions themselves, has reportedly decided to stay away, at least for the time being, from any official data collection or monitoring role on the subject, which is not currently in its agenda. Until the results of the Agenda 21 project are published, the only database of experiences available is therefore that of the Italian Healthy Cities network collecting all the HIAs of network members. The level of progress in the various priorities set in the EU policy documents can be summarised in Table 2.1 below.

[32] Age.Na.S., 'Metodi e strumenti per la partecipazione attiva dei cittadini alla valutazione dei servizi ed alle decisioni locali in materia di organizzazione dei servizi sanitari', 2007. All community-based empowerment initiatives documented by the study can be accessed through the designated database at http://www.agenas.it/database_empowerment.htm

[33] http://www.agenas.it/seminario_approfondimento_empowerment.htm

[34] http://www.ccm-network.it/Pnp_2010-2012_piani-regionali

[35] A baseline study on the state of HIA in Italy financed by the European Commission and by the WHO European Observatory, was conducted by the Istituto d'Igiene dell'Università Cattolica nel Sacro Cuore, member of the Italian Network on Health Impact Assessment (Italian HIA Network, hereafter). The research project, named "The effectiveness of Health Impact Assessment" started in April 2007. It included the following activities:
1.Mapping HIAs in all Italian regions from 2003 onwards (most recent information, however, dates 2004);
2.Identification of HIA activities performed and their features;
3.Analysis of HIA processes and results; and
4.Dissemination and communication of HIA culture.

2. Policy Implementation

Table 2.1 – Uptake and implementation of HIAP priorities

Priorities	Uptake/implementation
Develop the knowledge base on health and its determinants, associated trends, and trends in health inequalities.	The draft 2011-2013 National Healthcare Plan includes provisions on the need to develop intersectoral cooperation, following from the principles stated in the 1997 WHO Conference on Intersectoral Cooperation on Health. It solicits gathering a sounder basis of scientific evidence to demonstrate clear links between health and the various underlying policies. However, a comprehensive wealth of knowledge in this regard at national level has not been put together yet. Analysis of health determinants has been done regionally, in a number of cases. The seminal 2007 Health in All Policies project has contributed to demonstrating that the knowledge currently available is too anecdotal, and that would be much needed to support HIA in different policy areas.
In national policy formulation and implementation, take into account the added value offered by cooperation between government sectors, social partners, the private sector and the non-governmental organisations for public health.	The 2007 *Guadagnare Salute* project remains to date the major attempt to coordinate intersectoral coordination at national level. In 2007, Age.Na.S conducted an inquiry on the participatory mechanisms to involve NGOs and citizens in the health-related aspects of policymaking at all levels. The study concluded that there is currently no basis for a national plan to develop and coordinate institutional and capacity building in the field of intersectoral cooperation.
Undertake, where appropriate, health impact assessments of major policy initiatives with a potential bearing on health.	HIAs are not performed systematically anywhere in Italy. HIAs are restricted to a number of *projects*, mostly with an environmental bearing, while they are performed on *strategies*.
Pay special attention to the impact which major government policies have on equity in health, including mental health, and guarantee necessary efforts to tackle health inequalities.	A greater stress on equity has been put since the inception of the Health Equity Impact Assessment approach, supported by a EU joint action, which is, however, still at a seminal stage.
Focus on capacity building in policy analysis and development for improved intersectoral policies.	The 2007 study conducted by Age.Na.S. (see above) showed that there is no emphasis of a national strategy to develop capacities and institutional partnerships in favour of intersectoral coordination.

Table 2.2 – Intersectoral coordination programmes and initiatives

Year	Type	Entities involved	Title	Description
2007	**Intersectoral cooperation** programme	Multiple ministries	Gaining Health – Making healthy choices easier (*"Guadagnare salute – Rendere facili le scelte salutary"*)	Inter-ministerial, multi-component programme established by a Prime Minister's decree involving communication activities and actions to reduce alcohol and tobacco consumption and to increase fruit and vegetables intake, *inter alia*, to reduce the long-term burden of chronic diseases on the healthcare system and society.
Ongoing	**Intersectoral cooperation** agreements	Multiple Ministries	Bilateral cooperation protocols (*protocolli di intesa*)	Established under the *Guadagnare Salute* programme, agreed by the Health Ministry and the representatives of 22 Ministries, unions, and private sector organisations. These include the Ministry of Education, the Ministry of Agriculture, the Ministry of Sport and Youth, producers and public

Year	Type	Entities involved	Title	Description
				service operators, Local Health Enterprises, local administrative entities, unions, and planning agencies.
Ongoing	**Intersectoral cooperation** project	National Economy and Labour Council (Consiglio Nazionale Economia e Lavoro/CNEL); Italian Statistical Agency (ISTAT); Health Ministry	Well-being, Equity and Sustainability (*Benessere Equo-Sostenibile*/BES) Project	The project aims at overcoming GNP-bound indicators to measure a society's progress and well-being, and at developing alternative indicators encompassing a healthcare component.
2007-2011	**HIA** project	Health and Environmental Departments of the Emilia-Romagna Regional Government	Moniter project	It aimed to increase knowledge of incinerators' emissions and their impact on health and included a rapid HIA procedure.
Ongoing	**HIA** project	Agenda 21 Italian coordinating group, local authorities and public representatives	HIA working party	The aim of the working group is to establish common basic knowledge of HIA and procedural pathway to be extended nationwide.
Ongoing	**HIA** project	Six regional governments	VISPA project	A Moniter project offshoot, it aimed at testing a homogeneous methodology to carry out rapid HIA at the project level with a view for its possible adoption by all the Health Prevention Departments concerned
TBD	**HIA** project	TBD	VISPA2 project	A follow-up project of VISPA.

Intersectoral Coordination. A first reference to intersectoral coordination as a broad policymaking principle could be found in a footnote of the ***2010 National Prevention Plan*** (*Piano Nazionale di Prevenzione*/PNP[36]) incorporating in the national health strategy the *Guadagnare Salute* initiative that remains so far the major example of intersectoral cooperation at the national level in the country. ***Guadagnare salute – Rendere facili le scelte salutari***[37] *(Gaining Health – Making healthy choices easier)* is a 2007 inter-ministerial, multi-component programme established by a Prime Minister's decree involving communication activities and actions to reduce alcohol and tobacco consumption and to increase fruit and vegetables intake, *inter alia*, to reduce the long-term burden of chronic diseases on the healthcare system and society. The programme was developed by the Health Ministry in cooperation with the WHO European Observatory, and demands planning healthcare interventions in a concerted manner, so to produce a global approach to risk factors and to the consequent burden of chronic diseases. The strategy involves a division of responsibilities between all actors concerned (national and regional administrations, local entities and the private sector), so as to coordinate action and assess the health, environmental, social and economic implications of future policy. *Guadagnare Salute*, however, predates the EU Health Strategy and

[36] http://www.comunitapnp.it/file.php/1/Allegato1_PNP_10-12.pdf
[37] http://www.ccm-network.it/GS_intro; http://www.guadagnaresalute.it/programma/

was formally adopted in response to the 2006 WHO Europe Gaining Health initiative[38] that in turn summarises also a number of EU policy orientations on non-communicable diseases and can be considered the transposition with a broader mandate of the EU Platform on Nutrition and Obesity.

Therefore, for the time being, the only[39] other intersectoral cooperation agreements in place are the ***bilateral cooperation protocols*** (*protocolli di intesa*) established under the *Guadagnare Salute* programme, agreed by the Health Ministry and the representatives of 22 Ministries, unions, and private sector organisations. These include the Ministry of Education, the Ministry of Agriculture, the Ministry of Sport and Youth, producers and public service operators, Local Health Enterprises, local administrative entities, unions, and planning agencies. It is worth noting that while some of the protocols have been effectively put into practice, others have remained dormant.

The only recent notable example of intersectoral coordination is the ***Well-being, Equity and Sustainability*** (*Benessere Equo-Sostenibile*/BES) Project[40], a joint initiative of the National Economy and Labour Council (Consiglio Nazionale Economia e Lavoro/CNEL) and the Italian Statistical Agency (ISTAT). The project aims at overcoming GNP-bound indicators to measure a society's progress and well-being, and at developing alternative indicators encompassing a healthcare component. The Working Group in charge of developing such indicators sees contributions from experts from the Ministry of Health.

Local working practices are not generally intersectoral for a combination of traditional and institutional reasons, although there can be notable exceptions in certain regions. For instance, there can be examples of cooperation protocols between single municipalities and health departments, but this highly depends on the single regional policies, as responsibilities for programming and urban planning lies at the regional level. There are clear legal provisions to regulate cooperation between the Health Prevention Departments and the Local Environmental Agencies as far as health and the environment are concerned. The 2009 LEA performance indicators also included a reference to the technical assistance provided by health prevention departments to local governments on the relationship between health and land zoning, about environmental planning and on the link between road security and space programming, which would represent a further budgetary incentive to spur local intersectoral cooperation. But cultural and legal resistances remain strong and initiatives generally implemented on an *ad hoc* basis because of particular needs.

Health Impact Assessment (HIA). The history of HIA in Italy is strictly intertwined with the quite controversial implementation of the EU Directive (85/337/EEC) on Environmental Impact Assessments (known as ***the EIA Directive***) and the concept itself is hardly understood outside that context, but by a few specialists knowledgeable of International and European policy matters. There

[38] http://www.euro.who.int/__data/assets/pdf_file/0008/76526/E89306.pdf

[39] For the sake of completeness it is worth to quote yet another initiative bordering intersectoral cooperation: an intersectoral Working Group on HCAIs and antimicrobial resistance was established in 2009 following the Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine. According to the Recommendation, each Member State needs to have in place "*an appropriate intersectoral mechanism for the coordinated implementation of the [proposed] strategies [on the prudent use of antimicrobial agents in human medicine] as well as for the purposes of information exchange and coordination with the Commission and the other Member States*" - The Council of the European Union, Council Recommendation of 15 November 2001 on the prudent use of antimicrobial agents in human medicine (Text with EEA relevance) (2002/77/EC). The Group gathers specialists with mixed expertise in both human and veterinary medicine from AIFA, the National Health Institute and from the Prevention Department at the Ministry of Health. It aims to raise awareness and intersect skills and knowledge of these two areas of healthcare (AMR and HCAIs). However, the Working Group is only intersectoral in the sense that it forms an umbrella gathering a diverse set of institutions and organisations, but all related to healthcare (whether in terms of human or animal medicine, AMR or HCAIs).

[40] http://www.misuredelbenessere.it/

is no explicit provision to carry out a HIA either in the National Framework Law implementing the EIA Directive, or in the related Regional Sub-Laws, although health matters are mentioned in an annex among the aspects to be considered. However, irrespective of any environmental regulation the prevention of health threats due to environmental hazards is among the statutory responsibilities of the health prevention departments that sit in the intersectoral *Conferenza dei Servizi*[41], a joint authorisation procedure for approving projects with a major environmental impact. It can happen quite erratically (and critics say also quite arbitrarily) that the single health prevention department, at its discretion, might require not "the" health impact assessment, but "a" health impact assessment of any given project. This has given rise to a fairly chaotic and unpredictable series of documents with a very different scope and methodology, all labelled under the same confusing name of "health impact assessments". Needless to say, since these assessments have been usually requested for particularly sensitive projects with strong neighbourhood effects (e.g., landfills, incinerators, animal waste, etc.) the matter has become increasingly politicised and controversial and HIA also perceived as means to interfere on political decisions through bureaucratic command and control mechanisms rather than genuine consultative procedures. The same considerations apply possibly even on a larger scale to the SEA level, where HIA is also reportedly implemented quite erratically and without well defined methodologies or intersectoral cooperation protocols up to the point that a recent verdict of the Council of State has called for the Departments concerned to cooperate in its implementation and avoid command-and-control behaviours, or alternatively to carry it out with internal resources only, to avoid the underlying plan approval process to come to a complete standstill.

There has been a proposal in April 2012, from the mayor of the ***Turin municipality*** to institutionalise the process together with a commitment to conduct a HIA of all local government decisions, possibly also because the capacity of the local health prevention department is considered among the highest in the Country, but no concrete follow-up has been taken so far.

The first Italian region to try and explicitly regulate HIA as a routine and mandatory component of EIA and SEA was Abruzzo with a ***2008 regional law***[42]. But the matter remained so politically controversial that the subsequent Regional Government cancelled the law just a few months after its approval and the legal row that followed even ended before the Constitutional Court where it eventually subsided. Another attempt at better regulating environmental HIA by means of soft law instruments has stemmed from the CCM-funded ***Moniter project***[43], promoted by the Health and Environmental Departments of the Emilia-Romagna Regional Government between 2007-2011[44], with the aim to increase knowledge of incinerators' emissions and their impact on health. Since Moniter included a rapid HIA procedure, the initiative was subsequently expanded, rebranded and extended to five other regions under another CCM-funded project ***VISPA***[45] (literally HIA for the public administration). It aimed at testing a homogeneous methodology to carry out rapid HIA at the project level with a view for its possible adoption by all the Health Prevention Departments concerned. It seems very likely that VISPA will have a follow-up pilot VISPA2 to expand its scope and build consensus on a methodology at the programme or even possibly the policy level, although

[41] A *Conferenza di Servizi* is to be held whenever an agreement between two or more public administrations has to be reached, because a decision by one administration requires the participation of or has direct implications on other administrations. The Conference is a fully-fledged complex decisional process conceived in such a way as to take into account the interests and viewpoints of all the stakeholders involved.

[42] Art. 2 and 3 of Abruzzo Regional Law 2/2008, explicitly mentioned that HIA was an instrument to be incorporated in all EIA or SEA about the health risks and benefits of any project, plan or programme of interest to the region.

[43] http://www.arpa.emr.it/moniter/

[44] The Moniter Project was also presented by Linzalone *et al.* at the 2009 and 2011 chapters of the International HIA Conference. See http://www.apho.org.uk/resource/item.aspx?RID=110294 and http://si.easp.es/eis2011/wp-content/uploads/2011/04/cori-per-grenada-moniter.pdf

[45] http://www.saluter.it/ssr/aree/sanita-pubblica/il-progetto-vispa

this is still seen by some with some skepticism. To further clarify the legal framework some regions are considering better regulating HIA within the framework of revising their EIA laws with an emphasis on extreme simplification of procedures[46].

Most of the experiences carried out so far in Italy have been at the *project level and even of an ex post nature*. Also, VISPA originally intended to be tested in concrete cases had to be re-engineered to repeat assessments from an ex post perspective due to the lack of projects to be assessed caused by the economic crisis. While the level of methodological agreement reached at the project level is generally deemed reasonable there are still concerns about the lack of any real methodological stability as far as the programme level is concerned. No national technical bodies have been ever charged with developing national guidelines. The National Health Institute (*Istituto Superiore di Sanità*/ISS) has conducted a number of HIAs upon the request of the Health Ministry or other public administrations, as also WHO-Europe has done. Its HIA activities, however, have been limited to sites and project with a potential for environmental risk or crisis. The HIA practice is not systematic with the ISS, either. While the Institute makes recommendations and advocates in favour of a more far-reaching use of HIA, its role has been mainly of an advisory/consultative nature. Also its practitioners lament the absence of a clear codification of HIA countrywide, which makes it impossible to replicate the assessments according to one standard methodology throughout the country. Since there is *no lighthouse scientific institution specifically entrusted with dissemination of HIAP best practices* at all Government levels, but a network of centres of expertise, mostly of an academic nature, exists. Among them together with the Turin ASL mentioned above, the National Research Council (*Centro Nazionale di Ricerca*/CNR) is a recognised centre of expertise as regards health and the environment and related HIAs.

As of today a number of guidelines and policy documents have been produced on HIA at the regional level. Some are specifically on HIA, while others focus on closely related matters. To mention but some:

- The **2008 HIA guidelines** drafted in the **Abruzzo Region** for the implementation of the abovementioned cancelled law[47];
- A **2011 proposal for HIA guidelines** in the **Piedmont Region** to shed some light on procedural aspects and better regulate the use of HIA within the framework of EIA and SEA procedures[48];
- The **VISPA** project guidelines;
- The **Veneto Region guidelines** on the assessment of health risk caused by environmental pollution[49]; and
- A **white paper on HIA** in the **Tuscany Region**[50].

Other structured examples of attempts at performing some form of HIA at the programme level are represented by the Local Health Plans (*Piani Locali di Salute*) drafted by local governments at the County level in some Northern Regions (Piedmont, Lombardy, Veneto, etc.), although these initiatives are often explicitly inspired to the Healthy Cities network principles[51].

[46] For instance application of HIA may be envisaged as the mere filling out of checklists and tables.
[47] http://www.negrisud.it/ambiente/lineeguidaVIS.pdf
[48] http://www.arpa.piemonte.it/arpa-comunica/events/presentazioni-convegno-via-vas-vis/linee-guida
[49] http://www.arpa.veneto.it/servizi-ambientali/ambiente-e-salute/file-e-allegati/as_linee_guida_rischio.pdf/view
[50] http://www.rete.toscana.it/sett/pta/7a_conferenza_ambiente/documenti/bianchi_buiatti.pdf
[51] http://www.aslal.it/Sezione.jsp?idSezione=452

The same year, a HIA working party was created as part of the Agenda 21 Italian coordinating group, in response to the demand for common methodological HIA guidelines from an ever growing host of institutional counterparts. The aim of the working group is to establish "*common basic knowledge and procedural pathway to be extended nationwide*[52]". In fact, as acknowledged by the pioneers of this group on the occasion of the 2011 international HIA conference, "*[common] frameworks constitute the most effective means of institutionalising HIA*[53]". The Project sees contributions from an array of local authorities and other public representatives already active in developing local strategies for sustainable development; alongside with agreeing on a HIA common ground (especially in terms of a common HIA methodology), the group sets out to disseminate the knowledge so created, create the necessary expertise to incorporate a health impact layer in environmental and strategic impact evaluations (EIA, SEA).

The working group participants have signed an "Agreement of Intent" whereby three main actions[54] are identified:

1. Establish an archive of knowledge, data and available documents on national HIA experiences;
2. Pilot a national training course on HIA procedure to harmonise curricula and competencies of HIA practitioners; and
3. Propose a "best practice tool" aimed at increasing the value of the training experience performed at the local level.

A general commitment to carry out HIA or inspire activities to HIAP principles has long been a mainstay of the ***WHO Italian Healthy Cities Network*** and of its members that also participate to the European Network and technical assistance in this respect was received from both the EU and the WHO[55], but this has never extended to a full-fledged institutional HIAP policy. Examples of HIAs are documented, collected and shared within the Network. Based on data gathered during fieldwork, an archive including a complete list and documentation of HIAs performed. However, access to this source (through the Network's website) is restricted to the Network's members. The Healthy Cities Network in Italy has been active in conducting HIA particularly in the areas of Environment, as well as Nutrition/Obesity and Physical Activity particularly within the framework of the *Guadagnare Salute*-funded initiatives mentioned before.

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[52] Developing common best practices to promote urban health HIA in Cities
Linzalone, N., Lauriola, P., Cadum, E., Natali, M. and the Italian HIA group, 'Developing common best practices to promote urban health', Geneva Health Impact Assessment Conference, 7 April 2010

[53] Lauriola, P. and Linzalone, N., 'Developing best practices - A proposal for a field-based and validated approach to HIA training', 2011 http://si.easp.es/eis2011/wp-content/uploads/2011/04/Granada-2011_Ag21-finale.pdf

[54] These actions will be executed through four Work Packages coordinated by experts. WP1 inventories HIA experiences produced in Italy. The aim is to increase knowledge integration, providing a basis of evidence and information for new applications; WP 2 acts to train national officials to fill in the gap in national HIA expertise; WP 3 envisages that the training workshops conducted in the Italian regions that have joined the project, will help validate existing HIA protocols and the way they are adapted to suit specific regional contexts; and WP 4 aims to develop nationwide guidance on the use of HIA, with a particularly emphasis on its use in urban design and planning in all those instances where health is likely to be significantly affected.

[55] Through the PHASE project, co-funded by the European Commission, DG Environment 'Community Framework for Cooperation to Promote Sustainable Development', and by the WHO Regional Office for Europe, the PHASE Project produced http://www.comune.bologna.it/relazioni-internazionali/english/docs/Phase_eng.pdf: (i) A HIA Toolkit for European Cities; Bologna and the Italian Healthy Cities Network had been chosen as pilots for to study how the Toolkit might be introduced. See e.g. WHO Europe, 'Introducing health impact assessment in Bologna, Italy: A case study', 2004; (ii) A resource pack for European cities and towns, including a training module for decision-makers to integrate health and social considerations in their agenda for sustainable development. (iii) Guidelines for dissemination aimed at the Healthy Cities national networks to extend the use of HIA. That said, the cities belonging to the Italian Healthy Cities Network do not systematically perform HIA. This practice is entirely voluntary, and mostly utilised by Italian Healthy Cities in the areas of nutrition, environment and physical activity.

3. Difficulties in Implementation

The EU Health Strategy has certainly played a stewardship role in raising the broad issue of HIAP in the national policymaking agenda, as also demonstrated by the explicit reference in the draft PSN, but is deemed largely insufficient to promote actual inter-sectoral cooperation at the National Government level. On top of that there is widespread concern that there is an insufficient body of knowledge to justify a HIA procedure of all policies and this would result in *costs and delays largely outweighing benefits* and in an additional unnecessary *administrative burden*. This is recognised to be the case particularly in Countries following rigid *droit administratif* principles and where the more informal procedures reported in some Northern Countries (e.g. the quick over-the-phone HIA) would simply be unconceivable. To this aim it is noted that the EU could invest more in collecting this body of knowledge and making it available to all MS, if it exists and too much was invested in procedural guidelines of limited practical usefulness.

Much in the same vein, it is noted that the EU initiative almost presupposes a *tradition with the ex ante impact assessment of policies and their ex post evaluation* that is not necessarily found in all MS, and this poses major implementation barriers health policy on its own is unlikely to overcome. And therefore an entire cultural procedural background and frame of mind is simply missing.

At the regional level some Governments would be reportedly reluctant to consider the implementation of HIAP principles and HIA procedures because of *political expediency* considerations out of concern that their Health Departments that already control over 85% of the regional budgets would be perceived as the controllers of the rest of the regional administration.

Generally speaking, HIA has also suffered from its being associated in the political debate to *controversial environmental projects* only and for its being considered by some parties not as a neutral technical instrument but as an extremely politicised process.

As a result of that, the decision of *Conferenza delle Regioni* to stay away from the controversial subject has partly contributed to the relatively *little dissemination made of EU policy orientations* in this area at the regional and local level, as these matters as usually discussed in *Conferenza Stato-Regioni* where EU policy initiatives are reported to the regions and much of the institutional dissemination takes place.

On the positive side, it is also remarked that differently from other MS, in Italy there is a comparatively *smaller need for intersectoral coordination* because responsibilities for some horizontal policies already lie with the Ministry of Health. In fact, the Ministry already bears responsibility, *inter alia*, for the fields of health and the environment, occupational health, and veterinary services. Intersectoral cooperation as such is instead effected between the Ministries of Health and the Ministry of Education on specific aspects of broader prevention policies.

4. Indicators

Based on experts' opinions gathered during fieldwork, it appeared that the most relevant indicators to monitor uptake of HIAP principles in Italy would be:

- The number of regions indicating HIA as a priority in their PRP as far as HIA is concerned with the caveat that its understanding is much more limited in scope than envisaged in the EU policy initiative[56];

[56] This is also in line with the findings of the 2012 Review of Public Health Capacity in the European Union according to which the application of Health Impact- and Health Needs Assessments is scarce in Italy because "public health

- The physical indicators of implementation of the Guadagnare Salute programme that remains by far the largest and most important example of intersectoral cooperation in the Country[57]

Overall, however, the Country lacks a tradition of both intersectoral cooperation at all Government levels and of carrying out impact evaluation of Government policies. This also means that Italy is relatively far away from any indicator leading to an estimate of the costs of non implementing EU policies in this area. From what stems above the validity/relevance of the tested indicators can be broadly summarised as reported in Table 4.1 below.

thinking is still largely based on infectious or environmental pathways of disease and less oriented towards the integration, multiprofessionality, and efforts to face social and behavioural determinants of health and disease ", and ends with one recommendation: to increase the number and improve the governance of the few existing intersectoral plans/actions on public health issues. Aluttis, C. et al. 2012: Review of Public Health Capacity in the EU. Final Report. Maastricht/The Netherlands, March 2012

[57] The EU Crossing Bridges reports for Italy that an intersectoral plan to combat the four main risk factors (lack of physical activity, poor diet, obesity and alcohol/tobacco abuse) of chronic health problems in Italy exists and was approved by Government decree in 2007. The presence of a national platform for the promotion of health composed of nine Ministries, the Regions and other institutions; and that the Guadagnare Salute programme was for instance included in the Regional Prevention Plan of the Veneto Region, whereby i) ASLs and Hospital Trusts are required to implement, in collaboration with other public health bodies, activities or projects related to the promotion of health; ii) ASLs are required to support and/or to implement initiatives carried out in the framework of the Guadagnare Salute project; and iii) the development of an organisation model for the promotion of health in an intersectoral manner is under way in three Local Health Trusts in the Region.

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	ANA.1	Formal Adoption of EU HIAP definition and HIA methodology (incl. RE* level)	Would require separate analysis for HIAP and HIA and National and Regional level, but appears fairly feasible. The main issue is related to the validity and significance of citation of EU reference policy documents that would require some qualification.The EU Strategy is expressly quoted in the draft PNP, but HIAP is understood there more in participatory grassroots terms that are much closer to the original WHO understanding of the policy. Much in same vein the regional HIA guidelines are documents totally disconnected from the methodological documents produced by PHP projects, as they focus on environmental aspects only. The indicator is deemed: **fairly valid** **fairly feasible**
2	ANA.2	Evidence of a Significant Debate in the Scientific Literature about HIAP	Fairly feasible although not immediately available. It is considered as highly valid in the Italian case because it adequately reflects the fact that the debate on HIA is *de facto* related to environmental issues only and that there is a very limited understanding and echo in the policy debate, outside of a very limited circle of experts, of HIA as a part of a broader intersectoral policymaking process. The indicator is deemed: **highly valid** **fairly feasible**
3	PRI.1	Existence of Health Policy Documents Including a Commitment to HIAP Principle (incl. RE level)	The indicator is highly feasible and easily available. It is also fairly valid subject to some qualifications. Its main limitations are related to the unclear status of working papers as policy documents presupposing some degree of political endorsement and political commitment. Much in the same vein, as mentioned before it is not to be taken for granted that despite citation of EU documents, HIAP is understood in the EU original sense, but rather as something closer to the WHO understanding. The indicator is deemed: **fairly valid** **highly feasible**
4	PRI.2	Reporting to International Organisations of Commitment to HIAP Principle (for instance in the WHO Healthy Cities programme) *To become members of the Healthy Cities European network municipalities must declare commitment to HIAP principles.*	The indicator appears as highly feasible in terms of data availability and can be certainly considered as a good proxy of the general level of commitment towards HIAP principles. However its validity and significance as an indicator of actual implementation of intersectoral coordination at the local level through well-defined procedures, or of commitment to routine performance of HIA appears more dubious. The indicator's validity with specific reference to their understanding of the EU policy on the subject was partly questioned, on the ground that it could be somehow misleading. The indicator is deemed: **of dubious validity**

	Code	Indicator	Notes
		(Watch out National and European networks are different entities subject to different rules	**highly feasible**
5	PRI.3	Strategies/Programmes/Action Plans Specifically focusing on HIAP (incl. RE level)	As mentioned before this is usually quoted as a fairly valid, highly feasible and easily available indicator. However, it should be reminded that the limitations mentioned above apply also here and HIAP/HIA can be referred to in some strategies in a slightly different understanding from that of EU policy documents. The indicator is deemed: **fairly valid** **highly feasible**
6	PART.1	Existence of Advocacy NGOs Active in the HIAP Field	The indicator might look ambiguous and of dubious validity as there is no such thing as civil society organisations who have HIAP in their lobbying agenda. But the existence of academic networks who formally are also NGOs has been frequently mentioned as key factor in the development of HIAP across the Country. Data on the latter can be retrieved with some difficulty which makes the indicator of dubious feasibility. The indicator is deemed: **of dubious validity** **hardly feasible**
7	PART.2	Involving of Advocacy NGOs in the Policymaking Process (incl. RE level)	The same considerations above apply also here. The indicator can be considered of dubious relevance and feasibility. Grassroots NGOs are nowhere to be found in the HIAP policymaking process, but the academic networks above have played a major role in shaping the Country's policies. The indicator is deemed: **of dubious validity** **hardly feasible**
8	RES.2	Resources Made Available by MS to Research Programmes in HIAP Field in Either Absolute or Relative Terms	There is no dedicated budgetary line for research on HIAP and so the indicator does appear of dubious feasibility without a dedicated study. For the time being just a couple of major applicative projects have been funded from the Health and Environment enveloped of the CCM research programme. The indicator's validity is questioned, at least in part. While some consider that increased research funds may be a signal that HIAP is being seriously considered and that major knowledge gaps are being addressed, others question HIAP can be actually be push through by funding research projects. The indicator is deemed: **of dubious validity** **hardly feasible**
9	ORG.1	Identification of a Body Responsible for HIAP Coordination / a Focal Point	The indicator is fairly feasible and highly valid. There is no such body presently available in the Country, and again according to some its sheer existence would be an indicator that some more progress has been achieved in the level of policy uptake. This would be especially true if the body were located at the Prime Minister's office, and therefore in a

	Code	Indicator	Notes
			position to exert a really coordinating role. The indicator is deemed: **highly valid** **fairly feasible**
10	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices on HIAP (including HIA methodology)	The indicator would also be fairly feasible but of more dubious validity. Again there is no such body currently available in the Country, but some question the validity of the indicator on logical grounds. There are several public bodies that could play a lighthouse role if given the mandate. However, the mandate should also envisage that their dissemination is made for free as part of their institutional mandate. Given the current budgetary conditions, it seems extremely unlikely that any public institution could accept any mandate to disseminate anything for free or this could even impact on the quality of the advice provided. The indicator is deemed: **of dubious validity** **fairly feasible**
11	PRO.1	Introduction of HIA in Routine policy-making process (incl. RE level)	A fairly feasible indicator of dubious validity not to say definitely not valid. The indicator's validity is widely questioned, given that it is not considered suitable to reflect progress in the Italian context. Reservations also exist on the need to introduce legal procedures to clarify the implementation of HIAP. Some are against the introduction of any routine procedure not to kill the HIA concept as the say "in the cradle". It is noted that the reported success and appeal of Guadagnare Salute is due to its being an intersectoral programme with a dedicated intersectoral budget rather than a routine Government procedure and that the weight of coordination agreements was relatively limited in the process. It is possible that mandatory procedures will have to be introduced to better regulate SEA, but this would be in response to a binding EU directive and there is widespread awareness of the level of risk this could trigger on the smoothness of the decision making process. The indicator is deemed: **of dubious validity** **fairly feasible**
12	PRO.2	Number of Relevant Institutions Complying with the above Procedures (incl. RE level)	Indicator at least of dubious feasibility not to say definitely not feasible. Given the lack of clarity on HIA and EIA it is little surprise that some have been considering monitoring the number of EIA with a HIA component, although this would require a fully fledged quite cumbersome study, as these data are no routinely published. Again the main reservations on the indicator dubious validity are given by the exclusive focus on environmental issues only and the neglect of a wider perspective on intersectoral co-operation. The indicator is deemed: **of dubious validity** **hardly valid**

	Code	Indicator	Notes
13	EVAL.1	Implementation of Evaluations / Cost Effectiveness Assessments of their Policies (incl. RE level)	The indicator is considered of dubious validity. The Country lacks a real tradition of policy evaluation so again opinions diverge on whether this could be a valid indicator to highlight this major gap or an irrelevant one because it would be at any rate poorly understood across the system. There are uncertainties as to whether the scheduled evaluation of PNP, which will represent one of the first such instances of policy evaluation in a sense, will include also HIA matters in detail or ignore them because of its broad mandate. The indicator is fairly feasible if one routinely checks the studies commissioned by the Ministry. The indicator is deemed: **of dubious validity** **fairly feasible**
14	EVAL.2	Streamlining / modification of Policy as a Result of an Evaluation Exercise / Cost Effectiveness Assessment (incl. RE level)	The same validity considerations as for EVAL.2 apply here. Some have tried to build the case that the way the current draft strategy is formulated indicates the impact of evaluative baseline studies very broadly intended. Therefore, in the best of cases the indicator would appear controversial and open to possible manipulation. The indicator is however fairly feasible. The indicator is deemed: **of dubious validity** **fairly feasible**
15	EVAL.3	Setting up of a System of Indicators to Monitor HIAP uptake / Implementation (incl. RE level)	It is maintained that this could become a highly valid indicator if regions ever decided to put HIAP matters in their PRP and monitor them accordingly in a consistent way, or similar indicators are agreed at the central level. Until this happens, health prevention departments have limited financial incentive to progress along these lines. The indicator would be fairly feasible. The indicator is deemed: **highly valid** **fairly feasible**

***RE**=Relevant Entity

Proposed additional indicators

Indicator	Comments
Number of projects funded under Guadagnare Salute	This indicator would give some sense of the degree of uptake of intersectoral cooperation at the local level (some 120 projects) and is considered fairly valid by those knowledgeable with the programme; however data are not necessarily published, so hardly available from outsiders, which reduces its immediate feasibility.
Number of HIAP-related projects funded by the CCM	Same considerations as above on its validity. But there is no HIAP classification and all projects should be scrutinised to come to the data which makes feasibility more dubious and costly.
Share of EIA with a HIA component	There are diverging views on the dubious validity of this indicator that would reflect the actual uptake of HIA in the policy area where it has been most discussed which can have both pros and cons, depending on policymakers needs. Some would be curious to know related data and aim at a 100% threshold as a result of the current pilot projects. Feasibility is also dubious, as this would also require a dedicated study.

C - Patient safety (PS)

1. Legal, Policy and Institutional Framework

Table 1.1 - Legal and Policy Framework

Year	Type	Authority	Title	Comment
2003	National strategic document	Ministry of Health	National Health Plan 2003-2005 (*Piano Sanitario Nazionale* 2003-2005)	It includes among its objectives, (Obj. 2.3) "to ensure and monitor the quality of healthcare and of biomedical technologies".
2003	Decree	Ministry of Health	Decree of 5 March 2003	It establishes Technical Committee on Clinical Risk.
2004	Technical document	Ministry of Health	Clinical Risk Management: the Problem of Medical Errors (*Risk Management in Sanità. Il problema degli errori*)	It represents the Health Ministry's attempt to establish a national framework for the implementation of risk management activities at national, regional and local level.
2005	Decree	Ministry of Health	Decree of 14 May 2005	It establishes the Working Group on Clinical Risk (Gruppo di Lavoro per il Rischio Clinico).
2006	National strategic document	Ministry of Health	National Health Plan 2006-2008 (*Piano Sanitario Nazionale* 2006-2008)	Patient safety is included among the core priorities; it adopts the *standard definition of adverse events;* it stresses the importance of *introducing a patient safety culture* within the SSN.
2006	Decree	Ministry of Health	Decree of 20 February 2006	It establishes the Working Group on Patient Safety (*Gruppo di Lavoro per la Sicurezza dei Pazienti*).
2006	Survey	Ministry of Health	National Survey on Patient Safety Initiatives within the National Healthcare System (*Rilevazione Nazionale sulle Iniziative per la Sicurezza del Paziente nelle Strutture del SSN*)	A baseline study on the state of art of patient safety initiatives.
2007	Decree	Ministry of Health	Decree of 26 January 2007	It introduces a temporary National Reference System for Patient Safety.
2008	Institutional agreement	State and Regions	State-Regions Agreement on the Patient Safety National System	The agreement institutionalises three national observatories: 1) on sentinel events run by the Ministry, 2) on accidents and claims run by Age.Na.S. and on 3) best practices. It also establishes the National Strategic Committee for Clinical Risk Management (*Comitato strategico nazionale per la gestione del rischio clinico*).
2009	Protocol	Observatory on Sentinel	Protocol on sentinel events monitoring (*Protocollo per il*	It gathers information on: i) descriptive fact sheets of categories of sentinel events; ii)

Year	Type	Authority	Title	Comment
		Events	*monitoraggio degli eventi sentinella*)	template forms to report sentinel events; iii) template forms for the analysis of causes and contributing factors of the adverse events; and iv) the Action Plan for risk mitigation, i.e. the action items to be pursued to avoid recurrence and allow anonymous and blame-free reporting.
2009	Manual	CCM-funded; its members are the Regions	Summary of main HCAI prevention and control measures (*Compendio delle principali misure per la prevenzione e il controllo delle infezioni correlate all'assistenza*)	Reference document and a support to the training of healthcare personnel, as it is descriptive of the procedures to follow to prevent and control the prevalence of HCAIs.
2009	Decree	Ministry of Health	Decree of 16 October 2009	It establishes the intersectoral Working Group on HCAIs and antimicrobial resistance (AMR).

Background – The Policy Concept Phase (2003-2006). The ***2003-2005 Italian National Health Plan*** already included among its objectives, (Obj. 2.3) "to ensure and monitor *the quality of healthcare and of biomedical technologies*[58]". Patient safety as such, however, did not constitute an objective in itself yet or was clearly identified as a concept. The key elements of what would become the Italian Patient Safety strategy were outlined in the work of the ***Technical Committee on Clinical Risk***, established in ***2003***[59] who after carrying out a detailed review of the errors carried out in the SSN published in ***2004 a concept paper***[60] that is commonly considered the *"cornerstone of the patient safety strategy"* in Italy[61] and which represents the Health Ministry's attempt to establish a *national framework for the implementation of risk management activities at national, regional and local level.* Along with classifying clinical errors, the document also promotes the use of a standardised incident reporting system, both of adverse events and, more importantly, of near misses. In the document the Ministry recognised the importance of introducing a ***blame-free reporting culture*** in the Italian National Health Service. It promoted the importance of moving from an approach that looks up the causes of individual events to a systemic Root Cause Analysis (RCA), placing a greater stress on the improvement of processes, systems and products rather than on the performance of individual operators. The same document brought evidence of a parallel project commissioned by the Ministry intended to develop ***quality of care indicators***, based on the clinical evidence associated with given events (i.e. sentinel events, adverse events, near misses).

[58] Ministero della Salute, Piano Sanitario Nazionale (2003-2005), 2002
[59] D.M. 5 March 2003
[60] Ministero della Salute, "Risk Management in Sanità. Il problema degli errori", 2004
[61] A. Ghirardini, G. Murolo, F. Palombo, The Italian strategy for patient safety, Clinica Chimica Acta 404, pp.12-15, 2009

In ***2005*** as a result of the concept paper above data on sentinel events started being collected on a pilot basis across the country, and patient safety as such finally came to be included among the core priorities of the ***2006-2008 National Health Plan***[62]. In particular, the Plan:

- finally adopted the ***standard definition of adverse events*** in healthcare provided by Kohn[63] ("*the probability that a patient is victim of an adverse event, resulting from exposure to the health care system and causing a deterioration of health or death*");
- stressed the importance of ***introducing a patient safety culture*** within the SSN; and
- promoted the activation of a ***national reporting system***, operative at the national, regional and local levels

In ***2006*** a ***Working Group on Patient Safety*** (*Gruppo di Lavoro per la Sicurezza dei Pazienti*), was established[64] with the mandate of i) monitoring of adverse events, particularly sentinel events; ii) preparing recommendations[65]; iii) analysing adverse events and implementing training initiatives; and iv) taking care of patient involvement and legal/medical implications. In parallel, a separate ***Working Group on Clinical Risk*** (*Gruppo di Lavoro per il Rischio Clinico*), was also established[66]. A baseline study on the state of art of patient safety initiatives implemented in the framework of the SSN was eventually published[67] together with a national survey on insurance issues and risk management at SSN health trusts.

The Policy Development Phase (2007-2009). In ***2007*** a temporary ***National Reference System for Patient Safety*** was introduced by Decree[68] under the management of joint Ministry-Region steering committee who was also to propose the final governance model of the soon-to-be introduced Patient Safety National System. For the time being the National Reference System would act as a focal point on Patient Safety in the country and would run the National Patient Safety Observatory envisaged in the Public Health Plan, and would be particularly active in the fields of citizen's empowerment, training of staff, production of guidelines and recommendations, communication strategies and relations with European and international initiatives. The establishment of this national reference was followed by the setting of national and regional standards, which were subsequently replicated at healthcare provider level.

The ***framework State-Regions Agreement on the Patient Safety National System*** was eventually approved in March ***2008***[69] clarifying the roles and responsibilities of all the stakeholders involved. The agreement institutionalises three national observatories: 1) on sentinel events run by the Ministry, 2) on accidents and claims run by Age.Na.S. and on 3) best

[62] Ministero della Salute, Piano Sanitario Nazionale (2006-2008), 2005
[63] Kohn, L., Corrigan, J. Donaldson, M., *To err is human: building a safer health system*; National Academy Press; Washington D.C., 1999
[64] D.D. 20 February 2006
[65] The Working Group has been involved in the elaboration of a series of manuals and guidelines on patient safety published by the Ministry of Health. In 2008 it published the first nine guidelines for the implementation in a variety of contexts (e.g., hospital and home care) and by a diverse array of actors (e.g., healthcare specialists and practitioners, volunteers, patients' relatives).http://www.salute.gov.it/speciali/piSpecialiNuova.jsp?id=83
[66] D.D. 14 May 2005
[67] Ministero della Salute, Ufficio III, 'Rilevazione Nazionale sulle Iniziative per la Sicurezza del Paziente nelle Strutture del SSN', 2006.
[68] Decree of 26 January 2007 http://www.salute.gov.it/imgs/C_17_normativa_993_allegato.pdf
[69] http://www.agenas.it/agenas_pdf/INTESA_STATO_REGIONI_20-03-2008.pdf

practices. It also sanctions the appointment of a risk manager in every Local Healthcare Enterprise, promotes out-of-court settlement procedures, regulates health insurance behaviour, establishes a Patient Safety Network comprising all the risk managers above and envisages the creation by means of a Ministerial Decree of the ***National Board for Patient Safety (****Consulta Nazionale per la Sicurezza del Paziente)* as an advisory body whose members are the representatives of all bodies involved in the area of patient safety at regional and local level, including civil society organisations. The Board would also provide a mechanism to encourage an active role of health professional organisations in patient safety, at national and/or regional level. Its establishment has however not materialised yet because the related Decree has not been released.

Finally in ***2009*** the ***Monitoring Information System on Health Mistakes*** (Sistema Informativo sugli Errori in Sanità - SIMES) including both the sentinel event monitoring system and the observatory on accidents and claims was finally regulated by Decree and became officially part of the New National Health Information System[70]. The related ***Observatory on Sentinel Events*** protocol[71] gathers information on: i) descriptive fact sheets of categories of sentinel events; ii) template forms to report sentinel events; iii) template forms for the analysis of causes and contributing factors of the adverse events; and iv) the Action Plan for risk mitigation, i.e. the action items to be pursued to avoid recurrence and allow anonymous and blame-free reporting. These initiatives subscribe to the national effort to establish highly functional reporting and learning systems (RLS). .

Currently, in addition to the elements required by the Council Recommendation, the Italian national strategy and related policies cover also the issues related to patient involvement in patient safety. Notably, patient organisations are consulted for the purpose of implementing patient safety provisions and provide feedback. In a similar move to better reach out to patients, core competencies for patients have been developed. These competencies have been disseminated through publicity, ICT tools or paper documents; additionally, patient safety checklists and guides have been produced for patients and their relatives[72].

Governance. As mentioned above, the ***Ministry*** takes it upon itself to set out the strategy and planning of patient safety. It operates with the support of a number of committees and working groups, and specifically of the ***National Strategic Committee for Clinical Risk Management*** (*Comitato strategico nazionale per la gestione del rischio clinico*)[73] and directly runs the Observatory on Sentinel Events. The 2008 Agreement also entrusted patient safety-specific functions to the ***National Agency for Regional Health Services*** (*Agenzia Nazionale per i Servizi Sanitari Regionali*/Age.Na.S). The Agency performs two main tasks: i) it monitors patient safety best practices through the Observatory on Good Practices for Patient Safety (*Osservatorio Buone*

[70] http://www.nsis.salute.gov.it/nsis/nsis.jsp
[71] Osservatorio nazionale sugli eventi sentinella, 'Protocollo per il monitoraggio degli eventi sentinella', 2009
[72] *Ibid.*
[73] The Committee was established with the 2008 State-Regions Agreement. It is composed of Ministry's experts, the Regional Technical Committee on Clinical Risk (*Comitato Tecnico delle Regionio per la Sicurezza del Paziente*), the Agency for the Regional Health Services, the National Health Institute, the Italian Medicines Agency, and the Higher Institute for Prevention and Safety at Work.

Pratiche per la Sicurezza dei Pazienti)[74], and ii) it manages the National Observatory on Accidents and Claims. The latter was activated in 2009 and from 2012 it collects data on accidents and insurance claims.

Healthcare-associated Infections (HCAIs). HAI policy implementation in Italy is complicated by age-old legal issues. The policy and legal framework on healthcare associated infections is a particularly complex and delicate subject. In ***1985*** a Ministerial recommendation envisaged the creation of a ***technical commission on healthcare-associated infections*** *(Commissione Infezioni Ospedaliere*/CIO*)* in every hospital of a medium size, or for groups of small-size hospitals. The post of nurse responsible for HAI, acting as an interface between the CIO and day-to-day operations, was created; in addition to that, and a number of procedures were suggested. In 1988 standards on the ratio between nurses and patients and on the number of doctors specialised in hygiene and patients were also defined. But the 1985 and 1988 guidance was the product of non-binding legal instruments. It was only with a 1988 Decree that these provisions were enacted by law. The following year the ***Constitutional Court*** ruled that the law exceeded the National Government's powers on matters of competence of the Regions and the Decree was cancelled accordingly. To date, HAI Action Plans are available in eight regions[75] out of twenty, though at very different times (starting from Lombardy in 1990 till Campania in 2007)[76], so that the national 1985 recommendations have largely remained the official reference document on the subject. Dedicated budgets are appropriated for implementation of these Action Plans. The only other policy steering instrument available to the Ministry on HAIs was the LEA indicator system and its ex-post verification mechanism. In particular, the LEA grid is currently being reviewed and the grid now in use does not reflect the recent inclusion of a number of HAI-specific indicators.

On the face of this fragmented picture, the Ministry has been trying to build consensus among the regions by means of pilot projects. In 2006, the CCM funded a three-year ***INF-OSS project***[77] (*progetto interregionale "Prevenzione e controllo delle infezioni associate all'assistenza sanitaria e socio-sanitaria"*) with the multiple objectives to (i) describe the state of the art of HAI preventive and control measures, (ii) attempt to offer homogeneous models and procedures, (iii) test a pilot surveillance programme of sentinel events in Emilia-Romagna and Friuli Venezia Giulia[78], and (iv) implement the WHO Clean Care is Safer Care programme[79] in some hospital settings. Furthermore, guidelines were produced, as part of the project, summarising best practices at the international and national level and ranked a number of hospitals based on the French ICALIN methodology.

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[74] The Observatory on Good Practices has thus far documented 1200 cases. Age.Na.S also coordinates the communication and dissemination activities of the Technical Regional Committee for Patient Safety, whose role is to disseminate and promote the implementation of patient safety recommendations at the regional level, by bringing together the technical and scientific expertise of the Regions and Age.Na.S. itself.

[75] Apulia, Autonomous Province of Trento, Campania, Emilia-Romagna, Friuli-Venezia Giulia, Liguria, Lombardy, Piedmont.

[76] http://www.corist.it/corist/?q=node/19

[77] http://asr.regione.emilia-romagna.it/wcm/asr/aree_di_programma/rischioinfettivo/gr_ist/pr_inf_ccm/1-progetto/pr_inf-oss.htm

[78] To be subsequently implemented on an experimental basis in 11 regions.

[79] http://www.ser-veneto.it/public/File/documents/relazione_convegni/2009convegno_infezioni_chirurgia/2_moro.pdf

Additionally, Italy has a common core of competencies (curriculum) for specialised training on infection prevention and control for the infection control staff. In particular, the core curriculum of healthcare workers includes topics on the basic principles of hygiene and infection prevention and control. There are both legal recommendations and professional guidelines for an ***infection control committee*** in hospitals; and as regards ***infection control teams***, Italy has both legal requirements and professional guidelines as reference for healthcare practitioners. Nursing homes are responsible for the elaboration and monitoring of a programme for *infection prevention and control*.

Formally, all Regions participated in the project; however, only 15 of them have been playing an active role, with Emilia-Romagna being entrusted with overall coordination responsibilities. The project first highlighted how *HAI governance was extremely diversified across the country* with very different organisational models, decision-making levels, and availability of training programmes and pointed to the absence of a set of common process indicators. It then culminated in the development of ***guidelines***[80] that should serve as a reference document[81] and as a support to the training of healthcare personnel, as it is descriptive of the procedures to follow to prevent and control the prevalence of HCAIs. Along with specific recommendations, the document includes a list of process and outcome indicators (HCAI Project indicators, hereafter) to monitor the implementation of HCAI control measures and procedures. Following the document, "*it is crucial to systematically use a common set of structure, process and outcome indicators to document the actual improvement in the quality of care offered within each healthcare structure*[82]".

Ministerial attempts at building consensus proved their *limitations*, as manifested by the fact that the project guidance has not been uniformly applied throughout the country. First, alert and reporting systems are not mandatory everywhere in the country. Secondly, the set of HAI indicators reported in the HAI Project manual is applied more comprehensively and with greater frequency in some regions than in others. Notably, Emilia-Romagna, Marche, Toscana and Sicily have stood out for applying the manual's guidance systematically and have proven receptive to the issue of sentinel events reporting and appear to have assimilated the importance of offering refresher training for healthcare personnel. On the basis of the information collected through these indicators mainly in these regions, reports are sent to the ECDC.

2. Difficulties in Implementation

Patient safety is one of the ten priorities to have benefitted from the abundantly funded PROQUAL programme *(Programma Qualità e Sicurezza)*, so financial constraints are hardly

[80] Compendio delle principali misure per la prevenzione e il controllo delle infezioni correlate all'assistenza - Progetto "Prevenzione e Controllo delle Infezioni nelle Organizzazioni Sanitarie e socio-sanitarie – Progetto INF-OSS", 2009

[81] The guidelines include seven thematic areas, namely general good measures, hand hygiene, standard precautions and isolation measures, prevention of urinary tract infections associated with urinary catheterisation, prevention of urinary tract infections associated with intravascular catheterisation, prevention of surgical site infections, prevention of bacterial pneumonia associated with invasive treatment. For each area, recommendations have been issued. Examples are provided of criteria and indicators to be applied in each thematic area to assess the degree of compliance with suggested procedures.

[82] *Ibid.*

perceived as obstacles to implementation. Similarly, training of staff is not an issue, since the facilities currently available are regarded as sufficient. At the time of writing, Age.Na.S. is about to release the results of a survey on the difficulties faced by Local Health Enterprises in implementing the recommendations released by the Working Group. Respondents to the survey indicated that no better specified "cultural resistance" to change represented by far the main difficulty. Additionally, due to the need to prioritise some action items over others, patient safety still ranked low on the agenda of several Local Health Enterprises. In fact ASL management appeared to be more concerned with other issues, seen as more pressing than patient safety.

Although Italy's reporting and learning systems are differentiated from disciplinary systems and procedures for healthcare workers in order to ensure non-punitive context of reporting, it is generally admitted that the implementation of truly blame-free reporting system is practically unfeasible in the country. This is because medical malpractice can always qualify as a crime under certain conditions, and concealing information from legal prosecutors can ultimately represent obstruction of justice. This bottleneck is not likely to be solved any time soon, given that due to the legal setup in the country, personal data may be disclosed to justice at any point in time, thus defeating the patient safety protocol on the anonymous supply of information.

Reform of patient safety strategies is at a very early stage in non-hospital facilities and at other points of healthcare service (general practitioners, etc.), due to a generalised difficulty in evaluating quality of service in these settings. Bringing change about in the area of HAIs is all the more difficult given that it is traditionally considered a legally contentious issue. Reform in this field has been the object of wearisome Constitutional Court proceedings in the past (see above). Unsurprisingly, then, policy makers have refrained from any attempt to redress this stirring issue, where a top-down reform is *a priori* regarded as a no-go anyway.

Table 2.1 - Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Financial constraints	Not generally considered an issue as patient safety activities have been adequately funded.
Shortage of qualified staff	The situation has notably improved after a considerable number of staff has received dedicated training.
Legal issues (e.g. regarding the blame-free reporting)	This remains a practically insurmountable national obstacle which EU policy cannot possibly contribute to overcome.
Relevant entities' capacity (especially non-hospital facilities)	Implementation in non-hospital facilities is generally less advanced and difficult to assess, but recommendations have already been released.
Inadequate enforcement system (e.g. name-blame systems, acting as a disincentive to the open reporting of adverse events)	The policy is implemented and enforced by means of the ordinary LEA mechanisms.
Complex coordination with education authorities for the inclusion of patient safety in curricula	A minor issue. There were some problems in introducing patient safety in university curricula because, *ceteris paribus*, the integration of a new module would decrease the comparative value of other modules under the Italian academic credit accumulation system. By now, an agreement has been

Factors	Comments
	reached with the Universities so that there is at least a formal requirement to include patient safety modules in one or more types of education (e.g. postgraduate education, on-the-job training and continuing professional education).

3. Available Indicators

As mentioned earlier, patient safety is monitored by means of the ordinary ***LEA indicators***. As far as hospital settings are concerned, a number of OECD indicators are routinely published in a yearly report on hospital operations with a dedicated section on patient safety[83]. The Observatories publish regular reports with data on sentinel events and claims respectively. All regions would have the capacities to comply with ECDC HAI surveillance standard requirements; however, only a limited number of regions actually do so.

No comprehensive evaluation report is available on the progress reached as compared to the 2006 baseline data included in a study carried out by the ***Technical Committee on Clinical Risk.*** This survey supplied ***the state of the art of patient safety initiatives***[84] in the country and assessed the degree of awareness of patient safety in healthcare institutions. This can aptly be used as a baseline study since it was performed at a time when a lot many healthcare agencies had just begun to actively promote the adoption of risk management policies as reported in the table below.

2006 baseline findings[85]	
Delivery/reporting systems	89% of surveyed healthcare facilities declared having a system in place to deal with incident reports
	43% of the facilities claimed to have a system in place to report/signal prevalence of adverse events. The most common reporting method appears to be "spontaneous and non-anonymous reporting" (69% of reports)
	23% collects information on sentinel events
	Surveyed facilities urged introducing a patient safety culture based on the principle of "learning from error"
Monitoring	8% claims to conduct monitoring of near misses
Risk prevention	17% of respondents claimed having activated risk management prevention measures internally through a dedicated clinical risk management unit
Clinical risk analysis	Analysis of clinical risks is done in 28% of surveyed facilities
Training	PS training for healthcare personnel is organised in 38% of surveyed facilities

[83] http://www.salute.gov.it/imgs/C_17_pubblicazioni_1690_allegato.pdf

[84] Ministero della Salute, Dipartimento della Qualità, Direzione Generale della Programmazione Sanitaria, dei Livelli d'Assistenza e dei Principi Etici di Sistema, Ufficio III, 'Rilevazione Nazionale sulle Iniziative per la Sicurezza del Paziente nelle Strutture del SSN', 2006

[85] Source: Ministero della Salute, Dipartimento della Qualità, Direzione Generale della Programmazione Sanitaria, dei Livelli d'Assistenza e dei Principi Etici di Sistema, Ufficio III, 'Rilevazione Nazionale sulle Iniziative per la Sicurezza del Paziente nelle Strutture del SSN', 2006

2006 baseline findings[85]	
Harmonisation	The survey highlighted the need to adopt a common language in patient safety throughout the national territory and of greater homogeneity in the initiatives undertaken

The country's overall patchy picture displays anecdotal evidence of substantial progress also in regions traditionally lagging behind. For instance, in February 2011 Age.Na.S. hosted a joint conference[86] gathering the Italian Regions, representatives of WHO Europe, the Ministry of Health and Age.Na.S. itself. The event intended to assess Italy's response to the Tallinn Charter, prescribing actions that participating member states ought to pursue to strengthen their respective health systems[87]. The Age.Na.S. conference highlighted that application of the Charter's terms has been heterogeneous throughout the country, but noticed the progress made in the area of patient safety by Sicily, where a groundbreaking quality of care and patient safety programme was initiated. The programme includes the ***Joint Commission International*** regional project, envisaging the implementation in 2011 of around 75 international standards for the improvement of quality of care and patient safety in the region. Again in terms of Age.Na.S. involvement, the agency has collected, within a few years, some 1200 good practices countrywide.

Information on the costs and benefits of the reform is not yet available. Age.Na.S. has just conducted a pilot survey on the costs associated with patient safety strategies. Some regions invest heavily in patient safety programmes, but considerable variation exists among regions. Given that the response rate was too low (33%), the results of this study have not been validated. It is also too early to have consolidated trends on insurance costs and the impact of the reform. However it is observed that patient safety has become a priority in those regions that set up a self-insurance mechanism (*autoassicurazione*) to cover claims, whereby a dedicated line is included in the Local Health Enterprises' budget each year. This creates an outright incentive to put patient safety in place, as the mechanism is independently managed by the healthcare authority, so that the latter does not have to resort to private insurance companies for the purpose. The self-insurance mechanism results in a win-win situation for the ASL and the patients. Notable regions that pioneered the self-insurance system in healthcare include Piedmont and Tuscany.

[86] Carinci, F., Caracci, G, *et al.* 'L'esperienza italiana in risposta alla Tallinn Charter – Valutazione della performance, risposta alla crisi finanziaria e multisettoriale per il miglioramento della salute', 2011

[87] The Charter includes provisions regarding patient safety and intersectoral cooperation for health (the latter being relevant for the HIAP policy area). With regard to patient safety, the Charter reads: "*[participating States] shall strive to enhance the performance of [their] health systems, [considering that] patients want access to quality care, and to be assured that providers are relying on the best available evidence […] and using the most appropriate technology to ensure improved effectiveness and patient safety.* WHO European Ministerial Conference of Health Systems, "The Tallinn Charter: Health Systems for Health and Wealth", 2008

Table 3.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.4	Alignment of Data Classification Systems to Standardised Given Procedures.	The indicator would appear as both highly feasible and highly valid. The HCAI Project indicators are purposefully modelled on the ECDC process indicators. The OECD patient safety indicators are widely used, reported and easily available in official publications. The indicator is deemed: **highly valid** **highly feasible**
2	ANA.1	Adoption of a Methodology/Problem Definition in line with international standard.	The indicator is fairly feasible with some limited effort and highly valid. Both the working group on patient safety and the INF-OSS project produced guidelines in line with international standards. Additionally, Italy is involved in the work of the WHO International Classification for Patient Safety. The indicator is deemed: **highly valid** **fairly feasible**
3	OUT.1	Specific Outcome Indicator for the Stated Objective	The indicator is fairly valid and fairly feasible at least as far as HCAI is also concerned. Italy is involved in the EC co-financed project on healthcare quality indicators led by the OECD. Italy is involved in the project (a total six out of seven OECD indicators are regularly published) and it also collects other comparable patient safety indicators. The Italian Observatory on Sentinel Events only monitors the foreign body left in during procedure. Clinical risk in hospital settings is monitored in yearly reports by means of the following indicators: OECD PSI 7. Cure-related bloodstream infections OECD PSI 12. Postoperative pulmonary embolism or deep venous thrombosis OECD PSI 13. Postoperative sepsis OECD PSI 18 Obstetric trauma – vaginal delivery with instrument OECD PSI 19. Obstetric trauma – vaginal delivery without instrument Six regions (Apulia, Autonomous Province of Trento, Emilia-Romagna, Friuli-Venezia Giulia, Liguria, Piedmont) have indicators to assess the implementation of their HCAI strategy or Action Plan. The indicator is deemed: **fairly valid** **fairly feasible**
4	PROG.1	Establishment of a PS Strategy / Programme / Action Plan covering the Whole Population	The indicator would be fairly valid and highly feasible on patient safety. But it would seem definitely not valid as far as HCAI are concerned For complex historical and legal reasons there is a national PS strategy, but there cannot be a national HCAI strategy because this would not be considered as Constitutional (see the narrative in the main text). The indicator is deemed: **fairly valid**

	Code	Indicator	Notes
			highly feasible
5	PROG.2	Number of RE with Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	The indicator is highly valid but there may be dubious feasibility problems. There are easily available data on regional programmes, but these are limitedly significant, because the problem is often tackled at the lower (local) level. Data on HCAI action plans have therefore to be collected at the Local Health Enterprise level; data collection would require a dedicated survey and would be time-consuming. Such a survey was carried out as a part of the INF-OSS project, but there is no permanent monitoring system in place. Other proxies are not equally reliable because subject to interpretation and therefore of dubious validity. Formally all Regions and Autonomous Provinces participated in the INF-OSS Project. However, only 15 of them played an active role in the development of the working manual, and even fewer systematically apply the recommendations included therein. The indicator is deemed: **highly valid** **hardly feasible**
6	PROG.3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	The information would be fairly valid but of dubious feasiblity as far as HCAI is concerned, because related underlying information is not routinely collected and would require a dedicated study. The indicator is deemed: **fairly valid** **of dubious feasibility**
7	PROG.RES	Preparation of Specific Programmes, such as (but not only) Research Projects, on PS-related Subject	The indicator could be fairly valid but seems of dubious feasibility. There are at least five different possible sources of financing for a research project in the field of patient safety, including the recently established research budget of Age.Na.S. But there is no specific patient safety programme. The indicator is deemed: **fairly valid** **hardly feasible**
8	PART.2	Involvement of Advocacy NGOs in the Policymaking Process (incl. RE level)	The indicator is of dubious feasibility and validity and would be subject to diverging subjective interpretation problems. NGOs are not formally involved in the policymaking process, because related provisions of the State-Regions Agreement have not been enacted yet. So they are there on paper but not in practice, at least for the time being. Others maintain they are at any rate informally involved, but is unclear based on what criteria and in what stages of the policymaking process. Clarifiaction would require a small study/survey. The indicator is deemed: **of dubious validity** **hardly feasible**
9	PART.3	Provision of Support to Advocacy NGOs active in the Given Policy Field (incl. RE level)	The indicator would be of dubious feasibility and validity and subject to subjective interpretation. There is no explicit policy in this respect. It has happened that some of them have received financing on a case-by-case basis. So the validity of this indicator appears questionable.

	Code	Indicator	Notes
			The indicator is deemed: **of dubious validity** **hardly feasible**
10	RES.1	Existence of Research Programmes in the PS Field	The indicator is fairly feasible and valid. As mentioned above, PS-HCAI projects can be funded under several different research programmes. There is a national research programme on patient safety, but not clearly labelled as such. The indicator is deemed: **fairly valid** **fairly feasible**
11	RES.2	Resources Made Available by MS to Research Programmes in the PS Field in Either Absolute or Relative Terms	The indicator could be fairly valid but of dubious feasibility as data are not available, but related sources are public, so that figures could be calculated in a small dedicated study. For the development of the HCAI Project, the Emilia-Romagna Regional Government (entrusted with overall coordination responsibilities) was assigned 600.000 € by the CCM. The indicator is deemed: **fairly valid** **hardly feasible**
12	RES.3	Number of Studies/ Publications Produced by Research Programmes in PS Policy Field	This indicator would be fairly valid but of more dubious feasibility than the previous ones, as it would require some substantial data gathering effort. The indicator is deemed: **fairly valid** **hardly feasible**
13	RES:4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature	The validity of this indicator appears more dubious as it risks overemphasising the academic impact of research project. Also feasibility is dubious because of data gathering efforts. The indicator is deemed: **of dubious validity** **hardly feasible**
14	AWA.1	Number of Information/Awareness Raising Campaigns and Dissemination initiatives for practitioners on PS policies and issues in a Given Year	The indicator would be of dubious validity grouping together initiatives of different magnitude and scope. For instance, the Ministry of Health participates in and patronises the European Antibiotic Awareness Day and in the World Hand Hygiene Day. However, given the fragmentation of the actors involved there is no such thing as an inventory of the initiatives carried out on a yearly basis, and the way the system is organised today makes the indicator definitely not feasible. The indicator is deemed: **of dubious validity** **not feasible**
15	AWA.2	Level of Awareness about PS issues among the Population	The indicator has never been consistently pursued in the past and its validity never fully convincing because of the technicalities of the subject matter. However it is definitely not feasible as data are not available. There might have been

	Code	Indicator	Notes
			in the past some surveys on a limited scale but of limited significance. The main source of feedback on citizens' attitudes towards these issues is the *Cittadinanza Attiva - Tribunale del Malato* report. The indicator is deemed: **of dubious validity** **not feasible**
16	AWA.3	Trend in the Level of Awareness about PS issues among the Population	Same as above. The indicator is deemed: **of dubious validity** **not feasible**
17	AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target	The indicator would be of dubious validity in keeping track of different audiences and information needs at the same time. Moreover for the time being it is of dubious feasibility as related information is not available and would have to be collected from primary sources at considerable cost. The indicator is deemed: **of dubious validity** **hardly feasible**
18	FUND.1	Total Budgeted Funds to Specifically Implement PS Policy in Absolute or Relative Terms.	Given the amount of in-kind human resources invested in the policy it is unclear what a validity the indicator could have. However, the indicator would definitely appear as not feasible. Given the way the system is organised today, it would require a dedicated and very complex study. The indicator is deemed: **of dubious validity** **not feasible**
19	FUND.2	Total Public Expenditure to Specifically Implement PS Policy in Absolute or Relative Terms	Same as above. The indicator is deemed: **of dubious validity** **not feasible**
20	FUND.3	Total dedicated infection control staff (absolute terms or per 1000 beds)	There were national legal standards on the subject, eventually cancelled by the Constitutional Court, so the indicator was deemed as fairly valid as a benchmark. The indicator would at any rate be feasible only upon request and require data gathering and processing, as related data are not routinely published. The indicator is deemed: **fairly valid** **hardly feasible**
21	ORG.1	Identification of a Body Responsible for Policy Coordination / a Focal Point	It can be clearly identified for PS but not for HAI, unless one considers the case of the Emilia-Romagna Regional Government which was entrusted by the CCM with overall coordination responsibilities over the development of the INF-OSS Project. The indicator is fairly valid as it adequately describes the different levels of institutional uncertainty in

	Code	Indicator	Notes
			these policy areas especially if “policy coordination” were better defined. It is also fairly feasible. The indicator is deemed: **fairly valid** **fairly feasible**
22	ORG.2	Routine Interaction with European Institutions on PS by Means of a Well-identified Institution	Indicator fairly valid and feasible. The Ministry itself interacts with ECDC on HAI matters and with the Commission on PS. The indicator is deemed: **fairly valid** **fairly feasible**
23	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices in PS Area	Indicator fairly valid and feasible. This is definitely Age.Na.S. in the field of patient safety. No equivalent body exists for HAI. The indicator is deemed: **fairly valid** **fairly feasible**
24	NET.1	Creation of a Network of Institutions to Implement the PS Policy	Indicator fairly feasible but of dubious validity and prone to possible misunderstanding. An ‘intersectoral mechanism’ was created on HAI that is not however truly ‘intersectoral’ by European standards. It is however worth mentioning that the Ministry of Health in Italy has responsibilities in areas that in in other European countries are covered by other Ministries. The indicator is deemed: **of dubious validity** **fairly feasible**
25	DEL.2	Number of RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents	The indicator is fairly valid but of more dubious feasibility. The SIMES information system and related IT tools are common to all healthcare facilities in Italy. A blame-free reporting system and a mechanism to learn from best practices is in place. However, HAI active surveillance is implemented in a limited number of regions. There is no indicator published on the increase in number of single rooms, although data would be available in the Ministry’s databases and would need to be processed. A pilot handrub use project was carried out within the framework of INF-OSS and a few regions reportedly monitor this piece of information, although they do not necessarily publish it. The indicator is deemed: **fairly valid** **hardly feasible**
26	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken to Specifically Deliver Policy	The indicator could be fairly valid and feasible for those knowledgeable of the subject matter. For instance, one could count a pilot project on alcohol handrub. At the national level, the last campaign for hand hygiene had been conducted in 2008. A blame-free reporting system was established together with a a pilot HAI active surveillance system.

	Code	Indicator	Notes
			The indicator is deemed: **fairly valid** **fairly feasible**
27	TRAI.1	Implementation of Training Courses on PS-related Subject for Healthcare Personnel (incl. RE level)	The indicator could be fairly valid and feasible at least as far as PS is concerned. Since courses on the subject are delivered online related data could become easily available. The indicator is deemed: **fairly valid** **fairly feasible**
28	TRAI.2	Total Number of Trained Healthcare Workers on PS-related Subject	Same as above, although possibly with a bit more difficulty as far as data availability is concerned. The indicator is deemed: **fairly valid** **fairly feasible**
29	TRAI.3	Resources Made Available for Training in PS-related subject in Absolute or Relative Terms	The indicator is of dubious validity, because it is known that ICT systems are used to support patient safety education and training of healthcare workers and this has required investment, but it says little about how efficiently these resources have been effectively translated into concrete results. Moreover it is also dubiously feasible as related information is not currently available and it would require some major classification effort and ad hoc research to keep track of the various programmes funded. The indicator is deemed: **of dubious validity** **hardly feasible**
30	TRAI.4	Introduction of PS in Relevant Curricula (incl. RE level)	The indicator although potentially fairly valid in keeping track of a serious issue is definitely not feasible in the Italian context and too complex to implement and monitor. The indicator is deemed: **fairly valid** **not feasible**
31	EVAL.1	PS policy evaluation (i.e. regular review of practices and standards)	No ex post evaluation in the EU sense. Just intermediate evaluation or performance assessment. The indicator is deemed: **highly valid** **fairly feasible**
32	EVAL.2	Change of PS Policy as a result of the above evaluation	The indicator would be of dubious validity because it would lend itself to a qualitative study rather than sheer measurement. However, for the time being it is definitely not feasible because the benchmark would be missing. The indicator is deemed: **of dubious validity** **not feasible**

	Code	Indicator	Notes
33	EVAL.3	Establishment of a System of Indicators to Monitor Policy Implementation	The indicator would be fairly valid and feasible. Italy patient safety monitoring relies on the general LEA indicators and on the information provided in the reports described above. INF-OSS indicators are to measure the adoption of good practices/correct procedures (i) in sterilisation; (ii) in healthcare personnel's compliance with correct procedures in hand hygiene (based on the proportion of hand hygiene measures actually followed by healthcare personnel); (iii) in the delivery of refresher courses to healthcare personnel regarding isolation measures – this is to be assessed both qualitatively (actual offer of courses) and on the basis of participation (proportion of eligible staff actually attending the courses); (iv) in the control of urinary tract infections; (v) in the surveillance of infections associated with central venous catheter; (v) in antibiotic prophylaxis to prevent surgical site infections; and (vi) in the surveillance of ventilator-associated pneumonia. The indicator is deemed: **fairly valid** **fairly feasible**
34	EXC.1	Contribution by the MS of its Policy Experiences to the *PS and Quality of Care Working Group* *Not mere participation but presentation of national / regional policy*	The indicator would be considered of dubious validity given the development stage of European platform experiences on the subject and not necessarily indicative of exchanges with other countries and would require a better definition to be feasible. Experiences have been extensively shared and discussed at the national level but never shared at the EU level. The indicator is deemed: **of dubious validity** **hardly feasible**
35	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	Again the indicator would be ambiguous and of dubious validity although fairly feasible. Based on the information collected by adoption of the HCAI Project indicators, regional reports are compiled, unified and subsequently submitted by the Ministry to the ECDC. The ECDC annual report sees contributions from the Ministry of Health, supplying information on HCAI prevalence in Italy, but because there is a request. No report on PS is routinely sent to European institutions. The indicator is deemed: **of dubious validity** **fairly feasible**

***RE**=Relevant Entity

D – Cancer Screening (CS)

1. Governance, Legal and Policy Framework

Table 1.1 - Legal, Policy and Programming Framework

Year	Type	Authority	Title	Comment
2001	Law	Government/Parliament	Budget Law (*Legge Finanziaria* 2001) art.85(4)	Establishing that relevant target groups are exempted from charges on breast, cervical, and colorectal cancer screening tests.
2003	National strategic document	Ministry of Health	2003-2005 National Health Plan (*Piano Sanitario Nazionale* 2003-2005)	In the section regarding health promotion, the Plan stresses the need to administer evidence-based cancer screening tests to asymptomatic persons.
2004	National strategic document	State and Regions	State-Regions Agreement (*Intesa Stato-Regioni*) of 29 July 2004, including the 2004-2006 National Plan for Active Prevention (*Piano Nazionale di Prevenzione Attiva*)	The Plan identifies a number of recommended screenings among the key areas of intervention.
2004	Law	Government/Parliament	Law 138/2004 on public health	Under art.2bis allocated EUR 52 millions to redress the disparities across regions in CS activity levels and to introduce colorectal screening in CS programmes.
2004	National strategic document	Ministry of Health	2004-2006 Screening Plan (*Piano* Screening 2004-2006)	Adopted with the Ministerial Decree of 2 December 2004. The Plan allocated funds to the regions to improve screening programmes' 'structure' (including capacity, personnel, training, information system and communication to the public). Regions are requested to submit specific projects.
2005	National strategic document	State and Regions	State-Regions Agreement (*Intesa Stato-Regioni*) of 23 March 2005, including the 2005-2007 National Prevention Plan (*Piano Nazionale della Prevenzione*)	The reinforcement of CS programmes is among the general objectives of the Plan, which has a total financial allocation of EUR 440 millions/year.
2005	Policy document	Ministry of Health Department for Prevention	Recommendations for the planning and implementation of breast, cervical and colorectal cancer screenings (*Raccomandazioni per la pianificazione e l'esecuzione degli screening di popolazione per la prevenzione del cancro della mammella, del cancro della cervice uterina e del cancro del colon retto*)	The Recommendations implement art. 2bis of the Law 138/2004 and the 2005-2007 National Prevention Plan (*Piano Nazionale della Prevenzione*).
2007	National strategic	Ministry of Health	2007-2009 Screening Plan (*Piano* Screening 2007-	The Plan focuses on the disparities across Regions. In order to receive funds, regions are requested to submit

Year	Type	Authority	Title	Comment
	document		2009)	projects aimed at overcoming critical issues and achieve the quality standards required.
2011	Policy document	Prepared by the Oncology Planning Committee (*Commissione Oncologica Nazionale*) and published by the Ministry of Health	Technical Policy Document on the Reduction of Cancer Disease Burden – for the years 2011-2013 (*Documento Tecnico di Indirizzo per Ridurre il Carico di Malattia del Cancro 2011-2013*)	The document sets the strategy to reduce the cancer burden for the 2011-2013 period.

Overall Strategic Framework. The Italian cancer screening strategy is enshrined in several official documents drafted starting with 1998[88], but the policy debate on the subject started well before that date[89]. The most important such documents have been the ***two national Cancer Screening Plans*** laws covering respectively the 2004-2006 and the 2007-2009 periods[90]. Moreover, ***technical recommendations***[91] on the implementation modalities of the various screening programmes were released in 2006. Over and above this national reference framework, the Regional Governments have in some cases approved their own Cancer Screening Programmes, run accreditation schemes and released their own guidelines with a further level of detail and tailor-made to local conditions. It has therefore happened that certain Regions have decided to implement their own screening programmes differing from the national reference standards, as is for instance the case with colorectal screening in Piedmont. In fact, while the central Government retains responsibility for broad strategic orientations and for allocating resources, it is the ***regional and local administrations*** that are entirely responsible for the preparation and running of cancer screening programmes in their areas. In particular, regions are responsible for: (i) planning the execution of quality cancer screening programmes; (ii) evaluating programmes on the basis of local epidemiological data; (iii) implement training programmes for operators (based on national guidelines); (iv) design and run quality checks and other monitoring activities; (v) consult citizens' representatives. Conversely, Local Health Enterprises (*Aziende Sanitarie Locali*/ASL) run all operational activities involved in running cancer screening programmes including management of resources, involvement of GPs, public awareness-raising activities, management of training programmes, etc.

At the national level, responsibility for overlooking and managing the strategy is entrusted to the ***National Centre for Disease Prevention and Control*** (*Centro Nazionale per la Prevenzione e il Controllo delle Malattie*/CCM) attached to the General Directorate for Health Prevention of the Health Ministry. The mandate of the Ministry of Health/CCM in the field of cancer screening encompasses: (i) overall planning (objectives, timeframe, financial resources, etc.); (ii) financing (amount of allocations to regional authorities); (iii) guidance (preparation and dissemination of cancer screening guidelines); (iv) communication to the public (printed and website-based information campaigns, framework agreement with the postal service operator for call and recall actions); (v) technical assistance to regional administrations; (v) surveillance and monitoring system, evaluation and validation of outcome; and (vi) research. In performing its mandate the

[88] The narrative of the development of cancer screening regulation in Italy can be found at http://www.ccm-network.it/screening/intro_legislazione

[89] Since 1996, Italian national guidelines have recommended that regions implement organised screening programmes for ***cervical cancer***.

[90] The Italian cancer screening strategy is now also detailed in the Technical Policy Document on the Reduction of Cancer Disease Burden for the years 2011-2013 (*Documento Tecnico di Indirizzo per Ridurre il Carico di Malattia del Cancro* 2011-2013[90]), prepared by the Oncology Planning Committee (*Commissione Oncologica Nazionale*) and published by the Ministry of Health in February 2011.

[91] http://www.ccm-network.it/screening/files/documenti/raccomandazioni_linee_guida.pdf

CCM relies on the support of two technical bodies: the ***National Observatory of Screening*** and ***EpiCentro***.

The National Observatory of Screening (*Osservatorio Nazionale* Screening/ONS[92]) was created under the aegis of the Italian League for the Fight against Cancer (LILT) and institutionalised by the 2004-2006 National Screening Plan[93] and represents a very peculiar organisation by Italian governance standards. The ONS is an NGO run by the Italian League for the Fight against Cancer[94]. But at the same time it was designated by the Ministry of Health as the *technical advisory body to assist the Regions* in the execution of their cancer screening programmes and to support the Health Ministry in the design of overall cancer screening modalities; it was also entrusted with programme monitoring and evaluation responsibilities. The ONS works in close cooperation with three scientific societies that were nominated to support the Ministry, *inter alia*, in defining guidelines conducive to the successful implementation of the Screening Plans[95] and in releasing technical recommendations[96], and namely:

- The **Italian Working Group on Colorectal Cancer Screening** (*Gruppo Italiano Screening tumori colorettali*/GISCoR) – whose mandate is to promote population-based colorectal cancer screening programmes; establish contacts with similar international programmes; ensure quality standards, promote the use of process indicators; promote research and cooperation.
- The **Italian Working Group on Breast Cancer Screening** (*Gruppo Italiano Screening Mammografico*/GISMa) – whose mandate is to promote the creation of organised breast cancer screenings throughout the country and analyse the protocols followed and results achieved in the various cancer clinics.
- The **Italian Working Group on Cervical Cancer Screening** (*Gruppo Italiano Screening del Cervicocarcinoma*/GISCi) – active in the areas of diagnostics, organisation and evaluation of cancer screening programmes.

The ONS and the three scientific associations have all their own websites but also communicate through ***EpiCentro***, a web facility developed by the National Health Institute - Centre for Epidemiology, Surveillance and Promotion of Health (*Istituto Superiore di Sanità - Centro Nazionale di Epidemiologia, Sorveglianza e Promozione della Salute*), and supported by regional and local authorities. EpiCentro is a primarily web-based resource on public health, providing epidemiological information both national and local in scope. It includes a specific section on cancer screening containing updated epidemiological data, a selection of relevant links and documents, and a review of main initiatives at national and local level[97].

The Italian cancer screening strategy is also characterised by an emphasis on cooperating with ***Civil Society Organisations*** and by a focus on reducing the ***geographical disparities*** affecting the country and their consequent bearing on the population's health. Various agreements have been stipulated with representative organisations for actions in support of cancer screening programmes. Two organisations in particular are significantly involved in the promotion of screening, namely: (i)

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[92] http://www.osservatorionazionalescreening.it/

[93] Ministero della Salute, Centro Nazionale per la Prevenzione ed il Controllo delle Malattie, CCM, Piano per lo Screening del Cancro al seno, della Cervica uterina e del Colon-retto per il triennio 2007-2009, 2006

[94] It should be noted that the Observatory's governance structure has recently changed. In contrast with the past, a Steering Committee including representatives of the Regions has been established (*Comitato d'indirizzo misto*). The financing of the Observatory through regional budget appropriations may be the object of a future State-Regions Agreement. To date, the CCM has been the Observatory's only source of funding.

[95] Art. 3 D.M. 3 November 2004 http://www.ccm-network.it/screening/files/documenti/D_M_03_11_2004.pdf

[96] Art. 2 D.M. 18 October 2005 http://www.ccm-network.it/documenti_Ccm/normativa/DM_screening_18_10_05.pdf

[97] http://www.epicentro.iss.it/focus/screening/screening.asp

the Italian League for the Fight against Cancer (*Lega italiana per la lotta ai tumori*/LILT); and (ii) Women's Health Observatory (*Osservatorio nazionale sulla salute della donna*/ONDA). Redressing disparities in cancer screening by means of targeted *financial incentives* was the focus Law 138/2004 on public health[98] first (with a € 52 mn allocation) and more recently, of the 2007-2009 Screening Plan (*Piano* Screening 2007-2009). Results achieved by means of financial incentives have been modest, and significant disparities persist in the coverage ratio of the various programmes across the country, with the Northern regions substantially in line with European best practice standards, and some Southern Regions lagging far behind.

The Italian cancer screening programmes largely converge on the health system stewardship framework. Stewardship is not a governance system, but a complex of organisational arrangements (management, coordination and follow-up) that can ensure good governance, involving all phases of the policymaking process – from strategy formulation, to implementation and dissemination. The Italian cancer screening system was not expressely set up to be aligned with this model, but its structure snugly fits into this model, as it were, by construction[99]. Stewardship consists of strategising and rule-setting, as well as overseeing implementation by ensuring resource accessibility and compliance. The role of steward is not assigned to one body in particular; stewardship cascades from the higher ministerial level down to its subordinate levels of implementation. The Ministry of Health can thus be identified as a "steward of stewards". In particular, the Italian cancer screening programmes are aligned with the stewardship guidelines as these squarely involve six sub-functions of health system stewardship. The sub-functions in question are:

(F1) Formulate a strategic policy framework;
(F2) Fit policy objectives and organisational structure and culture;
(F3) Ensure tools for implementation: powers, incentives and functions;
(F4) Establish coalitions and partnerships;
(F5) Generat intelligence; and
(F6) Ensure accountability.

While some of these functions, taken separately or in bundles, feature in several national health systems, it is their very combination that compounds stewardship. In the case of Italian cancer screening, these functions are performed by the bodies listed in the earlier part of this section as follows:

F1: This function is performed in tandem by the Ministry of Health and the Regions. The Ministry draws up a plan, and then agrees on it with the Regions, as they meet in the main coordinating *lieu* where shared executive decisions are taken. This platform is the already mentioned *Intesa Stato-Regioni*. The national framework for prevention (the PNP) and the separate National Screening Plan spell out the strategy for CSP implementation.

F2: Planning of CS is laid out so to ensure consistency with overall health system architecture and to avoid duplication of efforts and overlapping of functions/competencies between involved actors. Coordination is ensured by the joint efforts of the Ministry of Health, the regional governments and the Local Health Enterprises (ASLs).

F3: This function involves making sure that the appropriate rules and tools are employed by the CS stakeholders. Powers should be coherent with and proportional to each stakeholder's

[98] http://www.parlamento.it/parlam/leggi/04138l.htm
[99] Novinskey, C. M., and Federici, A., 'Stewardship and Cancer Screening Programs in Italy', Italian Journal of Public Health, Year 9, Vol.8, No.2, 2011

responsibilities. To ensure implementation, each actor should have access to the appropriate tools, and in paralle, action shall be taken to have rules enforced, through a system of powers, incentives and sanctions. In the case of CSPs, these tools are provided by the two national-level plans setting the terms of CSP roll-out. Each envisages a different set of incentives and sanctions, although more so in the case of the National Screening Plan, where formal sanctions, as well as financial incentives are envisaged. In the National Prevention Plan, instead, sanctions only take the form of delays in the distribution of financial incentives that are tied to performance.

F4: Stewardship is reinforced when partnerships and alliances are formed with stakeholders not strictly involved in policy management and implementation. Notably, coalitions may be gathered on two levels: (i) with stakeholders that are loosely affiliated to the issue, for instance other ministries, patient associations etc. and (ii) with decentralised administrative entities (away from the central/national level).

F5: The Ministry of Health ensures the production and dissemination of data. Intelligence generation and dissemination is necessary to make informed and accountable decisions.

F6: Further emphasis is put on accountability, especially of the central government before the sub-national governments, and the population base at large. In Italy, some markers of accountability which proving how Sub-function 6 is performed in the area of CS include (i) the existence and activity of interest groups, (ii) the availability of published rules, (iii) the existence of independent watchdogs, and (iv) the level of access to political representatives.

2. Implementation

The ONS has been publishing yearly reports (some also bilingual in Italian and English) on the status of implementation of the Italian screening programmes since 2002[100]. It runs a centralised registry to monitor screening programmes and evaluate their performance according to a predefined set of indicators by means of annual surveys. The ONS is given this task by the law, but a further incentive to provide data to the Observatory is represented by the fact that the implementation of cancer screening programmes has long been part of the grid of performance indicators underlying the essential levels of care incentive system (LEA), therefore entitling to an additional 3% of resources in case of particularly good performance.

The ONS also routinely runs a performance quality review or intermediate evaluation by means as it checks for compliance with the performance indicators identified by the three screening Working Groups mentioned above. A number of process indicators[101] to monitor and evaluate the screening process were identified, and namely:

- *Structural indicators* – they include organisational and logistical parameters, and reflect the quality of the practical steps involved in conducting the screening;
- *Performance indicators of the clinical-diagnostic process* – they are applied in the diagnostic process which is the core of the screening process; and
- *Early impact indicators* – they are used to identify the impact of the screening as early as possible (which is not until 8-10 years after the screening has been performed).

[100] The entire set of reports is available at http://www.osservatorionazionalescreening.it/content/i-rapporti-annuali

[101] Ronco G, Giubilato P, Naldoni C, Zorzi M, Anghinoni E, Scalisi A, Dalla Palma P, Zanier L, Federici A, Angeloni C, Prandini S, Maglietta R, Mancini E, Pizzuti R,Iossa A, Segnan N, Zappa M., Extension of organised cervical cancer screening programmes in Italy and their process indicators, Epidemiologia e Prevenzione, Mar-Jun;31(2-3 Suppl 2):33-47, 2007

It is worth noting that the Italian recommendations were communicated and disseminated by the ONS itself by means of a dedicated dissemination programme inclusive of a *vademecum* for general practitioners, supplemented by press releases in the main Italian newspapers[102]. The contents of the recommendations were then evaluated through a survey administered to screening practitioners.

The CCM has also taken the first steps towards designing a more comprehensive evaluation of the programme results. So far, it has taken action by funding (i) a pilot study on the epidemiological impact of breast cancer screening programmes (IMPATTO project)[103] and (ii) an ONS study on the cost of running such programmes compared to opportunistic screening. However, both issues face considerable methodological problems. On the one hand, cancer registries in Italy are only made available, upon request, by certain counties; and even those registries that eventually became operative ceased to be so since approximately two years ago, due to the legal uncertainties related to personal data protection legislation. Therefore there are only few patchy data available throughout the country. On the other hand, data on programme costs have to be reconstructed on a case-by-case basis due to the lack of a homogenous accounting system, and experience shows there can be large discrepancies between unit costs from one location to another. This raises some doubts on the reliability of these data unless a relatively high number of cases are reviewed in detail. One region, Piedmont, has carried out in collaboration with the Working Group on Colorectal Cancer Screening a study on the costs of its colorectal screening programme[104], possibly also because some of its implementation features are not in line with the standards prevailing in the rest of the country. Italian citizens have the right to have screening fees reimbursed by the public health system provided that related tests are undertaken at regular intervals. It is difficult to have accurate data on the extent of opportunistic screening as these would have to be drawn from much more comprehensive datasets on tests for a variety of prevention purposes.

3. Difficulties in Implementation

The Italian experience with the cancer screening financing laws and the modest results achieved seem to indicate that financial constraints are much less of a limiting factor than many would be willing to admit. Rather, obstacles to the implementation of screening programmes appear to be linked to cultural and political resistance; this issue should be further investigated before proposing a revised strategy. It is a fact that nowadays many programmes face difficulties because of the general budgetary constraints, but it can be seen that even in the absence of such constraints no significant improvement was made in terms of coverage. Another factor that emerged during the field work is that the "cancer screening system" has not been particularly effective in communicating to the public health system, in general, and to the political counterparts, in particular, that cancer screening is a highly cost-effective investment that would allow substantial savings in the future, if properly implemented. Efficiency, however, is difficult to prove given that the beneficial effects of screening become manifest only in the long term (8-10 years later). Moreover a comparative analysis[105] of recent surveys shows that "*organised screening activity can reduce social inequalities of access to cancer screening, increasing screening utilisation particularly in less educated people*[106]". Furthermore, so long as cancer screening programmes are only sparsely implemented, consequently failing to achieve economies of scale, cost savings will remain far from evident. Cases are reported of screening management software resulting in very high costs across the country. Conversely an open-source facility available to all and based on the

[102] http://www.osservatorionazionalescreening.it/content/le-raccomandazioni
[103] http://www.ccm-network.it/documenti_Ccm/convegni/SANIT/materiali2008/24.6/3-Valutazione_impatto_Paci.pdf
[104] http://www.osservatorionazionalescreening.it/content/le-raccomandazioni
[105] Segnan N, Ronco G, Ciatto S., Cervical cancer screening in Italy, Eur J Cancer. 2000 Nov;36(17):2235-9
[106] *Ibid.*

same knowledge basis would allow for considerable savings. Competition from opportunistic screening in certain regions and related economic interests is an obvious obstacle to organised screening programmes. The fact that screening is publicly-funded and offered for free may paradoxically be perceived as indication of poor quality. Recently, the issue of *cancri intervallo* – i.e. cancers diagnosed to patient only just cleared by a screening - and the related risk of legal damages sentenced in Court have taken the forefront in the debate and could even represent a disincentive for certain ASLs to run related screening programmes. Finally, there can be specific bottlenecks in human resources due to the scarcity of certain specialised skills (radiologists, etc.) and of the capacity to interact with migrants. Views on the possible factors influencing policy uptake can be summarised in Table 3.1 below

Table 3.1 - Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Financial constraints (human and financial)	Less than could be expected.
Timeframe, the results and impacts will materialise after a much longer period	Part of broader difficulty in communicating results.
Lack of a sound efficiency assessment of CS	Policymakers unaware of potential benefits.
Technical and organisation issues connected to the complexity of CS nationwide programmes (issues of capacity, training of staff, management and service delivery etc.)	There is a general lack of capacity to exploit economies of scale and spill-over effects.
Legal issues in setting up registries as requested, and linking them to mortality databases (e.g. issues of personal data management)	Problems of legal responsibility related to *cancri-intervallo* have recently entered the debate and represent a potential cause of concern.
Cultural and political issues (e.g. political sensitivity of the matter in certain cultural environment, political difficulties to maintain a long-term commitment in this area etc.)	Generally identified as the most important obstacle, although still poorly understood in its specific components.

4. Available Indicators

The indicators commonly used are those identified in the Recommendations document by the various Working Groups after a scientific debate[107] and are aimed to:

- Identify and invite eligible women to the screening round:
- Obtain high turnout;
- Ensure high standards of quality during the actual screening, performed by competent personnel and with the appropriate technologies;
- Ensure that further diagnosis is performed, when needed;
- Minimise the negative effects of the screening;
- Monitor results and regularly evaluate the entire screening process; and
- Possibly provide preliminary elements to perform cost-effectiveness analyses.

Being part of the official LEA reporting system, these indicators are highly regulated and codified and are subject to legal verification by auditors for confirmation of expenses.

[107] Gruppo Italiano per lo Screening Mammografico (GISMa), 'Indicatori e standard per la valutazione di processo dei programmi di screening del cancro della mammella – manuale operativo', Epidemiologia e Prevenzione, Anno 30(2), marzo-aprile 2006, supplemento 1

As mentioned earlier, while monitoring indicators of programme implementation and quality standards are well developed, fewer are available for programme impact evaluation and cost effectiveness assessment. However, the preliminary elements to formulate an estimate of the cost of failure to implement the European recommendations could already be in place, although only in the form of pilot studies.

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.2	Compliance with Data Comparability Criteria based on Expert Assessment	Data are classified and analysed according to a transposal of the indications of the EU Guidelines. So the indicator is considered fairly valid and feasible provided it is understood that the Guidelines have been adapted to the local context, certain quality benchmarks made more stringent. The citation index would only partially apply because the Recommendations cannot take into consideration the EU Guidelines released after 2006. There also are technical guidelines released at the regional level, but these documents are not necessarily public and are sometimes circulated among practitioners only. An assessment of their degree of harmonisation would appear of more dubious feasibility and require a dedicated study also because there is currently no repository of such documents. The indicator is deemed: **fairly valid** **fairly feasible**
2	HAR.3	Establishment of Special Registries (centralised data systems for the management and assessment of CS data)	The indicator is both highly valid and feasible. The ONS can be considered exactly as such and was expressly created for this very purpose. The indicator is deemed: **definitely valid** **highly feasible**
3	HAR.4	Alignment of Data Classification Systems to Standards defined by the *European Network of Cancer Registries*	The indicator is considered definitely not valid in the Italian context where the problem lies with the extremely limited geographical coverage of cancer registries, rather than with related methodological classification standards. It is however fairly feasible. The indicator is deemed: **not valid** **fairly feasible**
4	ANA.1	Formal Adoption of the EU CS Guidelines (incl. RE* level) *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is fairly valid and feasible provided some clarification is made. The EU Guidelines as such were never formally "adopted". However, as mentioned under HAR2 above, they represented the basis of the Italian technical document on the programme features and as such were abundantly transposed into an official document. Much in the same vein, some Regions are considering "transposing" and "incorporating" the guidelines in their programme accreditation criteria, but this never translates into a formal adoption. The indicator is deemed: **fairly valid** **fairly feasible**
5	ANA.2	Evidence of a Significant Debate in the Scientific Literature of the MS about CS methodology and	The vast echo the guidelines have had in the Italian policy debate is adequately reflected in the literature; yet, the indicator's validity is partly questioned. At the disaggregated level there is no one-to-one correspondence between scientific activity and level of implementation. While it is certainly true that regions with a high level of scientific

	Code	Indicator	Notes
		specifically the EU Guidelines	production usually show high levels of implementation, the opposite does not necessarily apply and there can be regions with good degree of progress and limited visibility in the literature. Moreover there is the risk of overemphasising the importance of the academic impact. It is however easily feasible. The indicator is deemed: **of dubious validity** **highly feasible**
6	ANA.3	Effective Outreach Level of the EU Guidelines in the MS (downloads, webpages visited) in Absolute or Relative Terms (% of the target population) *Clearly distinguish b/w breast, cervical and colorectal CS*	Some chapters of the guidelines have been translated and made available in Italian and can be downloaded from the web. In the websites of the three scientific societies (the cancer screening Working Groups) links can be found to the EU website where the guidelines can be downloaded. However, there are some doubts as to the validity of this indicator, because these documents have also had a wide circulation as hard copies and because the indicator would not adequately reflect the language barrier which is arguably higher in Italy than in other countries, impinging on actual outreach. However, the indicator would also be feasible with some difficulty in gathering data from webmasters. The indicator is deemed: **of dubious validity** **hardly feasible**
7	OUT.1	Specific Outcome Indicator for the Stated Objective	The indicator is highly valid and feasible. Data have been systematically available all over the country since 2004 and have been published accordingly. There is a high degree of confidence in their validity (although certification for budgetary purposes reportedly goes only until 2009 and some data have not been verified in detail). The indicator is deemed: **definitely valid** **highly feasible**
8	IMP.1	Specific Impact Indicator for the Stated Objective	There are data on cancer mortality but the availability of data on cases of cancer from cancer registries is much more limited and scattered as can be seen in http://www.registri-tumori.it/cms/copertura. In the best of cases data are available until 2004 only and registries have had difficulty operating over the last couple of years. So the indicator, although fairly valid, would have some feasibility problems. The indicator is deemed: **fairly valid** **of dubious feasibility**
9	PROG.1	Establishment of a CS Strategy / Programme / Action Plan covering the Whole Population *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is fairly valid and easily feasible as there have been two dedicated national action plans on the subject. It would have to be better clarified to take into consideration that the programmes continue even if the last action plan formally expired in 2009. The indicator is deemed: **fairly valid** **highly feasible**

	Code	Indicator	Notes
10	PROG.2	Number of RE with CS Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered) *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is both fairly valid and feasible. The ONS provides data on the population actually covered by screening projects at the county level irrespective of whether there is a formal regional programme or not. Currently there is no repository of such regional documents and their gathering and classification into programmes, guidelines, accreditation schemes would require an ad hoc study. The indicator is deemed: **fairly valid** **fairly feasible**
11	PROG.3	Number of RE with a CS Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is both fairly valid and feasible. When there were such cases in Italy in the past, the ONS identified them in its annual report. The indicator is deemed: **fairly valid** **fairly feasible**
12	LEG.1	Adoption of appropriate data protection legislation	The screening registry does not cause any particular problem with personal data protection legislation; conversely, data protection is an issue for cancer registries. No legislation adopted. This indicator is considered particularly valid, in the light of the difficulties experienced in the past, and easily feasible. The indicator is deemed: **definitely valid** **highly feasible**
13	LEG.2	Appropriate data protection legislation Discussed but Not Yet Adopted	Indicator highly valid and feasible. Legislation on data protection and cancer registries has already been proposed and was about to be approved twice when Government crises arrived and the approval process had to re-start from scratch. The indicator is deemed: **definitely valid** **highly feasible**
14	LEG.3	Appropriate data protection legislation Still under Preparation and in its Drafting Stage	Same as above.

	Code	Indicator	Notes
			The indicator is deemed: **definitely valid** **highly feasible**
15	AWA.1	Number of Information/Awareness Raising Campaigns and Dissemination initiatives for practitioners on CS policies and issues in a Given Year	Such data are not routinely collected and would require a survey of a number of informants. Data on information and dissemination would be available for the Italian Guidelines only. Therefore it is considered of dubious feasibility. Lack of awareness among the population is not generally considered a cause of poor implementation and therefore the indicator appears of dubious validity. The indicator is deemed: **of dubious validity** **hardly feasible**
16	AWA.2	Level of Awareness about PS issues among the Population	The indicator would definitely not be feasible. There are only a few local surveys at the county level. Both the PASSI enquiry and the ISTAT indagine multiscopo that represent the main sources of information on these subjects do not expressly cover knowledge about the existence of the programmes. This would be considered a valid indicator for the migrant population only, but not a particularly relevant one for the rest of the population, for whom other factors would reportedly be at play. The indicator is deemed: **hardly valid** **not feasible**
17	AWA.3	Trend in the Level of Awareness about PS issues among the Population	Same as above. The indicator is deemed: **hardly valid** **not feasible**
18	AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target	Same as above. The indicator would be considered definitely not feasible even for the Communication Programme on the Italian guidelines above. The indicator is deemed: **hardly valid** **not feasible**
19	FUND.1	Total Budgeted Funds to assure appropriate organisation and quality control of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator would be of dubious validity to explain performance and definitely not feasible. The action plans allotted dedicated funds for the screening programmes and for the functioning of the ONS. But data would be available only for the latter because the organisation of the programmes depends on the regions and the accounting system do not necessarily envisage this piece of information. The indicator is deemed: **of dubious validity** **not feasible**

	Code	Indicator	Notes
20	FUND.2	Total Public Expenditure to assure appropriate organisation and quality control of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	Same as above. When data have been collected, they have been collected on a pilot case study basis. The indicator is deemed: **of dubious validity** **not feasible**
21	FUND.3	Total dedicated staff to implement and assure quality of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator would be of both dubious validity and feasibility because underlying data are not routinely available. Enquiries have been made to calculate costs on a pilot basis. It was noted that considerable differences would reportedly exist from one county to another which would make the indicator of complex interpretation. The indicator is deemed: **of dubious validity** **hardly feasible**
22	DEL.1	Population Reached by CS Programmes in the country, in Absolute or Relative Terms (out of the target population) *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is highly valid and easily feasible because related data are routinely published by the ONS. The indicator is deemed: **definitely valid** **highly feasible**
23	DEL.2	Compliance with the Relevant Features of CS Implementation Modalities Stated in the EU Documents (incl. RE level)	The indicator would be fairly valid and feasible although with some qualifications. The ONS routinely monitors and publishes data on compliance with the standards of the Italian recommendations. No data available on opportunistic screening for benchmarking. The indicator is deemed: **fairly valid** **fairly feasible**
24	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken, i.e. CS programmes set up *Clearly distinguish b/w breast, cervical and colorectal CS*	Same as above. The ONS routinely collects and publishes relevant data. The indicator is deemed: **fairly valid** **fairly feasible**
25	CAP.1	Compliance with Given Equipment Technical Standards and Operational Procedures	Same as above. The ONS publishes relevant data provided they are relevant to the Italian technical recommendations document. The indicator is deemed: **fairly valid**

	Code	Indicator	Notes
			fairly feasible
26	PRO.1	Introduction of a Given Procedure in CS Routine Operations (incl. RE level)	Same as above. The Piedmont region published a cost effective analysis of its newly proposed approach to colorectal cancer. The indicator is deemed: **fairly valid** **fairly feasible**
27	PRO.2	Number of Relevant Institutions Complying with Procedure (incl. RE level)	Same as above. ONS monitors compliance with national reference standards The indicator is deemed: **fairly valid** **fairly feasible**
28	TRAI.1	Implementation of Training Courses on CS for Healthcare Personnel (incl. RE level)	This indicator would pose some feasibility problems as data are not readily available. Its validity is deemed questionable because bottlenecks are more often related to the availability of a sufficient number of technical staff to carry out the programmes, than to the lack of specific training on the subject. The indicator is deemed: **of dubious validity** **hardly feasible**
29	TRAI.2	Total Number of Trained Healthcare Workers on CS	Same as above. The indicator is deemed: **of dubious validity** **hardly feasible**
30	TRAI.3	Resources Made Available for Training on CS in Absolute or Relative Terms	Same as above. The indicator is deemed: **of dubious validity** **hardly feasible**
31	EVAL.1	Evaluation of data from tests, assessments and diagnosis	The indicator would be highly valid and fairly feasible if definition problems are clarified. The ONS regularly publishes interim evaluations or quality performance assessments of screening programmes. Impact evaluations are much less developed and more in need. The indicator is deemed: **definitely valid** **fairly feasible**
32	EVAL.2	Change of CS Policy as a result of the above evaluation	For the time being the indicator would be of dubious validity and feasibility. No change of policy can result from the evaluations above, but changes in technical implementation modalities. This can be monitored by checking subsequent

	Code	Indicator	Notes
			performance over time. The indicator is deemed: **of dubious validity** **hardly feasible**
33	EVAL.3	Regularly Monitor CS Implementation and Outcome *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is considered highly valid and easily feasible as there is a full-fledged monitoring system in place. The indicator is deemed: **definitely valid** **highly feasible**
34	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	The indicator is highly valid and easily feasible, as Italy regularly sends data to the EU implementation report. The indicator is deemed: **definitely valid** **highly feasible**
35	REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing CS Containing Information Not Shared with the EU	Indicator of dubious validity and feasibility. It is not known whether the ONS reports are regularly transmitted to the Commission and if so to whow and from whom. The indicator is deemed: **of dubious validity** **hardly feasible**

***RE**=Relevant Entity

Proposed additional indicators

Indicator	Comments
Number of Health Technology Assessments on cancer screening-related matters	The EU policies should be more generally assessed based on their capacity to generate knowledge in a given country.
Amount of dedicated research resources devoted to cancer screening	One of the reported strengths of the last cancer screening action plan was a stand-alone budget line dedicated to applied research on the subject.

ANNEX C – CASE STUDY REPORT: FRANCE

A – Overall Health Strategy (White Paper)

1. Legal, Policy and Institutional Framework[108]

Two acts are worth mentioning from the beginning as they are crucial for the understanding of all that follows; they are the Public Health Act of 9 August 2004 (*loi du 9 août 2004 relative à la politique de santé publique*) and the Hospital, Patients, Health and Territories Act (*loi hôpital, patients, santé et territoires*).

The ***Public Health Act*** (no. 2004-806 of 9 August 2004) is the first legal document to reform the organisation of public health in France since 1902. It defines the role and the responsibility of the state in public health policy at the national and regional levels, defines five-year term public health measures, and identifies a set of 100 health-related issues as public health priorities for the 2005–2009 period. It also puts at its core *prevention* policy (defined as the "*axe majeur*" of the law), preferring it to a treatment approach.

Objectives are defined in terms of results to be achieved on the population health status. Five national plans were established in order to meet these objectives, namely the Cancer Plan; the Violence Plan, Addictions and Risk Behaviours Plan; the Environment and Health Plan; the Plan for the Quality of Life of Patients with Chronic Diseases; and the Plan for providing Health Care to Patients with Rare Diseases. The Law also prescribes that an evaluation shall be regularly performed of all actions undertaken.

Importantly, the inputs of the law do not affect solely the direction of the public health system (i.e. its objectives), but also its organisation, both at regional and national level. It designates the regions as key actors in the achievement of these objectives. From the standpoint of the institutional framework, major changes introduced by the law are:

- Establishment of the High Council for Public Health (*Haut Conseil de la santé publique*).
- Establishment of the National Institute for Cancer (*Institut national du cancer*).
- Creation of public health regional groupings (*groupements régionaux de santé publique*), although these will be subsequently replaced by alternative regional arrangements with the 2009 Law (see below).

The region is considered by the plan as the optimal level of the planning of practical actions and for the coordination of the various actors involved. The establishment of the regional groupings testifies to this credo and further materialises in the creation of a regional health conference (*conférence régionale de santé*) to facilitate consultation among actors, and of a regional health plan (*projet regional de santé*) for the coordination of programmes and individual action items.

The ***Hospital, Patients, Health and Territories Act*** (*loi hôpital, patients, santé et territoires*) aimed at improving regional governance by creating regional health agencies (ARSs), which merged and replaced regional hospital agencies, regional health insurance funds and other regional state and SHI institutions. This move was intended to improve local access and quality of care, improve preventive medicine, and modernise the organisation of hospitals by creating local hospital communities.

[108] The present section is extensively informed by: European Observatory on Health Systems and Policies, France – Health System Review, Health Systems in Transition, Vol.12 No. 6, 2010

From the standpoints of governance and planning, the Act reinforced the authority of local bodies in planning and simplified the pre-existing regional clusters of healthcare system governance; the Act provided the legal basis for the establishment of so-called regional health agencies (*agences régionales de santé*/ARS). In fact, from April 2010 ARSs have merged and replaced the previous regional agencies. Other provisions included in the Law are that:

- For the first time, the term primary care has entered into the public health code, as it did not legally exist before.
- Transfer of tasks between professionals is made legal beyond the mere scope of the previously mentioned experiments.
- Contractual agreements of care protocols between professionals are developed.
- The regionally assigned numbers in the distribution of doctors (medical *numerus clausus*) throughout the country is to be determined on the basis of local needs. Thus, the law establishes that a mapping of geographic needs has to be conducted.
- It also offers opportunities for increasing the attractiveness of underrepresented specialties and medically under-served areas are being developed.

Table 1.1 - Legal and Policy Framework

Year	Type	Authority	Title	Comment
1953	Code	Parliament	Code de la santé publique	The code was created in 1953 Major recent reforms in 2000, 2003 and 2005.
1996	Ordinance (equivalent of law)	Government (Prime Minister)	Juppé reform Ordinances no. 96-344, no. 96-345, no. 96-346 of 24 April 1996	The Ordinances introduced parliamentary control over the healthcare system and its resources and attempted to clarify the respective roles of the state and Statutory Health Insurance (SHI); it also reinforced the role of the regions.
1999	Law	Parliament	Universal Health Coverage Act (*couverture maladie universelle*)	The Law established universal health coverage, entitling all residents to the right to SHI coverage, financed mostly by the state.
2002	Law	Parliament	Patients' Rights and Quality of Care Act (*loi relative aux droits des malades et à la qualité du système de santé*)	It created the National Institute for Prevention and Health Education (INPES) and established principles to take full account of the expectations of healthcare users (including quality requirements and principles of health democracy).
2004	Law	Parliament	Loi du 9 août relative à la politique de santé publique/Public Health Act	The Law clearly lays out for the first time the State's responsibility in the area of public health. Proposing 100 health objectives to be met within the next five years, the Law aims to reduce mortality and morbidity whenever these can be avoided, and to decrease health-related inequalities across regions.
2004	Law	Parliament	Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie/Health Insurance Reform Act	The Law increased the Parliament's authority to establish health targets and to put in place a management system for the Statutory Health Insurance.
2009	Law	Parliament	Hospital, Patients, Health and Territories Act (*loi hôpital, patients, santé et territoires*)	*Inter alia* the Law merged several regional institutions into the regional health agencies (*agences régionales de santé*/ARSs).
2010	Progress report	HCSP	Objectifs de santé publique : Evaluation des objectifs de la loi du 9 août 2004 et propositions	Assessed the state of achievement of the objectives set out by the 2004 Health Insurance Reform Act; suggested new objectives.

National Level. The Parliament[109] and the Executive Government are in charge of producing public health regulation. In particular, within the Government, the Ministry of Health and Social Affairs (*Ministère des Affaires Sociales et de la Santé*), hereafter MoH, defines priority areas for the national programmes; it sets the policy agenda in the form of acts approved by the Parliament that define health targets. Additionally, the MoH prepares, in cooperation with other ministries, the social security budget, used for the most part by the Statutory Health Insurance. Since 1996, the budget has been voted in Parliament; given that there is no limit to social security spending, France faces a situation of chronic deficit in this respect.

In general terms, public health policy is formulated by the Ministry with the help of several advisory committees or councils such as the High Council for the Future of Health Insurance, the National Health Conference and the High Council on Public Health (see below). Depending on the incumbent government, the Ministry in charge of Health may comprise all four or less than four Directorates of the ***Administration of Health and Social Affairs*** (*Administration Sanitaire et Sociale*). This central Administration puts in place the policies decided by the Ministry. The partition of responsibilities among the four Directorates is as follows:

- ***General Directorate of Health*** (*Direction générale de la santé*/DGS[110]) contributes to (i) national health policy formulation and monitors its implementation; (ii) proposes objectives and priorities; (iii) defines health indicators; (iv) supervises the quality and the safety of care; (v) defines training needs; (vi) ensures that patients' rights are respected; and (vii) organises healthcare service provision.
- ***General Directorate of Health Care Supply*** (*Direction générale de l'offre de soins*/DGOS[111]) is in charge of resource management.
- ***General Directorate for Social Policy*** (*Direction générale de la cohesion sociale*/DGCS[112]) is responsible for (i) health and social care for the elderly, the disabled and the vulnerable; (ii) coordinates prevention activities; (iii) contrasts social exclusion; and (iv) promotes integration.
- ***Directorate of Social Security*** (*Direction de la sécurité sociale*/DSS[113]) is in charge of financial planning and supervises the Statutory Health Insurance.

The ***Directorate of Research, Studies, Evaluation and Statistics*** (*Direction de la recherche, des études, de l'évaluation et des statistiques* - DREES[114]) is the ministerial branch endowed with data collection, analysis and dissemination responsibilities.

The ***High Council for Public Health*** (*Haut conseil de la santé publique* - HCSP[115]) is one of the most prominent committees supporting the MoH in public health policy formulation. Enacted by the Law of 9 August 2004 and activated in 2007 merging the High Council for Health (*Haut conseil de la santé*) and the Higher Council for Public Hygiene (*Conseil supérieur d'hygiène publique*), the HCSP provides guidance and assists decision-making concerning public health problems and issues related to the organisation of healthcare; it also contributes to the definition of public health objectives and makes proposals for strengthening preventive measures. It is a public body of scientific expertise and it is composed of *specialised committees* and *permanent working groups* in charge of analysing and producing reports on select public health issues. To end with, the HCSP

[109] The 2004 Health Insurance Reform Act increased the role of the Parliament in determining health priorities and in setting up national management of the Statutory Health Insurance.
[110] http://www.sante.gouv.fr/direction-generale-de-la-sante-dgs.html
[111] http://www.sante.gouv.fr/la-direction-generale-de-l-offre-de-soins.html
[112] http://www.social-sante.gouv.fr/
[113] http://www.securite-sociale.fr/
[114] http://www.drees.sante.gouv.fr/
[115] http://www.hcsp.fr/explore.cgi/accueil

assesses the implementation of the 2004 ***Public Health Act*** and thus evaluates the **100 health target objectives**[116] established by this Law.

The 100 objectives are grouped as follows: (i) objectives on main health determinants *(objectifs liés aux principaux determinants)*; (ii) objectives on pathologies (*objectifs relatifs aux pathologies*) e.g. cancer, rare diseases; (iii) objectives on health of different age groups (*objectifs relatifs à la santé aux différents âges)*, e.g. the elderly, women at reproductive age; and (iv) social and demographic health inequalities (*inégalités de santé sociales et territoriales).*

In its 2010 Report[117], the HCSP assessed the state of achievement of the 100 objectives and, in addition to that, it suggested new objectives[118] with an eye to laying the foundations for a new public health policy framework following up on the 2004 Programme. In particular, its recommendations focused on (i) specific areas of intervention; (ii) transversal issues of social inequality and (iii) the need for a more effective information system to monitor the achievement of individual objectives.

Other bodies supporting the Ministry in strategic planning are as follows:

- The ***French High Council for the Future of Health Insurance*** (*Haut conseil pour l'avenir de l'assurance maladie* - HCAAM[119]) publishes an annual report on the situation of the healthcare system and provides detailed figures and policy forecasts on trends in the healthcare system.

- The ***National Health Conference*** (*Conférence nationale de santé* - CNS[120]) brings together relevant stakeholders to define healthcare priorities at the national level ("*propose chaque année les priorités de la politique de santé et des orientations pour la prise en charge des soins*[121]").

Further consultative and executive agencies and policy implementing bodies regularly partner up with the Administration of Health and Social Affairs. Far from being an exhaustive list, some worth noting and respective areas of activity are:

- The ***National Health Authority*** (*Haute Autorité de la santé* - HAS[122]) is the only independent institution of all these; it is a scientific society whose mandate includes:
    - to assess the medical relevance of drugs, medical devices, and procedures and to provide opinions on their reimbursement by the health insurance;
    - to promote best practices among care-givers and users;
    - to enhance the quality of care in primary and secondary health facilities and structures;
    - to oversee the quality of the medical information that is disseminated;
    - to inform health professional and the general public and improve the quality of the medical information;

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[116] Ministère du Travail, de l'Emploi et de la Santé, « Evaluation des 100 objectifs de la LSP 2004 – 'Scannographie' en
décembre 2009 », Evaluation des objectifs LSP 2004, février 2010

[117] Haut Conseil de la Santé Publique, 'Objectifs de santé publique : Evaluation des objectifs de la loi du 9 août 2004 et propositions', Collection Avis et Rapports, avril 2010

[118] Haut Conseil de la Santé Publique, 'Objectifs de santé publique : Evaluation des objectifs de la loi du 9 août 2004 et propositions', Annexes, Collection Avis et Rapports, avril 2010

[119] http://www.securite-sociale.fr/

[120] http://www.sante.gouv.fr/conference-nationale-de-sante-c-n-s.html

[121] Haut Comité de la santé publique, 'La Santé en France - 2002', 2002

[122] http://www.has-sante.fr/portail/jcms/j_5/accueil

- to support the collaboration and co-ordination among the players of French health system and with foreign entities.

More specifically, HAS activities include: (i) the production of recommendations for good clinical practice, studies in cross-cutting areas of health and economics, guidelines for the management of healthcare intended for medical professionals as well as for patients, etc.; (ii) health technology assessment of drugs, medical devices and procedures; (iii) the certification of healthcare facilities and the accreditation of certain medical practitioners.

- The ***National Food, Environmental and Occupational Health Agency*** (*Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail*/ANSES[123]), evaluating health and particularly food-related, environmental and workplace health risks. This Agency is the product of a merger where several agencies, including the French Food Health Safety Agency *(Agence française de sécurité sanitaire des aliments*/AFSSA) and the French Agency for Environmental and Occupational Health Safety (*Agence française de sécurité sanitaire de l'environnement et du travail*/AFSSET), have converged.

- The ***National Agency for the Safety of Drugs and Health Products*** (*Agence nationale de sécurité du medicament et des produits de santé*), under the supervision of the MoH, it took over the functions of the former AFSSAPS. It evaluates and risks and benefits associated with the use of health products throughout their life cycle. It assesses the safety of the use, the effectiveness and quality of these products.

- The ***National Institute for Prevention and Health Education*** (*Institut national de prévention et d'éducation pour la santé/*INPES[124]) contributes to the execution of concrete programmes and initiatives by implementing policies in matters of prevention and health education within the more general framework of public health policy set by the government; it also organises informational campaigns.

- The ***National Institute for Public Health Surveillance*** (*Institut national de veille sanitaire*/InVS[125]) in charge of detecting all public health risks and to release alerts to the public authorities, gather and analyse information on health risks and to conduct epidemiological studies.

- The ***National Institute for Cancer*** (*Institut national du cancer*/INCa) is the national health and scientific agency in oncology. It was set up by the first Cancer Plan for the 2003–2006 period and following from the 2004 Public Health Act. It is responsible for following up on the action items included in the Cancer Plans. Among the Institute's objectives are (i) survey and assess the measures taken against cancer, (ii) develop guidelines for the management of patients with cancer; and (iii) monitor and finance research and development in cancer.

- The ***National Centre for Scientific Research*** (*Centre National de la Recherche Scientifique*/CNRS), together with the aforementioned DREES, contributes scientific expertise through its research. It is a public body that operates under the supervision of the Ministry of Higher Education and Research (*Ministère de l'Enseignement supérieur et de la Recherche*).

[123] http://www.anses.fr/
[124] http://www.inpes.sante.fr
[125] http://www.invs.sante.fr/

- Finally, the ***School of Higher Education in Public Health*** (*Ecole des hautes études de santé publique*/EHESP[126]) is an academic research institution dedicated to the training of future healthcare administrators and contributes to the development of education and research in all fields of public health. The introduction of Public Health in established academic curricula and the maintenance of training capacities gains France the statute of one of the European countries with "fully developed educational infrastructures at both Master and PhD Level[127]" in public health.

Regional level. The Administration of Health and Social Affairs is represented at the regional level by the ***regional health agencies*** (*agences régionales de santé*/ARSs). Much of the authority in public health that used to be detained by regional prefects has, since the early 2000s, been transferred to the specialised agencies outside of the prefecture (i.e., first to the *Agences Régionales de l'Hospitalisation*, and since 2009 to the *Agences Régionales de Santé*). The ARS have been created in 2009 by the Hospital, Patients, Health and Territories Act (*loi hôpital, patients, santé et territoires*) as a product of the merger of several former regional institutions.

Although they always act in coordination with the national authorities listed above and they are overseen by a structure called *Secrétariat Général des Ministères Sociaux*, which belongs with the MoH[128], ARSs are considered independent in their healthcare planning and delivery functions. This is not the case for financial planning, however, which is still top-down and therefore has strings attached (see below).

Starting in 2009 they were given ever-growing responsibilities for planning and budgeting for hospitals. In particular, ARSs implement regional health policy related to occupational health services, mother and child health services (*protection maternelle et infantile*/PMI), and university and school health services. Additionally, they monitor and record population health status and produce hygiene rules and standards. ARSs also promote prevention campaigns and activities, and they participate in patient health education.

The 2009 Hospital, Patients, Health and Territories Act is considered the main legal contribution to regionalisation. Through this Act and following the constitution of ARSs, ARS Directors where attributed public health decisional powers. This shift towards regionalisation, however, was not accompanied by a corresponding increase in substantial budgetary autonomy of the ARS. Their room for manoeuvre ends with the allocations decided by the MoH, so in practice ARSs still endure the same dependency on central government decisions as prior to the 2009 Act. Consequently, under the existing system ARS Directors benefit from limited freedom as to how to allocate public funding to the various sectors and areas of the regional health system.

The main mechanism to coordinate policy implementation at regional and national level is the ***National Health Conference***. It is a consultative body in charge of facilitating concerted action in public health. It includes an array of boards representing key stakeholders, including patients and other public health system users. The Regions, too, are to be represented in the Conference, but their means are kept to a minimum. The Permanent Committee of the Conference is composed of eight sub-committees[129]; the regional sub-committee (*Collège des représentant(e)s des collectivités territoriales*) is the smallest, composed only of two members (one permanent and one substitutive),

[126] http://www.ehesp.fr/
[127] Aluttis, C. et al., 'Review of Public Health Capacity in the EU - Supplementary document to the final technical report of Tender No. EAHC/2009/Health/05: Developing public health capacities in the EU', 2012
[128] Aluttis, C. et al., 'Review of Public Health Capacity in the EU - Supplementary document to the final technical report of Tender No. EAHC/2009/Health/05: Developing public health capacities in the EU', 2012
[129] http://www.sante.gouv.fr/IMG/pdf/composition_cp_avec_orga_130412.pdf

equal in size only to the sub-committee of the research institutes, drug industries and qualified personnel (*Collège des représentant(e)s des organismes de recherche, des industries des produits de santé et des personnalités qualifiées*). Other than the Conference, the only other mechanism for the coordination and gathering of the ARS are the monthly meetings of the ARS Directors.

ARS and CRSA are the dedicated bodies for public health planning at regional level. The ***regional conference of health and autonomy*** (*conférence régionale de santé et de l'autonomie*/CRSA) is the main consultation body available to the regions for the development of regional policies. The conference aims to bring public health policy close to the citizen by involving all public health actors and users, including representatives of a composite array of social partners, healthcare practitioners, agents of prevention and health promotion, among others.

The ARSs can organise as many of these sub-regional conferences as they deem fit; the conferences' territorial coverage is also at ARS's own discretion. Concomitantly, the regional health observatories (*Observatoires régionaux de la santé* - ORS) collect information on the population health status and needs in their respective regions. The Observatories are scientific bodies that supply data to the MoH to support informed decision making. Each Observatory is headed by a Directorate where the State and the Region are represented in equal numbers. Its chairman is the President of the Regional Council (*Conseil régional*) with the ARS Director as his deputy.

One of the primary tasks of ARS consists of the development of the ***Regional Health Projects*** (*Projets régionaux de santé* - PRS). The Ministry of Health performs a stewardship role, establishing a listing of health services that the regions must incorporate in their plans. Based on a national needs and priorities assessment (politically driven, on occasion), this listing may include services in a variety of areas. The Regional Health Projects are threefold and include (i) an overall strategy, three planning blueprints[130] (known as *schemas*) and (iii) a regional health programme to action this strategy. Since their establishment, ARSs have mostly engaged in the preparation of these Plans; to date, not all ARSs have completed this task yet. Following fieldwork findings, it would seem that the strict submission requirements imposed by the central government have represented an obstacle to the successful completion of such documents. Additionally, the ARSs lack a reference Law at national level on which to model their own plans, given that the national Public Health Law – whose time scope ended in 2009 - has not been yet substituted by any new Law.

Local/departmental level. Each ARS covers several departments. The ARS is represented at department level by local delegations (*délégations territoriales de l'agence régionale de santé*), in charge of implementing ARS regional policies and of supporting local actors in the implementation of their projects. The delegations contribute to further decentralising the decision-making process, bringing it closer to the citizen. Local conferences are organised on specific topics, such as prevention and medicosocial issues.

Several health and social services come under the jurisdiction of the General Councils (*conseils généraux*), local assemblies elected by the departments. Falling within the remit of the General Councils are, *inter alia*: specialised health and social care institutions and services for the elderly and the disabled; prevention of certain diseases, such as tuberculosis, sexually transmitted diseases and cancer.

[130] The *schemas* detail orientation for, respectively: (i) prevention, (ii) healthcare service and (iii) services for persons with special needs.

Finally, *commune*-level initiatives focus mainly on the promotion of hygiene and health in general, ranging from the extermination of rats, HIV prevention, monitoring of drinking water quality, improvement of hygiene and living conditions of certain residential clusters.

Policy Implementation and Data Collection. From the viewpoint of *policy implementation*, State authorities and the Statutory Health Insurance (SHI) share management responsibilities of the national healthcare system. The SHI currently covers almost 100% of the resident population[131].

In terms of *data collection*, the Agency for Information on Hospital Care (*Agence technique de l'information hospitalière*/ATIH[132]) manages the information systematically collected from all hospital admissions and used for hospital planning and financing. A separate cluster can be identified of the agencies in charge of collecting and feeding back public health data. The host of these organisations include some that were already mentioned, such as ANSES, DGS, DREES and INPES, as well as a number of others.

Monitoring and Evaluation. The High Council of Public Health annually evaluates the state of achievement of the 2004 Public Health Act's "100 objectives" and suggests new ones. The Directorate of Research, Studies, Evaluation and Statistics (DREES) supports the HCSP in this activity.

2. Overall EU Health Policy Adoption/Implementation

The ***White Paper*** is currently not explicitly referenced in any French national policy. In the first place it is important to highlight that the last comprehensive public policy act was passed in 2004, i.e. before the release of the White Paper. A new national law is currently in the pipeline, however it is possible that it will not include reference to the White Paper since, according to some national experts it is not common practice to include reference to EU soft policies in national pieces of regulation.

The ***bibliographic research*** carried out in the framework of the Study on the reference to the White Paper in the French scientific literature on health policy did not provide significant result either. According to national experts the point is related to a general deficiency of research activity and scientific production on prevention policy in France.

Additionally it is worth to mention that in France there is no institutional mechanism for the stocktaking, analysis, and discussion of EU policies involving all the relevant advisory and technical bodies that are part of the institutional architecture, and there is limited dissemination of EU policies to concerned sub-national authorities (e.g. ARS).

A review of some possible factors affecting the adoption and implementation of EU polices on health is provided in Table 2.1 below.

Table 2.1 – Assessment of possible factors affecting the adoption and implementation of EU policy

Obstacles/drivers	Comments
Institutional architecture (since uptake might be more difficult in more decentralised systems)	The MoH concentrates the lion's share of decision-making authority over public health policy. Unquestionably the veneer

[131] The 1999 Universal Health Coverage Act (*couverture maladie universelle*) established universal health coverage, entitling all residents to the right to SHI coverage, financed mostly by the state.
[132] http://www.atih.sante.fr/

Obstacles/drivers	Comments
	of distribution of powers that came with regionalisation has not (yet) translated into an effective transfer of autonomy or decision-making authority in favour of the outer branches of administration. This situation would in principle be conducive to a rapid and smooth integration of EU policies in the national strategies; however, this seldom happens due to the lack of a structured mechanism for the discussion of EU soft policies office with the advisory public health bodies. There is also no mechanism for the dissemination of EU policies to policy-makers at regional level, who are reportedly often unaware of the existence of an EU policy in given fields.
The different nature of the soft law instrument chosen by the EU, i.e. whether Recommendations, Council Conclusions, or Commission Communications (since MS may attribute a different level of priority or deal with them in a different way)	France has a distinct regulative approach to health policy, which is connected to the above-mentioned centralisation of the policy-making at the MoH level. The establishment of HAS – whose activities largely consists in developing soft policy instruments – has partially mitigated this feature. Still, according to various experts, there remains a sort of cultural resistance towards the adoption of measures that are not mandatory.
Prior adequate discussion / consultation period before the adoption of a EU Policy (since this may facilitate adoption)	This is not perceived as a significant issue. In most of cases the matters addressed by EU health policy were already covered by national policies or being debated.
Other aspects of legislative techniques adopted to put pressure on recipients (such as the inclusion in the text of deadlines for compliance or explicit reporting requirements)	This is not perceived as a significant issue, since as mentioned above, EU soft policies have in general a limited influence on national policies. With respect to reporting, it appears quite symptomatic of this attitude the fact that entities like the *Commission spécialisée sécurité des patients* of the HCSP, who recently developed a major study on patient safety situation in France, have not being consulted by the MoH for the preparation of the report on the implementation of the EU Recommendation on patient safety recently requested by the EC.
Issues of national ownership (since policy items put forward in the European agenda by individual MS may encounter resistance in other MS due to national experiences, cultural factors, traditions or technical obstacles to transposition)	The main cultural/political obstacle to the uptake of EU policies in France is reportedly due to the fact that French health policy is traditionally focussed on care (and specifically hospital care), an comparatively less on prevention. The PHP Law (2004) has somewhat strengthen the focus on prevention but a major upgrade in this sense is expected with the upcoming new public health policy. The uptake EU soft policies, which are instead focussed on prevention, might have therefore be hampered by a sort of misalignment with the national political priorities. In this respect, the EU policy might have a greater relevance at regional level. The regional strategic documents are in fact significantly focussed on prevention.
Adequate maturity, i.e. existence of sufficient evidence ('pilot' experiences, evaluations, scientific studies) supporting the inclusion of a given policy approach in the European agenda	The maturity of EU policy is not perceived as a main issue. On the other hand, some national experts point at the weak link between the research/experimentation level and the policy-making level. In particular, there is the need to overhaul

Obstacles/drivers	Comments
	research and studies on the efficacy of prevention policies (which is still underdeveloped), since this may help political endorsement.
Programming capacity (since some MS could find it difficult to cope with the total number of programmes, action plans, strategies requested by the EU in a given period. Not only for internal capacity constraints, but also for the duration of the political approval process)	This is not perceived as an issue.
Clear prioritisation of actions (since the inclusion of too many European items in the policy making agenda might ultimately be detrimental for most urgent priorities, particularly in times of financial crisis)	This is not perceived as an issue.
Existence of relevant OMC / JA mechanisms on the subject at the European level and the MS participation therein (since this may facilitate adoption)	In principle, OMC / JA mechanisms are considered useful instruments that might support the mainstreaming of EU priorities in national strategy. While this happens in certain areas - especially as a result of scientific collaboration within networks or research projects - at the policy level these mechanisms are perceived as less effective for France.
Pressure from stakeholders' groups or lack thereof (since this may ultimately influence uptake)	Pressure from stakeholders' groups may support the adoption of policies in specific areas (an example is provided by the patient safety policy) but cannot be generalised.
Other	According to some national experts there would be a greater stocktaking of EU policies in France if the relevant documents were translated in French.

B – Health in All Policies

1. Legal, Policy and Institutional Framework

The *notion of* ***"Health in All Policies"*** is not codified in French public health general policy. Often expressions like "*santé dans toutes les politiques*" or "*santé dans les autres politiques*" are used in the literature but typically refer to the relevant EU and/or WHO concept, but there is no official translation in the national framework.

The matter has however been largely debated. In 2002 the *Haute Comité de la Santé Publique* (which in 2004 became the *Haute Conseil de la Santé Publique*) published the report « *La Santé en France* » that raised a point on the need to develop a horizontal dimension in public health policy which takes into account the health determinants originating in other sectors like education, agriculture, environment, industry, economy etc[133].

Reportedly, the possibility to include HIAP in the national framework was discussed in the process of the drafting of the 2004 PHP Law, but it eventually lacked the political support and the project was abandoned. On the other hand, the PHP Law substantially reformed the institutional mechanism for intersectoral coordination in public health policy-making, by creating the National Committee on Public Health (***Comité national de santé publique*/CNSP**), which merged the competences of two previous committees (*Comité national de la sécurité sanitaire* and *Comité technique national de prevention*). The CNSP involves representatives of all ministries, agencies and institutions whose activities are considered relevant in terms of possible consequences on health, assisted by a technical secretariat established under the DGS[134]. It holds quarterly meetings and prepares annual reports for the MoH. More specifically, the CNSP has three main tasks:

- to identify the short/medium-term priorities of public health as concerns prevention and health safety – taking into account the objectives laid down in the PHP Law;
- to coordinate the actions undertaken by the different bodies of the public administration and the health insurances in this field; and
- to establish the methods for the evaluation of the national policy in this field.

In 2008 the CNSP envisaged the creation of a working group on the integration of health in all national policies, with the mandate of devising concrete measures to facilitate the stocktaking of the possible impact on health of other sectoral policies. The working group has started operations in 2010, and so far its output has not led to any tangible effect. Actually, the main perceived constraint of overall CNSP activity is its scarce operational efficacy. As reported by the DGS general director it would be useful to reinforce the steering function (e.g. enhancing the juridical basis) and the participation of appropriate representatives of member institutions[135].

The PHP Law had a 5-year time scope, and it is expected that it will be revised during the next presidential term. In particular, it is anticipated that the new regulation would place more emphasis on prevention policies. The conclusions of a round table on public health priorities held in 2008 and involving the highest hierarchy of DGS, HCSP and HAS included a reference to HIAP as a "EU-

[133] Haut Comité de la santé publique, 'La Santé en France - 2002', 2002 « L'action sur les déterminants de la santé relève de domaines très variés, outre celui de la santé, en particulier éducation, agriculture, environnement, industrie, finances, etc. Cette dimension transversale n'est pas toujours appréhendée […] En fait, le degré de segmentation du système de santé constitue un écueil à toute recherche de cohérence ».
[134] http://www.cis.gouv.fr/spip.php?article716
[135] http://www.assemblee-nationale.fr/13/cr-mecss/11-12/c1112006.asp

promoted instrument that might be usefully introduced in a revised public health law[136]". However, according to the experts consulted in the context of this Study, the HIAP concept has 'lost momentum' and it is unlikely it will indeed be integrated in the new regulation.

The lack of an explicit reference to HIAP in the regulatory framework does not entail that its underlying vision and principles are entirely absent in national public health policy. In France, the basic HIAP principles are *de facto* subsumed in the policy on ***health inequalities***, which has been largely debated over the past few years, although it is still not formalised in a comprehensive document.

In this respect the PHP Law included the reduction of inequalities among the key principles of public health policy, stating that "*policy objectives and strategic plans should take into account disadvantaged groups, to the extent they are more exposed to health issue determinants*", but only two of the 100 PHP objectives focussed on this theme[137]. The HCSP's evaluation of PHP Law published in 2010 insisted on the need to scale up the commitment to the reduction of health inequalities, going beyond the traditional perimeter of equity of access to healthcare to embrace considerations on the social, economic, geographic and other contextual determinants[138]. The HCSP evaluation report cites the EU health programme 2008-2013 among the possible sources of inspiration for the development of the national approach on social and environmental determinants of health.

Other relevant recent publications issued by French health authorities in the past few years on this theme include:

- The 2009 HCSP report which described in detail the state of the art and proposed a series of priority actions[139];
- The IGAS report 2011 on social determinants of health inequalities[140];
- The INPES (i) guidelines suggesting possible actions to be taken by ARSs to tackle inequalities at regional level; and (i) review of relevant scientific literature and available best practices.

The work plan 2011-2014 elaborated by the *Conférence Nationale de Santé* indicates health inequalities as a top priority for the national health policy work.[141] In 2010, the Minister of Health announced that health inequalities will be a key theme in the next public health law.[142]

In addition to MoH (and line Ministries for cross-cutting policies), the following institutions complete the picture on French HIAP:

- ***HCSP*** – as seen above, it has a central role in the advisory support and promotion of an integrated policy on health inequalities, adapting to this end international approaches and practices.
- ***InVS*** – its involvement in HIAP-related matters concern essentially the health/environment theme. It conducts studies assessing the possible impact on health of environmental issues, including various 'zonal' studies focusing on critical geographical areas. It also provides methodological support, e.g. it has developed the "guide for the analysis of the health chapter of impact assessments" aimed at assisting public officers in the review of the dossiers submitted by

[136] http://www.has-sante.fr/portail/upload/docs/application/pdf/2009-02/synthesetr20_vvd2402.pdf
[137] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000787078&dateTexte=&categorieLien=id
[138] http://www.sante.gouv.fr/IMG/pdf/Rapport_Haut_conseil_de_la_sante_publique_-_Objectifs_de_sante_publique.pdf
[139] http://www.hcsp.fr/docspdf/avisrapports/hcspr20091112_inegalites.pdf
[140] http://www.ladocumentationfrancaise.fr/var/storage/rapports-publics/114000580/0000.pdf
[141] http://www.sante.gouv.fr/IMG/pdf/propositions_de_programme_de_travail_2011_2014_210611.pdf
[142] See : http://www.ladocumentationfrancaise.fr/var/storage/rapports-publics/114000580/0000.pdf

authorisation-seekers prior to the realisation of projects having a potential impact on the environment.

- ***INPES*** – the national institution for prevention and health education is engaged in developing and promoting knowledge of HIAP.
- ***ANSES*** – the national agency for health safety, food, environment and labour is a centre of expertise producing studies, scientific opinions reports and others, including studies on environment-related health hazards. It has an active role in the development of the intersectoral action plans on health and environment 2009-2013 and health at work 2010-2014.
- ***ARS*** – HIAP principles and practices, especially in the field of health inequalities reduction – have been included in the regional strategic health plans by numerous regions. The instrument used to support concrete activities is the local health contract (*Contrat Local de Santé - CLS*), through which ARSs may assist municipalities and other local bodies in implementing activities aimed at achieving the objectives of the regional plan. In some instances, specific provisions on HIA have been included in the regional plan or the related "regional health schemes".

2. Policy Implementation

Health Impact Assessment. The constitutional review[143] of 2008 and the following regulation modified Parliament functions, introducing in the law-making procedure an explicit provision requiring the *ex-ante impact assessment* of draft laws (*Loi Organique n° 2009-403* – art. 8)[144]. In particular, it becomes mandatory to evaluate *a priori* the likely economic, financial, social and environmental effects, as well as the expected costs and benefits for the public administration and the concerned citizens and private entities. Although not explicitly mentioned, potential health impacts should be part of the assessment, as confirmed by the Government general secretariat in charge for the methodological validation of these studies[145]. However, with the obvious exception of draft laws having a specific focus on health, this aspect seems only superficially taken into account in the studies conducted so far. The methodology for the ex-ante impact assessment of draft laws have not firmed up yet and, as highlighted by a report of the *Comité d'évaluation et de contrôle des politiques publiques*[146], there is much room to increase the quality and the utility of this instrument.

A specific type of health impact assessment is carried out *in the framework of environmental impact assessments* (EIA), which are mandatory prior to the realisation of works with potentially polluting effects (e.g. industries, infrastructures etc.) In a nutshell, the procedure involves the preparation of a dossier by the authorisation-seeker including a specific chapter on expected health impact of the project. The dossier is reviewed by the competent authority which, depending on the complexity of the matter, might be ARS, CIRE (the regional offices of InVS), or InVS itself in case of critical dossiers. A HIA manual was prepared by InVS in 2000 to assist decentralised authorities in the quality evaluation of the health section of the EIA dossiers presented by authorisation-seekers. When the competent authority establishes that the dossier is incomplete or undependable it hires an external contractor to carry out a new assessment, charging costs onto the authorisation-seeker.

Outside of the environmental domain, HIA-like exercises are sporadically being conducted at local level, where there is a growing interest in cross-sectoral health policies especially in fields like urban planning, housing, nutrition, education, sports, etc. These experiences are mostly driven by

[143] http://www.senat.fr/role/fiche/reforme_constit_2008.html
[144] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000020521873&dateTexte=&categorieLien=id
[145] Reported by the DGS General Secretary M. Mettendorf at the HIA seminar organised by the *Centre d'analyse stratégique* on 28.01.2010
[146] http://www.assemblee-nationale.fr/13/rap-info/i2094.asp

policies on health inequalities, and in this sense the approaches used seem more inspired by the so-called Health Equity Impact Assessment (HeIA) than HIA.[147]

Intersectoral Coordination. At the institutional level the above mentioned CNSP is the primary body tasked with ensuring an adequate coordination across ministerial services to ensure public health is adequately taken into account in other sectoral policies. As seen, a working group has begun elaborating possible concrete provisions to facilitate this process, but no output is available yet. Since CNSP's mandate also includes the development of methodology for the evaluation of health policies, its relevance has in principle been enhanced by the constitutional review brought by the *Loi Organique*, which introduced the mandatory *ex ante* impact assessment of draft policies.

The process of preparation of impact assessment studies already involves a certain degree of intersectoriality. The draft study is prepared by the service competent for the policy being proposed and submitted for review and approval to an inter-service group involving all other ministerial services concerned. In this respect it is envisaged that on matters having a possible effect on public health, the DGS would assist the proponent in the assessment of the possible health impacts. The study should ultimately be approved by the Government general secretariat.

Other experiences of intersectoral coordination are at the basis of a series of other cross-cutting initiatives like programmes (e.g. the various action plans on health at work, health/environment, health/nutrition) and regulations (e.g. tobacco taxation, food products regulation, etc.). However, these remain ad hoc isolated experiences, while as observed by some experts interviewed in the context of the Study, there is a need to establish a more structured framework for intersectoral coordination both at national and local levels.

Concrete experiences. In practical terms, examples of implementation of HIAP principles can be found – if any – at the local level. These experiences are often not even labelled or disseminated as such, but *de facto* can be classified as initiatives contributing to public health mobilised by non-health sectors. Most frequently these horizontal initiatives are activated at municipal level.

Community-level initiatives in France are supported by networks like:

- The WHO's Healthy Cities (*Réseau Ville Santé*), which includes some 70 members in France and encourages members to develop city 'health plans' by disseminating know-how and facilitating exchange of best practices among members[148]. The network promotes intersectoral activities that integrate health in overall assessments of city-level public policy. The Network declaredly focuses on intersectoriality in view of reducing inequalities. Operationally, it works as a platform for exchange of experiences and good practices, for which purpose it organises conferences, seminars and trainings. Performing HIAs is not a requirement to be part of the Network, and therefore HIAs are not an established practice. However, some HIAs have been conducted under the initiative of the Network.
- The association *Elus Santé Publique et Territoire* (ESPT) that gathers members of local councils interested in developing integrated territorial health policies, following up on the model of a series of workshops on health in urban contexts, the *ateliers santé ville*[149] (see below).

The *Ateliers santè ville* are another relevant local-level project. Established in 2000, they are an instrument to facilitate the coordination of actors and the realisation of actions to reduce health

[147] This also relates to the fact that HIA approaches in France are largely inspired by other francophone countries more advanced on the subject, and in particular by Quebec's policies and methodologies, which are largely centred on HeIA.
[148] http://www.villes-sante.com/
[149] http://www.espt.asso.fr/index.php?option=com_content&task=view&id=17&Itemid=27

inequalities in specific disadvantaged area. The mechanism is the keystone of the health section of CUCS – the contractual mechanisms through which the State supports social cohesion at local level. At present there are some 300 Ateliers in France.

At regional level some ARSs have included HIAP principles (in a broad sense) in their regional strategic health plans (PSRS) and in the connected regional prevention schemes (SRP). The implementation mechanism is based on the stipulation of local health contracts (*Contrats Locaux de Santé*/CLS) with local authorities and other territorial partners, as well as the facilitation of coordinated modalities for the inclusion of health in other sectoral policies.

At the national level, concrete initiatives touching on some key principles of HIAP include:

(i) in the field of intersectoral coordination, some examples are the various intersectoral action plans jointly set up and implemented by various Ministries and specialised agencies (e.g. health at work, health and environment, health and nutrition etc.);

(ii) with respect to HIA, similar instruments are used essentially in the context of studies on the impact on health of environmental issues (e.g. air pollution, exposure to dangerous substances etc.)[150]; and

(iii) conferences and seminars, such as the seminar organised in 2010 by the *Centre d'analyse stratégique* under the auspices of the MoH on HIA methods and analytical approaches[151].

Table 2.1 – Examples of relevant programmes and initiatives

Year	Level	Initiative	Description
2006	Local - Mouans-Sartoux	Action plan : *« Bien manger, bien bouger, c'est bon pour la santé »*	Intersectoral coordinated action involving various services (education, youth, sport, civil society, communication, urban planning, finance etc.) and implemented along various axes: (i) consumption of fruits and vegetables; (ii) active mobility; (iii) physical activity; (iv) youth and children education; etc.
2011	Local - Strasbourg	Health plan for the urban community	The health plan aims at supporting health promotion in all local policies, by means of introducing a health component in the various sectoral plans, e.g. housing policy, transport, education in disadvantaged areas etc. The initiative has since 2012 been financed by two Local Health Contracts[152].
2008	Local – Saint-Quentin en Yvelines	Health Impact assessment	An example of HIA applied to an urban planning project, i.e. the restoration of an urban area (i.e. Ecopôle-Gare)
2012	Regional - Alsace	Regional prevention schemes	The RPS recently passed in Alsace includes among strategic objectives the "adaptation of health policy to the local reality and the promotion of its stocktaking in other public policies".[153] More specifically, the documents envisages the promotion of practices aimed at supporting the introduction of health considerations in other policies, working in partnership with the competent authorities, and promoting

[150] In this respect see for instance the ANSES line of work on the estimation of health impact due to environmental pollution and the quantitative assessment of health hazards. http://www.afsset.fr/index.php?pageid=797&parentid=523

[151] http://www.strategie.gouv.fr/content/actes-du-seminaire-%C2%AB-evaluation-d%E2%80%99impact-sur-la-sante-methodes-diverses-d%E2%80%99analyse-%C2%BB

[152] http://www.strasbourg.eu/actus/actus?ItemID=39253884

[153] http://www.ars.alsace.sante.fr/fileadmin/ALSACE/ars_alsace/Projet_regional_de_sante/definitif/SRP_PRS_2012-2016.pdf

Year	Level	Initiative	Description
			coordination among the different actors.
2012	Regional – Ile-de France	Regional Strategic Health Plan	Two main pillars of the draft PSRS are[154]: (i) the foundation of regional health strategy on the participation of all concerned actors, including their involvement in the evaluation of health impact of actions in diverse fields, as well as a better integration of health policy in the urban, housing and environmental policy. And (ii) mobilising the various territorial actors in tackling social inequalities of health, utilising to this end the CLS instrument.
2010	National	Action plan 2010-2014 for health at work *PST2 Plan 'Santé au travail 2010-2014'*	The plan is a joint initiative of Ministries of Labour, Health, Ecology and Sustainable Development, coordinated by the Ministry of Labour. It involves also specialised bodies like ANSES (for risks associated to products, and work conditions) and InVS.[155]
2009	National	2° National Health and Environment Plan (2009-2013) *2° Plan National Santé Environnement*	The plan is a joint initiative of the Ministries of Ecology, Health, Education and Research, and Labour. It involves also various national technical agencies such as the Agency for Environmental and Occupational Health Safety (Afsset), the National Institute for Industrial Environment and Risks (Ineris), and InVS[156].
2011	National	National programme on health and nutrition 2011-2015 *Programme National Nutrition Santé 2011-2015*	The plan is a joint initiative involving numerous Ministries (health, agriculture, education, social cohesion, environment, finance, culture etc.) as well as public agencies like INPES, InVS, INCA, ANSES and ANSM[157].

3. Factors Affecting HIAP Uptake

The possible main factors influencing the uptake of HIAP principles and practices in France can be summarised as in Table 3.1 below.

Table 3.1 – Assessment of possible factors influencing the adoption and implementation of HIAP

Factor	Comment
Unclear legal framework and methodology for HIA use in the public administration	There is no obligation for public administration entities to use a standard HIA definition in the policy-making processes. As noted by the *Comité d'évaluation et de contrôle des politiques publiques* there is scope to improve the equality and utility of ex ante policy impact assessments by developing appropriate methodologies and reinforcing feedback mechanisms. The absence of a clear national legal framework on HIA (and HIAP in general) results in experiences at local level being quite fragmented and dissimilar. There is no efficient transmission mechanism to transfer EU and international guidelines to local authorities, so there is a proliferation of approaches inspired to a wide range of cross-border experiences. Some harmonisation is supported by networks

[154] http://www.ars.iledefrance.sante.fr/fileadmin/ILE-DE-FRANCE/ARS/1_Votre_ARS/3_Nos_Actions/3_PRS/psrs-idf-2011.pdf
[155] http://www.travail-emploi-sante.gouv.fr/espaces,770/travail,771/dossiers,156/sante-et-securite-au-travail,301/plans-de-sante-au-travail-pst,548/plan-de-sante-au-travail-2010-2014,1629/
[156] http://www.sante.gouv.fr/plan-national-sante-environnement-pnse,3480
[157] http://www.sante.gouv.fr/IMG/pdf/PNNS_2011-2015.pdf

Factor	Comment
	(e.g. Villes Santé). The above does not apply to health impact assessments carried out as part of mandatory EIA, for which a manual for public officers has been developed by InVS.
Availability of sufficient epidemiological information as a precondition	As showed in the HCSP evaluation report, the data available on contextual determinants of health and inequalities essentially come from 'one-off' research projects and studies, while there is a need for more regular and comprehensive monitoring. This would require: (i) the elaboration of ad hoc indicators; (ii) to scale up and coordinate data collection at all levels (local, regional, national); (iii) the adaptation of the existing health information systems.
Availability of a sufficient number of professionals trained in the subject matter	The education and training programmes for health professionals are mostly centred on biological determinants and modules on social sciences are little developed in the curricula.
Lack of a centre of expertise	The need to create a centre of expertise and coordination on social inequalities of health is among the key proposals of HCSP. The tasks would possibly include to facilitate coordination among institutions at national and sub-national level, to support research, to develop the expertise and practices on HEIA, to monitor the effects of policies addressing inequalities, and to oversee the availability and the coherence of relevant statistical and epidemiological data.
Political resistances in principle	A systemic vision of HIAP has been largely debated in France. The EU HIAP model has formally received credit by policy-makers and high officials in various instances (e.g. the seminar on HIA in 2010). However, declaration of principle has so far never translated into policy acts. The rationale behind the political unwillingness to follow up on this theme (e.g. at the time of drafting of PHP Law) is uncertain, but according to some experts it is connected with the traditional national approach on public health essentially focussed on care and only marginally on health prevention.
Weak structures of coordination of intersectoral cooperation	As reported by the health general director before the national assembly, the CNSP which is supposed to ensure intersectoral coordination at strategic level needs to be more effective. This might require to review its juridical basis and its structure/composition.

4. Indicators

There is no monitoring system currently in place on the degree of uptake of HIAP in the country and no indicator has been developed to that aim. Needless to say, no study has ever been conducted on the possible impact of implementing HIAP on the health status of the population. Summary considerations on the proposed set of possible EU indicators on the subject are reported in Table 3.1 below.

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	ANA.1	Formal Adoption of EU HIAP definition and HIA methodology (incl. RE* level)	The HIAP concept is not formally translated in French public health framework. In France, the basic HIAP principles are de facto subsumed in the policy on health inequalities, which has been largely debated over the past few years, although it is still not formalised in a comprehensive document. The HIA methodology is not currently formalised. HIA-like exercises have been conducted at local level but without harmonised approaches and methods. At the national level, health impact is considered part of the mandatory ex ante impact assessment of draft policies introduced by the *Loi Organique*. A clear methodology has not been developed yet but one is expected in the future. The indicator is deemed: **fairly valid** (the lack of a clear definition and methodology is highlighted as a key HIAP uptake indicator, althpugh with no specific link to EU policies) **highly feasible**
2	ANA.2	Evidence of a Significant Debate in the Scientific Literature about HIAP	Limited references to HIAP can be found in the scientific literature. Most of the relevant studies connected to HIAP principles relate to health inequality policy or environment–related health hazards. The indicator is deemed: **fairly valid** (the relevance of bibliographic references as an indicator is accepted, but given the specific health inequality focus, key words may need some adjustments) **fairly feasible** (the indicator is not used but bibliographic data can be easily retrieved trough popular search engines)
3	PRI.1	Existence of Health Policy Documents Including a Commitment to HIAP Principle (incl. RE level)	No reference to HIAP in national public health policy. The concept can instead be found in some regional strategic health plans (e.g. Ile-de-France, Alsace). The indicator is deemed: **definitely valid** **fairly feasible** (the source of information consists of published documents, but regional fragmentation may require some research effort)
4	PRI.2	Reporting to International Organisations of Commitment to HIAP Principle (for instance in the WHO Healthy Cities programme)	The WHO is informed of intersectoral activities conducted in the framework of the French Healthy Cities Network. Regular reports are published that report on the activities of the network through its website; publications and seminars' proceedings are made available. Other lines of communication between the French Network and the central coordination of the WHO Regional Office for Europe are the network coordinators. The indicator is deemed: **of dubious validity** (since HIAP is not explicitly included in French health strategy) **fairly feasible** (reports are published)
5	PRI.3	Strategies/Programmes/Action Plans Specifically focusing on	There are no specific strategies/programmes/Action Plans specifically focusing on HIAP at national or regional level. Regional strategic plans may include references to HIAP principles in relation to health inequalities reduction.

	Code	Indicator	Notes
		HIAP (incl. RE level)	The indicator is deemed: **fairly valid** (broadly relevant in principle, but it loses some importance if considered that there is no clear commitment on HIAP at the general strategy level) **fairly feasible** (the source of information consists of published documents, but regional fragmentation may require some research effort)
6	PART.1	Existence of Advocacy NGOs Active in the HIAP Field	Some organisations like the Société Française de l'Evaluation are active in the promotion of the HIA methodology. The ESPT network gathers members of local councils interested in developing integrated territorial health policies, following up on the model of *ateliers santé ville* (city health workshops). The indicator is deemed: **of dubious validity** (since it deals with a concept that is not systematised in the country and is not seen of immediate use for policy-making purposes. The concept of NGO unduly limits the typology of bodies potentially matching with the indicator) **hardly feasible** (the lack of a clear definition of scope and the absence of a co-ordination mechanisms of such NGOs makes it difficult to identify and quantify relevant actors)
7	PART.2	Involving of Advocacy NGOs in the Policymaking Process (incl. RE level)	Advocacy NGOs and stakeholders organisations are normally consulted in the process for the development of cross-sectoral action plans like Health and Nutrition, Health and Environment and Health at Work. The indicator is deemed: **of dubious validity** (for the obstacles indicated under PART.1) **fairly feasible** (official consultations of NGOs and stakeholders are tracked and in principle the information should be reasonably available on demand)
8	RES.2	Resources Made Available by MS to Research Programmes in HIAP Field in Either Absolute or Relative Terms	Sectoral experts lament the limited financial resources for the development of research on social determinants of health, and epidemiological studies supporting the collection of robust data to investigate social inequalities of health. The indicator is deemed: **fairly valid** (but validity is somewhat limited by the absence of a clear definition of HIAP) **not feasible** (since there is no specific budget line for research programme on HIAP, the information should be reconstructed via a potentially onerous and complex review and re-classification of data on health research expenditure)
9	ORG.1	Identification of a Body Responsible for HIAP Coordination / a Focal Point	The CNSP is the national body responsible to coordinate the actions undertaken by the different bodies of the public administration and the health insurances with possible impact on health and to establish the methods for the evaluation of the national policy in this field. Its mandate however does not include a clear reference to HIAP. The indicator is deemed: **definitely valid** **highly feasible**

	Code	Indicator	Notes
10	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices on HIAP (including HIA methodology)	No single centre of expertise can be identified. INPES is the only national institution having established an office engaged in developing and promoting knowledge of HIAP, but so far the output has been marginal. ANSES and InVS are centres of expertise with competences on health and environment. At local level, best practices are disseminated by networks such as ESPT and the WHO Healthy Cities The indicator is deemed: **definitely valid** **fairly feasible** (mostly available information, but some research is required)
11	PRO.1	Introduction of HIA in Routine policy-making process (incl. RE level)	Since the passing of the *Loi Organique*, the impact assessment of draft laws is mandatory. When the proposal is considered to have a potential bearing on health, the DGS is expected to assist the proponent in measuring health impacts. A specific type of health impact assessment is carried out in the framework of environmental impact assessments (EIA), which are mandatory prior to the realisation of works with potentially polluting effects (e.g. industries, infrastructures etc.). The indicator is deemed: **of dubious validity** (it requires a better specification of the methodology – which needs to be standardised, the scope of application, the modality etc., otherwise the indicator is imprecise) **fairly feasible** (feasible in principle, but depending on the abovementioned methods and procedures feasibility may be affected)
12	PRO.2	Number of Relevant Institutions Complying with the above Procedures (incl. RE level)	The indicator is scarcely relevant since the provisions of PRO.1 are mandatory. Local authorities may decide autonomously on the utilisation of HIA (e.g. in the framework of the CLS stipulated with ARS), but since this practice is not traced systematically and seldom evaluated, the information needed is not immediately available and would require some research. The indicator is deemed: **of dubious validity** (see PRO.1) **fairly feasible** (some degree of fragmentation at regional level)
13	EVAL.1	Implementation of Evaluations / Cost Effectiveness Assessments of their Policies (incl. RE level)	See PRO.1 on the introduction of mandatory impact assessment at national level. At regional/local level, evaluations of relevant initiatives are not systematic. The indicator is deemed: **highly valid** (as confirmed by high-level experts) **fairly feasible** (some degree of fragmentation at regional level)
14	EVAL.2	Streamlining / modification of Policy as a Result of an Evaluation Exercise / Cost	In principle, a policy-making process can be brought to a halt by the Government secretariat general on the basis of the above impact assessments. Information on the utilisation of such options is not available in aggregated form.

	Code	Indicator	Notes
		Effectiveness Assessment (incl. RE level)	The indicator is deemed: **highly valid** (demonstrating the usefulness of evaluation) **fairly feasible** (some degree of fragmentation of the information)
15	EVAL.3	Setting up of a System of Indicators to Monitor HIAP uptake / Implementation (incl. RE level)	There are no established indicators to measure HIAP uptake. With the expected new public health policy it is expected that this gap will be filled, at least as far as health inequalities indicators are concerned. However, HCSP respondents pointed to the absence of solid data to measure health inequalities, therefore an appropriate system for the collection and analysis of data shall also be set up. The indicator is deemed: **fairly valid** (logically sound, but requires a clear policy framework and a specification of what has to be monitored) **fairly feasible** (some degree of fragmentation of the information)

***RE**=Relevant Entity

C - Patient safety (PS)

1. Legal, Policy and Institutional Framework

A *general policy on patient safety* is currently being developed by the French *Ministry of Health and Sports* (MoH), and is expected to be released by the end of 2012. Until now, the matter has been dealt with through numerous but substantially fragmented 'sectoral' policies, focusing especially on health products (e.g. blood for transfusions, drugs etc.), and in most cases reacting to specific health crisis. In particular most efforts have focussed on tackling *healthcare associated infections* (HCAI or HAI, hereafter), and specifically *nosocomial infections*. This area is regulated in France since 1988, and various 5-year programmes have been implemented so far, the most recent covering the period 2009-2013.

In 2004 the issue of healthcare-related adverse events is for the first time formalised in the national public health policy. Two main pieces of legislation contributed to this:

- The ***Law on Public Health Policy (PHP)***, which (i) included five PS-related objectives among the 100 national public health priorities that were identified, (ii) lay the foundations for the experimentation of a system for the mandatory reporting of serious adverse events (implemented by InVS); and (iii) set up a medical hazard observatory.
- The ***Law on Health Insurance***, which established the HAS and paved the way for the inclusion of a notification of adverse events and 'near misses' as part of the health professional and facilities process of accreditation/certification. The introduction of the concept of 'integrated risk management' among the certification requirements has been conducive to the uptake of a more holistic view on patient safety.

The achievements of the PHP Law were evaluated by HCSP in 2010[158]. With respect to PS-related objectives, the study findings were not particularly encouraging: in only one case (i.e. the tackling of HAI) some progress could be appreciated; in another instance (i.e. the iatrogenic events related to treatments) no improvements were reported, while the remaining three objectives could not be measured for lack of data.

Taking stock of the limited progress made through the PHP Law (with the notable exception of action against HAI), the HCSP established a working group specialised in PS (*Commission spécialisée sécurité des patients*/CSSP) which prepared a ***detailed report on the situation of PS*** in France and provided a series of principles and suggestions for decision-makers centred on the need to develop an integrated, systemic PS policy. The report "*Pour une politique globale et intégrée de sécurité des patients*" was published in November 2011[159].

In the same period, the results of the second ***epidemiological survey*** of healthcare-associated adverse events (*Enquête nationale sur les événements indésirables associés aux soins*/**ENEIS**) conducted in 2009 were published. When compared to the results of the first ENEIS, rolled out in 2004, the findings further confirmed the limited progress achieved in the reduction of the incidence of adverse events, with most of the indicators having remained stable or registered only marginal variations[160].

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[158] http://www.sante.gouv.fr/IMG/pdf/Rapport_Haut_conseil_de_la_sante_publique_-_Objectifs_de_sante_publique.pdf

[159] http://www.hcsp.fr/docspdf/avisrapports/hcspr20111021_politiquesecuritepatients.pdf

[160] Michel P, Lathelize M, Quenon JL., Bru-Sonnet R, Domecq S, Kret M., Comparaison des deux Enquêtes Nationales sur les Événements Indésirables graves associés aux Soins menées en 2004 et 2009. Rapport final à la DREES (Ministère de la Santé et des Sports) – Mars 2011, Bordeaux.

Further evidence of the need to prioritise PS in the context of French public health policy has come from recent general public polls on confidence in the health system, and on the perceived *acceptability of adverse events* by users and physicians. The results of the survey conducted in 2011 by the *Collectif Inter-associatif Sur la Santé* (CISS) showed a dwindling trend in public trust as compared to previous years (and despite the improvements made in the fields of e.g. HAI and safety of transfusions)[161]. Similarly, the ***MALIS study*** (*Mesure de l'acceptabilité des risques Liés aux Soins*) published by DREES in 2011, indicates that all types of healthcare hazards are hardly considered acceptable by the general public and physicians alike[162].

Finally, a report published by DGOS in 2009 (known as the ***Dédale Report***) evaluated the impact of a ministerial circular disseminated in 2004 prompting healthcare facilities to set up an integrated risk management plan[163]. The circular was accompanied by a working document containing a series of recommendations and best practices for health facilities[164]. The results of the evaluation showed that while significant progress has been achieved in a number of areas, the uptake of a properly integrated and coordinated risk management system was lagging behind.

With respect to healthcare services organisation, the reform of the health system brought by the 2009 Hospital, Patients, Health and Territories Act (known as ***HPST Law***) also explicitly mentions PS issues among the primary responsibility of healthcare facilities. Art. 1 of the Law provides that healthcare facilities take active part in the implementation of the national public health policy *inter alia* by organising the fight against HAI and other iatrogenic events, and by adopting measures and procedures to ensure quality and safety of treatments (including drugs and devices).

The HPST Law also establishes (art. 118) the ***Regional Health Agencies*** (*Agences Régionales de Santé*/ARS) whose mission includes health surveillance (i.e. collection of reports of health-related events) and the monitoring of the quality and safety of treatments.

The authority responsible for the drafting of the PS policy that will be released at the end of 2012 is DGOS. A ***participatory policy-making process*** has been set up, including an advisory committee and a series of working groups on specific aspects of the policy. All relevant institutions and stakeholders organisations are involved, and mechanisms have been created for the consultation of civil society and patients' organisations.

While the detailed provisions of the draft law have not been disclosed yet, it has been anticipated that PS policy will be centred on "*quality management*", i.e. the regulation will require healthcare facilities to set up a quality system indicating, *inter alia*, one staff member in charge of quality assurance, an integrated system for risk assessment and risk management, and detailed procedures for the optimisation of "critical actions" (e.g. the preparation of drugs for injection). The new law is also expected to streamline the governance of the system, which is currently very complex (especially at national level) and with sometimes uncertain definitions of roles and responsibilities.

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http://www.ccecqa.asso.fr/sites/ccecqa.cpm.aquisante.priv/files/ENEIS-RapportComparaison_2004-2009%20final-Mars2011.pdf

[161] Astagneau P, L'Hériteau F, Daniel F, Parneix P, Venier AG, Malavaud S, et al. ISO-RAISIN Steering Group. Reducing surgical site infection incidence through a network: results from the French ISO-RAISIN surveillance system. J Hosp Infect. 2009;72(2):127-34

[162] Michel P, Quintard B, Quenon JL, Roberts T, Nitaro L, Kret M. Étude Nationale sur l'acceptabilité des principaux types d'événements indésirables graves associés aux soins en population générale et chez les médecins. Rapport final, Bordeaux, CCECQA. 2010. http://www.drees.sante.gouv.fr/IMG/pdf/serieetud108.pdf

[163] http://www.sante.gouv.fr/IMG/pdf/resume_rapp_DEDALE-2.pdf

[164] http://www.sante.gouv.fr/IMG/pdf/reco_gdr.pdf

Table 1.1 – Legal and Policy Framework

Year	Type	Authority	Title	Comment
1953 (major reforms in 2000, 2003 and 2005)	Law	Parliament	Public Health Code (*Code de la Santè Publique*)	In particular Part 6, Volume 1, Title 1, Chapter 1, Section 1 on the organisation of measures against healthcare-associated adverse events within healthcare facilities[165]. Major reforms in 2000, 2003 and 2005.
2002	Law	Parliament	Law on patient's right and the quality of health system (*Loi 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé*)	It establishes the fundamental right to health protection, which must be ensured by all means. It also provides that health structures must ensure equitable access to healthcare to all and the safety of care[166].
2004	Law	Parliament	Law on public health policy (*Loi n° 2004-806 du 9 août 2004 relative à la politique de santé publique*)	It includes three specific objectives (and corresponding indicators) focusing on the reduction of healthcare adverse events (objectives no. 26, 27and 28).[167]
2004	Law	Parliament	Law on health insurance (*Loi n° 2004-810 du 13 août 2004 relative à l'assurance maladie*)	It establishes the Haute Autorité de Santé (HAS) with *inter alia* the mandate of developing an accreditation system for health professionals and a certification system for health facilities, which involves the notification of 'near misses'[168].
2004	Ministerial Circular	Ministry of Health	Ministerial Circular accompanying recommendations for the establishment of risk management plan within health facilities (*Circulaire DHOS/E2/E4 N° 176 du 29 mars 2004 relative aux recommandations pour la mise en place d'un programme de gestion des risques dans les établissements de santé*)	It supports health facilities in drafting a general risk management plan, including goals and required actions concerning risk prevention and management, awareness-raising, information, training and evaluation[169].
2009	Law	Parliament	Law on the reform of hospitals with respect to patients, health and territories (*Loi n° 2009-879 du 21 juillet 2009 portant réforme de l'hôpital et relative aux patients, à la santé et aux territoires*)	Among other things, it defines the roles and responsibilities of healthcare facilities and ARSs in the implementation of the public health objectives related to the quality and safety of care (e.g. through surveillance mechanisms, quality plans and procedures, monitoring etc)[170].
2009	Inter-ministerial	Ministry of Health	Inter-ministerial Circular on the establishment of a national	It defines the national strategy for prevention of HAI at State, regional and local levels. It

[165] http://www.legifrance.gouv.fr/affichCode.do?cidTexte=LEGITEXT000006072665&dateTexte=20120515
[166] http://admi.net/jo/20020305/MESX0100092L.html
[167] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000787078&dateTexte=&categorieLien=id
[168] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000625158
[169] http://www.sante.gouv.fr/IMG/pdf/circ176.pdf
[170] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000020879475&categorieLien=id

Year	Type	Authority	Title	Comment
	Circular	Ministry of Labour	strategic plan 2009-2013 for the prevention of healthcare associated infections (*Circulaire Interministerielle N°DGS/DHOS/DGAS/2009/264 du 19 août 2009 relative à la mise en oeuvre du plan stratégique national 2009-2013 de prévention des infections associées aux soins*)	develops the global strategy, indicates the authorities responsible for the prevention and management of HAIs, and envisages specific actions to tackle HAI risk factors[171]. It complements two other HAI-related strategies, namely: (i) The plan for the safeguard of antimicrobial efficacy 2007-2010 (ii) The plan for the management of multi-resistant bacteria (yet to be released)
2009	Ministerial Circular	Ministry of Health	Ministerial Circular on the establishment of the national programme 2009-2013 for the prevention of nosocomial healthcare associated infections (*Circulaire N°DHOS/E2/DGS/RI/2009/272 du 26 août 2009 relative à la mise en oeuvre du programme national de prévention des infections nosocomiales 2009/2013*)	It provides the operational framework for the implementation of the national strategic plan on HIA with respect to nosocomial infections. It includes also specific quantitative targets and performance indicators. The document also contains the evaluation report for the 2005-2008 programme[172]. Analogous programmes for the prevention of HIA in primary care and long-term care facilities are expected to be released soon.
2010	Decree	Ministry of Health	Decree on fight against healthcare-related adverse events within healthcare facilities and related *Circulaire N. DGOS/PF2/2011/416* (Ministerial Circular) (*Décret no 2010-1408 du 12 novembre 2010 relatif à la lutte contre les événements indésirables associés aux soins dans les établissements de santé*)	It modifies some articles of the *Code de la Santé Publique'* defining, in particular the structure and the respective roles and responsibilities, within healthcare facilities, of: (i) the general manager; (ii) the medical committee; and (iii) the hygiene operational team[173]. The Circular provides for the implementation mechanism related to the strategic and operational governance, training of professionals, coordination among healthcare facilities and the like[174].
2011	Decision	Ministry of Health	Decision on quality management of treatments and drugs within healthcare facilities and related *Circulaire N. DGOS/PF2/2012/72* (Ministerial Circular) *Arrêté du 6 avril 2011 relatif au management de la qualité de la prise en charge médicamenteuse et aux médicaments dans les établissements de santé*	It supports the implementation of the HPST Law (2009) with respect to the objective of improving the prevention of errors related to treatments and drugs, and a better management of risks[175].

[171] http://www.sante.gouv.fr/IMG/pdf/circulaire_264_190809-2.pdf
[172] http://www.sante.gouv.fr/IMG/pdf/circulaire_272_260809-2.pdf
[173] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023086417&dateTexte=&categorieLien=id
[174] http://circulaire.legifrance.gouv.fr/pdf/2011/12/cir_34191.pdf
[175] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000023865866&dateTexte=&categorieLien=id

Year	Type	Authority	Title	Comment
2011	Review	HCSP	« For a general, integrated patient safety policy » Opinion *« Pour une politique globale et intégrée de sécurité des patients » Avis*	It reviews the situation of patient safety in France, illustrating the progress achieved and the challenges ahead. It encourages the adoption of a national PS policy in France, putting forward a series of principles and approaches[176].
2011	Decision	Regional Health Agency	Decision on the regional strategic plan on health for the Ile-de-France Region (*Arrêté N° DGA2011/207 Relatif au plan stratégique régional de santé de la région Île-de-France*)	It provides an example of regional strategic health plan. Patient safety is briefly mentioned among its strategic objectives (section 2.2.2. *Améliorer la sécurité des soins)*[177].

At the national level the institutions with responsibilities related to patient safety are as follows:

- ***Agence française de sécurité sanitaire des produits de santé (AFSSAPS) –*** overall supervision on health products (drugs, blood, tissues etc.);
- ***Institut de veille sanitaire (InVS)*** - nosocomial infections reporting system, toxicovigilance, and surveillance on diseases for which reporting is mandatory ;
- ***Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)*** - veterinary pharmacovigilance and nutrivigilance (e.g. food supplements);
- ***Agence de la biomédecine (ABM)*** - surveillance on medically assisted procreation;
- ***Autorité de sûreté nucléaire (ASN)*** - radioprotection; and
- ***Haute Autorité de santé (HAS)*** - reporting of potentially harmful events or 'near misses' (*événements porteurs de risques*/EPR), in the context of physicians' accreditation system.

Since 1999, there exists a coordination mechanism on surveillance grouping the above institutions (except ASN) and the DGS. In 2009, a working group on the organisation and functioning of surveillance systems was set up by the committee of public health agencies (CASA); the Group, however, does not really ensure coordination and management of healthcare-associated adverse events.

At the regional level, the law identifies ARSs as the pivotal institutions for the management of healthcare-related risk. ARSs should (i) define the overall regional health policy, which complements the national policy including elements related to territorial specificities, (ii) oversee policy implementation, and (iii) ensure coordination among the entities responsible for surveillance and risk management. The coordination with the national level is ensured by quarterly meetings with the MoH. In the future, ARSs will also centralise the collection of information and data and their transmission to the MoH. This will require the deployment of an information system capable of centralising all relevant information flows, part of which currently by-passes the ARSs.

In practice, a certain degree of fragmentation and uncertainty persists at regional level, e.g. with respect to the supporting bodies like the *centres régionaux de pharmacovigilance* (CRPV) and the *observatoires du médicament et des dispositifs implantables* (OMEDIT), whose tasks and coordination modalities with ARSs vary across regions.

[176] http://www.hcsp.fr/docspdf/avisrapports/hcspr20111021_politiquesecuritepatients.pdf

[177] http://www.ars.iledefrance.sante.fr/fileadmin/ILE-DE-FRANCE/ARS/1_Votre_ARS/3_Nos_Actions/3_PRS/psrs-idf-2011.pdf

ARS primary means to support better safety in the healthcare system consist at present of inspection and authorisation. ARSs have the mandate to investigate cases of serious adverse events and may include quality and safety targets in the agreement they stipulate with healthcare facilities. Conversely, the strategic functions (development of a PS culture, promotion of good practices etc.) are much less developed for now. The main reasons for this are (i) the recent establishment of ARSs (some of them have not yet finalised their regional plans and the related *schemas*), (ii) in the absence of internal PS expertise, ARSs are forced to rely on external bodies (e.g. OMEDIT for drugs, CCLIN for infections, or regional bodies like the *Comité de coordination de l'évaluation clinique et de la qualité* - CCECQA in Aquitaine), (iii) the internal organisation of ARSs where PS responsibility is typically fragmented among different directorates; and (iv) the limited budgetary resources (and scarce autonomy to decide allocations).

Compared to PS in general, the sub-national policy governance and implementation system in the specific field of HAI is much more established and well-oiled. The *Centres de coordination de la lutte contre les infections nosocomiales* (**CCLIN**)[178] exist since 1992, with the aim of facilitating the implementation of HAI programmes and act as the reference points for the MoH. They are located within university hospitals and operate as centres of expertise assisting health facilities in the optimisation of HAI risk prevention and management. CLLINs also coordinate the surveillance of nosocomial infections, the epidemic alert system, and conduct evaluations of the safety of care practices within healthcare structures. Each of the five CCLINs covers a macro-region and since 2006 they operate regional networks of *Antennes Régionales de Lutte contre les Infections Nosocomiales* (**ARLIN**). In partnership with the *Institut de veille sanitaire* (InVS), CCLINs have set up a national network for the surveillance, alert, investigation and reaction to HAI *(Réseau d'alerte, d'investigation et de surveillance des infections nosocomiales*/**RAISIN***).*

2. Policy Implementation

Monitoring and Evaluation. The overall implementation of the policy is monitored by the MoH, with the assistance of the various sectoral agencies and bodies and in coordination with the ARSs. In particular, the MoH oversees all aspects related to the quality of service. It develops appropriate indicators, defines roles and responsibilities of the monitoring system, receives monitoring data from the various actors involved, elaborates and disseminates information and ensures feedback on policy. A technical committee has been jointly established by DGS and DGOS to this end, i.e. *the comité technique des infections nosocomiales et des infections liées aux soins* (**CTINILS**).

As seen in the previous section, there are numerous agencies and bodies participating in the monitoring of healthcare-related adverse events, e.g. InVS for nosocomial infections and toxicovigilance, AFSSAPS for the safety of health products, HAS for the reporting system related to accreditation process, etc. Since their creation, ARSs have been assigned prime responsibility for the monitoring of policy implementation. In particular, the communication arrangements involve that healthcare facilities report relevant events to their respective ARS, which in turn transmits the information to the competent institution at national level. However, as discussed, ARSs have been created very recently, and a number of them haven't yet been able to make the necessary organisational arrangements required to carry out all tasks assigned by the law. An example is the reporting of 'near misses' by physicians, which reportedly often by-pass the regional level and instead, report directly to the national sectoral professional societies overseeing accreditation.

[178] http://www.cclin-france.fr/annexe.asp

At present, the information on healthcare-related adverse events comes essentially from the voluntary reporting system described above. The number of reports made by health professionals is however quite small, especially when compared to the epidemiological estimates (based on ENEIS). On top of that, the information is reportedly often incomplete and easily subject to bias. In this sense, the information currently available does not allow to draw an accurate epidemiological map of hazards, nor to evaluate the impact of the measures taken. Ultimately, the lack of adequate, solid information deprives policy-makers of fundamental inputs for the fine-tuning of the policy and the identification of priorities, both at national and regional level.

Nosocomial infections give a quite different, more encouraging picture. Since 2001 a well-oiled network is in place that monitors and analyses data on HAI (*Réseau d'alerte, d'investigation et de surveillance des infections nosocomiales*/**RAISIN**), based on a partnership between InVS and the five CCLINs. In the framework of RAISIN various thematic networks have been established (i.e on surgical site infections, multi-resistant bacteria, blood exposure incidents, bloodstream infections, HAI in intensive care units), which allow to have high-quality epidemiological databases on HAI[179]. Regular assessments of incidence and prevalence of HAI are conducted by InVS on the basis of the RAISIN data[180].

A comprehensive evaluation of the implementation of PS policy in France has not been conducted yet due to the absence of a full-fledged policy covering all PS aspects. On the other hand, various PS-related aspects have been assessed by sectoral evaluations and studies. In particular:

- The PS-related objectives included in the PHP Law have been assessed by HCSP in the context of the ***overall evaluation of the PHP Law*** carried out in 2010[181];
- The HCSP ***report on PS*** «*Pour une politique globale et intégrée de sécurité des patients*[182]
- The ***evaluation of the HAI programme 2005-2008***, which is included in the programme document for the 2009-2013 programme[183]; and
- Additionally the InVS report on a pilot project testing a system for the collection of reports of adverse events other than HAI should be published in the near future[184].

Factors Influencing Policy Implementation. The review of the evaluation reports available and the evidence collected during the fieldwork allow to identify a series of factors possibly influencing the implementation of EU policy provisions on PS.

Table 2.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Fragmentation	The lack of an integrated PS governance system is commonly seen as a major limitation of the French PS policy, which affects also the learning process on PS. This gap is expected to be filled by the upcoming PS policy due by the end of 2012. The fragmentation regards in particular: • the organisational structures, with numerous bodies involved having sometimes unclear or overlapping responsibilities, and little integration/communication among sectoral systems; • the approach to PS events, which appears not sufficiently patient-centred, i.e. the various

[179] http://www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Infections-associees-aux-soins/Surveillance-des-infections-associees-aux-soins-IAS
[180] http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19408
[181] http://www.sante.gouv.fr/IMG/pdf/Rapport_Haut_conseil_de_la_sante_publique_-_Objectifs_de_sante_publique.pdf
[182] http://www.hcsp.fr/docspdf/avisrapports/hcspr20111021_politiquesecuritepatients.pdf
[183] http://www.sante.gouv.fr/IMG/pdf/circulaire_272_260809-2.pdf
[184] http://www.sante.gouv.fr/IMG/pdf/ACTES_colloque_iROGER.pdf

Factors	Comments
	healthcare actions taken by the patient are considered in isolation from each other, and little attention is paid to generate an integrated overview of the patient's clinical pathway.
Financial constraints	Overall the budget allocations for 'systemic' PS have been limited so far and have not been made to any specific action plan and programme. In the field of HAI, the financing of the mechanism for surveillance and management (CCLIN, responsible staff) is instead an *acquis* since many years and has not been significantly affected by budgetary cuts. In some way, it is the French health financing system that may provide a disincentive to investment in PS. The financing system is not conducive to the establishment of a holistic approach to PS, since it is based on a parcelling of care actions where cause/effect links are not visible. The *"tarification"* model involves a fixed price per type of service, but there is no mechanism to track instances of hospitalisation due to consequences of the care received. Therefore, health structures may *de facto* be financed to treat health problems possibly caused by them. Similar 'reverse incentives' can be found also in primary care, where the patient's trajectory is also not traceable, and therefore adverse events due to possible malpractices do not imply financial sanctions.
Normative approach	As discussed, France has traditionally had a regulative approach in public health. This might influence the importance attributed to 'soft policy' measures such as the EU Recommendation and the like which, unless they are incorporated in national legal provisions, are not followed up on.
Legal issues (e.g. regarding the blame-free reporting)	Unlike other countries, the overall constitutional and legal framework in France does not protect anyone reporting the occurrence of an adverse event from juridical consequences. This represents a major obstacle inhibiting the functioning of a transparent and effective reporting mechanism. The experimental initiative on the creation of a voluntary declaration system for serious adverse events registered very limited participation (as compared for example with data collected through ENEIS). Reportedly, DGS has set up a working group in 2012 with the mandate of devising a possible follow up to this initiative.
Training and availability of qualified staff	In the field of training the dichotomy between PS education and the specific HAI domain is remarkable. With respect to HAI, health professionals have a wide portfolio of continuous training offered by professional associations, specialised training bodies, universities, and other entities at local and regional level. The availability of qualified staff in this area is reportedly a minor problem. PS training is comparatively less developed and fragmented. At present there is no one vision, strategy or organisation for the development of an integrated education on PS for health professional. Consequently, the availability of qualified staff may pose a problem.
Information system and data	Availability of data and indicators for the measurement of PS policy is variable. Comprehensive data are mostly available on nosocomial infections, with all other type of adverse events being measured only anecdotally. Outside of hospitals, i.e. in the fields of primary care and long-term care, measurable indicators on adverse events are almost non-existent. In 2010, the HCSP published a study focussed on the national system for the reporting of adverse events by means of a benchmarking with other countries (i.e. the UK, Denmark, USA, Australia and Canada)[185]. Two strategic priorities stemming from the results of the study are: (i) better and clearer governance and organisation for the detection and communication of adverse events other than HAI across the different levels (i.e. from hospitals to central institutions); (ii) a better integration of existing sectoral surveillance systems and databases (e.g. the SNIIR of the health insurance) into a comprehensive information system supporting integrated risk management.

3. Indicators

As concerns the ***indicators*** used to measure the performance of PS policy, the primary reference is the ***PHP Law***. The Law includes three specific objectives and corresponding indicators related to iatrogenic events, as follows:

[185] http://www.hcsp.fr/docspdf/avisrapports/hcspr20100701_anabibsecupatients.pdf

(i) Objective: reduce by 2008 the occurrence of iatrogenic events during hospital stays from 10% to 7%. Indicator: proportion of hospital stays during which a iatrogenic event occurs.

(ii) Objective: reduce by 2008 the incidence of iatrogenic events related to ambulatory treatments and requiring hospitalisation from 130,000 per year to less than 90,000 per year. Indicator: incidence of hospitalisations due to iatrogenic events related to ambulatory treatments.

(iii) Objective: reduce by one third the incidence of avoidable iatrogenic events in hospitals and primary care facilities. Indicators: (1) number of hospital stays registering an avoidable iatrogenic event; (2) number of hospitalisations due to iatrogenic events in a year; (3) number of deaths having iatrogenic events as primary cause. The Law specifies that the measurement of these indicators is subject to the availability of national epidemiological data collected through regular surveys.

It is unclear at this stage if and which indicators will be included in the upcoming new law on PS, since the matter is not included in the specifications of the working group currently working on the text. In any event, it is anticipated that possible indicators will focus on outcomes rather than on processes.

As concerns *nosocomial infections* and in connection with the RAISIN network, a series of indicators have been developed by InVS upon request of the MoH[186], aimed at measuring the actions undertaken by healthcare facilities to reduce HAI. The system is based on an electronic registry ("*tableau de bord*") developed by the *agence technique de l'information sur l'hospitalisation* (ATIH), where facilities must regularly feed updated information. About 2,800 facilities participate in this mechanism. The information collected is then aggregated at central level and used to: (i) compare the effects of the actions undertaken by facilities; (ii) analyse the evolution overtime; (iii) provide users with transparent information on HAI hazards. The elements of the registry have evolved since its establishment in 2004 and now comprise the following indicators:

- ICALIN2 – composite indicators compounding indicators related to the organisation, the resources and the process in place within facilities for the fight against nosocomial infections;
- ICSHA2 – indicator on the consumption of alcohol handrub products;
- ICA-LISO – composite indicator on the frequency of surgical site infections;
- ICA-BMR – composite indicator on the control of the diffusion of multi-resistant bacteria;
- ICATB – composite indicators measuring the correct use of antimicrobials (including organisational aspects, resources allocated and initiatives implemented); and
- SARM – incidence of infections due to Methicillin-resistant Staphylococcus aureus (MRSA).

The above indicators (except SARM) are further aggregated to provide a synthetic aggregated indicator assigning a 'score' (from A to E) to each facility.

The above indicators have been revised in 2012 by a ministerial decision in order to ensure better consistency with the indicators laid down in the ***2009-2013 programme document for nosocomial infections*** (see Table 3.1 below).[187] Some of the programme indicators are however not included in the registry, therefore alternative specific data collection actions should be envisaged. According to the ministerial decision, the nine quality indicator IPAQSS (*Indicateurs Pour l'Amélioration de la*

[186] These indicators have been developed by means of a Delphi methodology. The draft list of indicators have been further tested for feasibility by a research team of experts created by the MoH.

[187] http://www.legifrance.gouv.fr/affichTexte.do;jsessionid=?cidTexte=JORFTEXT000025145419&dateTexte=&oldAction=rechJO&categorieLien=id

Qualité et de la Sécurité des Soins) elaborated by HAS in the framework of the certification process are integrated in the list of the mandatory data to be periodically provided by facilities[188].

Table 3.1 – Objectives and indicators of the 2009-2013 programme document for nosocomial infections[189]

Theme	Objectives and indicators
Improve the prevention of infections related to 'invasive acts'	Outcome indicators: • Catheter-related bloodstream infections in intensive care decrease by 25% before 2012 (source: RAISIN) • Incidence of surgical site infections related to 'low-risk' operations decreases by 25% before 2012 (source: RAISIN) • Blood exposure incidents decrease by 25% (source: RAISIN) Process and structure indicators: • 100% of intensive care units adopt by 2012 a procedural tool, such as a check list, to be followed when installing central venous catheter to prevent infections; • 95% of surgical facilities integrate by 2012 the monitoring of surgical site infection in their information system; • 100% of surgical facilities adopt by 2012 a procedural tool, such as a check list, for the prevention of perioperative infections; • 100% of facilities have set up before 2012 a method to analyse the causes of serious adverse events; • 100% of facilities ensure the surveillance of blood exposure incidents and have a protocol for the rapid response to such events.
Control the diffusion of multi-resistant bacteria and the emergence of potentially epidemic infections	Outcome indicators: • Incidence of MRSA decreases by 25% before 2012 (source: RAISIN) • The proportion of *enterococcus faecium* stems resistant to glycopeptides remain below 1% at national level (source: EARSS network) Process and structure indicators: • 100% of facilities have achieved by 2012 their target of consumption of alcohol handrub products; • 100% of facilities have established by 2012 an action plan to fight the diffusion of multiresistant bacteria; • 100% of concerned facilities have introduced by 2012 the practice of the reassessment of antimicrobial therapy in their antimicrobial use policy; • 100% of facilities have set up by 2012 a response plan in case of potentially epidemic infections; • 100% of facilities have established by 2012 the monitoring of certain vaccination.
Improve the organisation of the mechanism for the prevention of nosocomial infections	Process and structure indicators: • 100% of facilities have set up by 2012 a procedure for the internal and external notification; • 100% of facilities are compliant with the specifications on the deployment of hygiene operational teams by 2012; • 100% of facilities have instruments for the evaluation of professional practices related to the management of infection hazards by 2012; • 100% of centres taking part in the programme for complex osteoarticular infections evaluate patients' satisfaction by 2012.

[188] http://www.has-sante.fr/portail/jcms/c_493937/ipaqss-indicateurs-pour-l-amelioration-de-la-qualite-et-de-la-securite-des-soins

[189] The indicators reported in Table 3.1 are drawn from the French national plan on nosocomial infections. They have been largely taken into consideration in the analysis of the proposed indicators developed under this Study, as provided in Table 3.2. In this respect, it is important to further highlight that the indicators elaborated under the Study are broader in scope, since they are not limited to noscomial infections but address the patient safety issue on the whole.

With respect to internationally-accepted patient safety indicators (PSI), in 2011 DREES has published the results of the ***research project on the development of PSI*** on the basis of hospital medical-administrative databases[190]. More specifically the project aimed at devising a methodology for the exploitation of the data available through the *Programme de Médicalisation des Systèmes d'Information* (PMSI), with a view to the creation of a model to forecast PS hazards. The project has been developed as a partnership among HAS, DREES and the Hospices Civils de Lyon, and is part of the international programme put in place by the IMeCCHI consortium (International Methodology Consortium in Coded Health Information) to harmonise and validate common PSI.

Finally, the above mentioned ***ENEIS*** surveys represent another useful source of data that can be used - although with some limitations - to measure the evolution of healthcare adverse events in France in a longitudinal perspective. The main indicator used in the ENEIS studies regards the frequency of serious adverse events occurred during hospitalisation (6.2 per 1,000 days in 2009), which is further broken down and analysed by medical service and typology of patients.

[190] http://www.sante.gouv.fr/IMG/pdf/seriesource_method20.pdf

Table 3.2 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.4	Alignment of Data Classification Systems to Standardised Given Procedures	In the field of HAI, the data collected by InVS through RAISIN are harmonised (and already exchanged) with ECDC classification system. With respect to other adverse events, the type of data and the modality of collection will be determined by the upcoming new regulation, so it is too early to tell whether this will be harmonised with relevant standards. The indicator is deemed: **definitely valid** **highly feasible** (the collection of information requires minimal effort)
2	ANA.1	Adoption of a Methodology/Problem Definition in line with international standard	With respect to adverse events, a recent DREES study pointed to the absence of a formal definition/classification. Operational definitions used so far are based on the main international classifications and academic works[191]. A similar issue emerged from the InVS pilot project on the reporting of adverse events other than HAI. The upcoming regulation on PS due by the end of 2012 is expected to fill this gap, and make this indicator feasible. As regards HAI, methodologies and definitions are consistent with ECDC work. The indicator is deemed: **fairly valid** (logically sound, but not particularly useful for policy makers) **highly feasible** (in perspective)
3	OUT.1	Specific Outcome Indicator for the Stated Objective	Part of the OECD outcome indicators of PS are being tested (but data are not systematically available at national level for all of them), i.e. – Catheter-related bloodstream infection – Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT) (included in the last generation of indicators to be reported by facilities) – Postoperative sepsis (it is part of the composite ICA-LISO indicator) No data are instead available for the other four OECD outcome indicators: – Accidental puncture or laceration – Foreign body left in during procedure – Obstetric trauma – vaginal delivery with instrument – Obstetric trauma – vaginal delivery without instrument The indicator is deemed: **fairly valid** (as demonstrated by partial adoption) **fairly feasible** (since part of them are already measured)

[191] Nacu A, Benamouzig D, Michel P. Analyse sociologique des politiques publiques de réduction des événements indésirables graves (EIG) à travers leur perception par les acteurs sanitaires ; Etude EvolEneis Socio. Rapport final à la DREES (Ministère du travail, de l'emploi et de la Santé), Paris, March 2012.

	Code	Indicator	Notes
4	PROG.1	Establishment of a PS Strategy / Programme / Action Plan covering the Whole Population	A comprehensive PS policy is expected by end of 2012. So far, national programmes have covered only HAI. With respect to the validity of this indicator, the lack of any reference to the content of possible programmes is seen as problematic. Disparities across programmes can be significant. The indicator can also be refined replacing the reference to the coverage of 'whole population' to the coverage of 'all facilities' or, even better, the inclusion of PS considerations in all sectoral health programmes. The indicator is deemed: **fairly valid** (see abovementioned suggestions for refinement) **highly feasible**
5	PROG.2	Number of RE with Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	The upcoming policy will have then to be integrated in regional health programme. Some ARSs have already established their programme, sometimes giving significant emphasis to PS issues. In the Nord-Pas-de-Calais Region, for instance, the regional programme on HAI goes well beyond national prescriptions due to the high frequency of epidemics. The existence of regional plans can be easily verified at central level, but the information on the content of programmes with respect to PS is not tracked and might be complex. However, it is likely that the new policy will envisage specific provisions for regional programmes and related monitoring mechanisms. The indicator is deemed: **fairly valid** (logically sound, but since PS policy is expected to be mandatory, compliace can be assumed and the indicator loses relevance) **fairly feasible** (some regional fragmentation issue is anticipated)
6	PROG.3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	As concerns the regional level see PROG.2 above At the local level (health facilities), it is relatively easy to retrieve the information on the facilities keeping a registry on HAI (i.e. through InVS) and having a quality of care plan in place (i.e. through HAS). Conversely, information on policies and actions taken with regard to other PS aspects, is available only for a very limited number of facilities. The indicator is deemed: **fairly valid** (see PROG.2) **fairly feasible** (see PROG.2)
7	PROG.RES	Preparation of Specific Programmes, such as (but not only) Research Projects, on PS-related Subject	There is no specific research programme for PS in France, but the PHRC (*programme hospitalier de recherche clinique*) includes nosocomial infections among its thematic priorities. PS-related themes are also addressed by research projects financed under the PREQHOS (*programme de recherche en qualité hospitalière*) The indicator is deemed:

	Code	Indicator	Notes
			fairly valid (subject to a clear definition of the scope) **highly feasible**
8	PART.2	Involvement of Advocacy NGOs in the Policymaking Process (incl. RE level)	NGOs and CSOs at large are usually consulted during the policy-making process. However, there seems to be no formal recognition of their right to be involved in the policymaking process. There are CSO representatives in the steering group of the nosocomial infections programme. The indicator is deemed: **fairly valid** (logically sound, but involvement is a vague term, and NGO seems too limited a category) **hardly feasible** (the absence of a structured mechanism would require to collect the information on a case-by-case level)
9	PART.3	Provision of Support to Advocacy NGOs active in the Given Policy Field (incl. RE level)	National experts consider it an interesting indicator but unlikely to be feasible. NGOs receive support for their activities mostly from the private sector (and sometimes by the pharmaceutical industry). The indicator is deemed: **fairly valid** (however consensus seems not unanimous, usefulness for policy-makers is not apparent) **hardly feasible** (see PART2)
10	RES.1	Existence of Research Projects in the PS Field	The indicator is considered very relevant, but the raw information on projects financed is not immediately available. The three main sources of financing are: • PHRC (see PROG.RES above) • PREQHOS (see PROG.RES above) • Research studies directly financed by DGS or DGOS Through the MoH website it is possible to consult the list of projects approved under each call, but a searchable database of projects allowing to filter those falling in the domain of PS is not available. The MoH published a list of HAI-related projects in the evaluation report of the 2005-2008 ProLIN programme. Information on privately-financed research is not available. The indicator is deemed: **definitely valid** **hardly feasible** (the information is fragmented and would require a non negligible effort to reconstruct it)
11	RES.2	Resources Made Available by MS to Research Programmes in the PS Field in Either Absolute or Relative Terms	The indicator is in principle considered very useful by some of the experts consulted since it would show how poorly research expenditure compares with overall health expenditure. The summary data sheets of projects made available on the MoH website do not indicate the projects' value. This information is presumably easily available through the MoH but not to the public. The indicator is deemed: **definitely valid**

	Code	Indicator	Notes
			hardly feasible (the information is fragmented and would require a non negligible effort to reconstruct it)
12	RES.3	Number of Studies/ Publications Produced by Research Programmes in PS Policy Field	This information can be in principle retrieved through ordinary international scientific databases, but at present it is reportedly not tracked by any institution and therefore it would require some efforts. On a different note, the scientific production of university clinics (CHU) is instead tracked by means of the SIGAPS system[192]; one reason for this is that the public financing they receive it tied to, *inter alia*, their scientific production. The indicator is deemed: **fairly valid** (standard indicator for research measurement, but usefulness for policy-making not fully recognised) **hardly feasible** (see RES.1)
13	RES.4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature	See RES.3 above The indicator is deemed: **fairly valid** (see RES.3) **hardly feasible** (would require an ad hoc research to identify the relevant studies – see RES.3)
14	AWA.1	Number of Information/Awareness Raising Campaigns and Dissemination initiatives for practicioners on PS policies and issues in a Given Year	A conceptual difficulty of this indicator is how to determine the unit of analysis (what is a 'campaign'? what actions does a campaign imply, concretely?). Unless the nature of the initiatives being measured is precisely defined, the validity of the indicators is questionable. Having said that, France has been among the major promoters of the WHO's "Global Handwashing Day" and since 2011 they organise in November the PS week with various initiatives to inform the general public. Other initiatives of this kind – if any - are typically organised at local/regional level. Some qualitative information in this respect can be then collected through ARSs but is not systematically available. INPES is the body normally responsible for educational initiatives on health. It has organised numerous initiatives on the correct use of antimicrobials, but not as much on PS. The indicator is deemed: **of dubious validity** **hardly feasible** (only very partial information can be retrieved, and in any case the effort required is potentially significant)
15	AWA.2	Level of Awareness about PS issues among the Population	CISS conducts periodically a 'barometer' survey measuring, *inter alia*: a. The proportion of people thinking they are well-informed on the quality of care they are going to receive when they see a health professional (down from 84% to 79% from 2010 to 2011);

[192] http://www.sigaps.fr/index.php

	Code	Indicator	Notes
			b. The proportion of people satisfied with the information made available to them on the action to take in case of post-treatment problems (from 70% to 66%). The facilities' registry system allows the public to have transparent information on the HAI situation in most of country's hospitals. No information is instead disseminated on other PS issues. Limited information is disseminated on the efforts that are being undertaken to ensure quality and safety within healthcare facilities. This may contribute to an overly negative perception of safety conditions (e.g. results of the MALIS study). The indicator is deemed: **definitely valid** **fairly feasible** (on the basis of existing report, but the scope can be enlarged)
16	AWA.3	Trend in the Level of Awareness about PS issues among the Population	Same as above The indicator is deemed: **definitely valid** **fairly feasible**
17	AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target	The indicator is deemed: **of dubious validity** (see AWA.1) **not feasible** (most of the information needed is essentially unavailable and cannot be reconstructed)
18	FUND.1	Total Budgeted Funds to Specifically Implement PS Policy in Absolute or Relative Terms	It is not feasible to disaggregate financial allocations to PS from the overall budget, since in the '*tarification*' system PS is a horizontal task included in the various services. Furthermore, regions provide additional financing to facilities on the top of the MoH budget, following their own criteria and modalities. Some hospitals keep very detailed records but this cannot be generalised. In principle it would be possible to retrieve financial data on the state budget and expenditure for risk management personnel at facility level. With respect to HAI there is an obligation to indicate resources allocated to specific actions (see the indicators included in the '*tableau de bord*'). These figures are however not very reliable since facilities tend to overestimate them in order to obtain higher scores. The indicator is deemed: **of dubious validity** (since PS is a cross-cutting theme and has no official dedicated budget) **not feasible** (most of the information needed is essentially unavailable or not reliable)
19	FUND.2	Total Public Expenditure to Specifically Implement PS Policy in Absolute or Relative	Same as above. The indicator is deemed:

	Code	Indicator	Notes
		Terms	**of dubious validity** **not feasible**
20	FUND.3	Total dedicated infection control staff (absolute terms or per 1000 beds)	This information may be relatively easy to obtain with respect to HAI, as this indicator is used in France. The indicator is deemed: **fairly valid** (definitely valid in the case of HAI, while it remains to be seen if a similar indicator may cover also PS) **fairly feasible** (indicators collected for HAI, but substantially no information available for the rest)
21	ORG.1	Identification of a Body Responsible for Policy Coordination / a Focal Point	At the national level the overall responsibility for PS is shared between DGS and DGOS. ARSs are the coordination bodies at regional level. At local level, Decree 1408 (and associated circular) provides that the medical committee of healthcare structures (*commission médicale d'établissement*/CME) identifies a risk manger coordinator. The indicator is deemed: **definitely valid** **highly feasible**
22	ORG.2	Routine Interaction with European Institutions on PS by Means of a Well-identified Institution	There is integration with the EU level in various areas: • HAI – via the RAISIN network to ECDC • Antimicrobial resistance – via InVS and Onerba to the European network EARSS • Antimicrobial consumption – via AFSSAPS to the ESAC network • Research – two programmes dedicated to research on HAI are coordinated by French bodies, i.e. IPSE and MOSAR The indicator is deemed: **fairly valid** (the possibility of numerous institutions involved should be forseen) **fairly feasible** (the information can be retrieved from relevant institutions with minimal effort)
23	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices in PS Area	There is no one body acting as the single PS national centre of expertise. At national level this role is played by HAS, but also by other sectoral agencies (InVS, AFSSAPS, etc.) At sub-national level there are bodies like the CECCQA in Aquitaine and the five interregional CCLINs that assist healthcare facilities. The indicator is deemed: **absolutely valid** (the issue has been pinpointed by some high-level French experts) **highly feasible**
24	NET.1	Creation of a Network of Institutions to Implement the PS Policy	The PS governance system is still to be defined. In the field of HAI there is a network including the national level bodies (e.g. InVS) and regional or interregional ones (CCLINs and ARLIN)

	Code	Indicator	Notes
			With respect to the intersectoral coordination mechanism, France has reportedly not implemented the EU recommendation on the creation of a coordination mechanism on the prudent use of antimicrobial agents. The indicator is deemed: **fairly valid** **highly feasible**
25	DEL.2	Number of RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents	Since the PS policy has not been released yet, it is too early to assess indicators in this respect. However, some preliminary feedback on specific aspects of the EU policy can be provided: • Development of tools/systems (incl. the use of ICT) – an upgrade of the information system will be necessary, especially with respect to the planned introduction of reporting of non-HAI adverse events. The sectoral information system needs better integration; • Blame-free reporting and learning system on adverse events – it is foreseen, but requires to be adapted to French juridical system. A ministerial committee is currently studying the matter; and • Active surveillance system for HAI – indeed, there are many thematic systems gathered under RAISIN. The indicator is deemed: **of dubious validity** (considering that various EU policy featuires are not openly adopted) **hardly feasible** (the information needed to measure this indicator is braod, complex and poorly structured, so it is estimated that a significant effort would be required)
26	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken to Specifically Deliver Policy	This indicator has the major limitation of not clarifying the nature of the initiatives that it aims to quantify. In the case of PS, they may be very different and not comparable. Serious doubts on its validity have been raised. For the same reason, its feasibility appears problematic. The indicator is deemed: **of dubious validity** **hardly feasible**
27	TRAI.1	Implementation of Training Courses on PS-related Subject for Healthcare Personnel (incl. RE level)	Training activities financed under the nosocomial infection programme are on best practices of hospital hygiene and management of infection hazards. In the HAI fields there are also various training modules organised by the professional associations, and local and regional institutions. The introduction in the '*tableau de bord*' of an indicator on the proportion of professionals having received specific training is reportedly being considered. The PS remains instead poorly addressed and at present there is no strategy, structure and organisation for the development of PS training. The indicator is deemed: **definitely valid** (it will possibly be included among national indicators)

	Code	Indicator	Notes
			hardly feasible (information fragmented)
28	TRAI.2	Total Number of Trained Healthcare Workers on PS-related Subject	There are figures available on trainings provided to health professionals under the nosocomial infection programme (330,000 in 2007), as well as on the total hours of training. More general data on all types of PS-related training attended would require specific research. The indicator is deemed: **definitely valid** (see TRAI.1) **fairly feasible** (in perspective)
29	TRAI.3	Resources Made Available for Training in PS-related subject in Absolute or Relative Terms	With the exception of the courses organised under the nosocomial programme, this information is considered very difficult to obtain. The indicator is deemed: **definitely valid** (see TRAI.1) **fairly feasible** (in perspective)
30	TRAI.4	Introduction of PS in Relevant Curricula (incl. RE level)	The PS is already in the curricula of nurses and physicians although there is scope for its strengthening, especially at higher education level. Since 2008 it is part of the mandatory modules for the continuous training of non-health professionals working within health facilities. The indicator is deemed: **definitely valid** **fairly feasible**
31	EVAL.1	PS policy evaluation (i.e. regular review of practices and standards)	Since PS policy is not in place yet, this indicator is of limited use. Individual aspects (practices, standards, results) of PS policy have however been extensively evaluated in the past year, and in particular: • The PS-related objectives included in the PHP Law have been assessed by HCSP in the context of the overall evaluation of the PHP Law carried out in 2010; • The HCSP report on PS «*Pour une politique globale et intégrée de sécurité des patients*» ; • The evaluation of HAI programme 2005-2008, which is included in the programme document for the 2009-2013 programme. The indicator is deemed: **definitely valid** **highly feasible** (evaluation reports)
32	EVAL.2	Change of PS Policy as a result of the above evaluation	The performance of the 2005-2008 nosocomial programme were explicitly taken into account for the formulation of the new Action Plan and related programme.

	Code	Indicator	Notes
			The above HCSP reports (see EVAL.1) did not have a formally recognised impact on the current decision of setting up a PS policy, but they likely had it 'informally' together with other inputs, such as the results of the ENEIS study. The indicator is deemed: **definitely valid** **fairly feasible** (it may require some minor research in the event the evaluation report is not explicitly referenced in the policy document)
33	EVAL.3	Establishment of a System of Indicators to Monitor Policy Implementation	As extensively discussed in the Study, various sets of indicators are currently used: • in the field of HAI, the seven indicators of the '*tableau de bord*' • the nine HAS indicators on quality of healthcare (IPAQSS) • the indicators corresponding to the PS-related objectives in the PHP law • the performance indicators to measure the implementation of the nosocomial programme Further indicators are expected to be established in the context of the upcoming new law on PS. The indicator is deemed: **definitely valid** **highly feasible**
34	EXC.1	Contribution by the MS of its Policy Experiences to the *PS and Quality of Care Working Group*	France is very active in EU networking on issues related to PS (and especially HAI) including a close cooperation with ECDC. The feedback collected suggested that there is comparatively less interest and commitment to participate and contribute experiences in policy-making mechanisms such as the PS and Quality of Care Working Group. The indicator is deemed: **of dubious validity** (not clear its usefulness for national policy-making) **fairly feasible** (the information require some elaboration, but data are already available to the EC)
35	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	No main difficulties envisaged in complying with the requirements of an implementation report. The indicator is deemed: **fairly valid** **highly feasible**

D – Cancer Screening

1. Legal, Policy and Institutional Framework

The fight against cancer is one of the three Presidential priorities for health, along with Alzheimer disease and palliative care. The current ***action plan on cancer*** (*Plan cancer 2009-2013*/PC) was launched by the French President in 2009. The PC, which follows up on an earlier plan covering the 2003-2007 period, was developed on the basis of the work of a committee of experts and representatives of the relevant health institutions (*Commission Grünfeld*), which saw also numerous consultations and contributions from external actors (e.g. civil society organisations).

The PC identifies three horizontal strategic priorities and five vertical axes, as shown in Table 1.1 below. A total of 30 different measures – of which, six flagship measures – have been designed, corresponding to 118 concrete actions. Screenings are included among the vertical axes, with four measures and a total of 15 concrete actions.

Table 1.1 – Priorities and axes of the Cancer Plan 2009-2013

Vertical axes	**Horizontal priorities**
• Research • Observation • **Prevention – screening** • Patient care • Life during and after cancer	• To better take into account health inequalities in the design of measures to fight against cancer • To enhance the customisation of care through a better analysis and stocktaking of individual and context factors • To strengthen the role of the referring doctors (*médecin traitant*) to ensure a better life quality during and after the disease
Measures related to screening	**Concrete actions related to screening**
M14 - Tackle inequalities in access and take-up of screening	1. Encourage high turnout and consistency in participation in screening programmes; reduce the discrepancies in participation rates 2. Implement actions designed to reduce socio-economic, cultural and regional inequalities in access to and take-up of screening 3. Support access to testing in line with the level of risk
M15 - Improve configuration of the national organised screening programmes	4. Improve the efficiency of organised screening programmes by optimising the operation of the cancer screening coordination centres 5. Improve follow-up of screening results
M16 - Involve referring doctors in national screening programmes and guarantee equality of access to the most effective techniques throughout the country	6. Increase the involvement of referring doctors in the system of organised national cancer screening programmes 7. Define ways of developing new screening techniques and strategies for national screening programmes 8. Gradually roll out use of the immunological test for colorectal cancer screening to the whole of the country 9. Define the technical conditions that will ensure full exploitation of the potential offered by digital mammography in breast cancer screening 10. Examine the impact of new technologies in *papillomavirus* research and vaccination on the strategy against cervical cancer. 11. Test different strategies for integrated cervical cancer screening activities by ensuring women who have not been screened or screened infrequently have access to screening
M17 - Monitor a scientific watch and improve knowledge of early cancer detection	12. Define an early detection strategy for prostate cancer 13. Improve early diagnosis of skin cancers 14. Improve the early detection of oral cavity cancers 15. Include new screening opportunities based on advances in knowledge and treatment

The overall PC implementation is steered by an inter-ministerial committee headed by the Director General of Health (*Directeur général de la santé*) and involving 10 representatives of relevant ministerial services, agencies (i.e. INCa), health insurances, individual experts, and civil society

organisations. The execution of individual actions involves numerous bodies in the capacities of action coordinator, co-coordinator, or partner. With respect to the actions related to screenings, the primary action coordinator is INCa, which has sole or joint responsibility for nearly the totality of actions. Other institutions entrusted with the execution of specific actions (or part of them) include DGS (actions 4, 11), DSS (action 6), HAS (action 9), INPES (action 13). INCa also oversees the implementation of the plan collecting the data related to the various indicators established by the plan, identifies possible constraints and reports to the steering committee.

The Cancer Plan integrates in its comprehensive strategy all the pre-existing ***cancer screening programmes.*** In particular the breast CS programme was set up by DGS in 1994 and spread to the entire country in 2004, i.e. under the action plan on cancer 2003-2007. The colorectal CS programme was extended to the entire country only in 2009, while the cervical CS programme is still in the pilot testing phase. The technical specifications and the governance arrangements have been revised lately by the Ministerial Decision on cancer screening programmes (2006).

Table 1.2 - Legal, Policy and Programming Framework

Year	Type	Authority	Title	Comment
1953	Code of Law	Parliament	Public Health Code *Code de la Santè Publique*	In particular, Article L1411-6 (as modified by the Law 2006-1640) attributes to the MoH the competence for the establishment of health prevention programmes[193]. Major reforms in 2000, 2003 and 2005.
2001	Decision	Ministry of Labour (charged of Health)	Decision 24.09.2001 on the list of organised screening programmes for avoidable mortal diseases *Arrêté du 24 septembre 2001 fixant la liste des programmes de dépistage organisé des maladies aux conséquences mortelles évitables ;*	It identifies a list of possible organised screening programmes to be established. The list includes: (i) breast CS programme (ii) colorectal CS programme (iii) cervical CS programme[194]
2002	Circular	MoH	*Circulaire DGS n° 2002-21 du 11 janvier 2002 relative à la généralisation du dépistage organisé des cancers du sein* Circular 11.01.2002 providing for the generalisation of breast CS programme	It provides for the extension of the organised breast CS programme to the entire country. It establishes the governance structure and the requirements and tasks of the local management structures[195].
2006	Decision	MoH	**Decision 29.09.2006 on cancer screening programmes** *Arrêté du 29 septembre 2006 relatif aux programmes de dépistage des cancers*	It established and provides the technical specifications (annexed document) for the organised breast and colorectal CS programmes, repealing the previous decision (24.09.2001)[196].
2008	Decision	MoH and Ministry of	**Decision 24.01.2008 on the introduction of digital**	It amends the specifications of the Decision of 29.09.2006 above introducing digital

[193] http://www.legifrance.gouv.fr/affichCodeArticle.do?idArticle=LEGIARTI000006686924&cidTexte=LEGITEXT000006072665
[194] http://www.arcades-depistages.com/MESS0123411A.pdf
[195] http://www.sante.gouv.fr/fichiers/bo/2002/02-06/a0060491.htm
[196] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000000460656&dateTexte=

Year	Type	Authority	Title	Comment
		Labour	**mammography in the breast CS programme** *Arrêté du 24 janvier 2008 portant introduction de la mammographie numérique dans le programme de dépistage organisé du cancer du sein*	mammography in the protocol for breast screening[197]. The decision follows the conclusions and recommendations of the HAS report on digital mammography of October 2006[198].
2009	Action Plan	President of the Republic	Cancer Plan 2009-2013 *Le Plan cancer 2009-2013*	It consists of a comprehensive integrated plan with 30 measures and nearly 120 actions for the fight against cancer. One of the five vertical axes of the plan concerns prevention/screening[199].

The organised CS programmes are steered at the central level by ***DGS*** in collaboration with ***INCa*** and the ***health insurance***. Its annual evaluation is conducted by ***InVS***. The operational roll-out of programmes is entrusted to ***management structures*** (*structures de géstion*) established at departmental or inter-departmental levels. Overall there are 90 management structures covering the whole territory. The juridical status of most of management structures is of public utility associations. They are financed by State budget, health insurance and some half of them also by the local general councils. The tasks of management structures include:

- handle and ensure protection of personal data of people participating to CS programmes
- send invitations and recalls to the target population
- organise information and communication actions for the target population
- organise the training on CS for the concerned health professionals
- ensure the monitoring and follow up of screening
- oversee the quality of the overall system
- collect data for the monitoring and evaluation and transmit them to the competent authorities
- supply referring doctors with test-kits for colorectal CS

Management structures receive assistance by DGS and INCa via regular meetings, trainings, and guidelines (e.g. the juridical guide for the actors of screening published in 2011)[200]. ***ARS*** do not have a direct responsibility on operations but are required to adapt the national strategy to the specificities of the region (e.g. set participation targets and measures to fight inequalities etc.), facilitate coordination among the various actors, and support the programmes through specific actions (e.g. information campaign etc.). However, in many regions ARS are still not in the condition to fulfil this role completely, since they have not completed the preparation of the regional strategic health plan and/or the health prevention scheme.

Other relevant entities involved include:

- ***HAS*** – it provides technical and strategic advisory support, publishing guidelines, studies, and evaluation reports. Among other things, HAS has provided scientific opinions on the use of digital mammography, on immunological testing for colorectal CS, and recommendations on the country-wide implementation of the pilot cervical CS programme.

[197] http://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000018071400
[198] http://www.has-sante.fr/portail/jcms/c_461657/place-de-la-mammographie-numerique-dans-le-depistage-organise-du-cancer-du-sein
[199] http://www.e-cancer.fr/plancancer-2009-2013
[200] http://www.e-cancer.fr/component/docman/doc_download/7552-guide-juridique-a-destination-des-acteurs-du-depistage

- ***ANSM*** – it is responsible for the quality control of mammography instruments (instrument check must be carried out every six-month).
- ***Court of Audit*** – responsible for the financial audit of the overall Cancer Plan 2009-2013.

2. Policy Implementation

CS Programmes implementation:

- ***Breast CS programme.*** After an initial pilot phase, the breast CS programme has been extended to the whole relevant population in 2004. The programme addresses women aged 50-74 with 'moderate' risk factor (i.e. no symptoms and no breast cancer history), i.e. some 9 million women. It includes a clinical exam and a mammography to be carried out every two years. The costs of these exams are entirely covered by the health insurance. The protocol involved two reviews of the mammography, unless anomalies in the first stage of the process require further exams and the undertaking of the case by the healthcare system. The average participation rate is around 50% of the target population, with significant disparities across territories (from as low as 27% up to 67%).

  Operationally, the programme is managed by departmental or inter-departmental structures (*structures de gestion*), which liaise with the health professionals actually conducting the screenings. Every two years, the management structures send the target population an invitation to undertake a mammography and a clinical exam by an accredited practitioner. The management structures also collect and aggregate data on programme implementation and transmit them to the competent national authorities. A quality control of the instrument for the mammography must be done twice a year by an authorised body, in compliance with the quality provisions elaborated by ANSM (former AFSSAPS).

  In parallel with organised CS programmes, it is estimated that some 10% of the target population undergoes opportunistic screenings[201].

- ***Colorectal CS programme***. An organised, population-based programme for colorectal CS was set up only in 2009. The programme addresses all population aged 50-74 at 'moderate' risk (i.e. individuals with no symptoms and no cancer history), i.e. some 17 million persons, making up for 80% of the population in this age group. In the 2010-2011 period the participation rate has been of some 32%, being slightly higher among women. The programme was established after a pilot experimentation in 23 departments, evaluated by InVS[202]. The protocol includes a faecal occult blood test followed by colonoscopy in case of positive result. After a HAS recommendation, the guaiac test previously used in the French programme is being replaced by a more efficient immunochemical test which should be extended to the entire country in the coming years.

  The operational arrangements are similar to those set up for breast CS, i.e. every two years the target population receives from the local management structure a personal invitation to collect the test kit distributed by the referring doctor and send the test sample to the reading centre.

- ***Cervical CS programme.*** Cervical CS is recommended in France to all women aged 25-65 and was also included among the objectives of PHP Law, whereby coverage targets have been set. However, at present there is no organised, population-based cervical CS programme in France, and screenings are mostly conducted on an individual basis under the initiative of the referring

[201] http://www.e-cancer.fr/depistage/depistage-du-cancer-du-sein
[202] http://opac.invs.sante.fr/doc_num.php?explnum_id=108

doctor or gynaecologist. The HAS recommendations[203] on cervical CS involve the execution of a pap-test every three years (after two consecutive negative tests carried out on a yearly basis).

Some pilot experiences of organised programmes exist at local level. Since the 1990s, screening programmes have been conducted in five departments (Bas-Rhin, Haut-Rhin, Isère, Martinique, Doubs). These initiatives followed different organisational arrangements and protocols, which were evaluated by InVS in 2007[204]. Based on the outcomes of these early experiences, another pilot project was launched, involving 13 departments (Haut-Rhin, Bas-Rhin, Isère, Martinique, Allier, Cantal, Haute-Loire, Puy-de-Dôme, Cher, Indre-et-Loire, Maine-et-Loire, La Réunion, Val-de-Marne) and with a common methodology drawn from the above recommendations. Unlike the other CS programmes, the cervical CS programme does not involve personal invitation of all the target population, but a focussed invitation addressing only women not regularly followed by a gynaecologist and who have not taken a pap-test in more than three years.

The definitive results of this pilot programme will be known by the end of 2012, when a final decision on the possible extension of the programme to the entire country will be taken. At present, according to InVS data, the coverage rate in the concerned departments is around 57%, which is a rate considered sufficiently high to justify a programme focussed only on the population not currently covered through individual screenings. On the other hand, it is reported that only some 10% of women do undergo screenings at the recommended frequency, the rest doing it too frequently or too rarely.

Monitoring and Evaluation. The overall ***monitoring of the Cancer Plan 2009-2013*** is entrusted to the steering committee and coordinated by INCa, which has also developed an IT application to support the gathering of monitoring data. The monitoring system involves three aspects:

- ***Outcome indicators*** – a set of indicators has been retained for each of the measures foreseen by the plan, in order to allow an objective assessment of the degree of achievement of stated objectives. The responsibility for the measurement of indicators lies with the body entrusted of the coordination of individual actions.
- ***Monitoring of progress*** – a timeframe for the completion of each action of the plan has been established. The periodical assessment includes progress indicators stating whether the implementation schedule is in line with plan or is delayed.
- ***Monitoring of budget execution*** – the expenditure of each body involved in the implementation of the plan is detailed in the financial report that is prepared on a yearly basis.

The monitoring output consists of a quarterly document prepared by the steering committee containing 30 data sheets, describing the progress achieved under each measure of the plan. A six-month monitoring report is submitted by the steering committee to the President of the Republic and the concerned Ministries.

The ***evaluation*** of the Cancer Plan 2009-2013 is entrusted to: (i) HCSP for the overall plan; and (ii) AERES for the measures included in the research axis. A first mid-term evaluation has been carried out at end of 2011[205], and a second is expected following the end of the initiative in 2013.

[203] http://www.has-sante.fr/portail/jcms/c_272243/conduite-a-tenir-devant-une-patiente-ayant-un-frottis-cervico-uterin-anormal-actualisation-2002
[204] http://opac.invs.sante.fr/doc_num.php?explnum_id=3652
[205] http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?ae=avisrapportsdomaine&clefdomaine=6&clefr=259&ar=r&menu=09

Table 2.1 summarises the indicators that are used to assess the progress and results of the PC with respect to the four measures on cancer screening. It also indicates the entity responsible for the provision of data and the results of the last assessment (January 2012).

Table 2.1 – Indicators for PC measures on screening

Indicator	Associated PC Measure*	Type of data	Source	Last assessment (Jan 2012)
Breast CS participation rate	M14, M15	No. of persons screened out of target population (in the reference year)	InVS	52%
Colorectal CS participation rate	M14, M15	No. of person undergoing tests in a given year out of target population of the year	InVS	34%
No. departments with a breast CS participation rate < 50%	M14	No. of dept. having a participation rate < 50% out of total dept.	InVS	24%
Coverage rate of mammography for women having CMU/CMU.C[206]	M15	No. of women CMU/CMU.C who did a mammography in a given year out of the total CMU/CMU.C women in the target population for that year	CNAMTS - SNIIRAM	N.A.
No. of dept. providing complete data on breast CS	M15	No. of dept.	InVS	66
No. of dept. providing complete data on colorectal CS	M15	No. of dept.	InVS	95
No. of dept. using the immunological test for colorectal CS	M16	No. of dept. authorised to use the immunological test	INCa	4
Participation rate of referring doctors to CAPI[207]	M16	No. of referring doctors having signed CAPI on the total number of referring doctors	DSS	38%
No. of HPV genotyping made by CNR	M16	No. of HPV genotyping	*Centre National de Référence des papillomavirus* (national centre of reference on HPV)	ongoing
No. of referring doctors having received an on-site training on	M17	No. of referring doctors	INCa	N.A.

[206] Universal health coverage/Complementary universal health coverage (*Couverture maladie universelle / Couverture maladie universelle complémentaire*) http://vosdroits.service-public.fr/F13192.xhtml

[207] Contract on individual practice amelioration (*contrat d'amélioration des pratiques individuelles).* It is the agreement under which doctors practice through realistic, contractual measures and incentives designed to improve the level of inclusion in CS by referring doctors in line with national negotiated targets and recognise their public health role in preventing cancer.

Indicator	Associated PC Measure*	Type of data	Source	Last assessment (Jan 2012)
skin cancer				
No. of referring doctors having received an on-site training on oral cavity cancer	M17	No. of referring doctors	INCa	N.A.
No. of published recommendations on prostate CS for health professional	M17	No. of publications	INCa-HAS	N.A.
Share of melanoma cancer with Breslow 1,2 or 3 index diagnosed	M17	Incidence of melanoma Breslow 1,2, or 3 on total melanomas	InVS	N.A.

** See Table 1.1*

With respect to ***specific CS programmes*** the regulation attributes to the management structure the role of monitoring on the operational implementation of programmes, collecting the relevant data and transmitting them to the decentralised State services (DRASS) and the health insurance local structures. The information is further transmitted to the national level, to be elaborated and analysed by InVS. On this basis, InVS produced regular epidemiological studies and annual evaluation reports. The monitoring system managed by InVS includes a series of indicators. The indicators used for breast, colorectal and cervical CS programmes are reported in Table 2.2 below.

The evaluation function is also supported by HAS, which conducts *ad hoc* strategic assessments of programme including quality and cost-effectiveness aspects. An example is the evaluation conducted in 2010 on the pilot programme on cervical CS rolled out in 13 departments[208].

Table 2.2 – CS indicators collected and analysed by InVS

CS site	Indicators
Breast	• Participation rate to the CS programme (broken down by region) • Participation rate to the CS programme (broken down by department) • Performance of mammography in breast CS (sensitivity, specificity, reliability) • Number of cancer cases detected in the framework of organised CS • Coverage rate of breast cancer screening through mammography (organised and individual screenings) • Stage of cancer diagnosed by screening • Impact of organised CS on the stage of cancer diagnosis • Coverage rate of mammography by socio-economic conditions of patient • Evolution of the rate of participation to national CS programme since 2003
Colon-rectum	• Participation rate to the CS programme (broken down by region) • Participation rate to the CS programme (broken down by department) • Evolution of the rate of participation to national CS programme since the beginning of the programme • Number of cancer cases detected in the framework of organised CS • Proportion of positive tests under the organised CS programme • Impact of organised CS on public health (mortality decrease) • Exclusion rate in the participation to CS programme across departments
Cervix	• Cervical cancer protection factor (qualitative) • Smear test as the reference exam for CS (qualitative) • Experimentation of HPV test for CS (qualitative) • Coverage of departments by pilot organised CS

208 http://www.has-sante.fr/portail/jcms/c_1009772/etat-des-lieux-et-recommandations-pour-le-depistage-du-cancer-du-col-de-luterus-en-france?xtmc=&xtcr=2

CS site	Indicators
	• Coverage rate of smear test among women (by age group) • Evolution of the coverage rate of smear test • Social inequalities in the access to cervical CS

Factors affecting policy implementation. The following table provides an overview of the main constraints and difficulties affecting the implementation of CS policy in accordance with EU recommendations and guidelines. It is important to highlight that two factors reportedly affecting implementation in other countries does not pose any particular problem in France, namely:

- ***Political support*** – the Cancer Plan 2009-2013 is a presidential priority, i.e. is among the three main themes of the health policy directly promoted by the President of the Republic;
- ***Financial constraints*** – in connection with the above, the plan has been allocated a substantial envelope of EUR 750 million.
- ***Management of personal data*** – the MoH Decision establishing organised CS programmes include provisions for the protection of personal data collected by the management structures. These structures should obtain an authorisation from CNIL (*commission nationale informatique et liberté*) and ensure confidentiality and transparency.

Table 2.3 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factor	Comment
Screening delivery model	The simultaneous rolling out of organised CS programmes and opportunistic screenings is perceived as a major issue in various respects: • efficacy of screening (since opportunistic screenings do not often respect the recommended time intervals) • quality of screening (which is more difficult to control in the case of opportunistic screenings) • cost-effectiveness (too frequent opportunistic screenings represent an extra burden for the health system) • impact assessment (data on opportunistic screening are not systematically available, so statistics may be distorted)
Organisational arrangements	The rolling out of CS programmes has not been sufficiently adjusted since the introduction of 'regionalisation' (HPST Law). The role of the regional level needs further clarification and its capacity possibly enhanced. Regions may play a crucial role in collecting and aggregating information and provides feedback to the national level on constraints, best practices and possible policy refinement, but so far this is only marginally done.
Data availability	The information system in place might be further improved. Reportedly the data collected at department level and transmitted to the competent authorities are often incomplete and/or imprecise. The monitoring data published by InVS are only a portion of the information possibly available, and are not issued in a timely manner. Data on opportunistic screenings are not systematically available. Cancer registries exist only in less than half of the departments. This is a major obstacle to the possibility to cross-reference CS and cancer mortality data.

3. Indicators

Summary views on the possible relevance and feasibility of a proposed set of EU policy uptake indicators are reported in Table 3.1 below.

Table 3.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.2	Compliance with Data Comparability Criteria based on Expert Assessment	There is reportedly an issue with the quality and consistency of statistical data transmitted from the departments to the national level (InVS). In the EU dimension, data are in principle broadly comparable (for breast and colorectal CS), however, there are differences across MS in the definition of the target population (e.g. age, criteria for risk factor assessment). The indicator is deemed: **fairly valid** **fairly feasible** (it requires an expert assessment; some data quality issues)
2	HAR.3	Establishment of Special Registries (centralised data systems for the management and assessment of CS data)	Management structures at departmental (or inter-departmental level) have set up databases for the collection of CS data. These are aggregated at national level by InVS. The indicator is deemed: **definitely valid** **highly feasible**
3	HAR.4	Alignment of Data Classification Systems to Standards defined by the *European Network of Cancer Registries*	The main issue with cancer registries in France is the lack of a uniform coverage of the whole country. There are two kinds of cancer registry in France: (i) general registries and (ii) specific registries. General registries do not cover the entire country. As of 2011, there were 13 registries covering 14 departments, i.e. 20% of the population. Specific registries include: 9 site-specific cancer registries and two childhood cancer registries. All registries are part of the *European Network of Cancer Registries,* and data classification system are therefore consistent with the standards. The indicator is deemed: **definitely valid** **highly feasible**
4	ANA.1	Formal Adoption of the EU CS Guidelines (incl. RE* level)	No formal adoption or reference to the EU Guidelines in any official act. The indicator is deemed: **fairly valid** **highly feasible**
5	ANA.2	Evidence of a Significant Debate in the Scientific Literature of the MS about CS methodology and specifically the EU Guidelines	There is limited evidence of a debate on EU Guidelines in the scientific production of agencies and other institutions concerned with CS policy and programmes. Therefore reference to EU Guidelines can be found essentially in academic literature. In this sense, ANA.2 may contribute to assess how the Guidelines are received and debated. The indicator is deemed: **fairly valid** **fairly feasible** (it entails some research effort through scientific literature repositories)
6	ANA.3	Effective Outreach Level of the	The Guidelines are not translated, disseminated, or published on national authorities' website. The lack of proper

	Code	Indicator	Notes
		EU Guidelines in the MS (downloads, webpages visited) in Absolute or Relative Terms (% of the target population)	dissemination at sub-national level has been lamented by some stakeholders. The indicator is deemed: **fairly valid** (the lack of dissemination in itself tells a lot on GL uptake) **fairly feasible** (under present circumstances. In case of future GL dissemination this indicator should be reassesed)
7	OUT.1	Specific Outcome Indicator for the Stated Objective	The output indicators stated in the EU policy are so far consistent with the indicators used in France. A new evaluation of the implementation of the EU Recommendation will be conducted by IARC in the coming months. Reportedly, IARC is considering modifying the list of indicators used in the previous evaluation, but the list is not firmed up yet. It is therefore possible that some of the retained indicators will not be measurable in France. The indicator is deemed: **definitely valid** **fairly feasible** (some updating issues are possible)
8	IMP.1	Specific Impact Indicator for the Stated Objective	See OUT.1 above re: the possible indicators that will be used by IARC in the next evaluation of EU Recommendation on CS. With respect to the possible measurement of impact of CS on mortality, the main difficulties are: (i) cancer registries do not cover the entire country; (ii) cancer cases detected outside of the organised CS programme (e.g. through individual screenings) are not tracked. Reportedly, InVS is trying to build a model on the basis of the information currently available, but it is still at the research stage. The indicator is deemed: **fairly valid** (in principle very useful indicators, **but needs to be better specified)** **not feasible** (under present circumstances)
9	PROG.1	Establishment of a CS Strategy / Programme / Action Plan covering the Whole Population	Organised CS programmes covering the whole (target) population have been set up for breast and colorectal cancer. The cervical CS programme is still in the pilot phase, and covers only the population not undergoing opportunistic screenings. The indicator is deemed: **definitely valid** **highly feasible**
10	PROG.2	Number of RE with CS Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	Organised breast and colorectal CS programmes are being implemented in all departments. CS programmes are national, so there are no parallel programmes or plans at regional or local level. The indicator is deemed: **fairly valid** (although not particularly informative under the present framework) **fairly feasible**
11	PROG.3	Number of RE with a CS Strategy/Programme/Action Plan still in its Planning Phase,	A cervical CS programme is implemented on a pilot basis in only 13 departments. The indicator is deemed:

	Code	Indicator	Notes
		or Implemented on a Local Pilot Basis only	**fairly valid** (see PROG2) **fairly feasible**
12	LEG.1	Adoption of appropriate data protection legislation	The matter is covered by the 2006 Ministerial Decision on the establishment of CS programmes. Management structures must seek the authorisation of CNIL on the basis of adequate confidentiality and transparency arrangements. Reportedly, feedback from CNIL to such requests is still pending. The indicator is deemed: **fairly valid** **fairly feasible**
13	LEG.2	Appropriate data protection legislation Discussed but Not Yet Adopted	Same as above. The indicator is deemed: **fairly valid** **fairly feasible**
14	LEG.3	Appropriate data protection legislation Still under Preparation and in its Drafting Stage	Same as above. The indicator is deemed: **fairly valid** **fairly feasible**
15	AWA.1	Number of Information/Awareness Raising Campaigns and dissemination initiatives for practitioners on CS in a Given Year (period)	Information and promotional campaigns are being carried out on a yearly basis in the framework of the Cancer Plan; they include *Mars bleu* (on colorectal cancer), and *Octobre rose* (on breast cancer). These initiatives are coordinated by INCa. Some doubts have been raised on the validity and relevance of quantitative indicators related to these actions, such as volume of materials produced and distributed, etc. At local level, management structures may roll out information campaigns on screening site. Some structures have reportedly set up a mechanism to measure the effect of such campaigns (i.e. conducting before/after assessments in 'sentinel' facilities). The collection and systematisation of these data would require some effort. There appears to be no information/communication initiatives to disseminate the EU Guidelines. Every year, a 2-day workshop on breast and colorectal cancer (not only CS) is organised by the MoH addressing the personnel of the management structures. Information on the possible discussion/dissemination of the EU Guidelines would require the review of the workshop materials and minutes. The indicator is deemed: **of dubious validity** **hardly feasible**
16	AWA.2	Level of Awareness about CS issues among the target Population	Regular popular surveys (e.g. the cancer barometer, the survey on factors impacting on participation in CS etc.) are carried out by various national authorities (InVS, INCa, INPES, etc.). The results are publicly available on their websites.

	Code	Indicator	Notes
			The indicator is deemed: **definitely valid** **fairly feasible** (it requires minor processing of proxy data)
17	AWA.3	Trend in the Level of Awareness about CS issues among the target Population	The above (AWA.1) surveys are conducted at regular intervals, e.g. the survey on factors impacting on participation in CS (FADO) is rolled out every five years. The indicator is deemed: **definitely valid** (see AWA.2) **fairly feasible** (see AWA.2)
18	AWA.4	Estimate of Population Reached by Information Initiatives on EU guidelines in Absolute Terms or Relative to the Potential Target	Same as above (AWA.1) The indicator is deemed: **of dubious validity** **hardly feasible**
19	FUND.1	Total Budgeted Funds to assure appropriate organisation and quality control of CS programmes	While there is a clear budget for the overall Cancer Plan, the total budget for CS may be difficult to calculate. The MoH allocations are known, but at the regional level the budgets are not always detailed and transparent, and figures allocated to CS programmes are commonly not transmitted to the national level. A software information system is reportedly being developed; this will facilitate the tracking of all administrative data on CS. The issue of resources for quality control is more complex. Back-of-the-envelope estimates made by INCa indicate that some 10-20% of programme budgets are spent on quality assurance; more solid figures are currently unavailable. The indicator is deemed: **fairly valid** **hardly feasible** (under present circumstances)
20	FUND.2	Total Public Expenditure to assure appropriate organisation and quality control of CS programmes	Same as above (FUND.1) The indicator is deemed: **fairly valid** **hardly feasible**
21	FUND3	Total dedicated staff to implement and assure quality of CS programmes	The above mentioned information system currently under development is expected to provide not only the list of the actors actually involved in conducting CS programmes but also the level of effort devoted to it. A possibly useful indicator is the appointment of staff responsible for quality at national and regional level. The indicator is deemed: **fairly valid**

	Code	Indicator	Notes
			hardly feasible (under present circumstances)
22	DEL.1	Population Reached by CS Programmes in the country, in Absolute or Relative Terms (out of the target population)	These indicators are currently measured as part of the monitoring system in place, and are available on the InVS and INCa websites. The indicator is deemed: **definitely valid** **highly feasible**
23	DEL.2	Compliance with the Relevant Features of CS Implementation Modalities Stated in the EU Documents (incl. RE level)	The compliance with the EU Guidelines is not formally assessed. Qualitative indications can be drawn from the analysis of the CS programme specifications annexed to the Ministerial Decision of 2006. The indicator is deemed: **fairly valid** **fairly feasible** (it requires a review of CS programmes founding documents)
24	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken, i.e. CS programmes set up	Organised CS programmes are set up at national level, and the relevant information can be easily retrieved from the official website of the national coordinator (INCa). The indicator is deemed: **fairly valid** (although the quantitative approach is not deemed as particularly relevant for the French, centralised CS model) **highly feasible**
25	CAP.1	Compliance with Given Equipment Technical Standards and Operational Procedures	See (DEL.2); technical and organisational specifications for CS are laid down in the annexes to the Ministerial Decision of 2006. The indicator is deemed: **fairly valid** **fairly feasible** (it requires a review of CS programmes founding documents)
26	PRO.1	Introduction of a Given Procedure in CS Routine Operations (incl. RE level)	See (DEL.2); standard procedures for the execution of CS operations are established in the annexes to the Ministerial Decision of 2006. In addition, HAS and INCa develop guidelines for referring doctors and other health professionals involved in CS. HAS is also involved in the scientific assessment of new tests and techniques before their introduction (e.g. immunological tests for colorectal screening); as well as in the cost-effectiveness assessment of pilot CS programmes (e.g. the cervical CS programme). Measure 17 of the Cancer Plan envisages actions for the scientific testing of new techniques for early detection of cancer in other sites (e.g. oral cavity, skin, prostate) The indicator is deemed: **fairly valid**

	Code	Indicator	Notes
			fairly feasible (it requires a review of CS programmes founding documents)
27	PRO.2	Number of Relevant Institutions Complying with Procedure (incl. RE level)	The control of the activities of management structures is under the responsibility of ARSs. However, the indicator is poorly relevant, since procedures are mandatory and not voluntary; therefore infringements are subject to legal sanctions. The indicator is deemed: **of dubious validity** **fairly feasible**
28	TRAI.1	Implementation of Training Courses on CS for Healthcare Personnel (incl. RE level)	There is a legal obligation for both radiologists and support staff to take appropriate training on both analogical and digital mammography. The programme foresees also CS training for referring doctors. The management structures are responsible for training of health professionals, and their staff receive specific 'training for trainers'. Data on CS training might be made available by the training providers, e.g. FORCOMED, and the *Ecole nationale de santé publique* The indicator is deemed: **fairly valid** **fairly feasible**
29	TRAI.2	Total Number of Trained Healthcare Workers on CS	Since there is a legal obligation to receive appropriate training before CS roll-out, it can be assumed that all practitioners involved had attended such training. Their number is only available though management structures, and not as aggregate figures - although it will probably be in the future (see FUND.3) The indicator is deemed: **of dubious validity** (since compliance with the regulation can be assumed) **hardly feasible** (under present circumstances, since the information appears highly fragmented)
30	TRAI.3	Resources Made Available for Training on CS in Absolute or Relative Terms	Unavailable at the moment (except through management structures). It is still unclear whether such figures will be included in the information system currently being developed (see FUND.3). The indicator is deemed: **of dubious validity** (since it poses problems of definition and delimitation of scope) **not feasible**
31	EVAL.1	Evaluation of data from tests, assessments and diagnosis	InVS produced annual evaluation reports based on epidemiological data collected through the management structures. More general evaluation of the programmes performance, including recommendations for policy-makers are prepared by HAS. The measurement of the overall impact of programmes (i.e. cancer mortality) has not been done yet since (i) some programmes are too recent; (ii) systematic data are unavailable (partial coverage of cancer registries). With respect to the overall Cancer Plan, a mid-term evaluation has been published by HCSP in March 2012.

	Code	Indicator	Notes
			The indicator is deemed: **definitely valid** **highly feasible**
32	EVAL.2	Change of CS Policy as a result of the above evaluation	There is no evidence that the above evaluations have has any influence on CS policy. A relevant indicator in this sense will be the possible decision to set up an organised population-based cervical CS. The decision is reportedly due by the end of 2012 and will be based *inter alia* on the results of the evaluation of the pilot programme. The indicator is deemed: **definitely valid** **fairly feasible**
33	EVAL.3	Regularly Monitor CS Implementation and Outcome	There is an indicator-based monitoring system in place for breast and colorectal CS programmes that consists in the collection of data by management structures and their transmission to DRASS and finally to InVS. Reportedly, the system would need some overhaul, with a more active role of ARSs, and more timely submission of data to the central level. The Cancer Plan is monitored by the steering committee, which issues progress data sheets for all the measures included in the plan on a quarterly basis. The indicator is deemed: **definitely valid** **fairly feasible**
34	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	France was compliant with the reporting requirement of the EU Recommendation. A new report on the implementation of the Recommendation is expected in 2013. The indicator is deemed: **fairly valid** **highly feasible**
35	REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing CS Containing Information Not Shared with the EU	Data on the progress in the implementation of CS programmes are available in France at regular intervals but there is no established mechanism for the dissemination of the information outside of the country (e.g. through EU networks, or IARC). Similarly, it appears that the main documents (policy acts, evaluation reports, plans etc.) are not systematically shared at the EU level. The indicator is deemed: **fairly valid** **hardly feasible** (it requires some substantial desk research effort)

***RE**=Relevant Entity

ANNEX D – CASE STUDY REPORT: SWEDEN

A – Overall Health Strategy (White Paper)

1. Legal, Policy and Institutional Framework

Table 1.1 - Legal and Policy Framework

Year	Type	Authority	Title	Comment
1982	Law	Government / Parliament	'Healthcare Law' (*Hälso- och Sjukvårdslagen*), SFS 1982:763 up until the most recent modification/addition 2011:1576	A framework law regulating the roles and responsibilities of the county councils (or regions) and the municipalities towards providing good healthcare and social care to their citizens.
2000	Official govern-ment inquiry	National Public Health Committee (*Nationella folkhälso-kommittén*) for the Ministry of Health and Social Affairs	'Health on equal terms – national objectives for public health' (*Hälsa på lika villkor – nationella mål för folkhälsan*), SOU 2000:91	Final report of the National Public Health Committee (see Section D below).
2002	Policy bill	Government	'Public health objectives' (*Mål för folkhälsan*), Prop. 2002/03:35	This bill (adopted by Parliament on 16 April 2003) established a new PH policy aiming to 'create the social conditions to ensure good health on equal terms for the entire population'. It outlines clear goals, which are organized into 11 objective domains encompassing the entire lifespan of the population with the goal of providing the collective possibility of long and continually healthy lives for its residents; namely: 1. Participation and influence in society; 2. Economic and social prerequisites; 3. Conditions during childhood and adolescence; 4. Health in working life; 5. Environments and products; 6. Health-promoting health services; 7. Protection against communicable diseases; 8. Sexuality and reproductive health; 9. Physical activity; 10. Eating habits and food; and 11. Tobacco, alcohol, illicit drugs, doping and gambling. The policy assigned the tasks of the collective monitoring of the overall objective and the coordination of the national monitoring of measures within the 11 objectives domains (by developing indicators for health

Year	Type	Authority	Title	Comment
				determinants) to the Swedish National Institute of Public Health (*Statens folkhälsoinstitut, FHI*)[209] - see further Section D below.
2005	Policy report	Swedish National Institute of Public Health (*Statens folkhälso-institut, FHI)*	'2005 Public Health Policy Report' (*Folkhälsopolitisk rapport 2005*)	Per the 2002 PH policy bill, results from the monitoring of the overarching aim and the 11 objective domains are to be presented in the form of PH policy reports, which provide the basis for the Government's progress reporting to the Parliament on the development of PH and on measures implemented to improve it (as such, the reports also feed into the preparation of a change in policy, strategy, recommendations, guidelines, etc.). The 2005 report was the first PH policy report and was based on 42 multi-sectoral determinants of PH (measured by 36 principal indicators and 47 sub-indicators) – see further Section D below. The PH policy report differs from the PH reports prepared by the National Board of Health and Welfare, which reports on the status and trends of health *per se* among the population.
2008	Policy bill	Government	'Renewed National Public Health Policy' (*En förnyad folkhälsopolitik*), Prop. 2007/08:110	The policy (adopted by Parliament on 5 June 2008) aims to create societal conditions that will ensure good health, on equal terms, for the entire population. It proposes to focus (priority areas) on five of the 11 objective domains; namely: 3. Conditions during childhood and adolescence; 6. Health-promoting health services; 9. Physical activity; 10. Eating habits and food; and 11. Tobacco, alcohol, illicit drugs, doping and gambling. The Ministry of Health and Social Affairs is currently finalizing a proposal for a new PH policy.
2010	Open compa-rison	Swedish Association of Local Authorities and Regions (*Sveriges Kommuner och*	'Open comparisons 2009 – public health' (*Öppna jämförelser 2009 - Folkhälsa*)	Prepared together with FHI and the National Board of Health and Welfare (*Socialstyrelsen*)[211].

[209] Government agency working to promote health and prevent ill health and injury, especially for population groups most vulnerable to health risks, by: (i) monitoring PH trends and evaluating the progress of the implementation of the national PH policy in relation to a broad number of indicators for determinants of health for each objective domain; (ii) acting as a national expert agency for the development and dissemination of PH programs and strategies (based on scientific evidence) across all sectors; and (iii) exercising supervision regarding legislation and regulatory policies in the areas of alcohol, tobacco and illicit drugs. It provides the Government with an information base allowing decision makers to continue to develop effective PH policies. www.fhi.se See also: von Kappelgaard, LM. 'News on health policy and public health: The Swedish National Institute of Public Health', *Scandinavian Journal of Public Health*, 2011;39, 106-111.

Year	Type	Authority	Title	Comment
		Landsting, SKL)[210]		
2010	Stra-tegy	Government	'Collective strategy on alcohol, illicit drugs, doping and tobacco' (*En samlad strategi för alkohol-, narkotika-, dopnings- och tobakspolitiken*), Prop. 2010/11:47	FHI is assigned to support the implementation of this strategy / action plan (approved by Parliament on 30 March 2011) at local and regional levels.
2010	Policy report	Swedish National Institute of Public Health	'2010 Public Health Policy Report' (*Folkhälsopolitisk rapport 2010: Framtidens folkhälsa – allas ansvar*)	FHI is assigned to analyze and follow-up on the national PH policy. In order to facilitate strategic choices and selection of priorities for the Government, the report seeks to provide: (i) an overview of the PH situation and its developments as well as of the results of implemented PH measures; and (ii) recommendations for future measures. The report addresses all 11 objective domains of the Renewed National Public Health Policy.

The ***Healthcare Law*** (*Hälso- och Sjukvårdslagen*) is the main legislative framework regulating the Swedish healthcare system. It is a framework law that states the objectives and requirements for good care and that regulates the responsibilities of the county councils (or regions) and the municipalities. The primary responsibility for meeting the healthcare needs of the population lies with the ***counties (län) and their councils*** (*landsting*). The municipalities (*kommun*er) are responsible for caring for the elderly as well as for support and services to former patients or out-patients (who no longer require healthcare within a hospital or other healthcare structure) and to people with mental disabilities. Overall, the county councils and the municipalities enjoy quite a *large amount of freedom* in organizing the healthcare activities within their areas of competence towards meeting the goals and requirements set out by the Healthcare Law.[212]

From an organizational point of view, the counties (or regions) and the municipalities are structured into six ***'healthcare regions'*** (*sjukvårdsregioner*) in order to facilitate cooperation and coordination with regard to the utilization of healthcare resources within the different regions. The six healthcare

[210] SKL is the employers' organisation for the regional and local government authorities (namely county councils, or regions, and municipalities) and works in various areas, such as healthcare (including PS and CS). SKL seeks to fill the 'gap' between the government and the autonomous counties. www.skl.se

[211] Government agency under the Ministry of Health and Social Affairs with activities and duties within the fields of social services, health and medical services, environmental health, communicable disease prevention and epidemiology. It supports, exerts influence and supervises through: (i) monitoring and evaluation; (ii) compiling and passing on knowledge and information; (iii) developing standards based on legislation and the compiled information; and (iv) exercising supervision to ensure compliance with the law and to minimize risks. www.socialstyrelsen.se

[212] Furthermore, both regional (county council or regions) and local (municipalities) levels of government generally participate in the decisions regarding the amount of resources to be collected and/or allocated to the healthcare system (including allocations to research). With regard to setting the basis for and level of social contributions for health and setting the total budget for public funds allocated to health, all three levels of government (central, regional and local) are involved and all decisions have to be approved by Parliament (legislature). All three levels of government are also involved in decisions concerning setting the level of taxes to be earmarked to healthcare, which do not require the approval of Parliament. While the regional governments (county councils, or regions) make their own decisions with regard to the allocation of resources between sectors of care (including planning their own capacities with regard to increasing, or decreasing, the supply of hospital beds and with regard to opening new hospitals or other institutions within their county of competence), the central government determines the allocation of resources between regions.

regions (which do not constitute another administrative/government level) are organised as follows[213]:

Healthcare regions (*sjukvårdsregion*)	Members: county council (*landsting*), region, municipality (*kommun*)	Counties (*län*)	Municipalities (*kommuner*)
Norra sjukvårdsregionen	Norrbottens läns landsting	Norrbottens län	All municipalities
	Jämtlands läns landsting	Jämtlands län	
	Västerbottens läns landsting	Västerbottens län	
	Landstinget Västernorrland	Västernorrland län	
Uppsala-Örebro sjukvårdsregion	Landstinget Gävleborg	Gävleborgs län	All municipalities
	Landstinget Dalarna	Dalarnas än	
	Landstinget i Uppsala län	Uppsala län	
	Landstinget i Värmland	Värmlands län	
	Örebro läns landsting	Örebros län	
	Landstinget Västmanland	Västmanlands län	
	Landstinget Sörmland	Sörmlands län	
Stockholms sjukvårdsregion	Stockholms läns landsting	Stockholms län	All municipalities
	Gotlands kommun	Gotlands län	
Sydöstra sjukvårdsregionen	Landstinget i Östergötland	Östergötlands län	All municipalities
	Landstinget i Jönköpings län	Jönköpings län	
	Landstinget i Kalmar län	Kalmar län	
Västra sjukvårdsregionen	Västra Götalandsregionen	Västra Götalands län	All municipalities
	Landstinget Halland	Hallands län (north)	Kungsbacka kommun
			Varbergs kommun
			Falkenbergs kommun
Södra sjukvårdsregionen		Hallands län (south)	Halmstad kommun
			Hylte kommun
			Laholms kommun
	Landstinget i Blekinge	Blekinge län	All municipalities
	Landstinget i Kronoberg	Kronobergs län	
	Region Skåne	Skåne län	

Official government inquiries (*statens offentliga utredningar*, *SOU*) are mandated by the Government to a relevant ministry (or other entity), which in turn appoints either a committee of investigators or a special investigator (individual) to examine a certain issue. These inquiries serve to provide information and support to the Government (and relevant ministry) in drafting new policies, making recommendations, developing strategies or action plans, etc. One such inquiry, the 2000 'Health on equal terms – national objectives for public health', the final report of the National Public Health Committee (see Section D below) involving the consultation of 69 referral bodies, served as the base for the preparation of the 2002 policy bill 'Public health objectives'.[214]

The 2005 PH policy report (the first such report) was drafted by the ***Swedish Institute of Public Health (Statens folkhälsoinstitut, FHI)*** based on its own research as well as on information provided, upon request of the Government, by 13 different authorities. A draft of the report was referred to the counties, numerous authorities as well as voluntary organizations for their opinions before the final version was submitted to the Government (Ministry of Health and Social Affairs). Based on this report, the new Government (following elections in 2006) prepared a proposal for a

[213] From an administrative point of view, Sweden is composed of 290 municipalities (kommuner) divided into 21 counties (län). The 21 counties in turn include 18 county councils (landsting), two regions with expanded regional development responsibilities (Skåne and Västra Götaland) and one municipality with county level responsibilities (Gotland). In terms of governance, Sweden applies the rule of local self-government.

[214] 'Chapter 1: Background to the new Swedish public health policy', *Scandinavian Journal of Public Health*, 2004 32 (Suppl 64): 6-17, (p.8).

new PH policy (the ***2007/2008 policy bill 'Renewed Public Health Policy***). Once the draft policy proposal was prepared it went through the normal referral system of the Swedish legislative/regulatory process before its final version was submitted to the Parliament (which subsequently adopted it on 5 June 2008). With regard to the ***2010 PH policy report***, the second one (currently under review at the Ministry of Health and Welfare), the more common (and the more time consuming) referral system was replaced by hearings at the Ministry of Health and Welfare (at which interested representatives from authorities, counties and organizations could provide their opinions and make suggestions on the draft report before a final version was submitted).

Since 2006, the ***Swedish Association of Local Authorities and Regions (Sveriges Kommuner och Landsting, SKL)*** publishes '***open comparisons***' (*öppna jämförelser*) between counties (or regions) and municipalities with regard to several areas, including healthcare services, together with the National Board of Health and Welfare (*Socialstyrelsen*) and public health, together with FHI and the National Board of Health and Welfare. These assessments compare quality, results and costs towards stimulating the counties and municipalities to analyze their activities, learn from each other and improve quality and effectiveness. Apart from providing input into the policy making (or revision) process, the comparisons implicitly also serve to monitor policy implementation with regard to certain areas.

2. Governance

Regulation. The state is responsible for formulating overall healthcare policies and establishing basic principles. ***The Ministry of Health and Social Affairs*** (*Socialdepartementet*) is responsible for drafting proposals for decrees (*förordningar*) or acts/laws (*lagar*), which are both law binding once presented by the Government and approved by the Parliament. ***The National Board of Health and Welfare*** can issue directions (*föreskrifter*), which are binding, and recommendations (*rekommendationer*) or guidelines, which are not binding, with regard to issues that are more or less strictly related to healthcare. While there is a national framework of recommendations, guidelines, etc., *very little is regulated on a national level because of the principle of local self government.*

Strategic planning. Both FHI and the National Board of Health and Welfare provide a national strategy framework for PH (and healthcare in general), while responsibility for actual and more practical *strategic planning lies with the county councils (or regions) and municipalities*. Within the county councils and the municipalities, ***the healthcare boards*** (*hälso- och sjukvårdsnämnder*) are assigned with the task of representing the population within the county or the municipality. The boards (with elected representatives) are responsible for identifying the healthcare needs of the population and prioritize among the different needs and population groups.

Implementation of programmes/initiatives. While SKL supports the county councils (or regions) and municipalities in policy implementation, *responsibility for implementation lies entirely with the county councils (or regions) and municipalities*. The regional and local healthcare boards are supported in their role to ensure that the healthcare needs of the population are met by ***healthcare offices*** *(hälso- och sjukvårdskansli),* composed of public officers. The offices provide basis for budget decisions, guidelines and healthcare orders.

Promotion and dissemination. Promotion and dissemination activities for relevant entities and professionals (county councils, regions, municipalities, healthcare workers, government agencies, etc.) are carried out by FHI and SKL. While FHI is a government agency and has been assigned this task by the Government, SKL (which is not a government agency, but an employers' organization for the regional and local authorities) has taken on this role based on agreements with the Government. County councils (or regions) and municipalities are responsible for promotion and

dissemination activities targeted at the general public (or target groups within the general population). Given the cross-sectoral nature of the Swedish PH policy, several other government agencies might also be assigned to carry out promotion and dissemination activities. For example, *Systembolaget* (the national alcohol monopoly) is responsible for providing and disseminating information (by way of full scale campaigns, leaflets, etc.) to the general public regarding the risks of drinking alcohol.

Furthermore, the Public Health Guide (*Folkhälsoguiden*) is an online portal managed by the Public Health Academy (*Folkhälsoakademi*) at *Karolinska Institutet* towards sharing information on PH issues and providing materials and methods to support PH and prevent ill health and illnesses.[215]

Collection of data and statistics. On a national level, FHI and the National Board of Health and Welfare are assigned with the task of collecting data and statistics. While the National Board of Health and Welfare focuses on data (statistics) related to the *status and trends of (public) health per se*, FHI is responsible for collecting data (survey data) concerning the *status and trends of health determinants*. On a regional and local level, data collection is carried out by the county councils (or regions) and municipalities. While most data collection is voluntary, data collection and reporting for some issues/registries are mandatory.

The National Board of Health and Welfare and SKL support the development and use of ***voluntary National Quality Registries***. The registries are developed and managed by representatives of the professional groups that use them (doctors, nurses, etc.). These registries are also organized into three special competence centres towards promoting the development of new registries, creating synergies between registries and assist in their functional use.[216]

According to the Healthcare Law, it is also the responsibility of the county councils to collect and report on data and information into various national health databases (hence not voluntary, but mandatory) and the government, or any authority designated by the government, may issue regulations regarding the county councils' reporting obligations. The National Board of Health and Welfare is responsible for the current ***five mandatory health data registries***, namely: (i) patient registry; (ii) medical birth registry; (iii) cancer registry; (iv) pharmaceutical registry; and (v) cause of death registry. The Centre for Epidemiology with the National Board of Health and Welfare also has the "overall responsibility for collecting and maintaining databases for epidemiological surveillance".[217]

Finally, again, given the cross-sectoral nature of the Swedish PH policy, various other government agencies (related to transport, environment, food, physical planning, etc.) are also required to collect data relevant to PH.

Monitoring of policy implementation. While the National Board of Health and Welfare monitors the development of (public) health *per se*, FHI is responsible for monitoring health determinants and implemented PH measures. Indirectly, the 'open comparisons' prepared by SKL (in collaboration with the National Board of Health and Welfare and FHI) also perform an indirect monitoring role with regard to policy implementation in selected areas. Within the county councils

[215] www.folkhalsoguiden.se

[216] Schiøtz, Michaela and Sherry Merkur. 'Health Quality Information in Sweden' in *Euro Observer*, vol. 9, no. 3. Autumn 2007.

[217] Glenngård, Anna H. (European Observatory on Health Systems and Policies). *Health Systems in Transition: Sweden*, 2005, p.38. Furthermore, the *Swedish Institute for Communicable Disease Control* (*Smittskyddsinstitutet*) is a government expert agency responsible for monitoring the epidemiological situation for communicable diseases in humans as well as for promoting protection against such diseases. www.smittskyddsinstitutet.se

(or regions) and municipalities, the healthcare offices monitor the implementation of political decisions and conduct ongoing consequence analyses.

A recent official government inquiry, presented on 15 May 2012, points to the increasing need for national coordination, stronger supervision, stronger impact of guidelines, enhanced strategic management among others. To these ends, it proposes a ***new government agency structure*** based on four main tasks (and agencies instead of the current 12 agencies); including one "that monitors the overarching development of public health, disability issues, healthcare and social services – and in so doing strengthens the prospects of strategic governance" towards promoting a long-term sustainable system of health care and social services focused on health-promoting and disease-preventing efforts with the aim of promoting health and reducing ill-health and future care needs and bring about equal health care and social services throughout the country."[218]

Evaluation of policy outcomes and impacts. FHI is responsible for assessing the outcomes and impacts of measures taken within the field of PH towards meeting the goals of the PH policy. The ***Swedish Agency for Health and Care Services Analysis*** (*Myndigheten för Vårdanalys*)[219] can also, upon special assignment from the government, be charged with the task of evaluating the effects of healthcare related reforms and initiatives (which might be related to PH).

The Swedish Council for Working Life and Social Research (*Forskningsrådet for Arbetsliv och Socialvetenskap, FAS*) seeks to initiate and support research in areas of working life, PH and welfare. In 2011, it published, upon assignment from the Government, a proposal for a collective strategy regarding research within healthcare.[220]

In 2010, FHI, in cooperation with the region of Västra Götaland and county council of Sörmland, embarked on an assignment (mandated by the Government) to develop a web-based 'method bank' towards enabling the collection and presentation of evidence-based practices and other health promotion actions. This bank would generate a basis for comparisons, planning, quality assurance and performance management to support health promotion at local, regional and national levels.[221]

[218] 'Make it simpler! Final report of the healthcare and care government inquiry' (*Gör det enklare! Slutbetänkande av Statens vård- och omsorgsutredning*), SOU 2012:33, 15 May 2012, pp.28&29.

[219] A government agency established in 2011, primarily responsible for following up on and analyzing, from the point of view of the patient (user or citizen), the activities and conditions within healthcare and dental care as well as within areas in the interface between health and social care. Its tasks also include international comparisons and assistance to the government with regard to evidence and recommendations for streamlining government operations and management. www.vardanalys.se

[220] www.fas.se/pagefiles/4481/Forskningsstrategi%20h%c3%a4lsa%20och%20v%c3%a4lf%c3%a4rd.pdf

[221] See also Swedish National Institute of Public Health. 'Final report Method Bank – public health initiatives', (*Slutrapport Metodbanken -insatser för folkhälsa*), 24 March 2011.

3. Overall EU Health Policy Adoption/Implementation

An assessment of the main possible factors influencing overall EU policy uptake is reported in Table 3.1 below.

Table 3.1 – Assessment of possible factors affecting the adoption and implementation of EU policy

Obstacles/drivers	Comments
1. Institutional architecture (since uptake might be more difficult in more decentralised systems)	The institutional architecture can affect EU policy implementation and adoption both positively and negatively; it depends on the issue at hand. *While a decentralized system can be an obstacle for policy implementation in some cases, local solutions might be a driver in other cases* (for example with regard to the eHealth initiative seeking to provide local standardized solutions or basic hand hygiene initiatives). On the whole, adoption and implementation of EU policy clearly takes time in a decentralized country, but this is not really considered to be an issue (neither hampering nor driving). In any case, it is believed that EU policies need to be adapted to the fact that MS have different systems (as well as varying degrees of available resources).
2. The different nature of the soft law instrument chosen by the EU, i.e. whether Recommendations, Council Conclusions, or Commission Communications (since MS may attribute a different level of priority or deal with them in a different way)	*Soft law instruments in general (with no distinction between their types) are usually harder to adopt, especially in countries with local self government* (like SE). There is some evidence that, on the whole, the type of instrument (even when considering both hard and soft instruments) does not really have an effect on adoption and implementation. In other words, SE is usually very responsive and 'obedient' with regard to what happens at EU level and tries to keep up with EU policy (regardless of whether it is expressed as soft or hard instruments). On the other hand, some also suggest that, even if stronger regulation *per se* is not desirable on the whole, it might be useful to strengthen the legal ground with regard to some very important and carefully selected issues in order to promote more concrete, and binding, action in the MS. Here it is especially important to focus on a few very carefully selected areas (see also point 8 below) with true EU value added (such as patient mobility) and, as much as possible, to take a proactive approach (in this regard the patient mobility directive was rather a reactive, than a proactive, directive in response to court rulings that already had to deal with the issue). In any case, there is consensus on the fact that both soft and hard law instruments should not seek to micro manage.
3. Prior adequate discussion / consultation period before the adoption of a EU Policy (since this may facilitate adoption)	There is agreement that *prior discussions/consultations have a strong positive effect on policy implementation*. It is important that debates/consultations with regard to specific issues precede the drafting recommendations, etc. as this clearly is a supporting factor for drawing the attention of policy makers (adoption) and subsequent implementation. Prior discussions/consultations are also very important for interest groups (see point 10 below).
4. Other aspects of legislative techniques adopted to put pressure on recipients (such as the inclusion in the text of deadlines for compliance or explicit reporting requirements)	These aspects *can either have a marginal effect or be a slightly hindering factor* (maybe even more so for other MS than for SE). It is important that compliance and/or reporting requirements are in sync with already existing processes; i.e. it is easier if they can be attached to processes that are already

Obstacles/drivers	Comments
	there. Otherwise they could force an issue forward without considering actual quality of the proposal (or report). The Swedish budget cycle, for example, does not really allow for the presentation of policy bills during the fall and even if bills are presented during this period in any case, it is not optimal. Finally, reporting formats should be a bit more flexible so as to allow for MS to report on various areas in a way that best fit their own policy - the 11 objective domains of the Swedish PH policy do not necessarily fit with the areas of EU policy. For example, in SE, adverse events are relevant for (and divided into) ten different policy areas, which do not fit with the reporting of adverse events to the EU (making reporting somewhat complicated).
5. Issues of national ownership (since policy items put forward in the European agenda by individual MS may encounter resistance in other MS due to national experiences, cultural factors, traditions or technical obstacles to transposition)	There is consensus on the fact that a *sense of national ownership definitely has a positive influence*. National support and expectations behind issues clearly facilitate their adoption and implementation. Furthermore, issues of particular national interest have usually been referred to / fed into the EU debate beforehand, so once such an issue is addressed at EU level it is naturally easier for a country to adopt related principles and methods.
6. Adequate maturity, i.e. existence of sufficient evidence ('pilot' experiences, evaluations, scientific studies) supporting the inclusion of a given policy approach in the European agenda	It is important that the issues raised are already 'established' (discussed, assessed, etc.) beforehand. If recommendations, proposals, etc. are evidence based (rather than 'value' based), it *clearly facilitates the adoption/implementation process*. It is hence generally agreed that this is a very important supporting factor – in fact, since a lot of effort and costs are connected with policy change, proposals should be sufficiently explored and not just 'spur of the moment'.
7. Programming capacity (since some MS could find it difficult to cope with the total number of programmes, action plans, strategies requested by the EU in a given period. Not only for internal capacity constraints, but also for the duration of the political approval process)	There is some evidence that the *programming capacity does not have any real effect with regard to soft law instruments. With regard to directives*, on the other hand, SE has fairly long legislative process and hence has *problems in adopting them within the recommended time period*. It was also suggested that while 'overload' naturally occurs from time to time (even if not always caused by EU policy), a small country needs to prioritize and dedicate resources to the most important issues. Furthermore, the national policy process/cycle might not always be in sync with EU compliance requirements (see also point 4 above).
8. Clear prioritisation of actions (since the inclusion of too many European items in the policy making agenda might be ultimately detrimental for most urgent priorities, particularly in times of financial crisis)	Prioritization is generally considered key. In particular, emphasis is put on the importance of the EU focusing on and prioritizing a few carefully selected issues/actions where true EU value can be added rather than targeting very specific issues with no real EU dimension or value added (such as specifying the procurement of flu vaccines). In fact, there is agreement that this is the *most important factor and where EU can provide a concrete and positive value added*. When EU actions are clearly prioritized and have a clear EU vale added, it makes adoption and implementation much easier. On the other hand, too many ideas and actions without prioritization and actual EU value added hinder the adoption and implementation.
9. Existence of relevant OMC / JA mechanisms on the subject at the European level and the MS participation therein (since this may facilitate adoption)	Generally speaking, while these mechanisms can facilitate adoption and implementation, issue do not usually loose importance without them (hence their existence has a ***slightly positive effect***). Some of the evidence suggests that since the OMC mechanisms are not particularly transparent (relevant institutions from MS meet and coordinate with regard to a

Obstacles/drivers	Comments
	specific issues, but this work is then not disseminated to other relevant entities at home), it is hard to assess their value/effectiveness with regard to facilitating adoption.
10. Pressure from stakeholders' groups or lack thereof (since this may ultimately influence uptake)	The effects of pressure from stakeholder or interest groups can be both positive and negative. Interest groups are often involved in the consultation process at EU level (see point 3 above) and their interest and pressure commonly have a strong positive effect on national adoption and implementation (for example concerning rare diseases). However, in some cases (namely with regard to one case in particular; that of alternative medicines) interest groups have had a strong negative effect – very strong opposition to requiring alternative medicines having to go through the same approval process as 'normal' medicines. *If interest groups work along the same line as the Government (and the EU), they can surely facilitate adoption and implementation. If they instead are of another point of view, their pressure can rather have a hampering effect.*

B – Health in All Policies (HIAP)

1. Legal, Policy and Institutional Framework

The HIAP term as such *('hälsa i all politik'; 'hälsa i alla politikområden'*) is not commonly used in Sweden, primarily because it is *not considered as a stand-alone concept, but rather as an integrated part of PH in general*. PH per definition, at least in SE, already includes HIAP and the country ***applies a wide, cross-sectoral PH policy*** (*'sektorsövergripande folkhälsoarbete'*). Already in 1988, when establishing the Public Health Group, an advisory group for the development of PH policy, "reference was made to the importance of viewing public health as the responsibility of many different sectors of society and not just a matter for the health services".[222] Representatives from different sectors were thereby included in the group (inter-sectoral coordination mechanism). With specific regard to HIAs, "HIA development began in 1996 to place public health issues on the political agenda, help reduce health inequality and vitalize political work".[223] The Swedish Government has long recognized the relevance of other policies on PH, including for example the effects of the Common Agricultural Policy (CAP) on food and alcohol consumption patterns[224] and the role of transport policies, which include a health component towards reducing deaths and injuries.

Since HIAP is considered part of Sweden's PH policy, the legal/strategic documents related to HIAP are the same as those related to PH in general (as presented in Section A above, with some additional specifications in Table 1.1 below). The general policy making process (as presented in Section A above) is hence also the same.

Table 1.1 – Legal and policy framework

Year	Type	Authority	Title	Comment
2000	Official govern-ment inquiry	National Public Health Committee (*Nationella folkhälso-kommittén*) for the Ministry of Health and Social Affairs	Health on equal terms – national objectives for public health' (*Hälsa på lika villkor – nationella mål för folkhälsan*), SOU 2000:91	Final report of the National Public Health Committee (see below).
2002	Policy bill	Government	'Public health objectives' (*Mål för folkhälsan*), Prop. 2002/03:35	This proposition (adopted by Parliament in 2003) established a new, inter-sectoral public health policy with the overarching aim of creating "social conditions for good health, on equal terms, for the entire population", which in turn is divided into 11 objective domains (target areas). It consolidated the importance

[222] 'Chapter 1: Background to the new Swedish public health policy', *Scandinavian Journal of Public Health*, 2004 32 (Suppl 64): 6-17, (p.8).
[223] Berensson, K. (2000) 'Health impact assessment of political proposals at the local and regional levels' in Magnusson G. and Ritsatakis, A. (eds), 'Health Impact Assessment: From Theory to Practice' (NHV-Report 2000:9, Göteborg, Sweden) in: David Finer et al. 'Implementation of a Health Impact Assessment (HIA) tool in a regional health organization in Sweden—a feasibility study', *Health Promotion International* 2005;20, 277-284 (p.278).
[224] See also a study/HIA of the CAP on four sectors (fruit & vegetables, dairy, wine and tobacco): Schäfer Elinder, Liselotte (Swedish National Institute of Public Health). 'Public health aspects of the EU Common Agricultural Policy', 2003.

Year	Type	Authority	Title	Comment
				of carrying out HIAs (assigning the task of supporting authorities in using this instrument to FHI); the policy has in fact had a crucial effect as a framework for HIA in Sweden.[225] Finally, the policy made provisions for the establishment of the National Steering Group for Public Health (*Nationell ledningsgrupp för folkhälsa*), an inter-sectoral coordination mechanism (see below).
2005	Policy report	Swedish National Institute of Public Health	'2005 Public Health Policy Report' (*Folkhälsopolitisk rapport 2005*)	The 2005 report was the first PH policy report and is based on 42 multi-sectoral determinants of PH (measured by 36 principal indicators and 47 sub-indicators). It clearly stresses the important of commitment by and cooperation between various actors at all levels, i.e. municipalities and county councils, NGOs, and private sector.
2008	Policy bill	Government	'Renewed National Public Health Policy' (*En förnyad folkhälsopolitik*), Prop. 2007/08:110	The policy (adopted by Parliament on 5 June 2008) "highlights the importance of other sectors' role for health, where 'health in all policies' is seen as essential for good population health. Research, policy, and practice function in partnership as part of a whole government approach to providing citizens with the right conditions to make easy choices for their own good health".[226] The bill specifically proposes the allocation of SEK 50 billion towards developing local and multidisciplinary and cross-sectoral health promotion. It also stresses the importance of equitable health.
2010	Stra-tegy	Government	'Collective strategy on alcohol, illicit drugs, doping and tobacco' (*En samlad strategi för alkohol-, narkotika-, dopnings- och tobakspolitiken*), Prop. 2010/11:47	The strategy makes reference to the responsibilities of entities/authorities across various sectors and points to the importance of multi-sectoral collaboration and coordination.
2010	Policy report	Swedish National Institute of Public Health	'2010 Public Health Policy Report' (*Folkhälsopolitisk rapport 2010: Framtidens folkhälsa – allas ansvar*)	The report clearly stresses PH as a cross-cutting issue calling for coordination among all actors. To this end, it invites the Government to (re-)appoint a national coordination group for PH, consisting of representatives from various authorities and ministries, as well as for the possibility of making the municipalities' PH missions statutory. Furthermore, the report particularly calls for greater use of HIAs as well as more evaluation of activities carried out to promote PH. It is suggested that the county administrative boards (*länsstyrelserna*), the Government representatives at the county level, are to be given an enhanced role in this

[225] Knutsson, Ida and Anita Linell. 'Review Article: Health impact assessment developments in Sweden', *Scandinavian Journal of Public Health*, 2010 38: 115-120.
[226] Swedish National Institute of Public Health, 'Public Health Priorities in Sweden', 2011, p.2

Year	Type	Authority	Title	Comment
				regard. The preparation of the report included the participation of various sectors.

Governance

Given that HIAP is not considered as a policy area on its own, but rather a natural component of PH, the distribution of roles and responsibilities among various actors and levels is also more or less the same (see Section A above). With specific regard to HIAP implementation, FHI plays a particularly important supporting role. However, even if FHI can provide HIAP-related instruments (for example HIA methodology and other related material – see below) or incentive payments for carrying out specific programmes/initiatives, the primary responsibility lies with the county councils (or regions) and municipalities. With regard to collection of data/statistics, the major responsibility lies with FHI (in charge of the public health surveys and the 'municipal basic facts for public health planning' – see below), but the county councils (or regions) naturally also play a role (they can for example add their own questions to the surveys). At a regional level, the PH centres of the county councils (acting as resource and knowledge centres for PH issues – see below) address HIAP in their work (the PH council in Lidköping municipality, for example, also acts as a crime prevention council and is responsible for promoting safety in the community).

A 2007 study aimed at analyzing the agenda setting, formulation, initiation and implementation of the new inter-sectoral Swedish public health policy and the use of HIAs at the national and county level, showed that even if the different actors perceived the PH problem (or rationale) differently (depending on their agenda and interest), *both politicians and experts have had a strong impact on formulating the policy and setting the goals. However, on the whole, there had been little focus on and few guidelines for translating policy into actual implementation* due to difficulties on part of both policy makers and experts in terms of agreeing on action plans (for example, there was some discussion over the actual effectiveness of HIAs).[227]

2. Policy Implementation

Table 2.1 below summarises the main elements available on the progress reached by HIAP in Sweden on the basis of the categories envisaged in the EU policy documents.

Table 2.1 – Uptake and implementation of HIAP priorities

Priorities	Uptake/implementation
Develop the knowledge base on health and its determinants, associated trends, and trends in health inequalities;	Yes, definitely – this is the *primary responsibility of FHI*.
In national policy formulation and implementation, take into account the added value offered by cooperation between government sectors, social partners, the private sector and the non-governmental organisations for public health;	Yes, definitely – *both various authorities/sectors and voluntary organizations are involved either through the referral system or through participative hearings*. The Swedish National Agency for Education (*Skolverket*) is considered by some the "most important piece of the PH puzzle". There is also the ***National Steering Group for Public Health*** (*Nationell ledningsgrupp för folkhälsa*), set up in 2003. The structure of this group remains on the county/municipal level,

[227] Nilunger Mannheimer, Louise, Juhani Lehto, and Piroska Östlin. 'Window of opportunity for intersectoral health policy in Sweden—open, half-open or half-shut?' *Health Promotion International* 2007;22(4), 307-315. See also Lager A, Guldbrandsson K, and Fossum B. 'The chance of Sweden's public health targets making a difference', *Health Policy* 2007;80(3), 413-21.

Priorities	Uptake/implementation
	but it needs to be revived at the national level (as proposed also by the 2010 PH policy report). There is evidence in support of stressing the importance of such a mechanism since many departments or agencies still do not exactly have "health in the backbone".
Undertake, where appropriate, health impact assessments of major policy initiatives with a potential bearing on health;	Following the 2002 PH policy bill, FHI (in cooperation with the county administrative boards) started to *introduce HIAs as add-ons to EIAs* (easier to add a dimension to an already used instrument, than starting something from scratch). Initially, HIAs were hence primarily carried out with regard to policies concerning urban planning, transport, etc. The *instrument has subsequently been introduced when assessing policies related to lifestyles* (physical activity, eating habits – particularly important to education/school related policies), *physical planning* of segregated areas (how to develop social meetings places, encourage activities for youth, etc. – mostly 'softer' variables) and *reduction of risks of injury* as a result of the physical environment/setting (namely home, school and recreational areas). With the change in government in 2006, however, it appears that HIA as an instrument to be used by various ministries has to some extent been "taken away". One estimate has it that *around 80-85% of all HIAs carried out today are on a county level with specific regard to healthcare policy initiatives*. The country councils have procedures in place with regard to applying HIA to their policy-making.[228] *HIAs with regard to political decisions on a national level are still very scarce*. It was suggested that it would for example have been very useful for the Ministry of Education to have carried out HIAs prior to the school reform introducing the free selection of school on part of the students themselves (instead of attending the school in their neighbourhood, student can attend any school – involving longer transportation, etc.) Furthermore further evidence shows that *HIAs with regard to national policies* (for example those related to alcohol*) are commonly carried out too late in the process*; even if the approach is supposed to be proactive, there is usually not enough time to carry out a proper assessment before a decision needs to be made. Since 2000, the Swedish Government has taken a number of initiatives to increase the application of PH and HIA. National agencies and all of SE's county administrative boards have received government assignments to this end with FHI in a supportive role. Some *facilitators of HIA implementation* have been: (i) utilizing existing impact assessment knowledge; (ii) connecting HIA with the concept of a sustainable social development; and (iii) awareness of the time needed to adopt complex information. *Obstacles include*: (i) the lack of a mandatory law for HIA; (ii) a lack of funding (there is no specific national HIA budget); and (iii) an occasional lack of PH skills.[229] Finally, a 2011 cross-country report on HIAs by the JA on Health Inequalities concludes that countries with more established processes (like SE) have undertaken many HIAs in

[228] www.who.int/hia/examples/en/HIA_sweden.pdf

[229] Knutsson, Ida and Anita Linell. "Review Article: Health impact assessment developments in Sweden", *Scandinavian Journal of Public Health*, March 2010 38: 115-120.

Priorities	Uptake/implementation
	different policy areas outside of health, even if the use of HIAs outside the field of healthcare is somewhat patchy and not so well established.[230]
Pay special attention to the impact which major government policies have on equity in health, including mental health, and guarantee necessary efforts to tackle health inequalities;	As disparities have increased in recent years, *equity in health is currently very high on the political agenda at all levels* and there is a lot of effort on the part of both county councils/regions and municipalities on reducing disparities. Health is most commonly considered with regard to policies related to environment, traffic and urban planning and development, but also increasingly with regard to policies related to physical planning (living, working and recreational areas), education and food.
Focus on capacity building in policy analysis and development for improved intersectoral policies.	*Yes on a county/municipal level, but no on a national level.* Although not related to capacity building *per se*, but SE has a long tradition of a referral system in its policy process and this system can indeed be considered a sort of HIAP / inter-sectoral coordination mechanism in a larger sense. There are also the official government inquiries which usually take a multi-sectoral approach.

A number of factors (see Table 2.2 below) were considered to bear the most important obstacles (major issues) to the implementation of a 'HIAP policy' in Sweden (and hence not necessarily only the adoption of the EU policy), including: (i) *lack of a clear legal framework* for the use of HIA within the public administration (most notably at the national level); (ii) *financial resource constraints*; (iii) *insufficient number of professionals* trained in the subject matter (human resource constraints); (iv) *lack of a 'technical secretariat'* responsible for coordinating inter-sectoral cooperation (the National Steering Group for Public Health is currently not active); and (v) *lack of convincing evidence* from other countries' experiences. Other factors also negatively influencing implementation, but to a lesser extent (minor issue), include: (i) availability of sufficient information as a precondition (including privacy issues); (ii) lack of a centre of expertise (even if FHI has taken on this role in practice with regard to HIA); and (iii) lack of active dissemination of HIAP principles at all levels (most notably at the national level).

Table 2.2 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Lack of a clear legal framework for HIA use in the public administration	Major issue
Availability of sufficient epidemiological information as a precondition / privacy issues	Minor issue
Availability of a sufficient number of professionals trained in the subject matter	Major issue
Lack of a centre of expertise	Minor issue
Political resistances in principle (e.g. to considering income distribution also a health equity issue)	Minor issue
Lack of a technical secretariat responsible for coordinating intersectoral cooperation / HIA	Major issue
Lack of active dissemination of HIAP principles at all Government levels	Minor issue
Resource constraints	Major issue
Lack of convincing evidence coming from other Countries' experiences	Major issue

[230] Equity Action – Joint Action of Health Inequalities. 'Health Impact Assessment: Pre-meeting questionnaire summary report', 2011.

3. Specific Programmes and Initiatives

Public health centres (*folkhälsocentra*). Several county councils have set up these resource and knowledge centres regarding PH issues (including HIAP).

National Public Health Committee (*Nationella folkhälsokommittén*), 1997-2000. Composed of members of all the parliamentary parties as well as of experts from both central government agencies and various other authorities and sectors in society (the research community, labour market and organizations representing older people, immigrants and the disabled).[231] The committee was charged with the task of developing proposals for the goals for the national PH policy. Based on analysis and evaluation of both current and future health problems (pinpointing the most important problem areas), the committee proposed priorities and goals as well as strategies to meet these goals. Its final report, 'Health on equal terms – national objectives for public health' (see Table 1.1 above) served as the base for the preparation of the 2002 policy bill 'Public health objectives' (see Table 1.1 above) and involved the consultation of 69 referral bodies.[232]

While the National Public Health Committee no longer exists, its structure has to some extent been replicated on a regional level. For example, the region of Västra Götaland has created a public health committee with political representatives. The committee's mission is to lead, manage and coordinate cross-regional PH efforts, conducted across organizational and sectoral boundaries, towards promoting equitable and equal health in the region. Its tasks involve developing (including drafting action plans) and evaluating PH measures as well as disseminating experiences. It specifically calls for cooperation with voluntary organizations within areas that aim to create conditions for citizen participation and promotion of public health. [233]

National Steering Group for Public Health (*Nationell ledningsgrupp för folkhälsa*). Following the adoption of the 2002 PH policy bill, this group was set up for the preparation of PH (and HIAP) issues. The group included general directors from 19 different government agencies/authorities, covering all 11 objective domains, as well as SKL. However, since the change in government in 2006, the group has convened only once. The structure is there, but it is no longer active. The 2010 PH policy report calls for the restoration of such an inter-sectoral coordination group for PH issues. Some stress the importance of this mechanism, especially with regard to deciding which specific issues require collaboration and whether or not the mandates of certain authorities need to change as a result.

Örebro University offers long-distance courses for municipalities towards strengthening their HIAP capacities. The training seeks to create inter-sectoral links, which are formalized by the establishment of ***inter-sectoral committees*** in the participating municipalities. *HIAs are also part of public health courses at various universities.*

A HIA tool (divided into three levels: the health question, the health matrix and the health impact analysis), was initially developed by SKL. The *methodology for conducting HIAs at local, regional and national levels is now managed by FHI* (which has also published several handbooks on the subject for policymakers) *through its HIA website*.[234]

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[231] 'Chapter 1: Background to the new Swedish public health policy', *Scandinavian Journal of Public Health*, 2004 32 (Suppl 64): 6-17, (p.8).
[232] 'Chapter 1: Background to the new Swedish public health policy', *Scandinavian Journal of Public Health*, 2004 32 (Suppl 64): 6-17, (p.8).
[233] www.vgregion.se/sv/Vastra-Gotalandsregionen/startsida/Vard-och-halsa/Folkhalsa/Kommitten-for-folkhalsofragor-och-halso--och-sjukvardsnamnderna/Kommitten-for-folkhalsofragor/
[234] www.fhi.se/Metoder/Planeringsverktyg/Halsokonsekvensbedomning-HKB/

2004 and 2005 saw the publication of a couple of HIA-related articles by Swedish experts (and others) in scientific journals.[235]

A background report[236] to the 2010 PH policy report sought to assess: (i) the costs of illness to society; (ii) the budgetary costs for recommended measures; and (iii) the cost-effectiveness of some of the recommended measures. These ***economic estimates and assessments*** (*kostnadsberäkningar och bedömningar*) have proven to be an 'HIAP eye opener' for many authorities. The calculations illustrate how delayed/late measures in one area (say for example education) could imply significant health-related costs for the society in the future (and who actually pays in the end?). It is suggested that some authorities have even create a pot (dedicated budget line) in the beginning of the budget year to finance early measures towards addressing certain issues (with possible health consequences) sooner rather than later (as this would imply even higher costs, and most likely even for someone else, in the future).

The ***Ministry of Rural Affairs*** (Ministry of Agriculture until 2010) is working on several health-related issues; for example, together with the National Board of Health and Welfare, it is seeking to create a platform for dialogue on how to advance the promotion of physical activity and healthy eating habits (healthy/good food products).

In 2010, FHI and the National Board of Health and Welfare and the Swedish Institute of Public Health started a project to develop a long-term plan for PH reporting at national level (towards the creation of a *common reporting platform and collaboration between authorities*).

Centre for Health Equity Studies,[237] Stockholm University and *Karolinska Institutet*. Founded in 2000 with financial support from the Swedish Council for Working Life and Social Research (*Forskningsrådet för arbetsliv och socialvetenskap, FAS*) with the aim of promoting postgraduate training in the field of health equity studies. Also involved in research – current research programme (2007-2016) 'Human society as a life-long determinant of Human Health' is a multidisciplinary effort to explain why health inequalities re-emerge in every new generation, in spite of modern welfare developments.

The share of fieldwork focusing on ***HSIA*** has shown that some such assessments were carried out in the late 1990s, but the process had been very complicated and not very effective (involving almost 'ethical reasoning' at ward and hospital level). More recently, when some attempts were made to reintroduce this instrument, the counties viewed it as too cumbersome (and simply as 'one more thing' for which they do not have resources to dedicate).

[235] Namely: (i) Nilunger L. et al. 'Using risk analysis in Health Impact Assessment: the impact of different relative risks for men and women in different socio-economic groups', *Health Policy* 2004;67: 215-224; (ii) David Finer et al. 'Implementation of a Health Impact Assessment (HIA) tool in a regional health organization in Sweden—a feasibility study', *Health Promotion International* 2005;20, 277-284; and (iii) Forsberg B. et al. 'Comparative health impact assessment of local and regional particulate air pollutants in Scandinavia', *Ambio* 2005;34, 11-19.

[236] 'Financial calculations and estimates: A knowledge base for the 2010 Public Health Policy Report' (*Ekonomiska beräkningar och bedömningar: Kunskapsunderlag för Folkhälsopolitisk rapport 2010*), Swedish National Institute of Public Health, 2011:20.

[237] www.chess.su.se

4. Available Indicators

No evaluation on HIAP uptake/implementation has been carried out to date on a national scale. It appears that assessing whether HIAs and/or inter-sectoral coordination mechanisms actually have an effect/impact seems like a very complicated thing to do (difficult to evaluate).

Nevertheless, some local/regional HIA assessments have been carried out. For example, following the 2001 decision of the Örnsköldsvik city council to carry out HIAs, or rather health impact descriptions (*hälsokonsekvensbeskrivningar*), on all matters regarding children and youth (0-25 years), an evaluation of the municipality´s HIA activities was carried out in 2004.[238] Furthermore, in 2000-2001, a team of experts assessed the very first HIA to be carried out (in 1999 by the Stockholm county council regarding one of its healthcare districts), with the subsequent publication of a scientific article.[239] This assessment was, however, rather a feasibility study of the HIA than a proper evaluation of the impacts of its use.

There is no structured system for the specific monitoring of HIAP uptake (regarding the local or regional use of inter-sectoral coordination mechanisms and HIAs). Some believe that it is not an easy thing to do in a country with self government rule and 290 municipalities. While FHI does not monitor HIAP uptake *per se*, it does carry out ***case studies of HIAs*** implemented at the county or municipal level.[240]

Furthermore, with regard to PH policy, FHI is responsible for coordinating the monitoring efforts within the 11 objective domains on the national level as well as for the collective monitoring of the overarching aim. It does this by measuring a numerous indicators for 50 (originally 42) *cross-sectoral health determinants* across the 11 objectives domains (indicators for domain #6, health-promoting health services, are still under development). Around 20 agencies are involved in providing data (most commonly on a yearly basis). FHI also carries out interviews and its own ***public health surveys*** (*folkhälsoenkäter*) for the collection of data for and the measurement of some indicators. This monitoring process has proven an important tool in demonstrating certain trends (such as the increased alcohol consumption by women over 50 as a result of the introduction of bag-in-box wine) on which the Government can require relevant agencies/sectors to follow up.[241]

Since the late 1990s, Swedish municipalities, supported by FHI and SKL, have been compiling so called ***'local welfare accounts'*** (*lokala välfärdsbokslut, VBF*)[242], which are based on the 11 national PH objective domains. Most local government activities, which are also at the core of welfare policy actions, affect health either directly or indirectly. The local welfare accounts provide a instrument for managing and monitoring the effect of local government activities on health and wellbeing of its residents towards reducing disparities in health. FHI and SKL have, together with 17 municipalities and county councils, developed a model (with around 30 determinants and 39 indicators) for these accounts, which are currently used by 50 of the 290 municipalities in the

[238] Edin-Westman, Birgitta. 'Evaluation of health impact descriptions before municipal council decisions' (*Utvärdering av Hälsokonsekvensbeskrivningar (HKB) inför beslut i kommunala nämnder*), Public health unit, Municipality of Örnsköldsvik, 18 October 2004.
[239] David Finer, Per Tillgren, Karin Berensson, Karin Guldbrandsson and Bo J. A. Haglund. 'Implementation of a Health Impact Assessment (HIA) tool in a regional health organization in Sweden—a feasibility study', *Health Promotion International* 2005;20, 277-284.
[240] See Knutsson, Ida, Anita Linell and Henry Stegmayr, 'Health impact assessment in physical planning', Swedish National Institute of Public Health, 2008:06.
[241] See also Lundgren B. 'Experiences from the Swedish determinants-based public health policy', *Int J Health Serv*. 2009;39(3), 491-507.
[242] www.skl.se/vi_arbetar_med/halsaochvard/folkhalsa_1/metoder_och_verktyg_1/valfardsbokslut

country. Within the first five objective domains, nine indicators have been identified as base indicators because of their strategic relevance. Data for these indicators are available in FHI's national public health data bank (*folkhälsodata*), with a municipal breakdown (even of neighbourhoods for the three largest cities), formerly known as the '***municipal basic facts for public health planning***' (*kommunala basfakta för folkhälsoplanering, KBF*).[243]

[243] Available at http://app.fhi.se/PXwebFHI/database/folkhalsodata/databasetree.asp

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	ANA.1	Formal Adoption of EU HIAP definition and HIA methodology (incl. RE* level)	Formally speaking, the EU definition has not been adopted in SE, but HIAP (and HIA) has been an important part of SE's public health policy since the 2002 bill. The indicator is deemed: **of dubious validity** (MS might define HIAP differently and the definition needs to be backed up by concrete examples. Just a formal adoption of the definition (or methodology) does not really say much; it is more important to look at how the MS work on HIAP/HIA issues. A country, like SE, can work well on HIAP/HIA issues without having formally adopted the EU definition or methodology); **fairly feasible** (even if not used as indicator in SE and data/information is apparently not collected). Proposed change: Need to specify what 'formal adoption' would entail (concrete examples).
2	ANA.2	Evidence of a Significant Debate in the Scientific Literature about HIAP	The indicator is deemed: **of dubious validity** (Need to take a closer look to see if the debate in scientific literature can be regarded as representative of what is actually going on in a country. Furthermore, SE, a small country, does not really have any specific scientific HIAP/PH-related literature, but that does not mean HIAP work is not carried out); **hardly feasible** (Not used as indicator in SE and data/information is apparently not collected. In the case of SE, a small country, which does not really have any specific scientific HIAP/PH-related literature, you would have to look for Swedish contributions in other publications. This would be a time consuming and complicated task; would need to search for individual Swedish contributions in literature or maybe even PhD theses on the subject to find 'evidence'; involving the great risk of missing something. The Scandinavian Journal of PH could be a relevant source. Current debate in SE circles a lot around reducing differences in health among different groups; an issue that is also very high on the political agenda.).
3	PRI.1	Existence of Health Policy Documents Including a Commitment to HIAP Principle (incl. RE level)	The 2010 PH policy report calls for local HIAP commitments. The indicator is deemed: **definitely valid** (also need to look at all levels – national, regional and local); **fairly feasible** (even if not used as indicator in SE and data/information is apparently not collected - needs to be collected from the various counties and municipalities; possibly by FHI or SKL?). Proposed change: Perhaps even more important to look at if these documents states how the principle is intended to be followed up (not just that the documents states a commitment to the HIAP principle *per se*).
4	PRI.2	Reporting to International Organisations of Commitment to HIAP Principle (for instance in the WHO Healthy Cities programme)	The indicator is deemed: **of dubious validity** (Only reporting, or participation at ad hoc conference and alike, is not really a valid measurement of what is actually going on); **fairly feasible** (even if not used as indicator in SE and data/information is apparently not collected). Proposed change: The type of commitment needs to be further specified to make it more detailed (or technical); not just commitment to the HIAP principle in general.

	Code	Indicator	Notes
5	PRI.3	Strategies/Programmes/Action Plans Specifically focusing on HIAP (incl. RE level)	The indicator is deemed: **fairly valid** (Relevant if actual application of the HIAP principle is specified. In that case one needs to look at both explicit and implicit HIAP actions; a strategy or action plan may not specifically or explicitly focus on HIAP, but in practice the actions might involve HIAP implicitly); **hardly feasible** (Not used as indicator in SE and data/information is apparently not collected; needs to be collected from the various counties and municipalities, possibly by FHI or SKL? Countries, especially larger ones, would need a very good reporting system for this. It is not be so easy to collect this information from all levels in a country with local self government and with strategies and plans covering all 11 PH policy objective domains; especially if implicit HIAP focus/actions should be taken into account).
6	PART.1	Existence of Advocacy NGOs Active in the HIAP Field	In SE, the existence, and the involvement, of NGOs and voluntary organizations (which commonly would not be classified as advocacy NGOs) is more important for actual application and implementation of HIAP measures. Civil society plays a very important role in this regard in SE, especially concerning the reduction of disparities in health (minority organizations and sport clubs are for example very important actors). The indicator is deemed: **fairly valid** (Maybe relevant for other MS, but not so relevant in the case of SE - some private or public interest groups are very active in the referral and/or hearing process with regard to certain specific topics, but 'proper', full-fledged advocacy NGOs in the HIAP field as such hardly exist); **fairly feasible** (even if it might be hard to properly measure their existence. Not used as indicator in SE and data/information is apparently not collected). Proposed change: Need to specify what an advocacy NGO actually means – otherwise any organization can say that they advocate HIAP issues and then the indicator is not useful.
7	PART.2	Involving of Advocacy NGOs in the Policymaking Process (incl. RE level)	There is a great involvement on part of various interest groups in the policy making process in SE (invited on an ad hoc basis depending on the topic at hand to provide support/evidence, be part in the referral or hearing process, etc.). The indicator is deemed: **definitely valid** (if refer to 'interest groups' instead of 'advocacy' NGOs); **hardly feasible** (not used as indicator in SE and data/information is apparently not collected). Proposed change: Interest groups are more relevant than 'proper', full-fledged advocacy NGOs (at least in the case of SE).
8	RES.2	Resources Made Available by MS to Research Programmes in HIAP Field in Either Absolute or Relative Terms	On a national level there are specific budget lines for PH, but most likely these do not specify what might go to HIAP-related research. The indicator is deemed: **of dubious validity** (How would you actually defined this research?); **not feasible** (Not used as indicator in SE and data/information is apparently not collected. It is very doubtful that anyone would be able to actually discriminate how much or what share of a budget goes to fund HIAP-related research; there are no separate budget lines for this, so it would be hard to determine the actual numbers – very complicated. The

	Code	Indicator	Notes
			scientific councils (*vetenskapliga råden*), appointed by the National Board of Health and Welfare, the Research Council for Working Life and Social Sciences (*Forskningsrådet för arbetsliv och socialvetenskap, FAS*) or the Centre for Health Equity Studies might, however, be able to provide some limited information in this regard).
9	ORG.1	Identification of a Body Responsible for HIAP Coordination / a Focal Point	The indicator is deemed: **definitely valid** (even if need to further specified what 'responsible body' means. It is important to have a national entity who supports and follows up on the development of HIAP-related work); **highly feasible** (Not used as indicator in SE, but with regard to overall coordination/steering, there is the National Steering Group on Public Health, even if currently dormant. On a more practical level, focal point and follow-up, even if not formally assigned this role, FHI has taken on this role). Proposed change: Need to specify what 'responsible body' entails – body responsible for overall HIAP coordination/steering (as the National Steering Group) or more practical support, coordination and follow-up (as FHI)?
10	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices on HIAP (including HIA methodology)	The indicator is deemed: **definitely valid** (if the definition of a centre is further clarified – see below); **highly feasible** (Not used as indicator in SE, but nationally, this is one of the primary roles of FHI. On the regional level there are public health centres *[folkhälsocentra]*). Proposed change: Suggest to call it 'centre of knowledge' instead of 'centre of expertise' (there is a difference). There are different degrees of such 'centres of expertise' – need to specify that it does not necessarily involve a full-fledged research unit on PH/HIAP issues (such as in the UK), but it is with an entity (such as FHI or alike) responsible for the disseminating best practices.
11	PRO.1	Introduction of HIAP (including inter-sectoral coordination mechanisms) in Routine policy-making process (incl. RE level)	With regard to inter-sectoral coordination mechanisms: (i) the 2003 cross-ministerial and cross-sectoral National Steering Group on Public Health – the structure is there, even if it has only met once since the change in government in 2006; and (ii) local public health councils (*lokala folkhälsoråd*) at the municipal level. A very effective mechanism at the municipal and county level (especially with regard to planning of physical spaces to encourage physical activity, social interaction, etc.). At the national level, even if the National Steering Group on Public Health is dormant, inter-sectoral coordination occurs on an ad hoc basis – depending on the issue at hand, but many of FHI's assignments involve coordination with various areas (often included as a requirement of the assignment given by the Government). The indicator is deemed: **definitely valid**; **fairly feasible** (even if not used as indicator in SE and it would be quite time-consuming when looking at the local level).
12	PRO.2	Number of Relevant Institutions Complying with the above Procedures (incl. RE level)	The indicator is deemed: **fairly valid** (Maybe not so relevant as an initial indicator; perhaps it can be included in a second phase and concentrate first on PRO.1); **hardly feasible** (Not used as indicator in SE and data/information is apparently not collected. Especially with regard to the local level, this would require a lot of work – how do you actually check this when you cannot just ask whether or not an entity complies with the procedure, but need to gather actual evidence of meetings, etc.? In case, maybe it could be included in the PH surveys (*folkhälsoenkäter*) carried out by FHI?).

	Code	Indicator	Notes
13	EVAL.1	Implementation of Evaluations / Cost Effectiveness Assessments of their Policies (incl. RE level)	The indicator is deemed: **fairly valid** (It is important to see who gains and who pays for the policy and this can serve as a proper base for better political decisions in the future. However, there is doubt on the existence of proper methodologies for this – i.e., a cost-effectiveness assessment seems to be "doing violence on" the HIAP model; for example how can the traffic policy with a 0 death objective be evaluated in terms of cost-effectiveness; how do you measure the value of even one life, or one year of an adult life? Furthermore, it might be more important to calculate/estimate the societal costs of early and late PH measures as evaluating the cost-effectiveness of carrying out HIA or HIAP seems "as a little far off the target"); **fairly feasible** (even if not used as indicator in SE, FHI seems to collect some information on this). Proposed change: Maybe this indicator can be substituted with a indicator on the possible use of economic estimates and assessments (*kostnadsberäkningar och bedömningar*), such as those carried out by FHI, towards realizing PH costs of early and late measures (in many fields) and who (which sector) bears the costs (a late measure in the field of education for example can cost a lot in terms health and this cost is borne by another non-education related entity).
14	EVAL.2	Streamlining / modification of Policy as a Result of an Evaluation Exercise / Cost Effectiveness Assessment (incl. RE level)	The indicator is deemed: **fairly valid (**even if it is more important that actual measures/actions taken, not the policy *per se*, are changed if they prove not to have been particularly effective); **hardly feasible** (Not used as indicator in SE and data/information on change of policy is apparently not collected, even if new policy propositions could provide such evidence. Also very complicated when one need to look at local level too).
15	EVAL.3	Setting up of a System of Indicators to Monitor HIAP uptake / Implementation (incl. RE level)	Some claim that the Swedish national PH policy can by itself in fact be consider a giant HIA of the entire country. The indicator is deemed: **fairly valid** (even if not so relevant for SE, which has an established and traditional referral process and with a system for the monitoring of cross-sectoral public health determinants, the final outcome of HIAP, already in place. There is overall agreement that it more important to monitor actual measures taken on national, regional and local level and not HIAP uptake *per se*); **hardly feasible** (Not used as indicator in SE and it would be a cumbersome and time consuming process and hard to follow-up on. The 'local welfare accounts' (*lokala välfärdsbokslut*) could possible collect information on this indicator even if not done to date).

***RE**=Relevant Entity

Proposed additional indicators

Indicator	Comments
Perhaps some sort of measurement on whether PH/HIAP is part of the collective planning and budget process.	PH/HIAP should be integrated into the general planning and the overall budget – taking it out as a separate, stand-alone initiative/programme counteracts the whole idea of PH/HIAP.

C - Patient safety (PS)

1. Legal, Policy and Institutional Framework

Swedish policy has had a strong national focus on PS since 2006. A unique ***new Patient Safety Law*** came into force on 1 January ***2011***. This law stresses the importance of clarifying responsibilities as well as of open and constructive discussions involving both healthcare workers and patients themselves (especially when mistakes are made or something goes wrong). While it recognizes the importance of knowledge on part of individuals, it is even more important that PS is built into routines, processes and structures. Prior regulations focused more on seeking to identify those who bear responsibility for adverse events (a scapegoat thinking that hinders preventive measures). The new law hence aims to create a healthcare sector as a 'learning organization' that facilitates for workers to work safely and stresses the importance of preventive measures (it is not enough to just identify and measure risks, but rather to change working methods and processes through risk analysis). The position of the patient is also greatly strengthened by the new PS law.

Table 1.1 - Legal, policy and programming Framework

Year	Type	Authority	Title	Comment
1982	Law	Government / Parliament	'Healthcare Law' (*Hälso- och Sjukvårdslagen*), SFS 1982:763 up until the most recent modification/addition 2011:1576	General references to patient safety and 'healthcare guarantee' (*vårdgaranti*).
2000	Action plan	National Board of Health and Welfare	'Swedish plan of action against antibiotic resistance'	Proposal for action plan prepared upon assignment of the Government and in collaboration with relevant authorities and organizations towards combating antibiotic resistance as it poses a great threat to treating bacterial infections.
2003	Official govern-ment inquiry	Ministry of Health and Social Affairs	'Improved patient safety in the pharmaceutical sector' (*Ökad patientsäkerhet på läkemedelsområdet*), SOU 2003:52	
2005	Policy bill	Government	'Strategy for coordinated activities against antibiotic resistance and healthcare related illnesses' (*Strategi för ett samordnat arbete mot antibiotikaresistens och vårdrelaterade sjukdomar*), 2005/06:50	Strategy, adopted by Parliament on 16 March 2006, calling for cross-sectoral coordination.
2006	Official govern-ment inquiry	Ministry of Health and Social Affairs	'Patient data law' (*Patientdatalag*), SOU 2006:82	Proposal for special regulation regarding the national quality registers (privacy issues classified under PS).
2008	Law	Government / Parliament	'Patient data law' (*Patientdatalag*), SFS 2008:355	A new patient data law, adopted on 28 May 2008. Nevertheless, the discussion with regard to including healthy people in a CS register is still ongoing (see Section C below).
2008	Policy bill	Government	'Renewed National Public Health Policy' (*En förnyad*	One of the 11 objective domains is the protection against communicable diseases

Year	Type	Authority	Title	Comment
			folkhälsopolitik), Prop. 2007/08:110	(#7), which specifically addresses the importance of PS with regard to infections caused by antibiotic resistant bacteria.
2008	Official government inquiry	Ministry of Health and Social Affairs	'Patient safety. What has been done? What needs to be done?' (*Patientsäkerhet. Vad har gjorts? Vad behöver göras?*), SOU 2008:117	Assessment and proposal for a new PS law.
2010	Policy report	Swedish National Institute of Public Health	'2010 Public Health Policy Report' (*Folkhälsopolitisk rapport 2010: Framtidens folkhälsa – allas ansvar*)	The report makes specific reference to PS (namely HCAI) in its recommendations for action. The target area regarding protection against communicable diseases includes a priority recommendation for the establishment of a health data register to monitor HCAI and diagnosis-related antibiotic prescriptions. SKL and the Centre for eHealth have since developed a national coordinated IT system, the '***Infection tool***' (*Infektionsverktyget*)[244], launched in December 2011, to record and report on HCAI and diagnosis-related antibiotic prescriptions (see below). Since 2008, local and regional authorities, with the support of SKL, have carried out so-called 'point prevalence measurements' (*punktprevalensmätningar*) twice a year, but these do not allow for the measurement of infections in real time.
2010	Open comparison	SKL and National Board of Health and Welfare	'Open comparisons 2010: Healthcare and social care for the elderly' (*Öppna jämförelser 2010: Vård och omsorg om äldre*)	Addresses important PS issues, including 'pressure wounds' (*trycksår*), or decubitus ulcers, and fall injuries.
2010	Law	Government / Parliament	'Patient Safety Law' (Patientsäkerhetslag), SFS 2010:659	This new law, which came into force on 1 January 2011, includes provisions for: • Notification of activities on part of healthcare institutions and professionals (chapter 1); • Responsibility on part of the caregiver (healthcare institutions) to carry out systematic PS activities (chapter 3) towards complying with the PS requirements set out by the Healthcare Law, including reporting and documentation obligations (to the National Board of Health and Welfare and to patients) as well as specific reference (§ 4) to the involvement of patients (or persons close to them) in the PS activities; • Responsibilities on part of healthcare professionals (chapter 6), including the obligation to report on wrongdoings/anomalies within the

[244] www.cehis.se/vardtjanster/infektionsverktyget

Year	Type	Authority	Title	Comment
				healthcare system (§ 4, also referred to as ***Lex Maria***);[245] and • Supervision, guidance and information sharing & dissemination (within the healthcare system as well as to the patients and the public) to be provided by the National Board of Health and Welfare (chapter 7), including addressing reports and complaints from caregivers and/or patients (or persons close to them), initiating investigations on its own accord, and undertaking actions (and sanctions) to address wrongdoings and shortcomings on part of the caregivers (healthcare institutions and professionals).[246] The law further clarifies that, ultimately, it is always the head of a county (or region) or a municipality who is responsible for PS. The new law requires all healthcare providers and care givers to draft annual '***patient safety accounts***' (*patientsäkerhetsberättelser*), which include a description of the strategies, goals and results that are available PS activities. They should outline implemented as well as future PS measures. The accounts should also define the persons responsible for the safety of patients at different levels and describe how (health)care injuries (*vårdskador*), or adverse events, are measured and monitored.
2010	Decree	Government	'Patient Safety Regulation' (*Patientsäkerhets-förordning*), SFS 2010:1369	Provides additional instructions to the Patient Safety Law, including some further specifications with regard to the responsibilities on part of healthcare professionals (chapter 7).
2011	Stra-tegy	Government	'National Medical Products Strategy' (*Nationell läkemedelsstrategi*)	Presented by the Government and developed by the Medical Products Agency in cooperation with the National Board of Health and Welfare, SKL and other actors. The strategy covers the entire medicinal value chain, from research and innovation to the monitoring of the effects in clinical practice. It puts great emphasis on PS regarding the use of medical products (including efforts to combat antibiotic resistance) and manages the effects of pharmaceutical drugs on the

[245] There is also an obligation (*Lex Sarah*) on part of caregivers to report on wrongdoings/anomalies within the social services system (which include services to disabled persons). Chapter 14, § 2 of the Social Services Law (*Socialtjänstlagen*), SFS 2001:453 and the Law on Support and Services for the Disabled (*Lagen om stöd och service till vissa funktionshindrade*), SFS 1993:387.

[246] The law also includes provisions for: (i) eligibility and limitations on the right to practice (chapters 4 and 5) as well as probations and revocations (chapter 8); (ii) penalty provisions and appeals (chapter 10); and (iii) the Authority of the Health Care Responsibility Board/Committee (*Hälso- och Sjukvårdens Ansvarsnämnd, HSAN*) (chapter 9). HSAN (www.hsan.se) is the government board authority with responsibility over strengthening PS. When the new Patient Safety Law came into force, HSAN's duties related to the handling of patient complaints were taken over by the National Board of Health and Welfare. Its role is hence now only concerned with administration of so-called jurisdictional/competence issues. See also the 2011 regulation with instructions for HSAN (*Förordning med instruktion för Hälso- och sjukvårdens ansvarsnämnd*), SFS 2011:582.

Year	Type	Authority	Title	Comment
				environment. The strategy is intended to provide a platform for discussion and development in the pharmaceutical sector at national level and to contribute to coordination and cooperation between actors (authorities, county councils and private operators). Patients are also represented in decisions pertaining to the licensing of pharmaceuticals.[247]

2. Governance

Regulation. The ***Ministry of Health and Social Affairs*** is responsible for drafting proposals for decrees (*förordningar*) or acts (*lagar*), which are both law binding once presented by the Government and approved by the Parliament. The ***National Board of Health and Welfare*** can issue directions (*föreskrifter*), which are binding, and recommendations (*rekommendationer*), which are not binding, with regard to issues related to PS. The ***Swedish Institute for Communicable Disease Control*** (*Smittskyddsinstitutet*)[248] and the ***Medical Products Agency*** (*Läkemedelsverket*)[249] can also play a role with regard to regulating PS-related areas.

Strategic planning. The ***National Board of Health and Welfare*** has been assigned by the Government to develop a national strategy and common platform for PS. While SKL also provides support to a national strategic framework for PS, responsibility for actual and more practical strategic planning lies with the county councils (or regions) and municipalities.

Implementation of programmes/initiatives. Responsibility for PS implementation lies entirely with the county councils (or regions) and municipalities (and some have progressed further than others), although SKL plays an important supporting role also in this regard. As mentioned also in Section A above, SKL is not a government agency, but an employers' organization for the regional and local authorities. As such, it can only take on certain roles on a voluntary basis or in agreement with the Government (i.e. the Government cannot assign roles to SKL without prior agreement).

Since 2008, SKL has in fact sought to create a node around which PS work should be organized and implemented (previously PS efforts were based on informal networks). As a first step to support the healthcare sector at regional and local level, SKL has developed eight ***'care bundles'*** (*åtgärdspaket*), or sets/packages of measures, within different risk areas ***towards effectively reducing the number of (health)care injuries*** (*vårdskador*), or adverse events. While HCAI are not specifically mentioned in the new PS law, three of these eight packages are concerned with HCAI (namely healthcare associated urinary infections, infections from central IV lines and post-operative wound infections). Furthermore, in 2009, various healthcare workers started working together to, based upon measurements and smaller changes, reduce the incidence of adverse events. Furthermore, in 2010, a first national measurement of basic hygiene (and clothing) routines was

[247] Paris, V., M. Devaux and L. Wei. 'Health Systems Institutional Characteristics: A Survey of 29 OECD Countries', *OECD Health Working Paper* No. 50. 2010.

[248] A government expert agency responsible for monitoring the epidemiological situation for communicable diseases in humans as well as for promoting protection against such diseases. www.smittskyddsinstitutet.se

[249] The authority responsible for regulation and surveillance of the development, manufacturing and marketing of drugs and other medicinal products towards ensuring that both the individual patient and healthcare professionals have access to safe and effective medicinal products and that these are used in a rational and cost-effective manner. It runs an telephone-based information service (*Läkemedelsupplysningen*) responding to general questions regarding medical products from the general public. www.lakemedelsverket.se

carried out and, in 2011, it was extended to include also the measurement of 'pressure wounds' (decubitus ulcers).

In December 2011, SKL, in an agreement with the Government,[250] set aside SEK 525 million to encourage the county councils (or regions) to further strengthen PS towards meeting the requirements of the new PS law (through improved communication between healthcare professionals, better education/training on issues related to PS for healthcare professionals, improved organizational culture that encourages reporting and avoids blame, etc.). This agreement provides economic incentives to support implementation of the law through performance compensation based on basic requirements and a number of indicators (including the reduction in antibiotic prescriptions or the setting up of local so called 'Strama' groups).[251]

In 1995, the ***Strategic group for the rational use of antibiotics and reduced antibiotic resistance (Strama)*** was founded as a voluntary network of experts upon the initiative of the Swedish Institute of Communicable Disease Control, the Medical Products Agency and the Reference Group for Antibiotic Questions (*Referensgruppen för Antibiotikafrågor*, *RAF*). Local Strama groups have subsequently been established in all counties in order for all relevant agencies and organizations to take joint responsibility for the development and enforcement of a coherent strategy. In 2006, Strama received an instruction and permanent financing from the Government with the aim of promoting a cross-sectoral and community-based approach that includes relevant authorities, county councils, municipalities and NGOs. The official Strama network, a voluntary coalition of the local Strama groups, was created in 2011 to support and promote increased coordination of local efforts. The Strama mechanism, now hosted by the Swedish Institute for Communicable Disease Control, is considered to have brought SE "at the forefront of establishing an integrated strategy for the control of" of antimicrobial resistance.[252]

In order to further support compliance with the new law (which requires that patients, and their families, are given the opportunity to participate in PS efforts as well as increases the demand for the healthcare system to provide information on medical injuries), ***SKL developed, in 2010 and 2011*** within the framework of another government agreement, ***a number of support material*** on patient involvement in PS work. Within the county councils, the ***patient boards*** (*patientnämnd*) are independent and impartial entities working to assist patients and families to resolve problems encountered when dealing with healthcare.[253] County councils (and indeed individual hospitals) may also have a patient ombudsman (*patientombudsman*) to whom patients can address their opinions and complaints. Furthermore, towards improving communication within the healthcare system and among healthcare professionals (but also with patients and their families), SKL has developed a tool (*SBAR verktyget*[254]) to provide and retrieve important information in a structured manner. Finally, SKL has developed guidelines for how the 'patient safety accounts' (as required by the new PS law) should be structured.

Promotion and dissemination. Promotion and dissemination activities for relevant entities and professionals (county councils, regions, municipalities, healthcare workers, social workers etc.) as well as to the general public are carried out by the National Board of Health and Welfare, SKL

[250] www.skl.se/press/nyheter_2/nyheter-2011/fortsatt-satsning-pa-patientsakerhet
[251] SKL, 2011 Activity Report on Patient Safety.
[252] 'Report from the ECDC Visit in Sweden to Discuss Antimicrobial Resistance, 25-29 January 2010', p.1.
[253] Patients can also file formal complaints with these boards, even if a high degree of under-reporting is likely; see for example Wessel, Maja et al. 'The tip of an iceberg? A cross-sectional study of the general public's experiences of reporting healthcare complaints in Stockholm, Sweden', *BMJ Open* 2012;2(1); 1-5.
[254] SBAR = Situation, Bakgrund (Background), Aktuellt tillstånd (Current state), Rekommendation (Recommendation). www.skl.se/vi_arbetar_med/halsaochvard/patientsakerhet/sbar_minskar_risker_i_varden

(again, upon agreement with the Government), the Swedish Institute for Communicable Disease Control and the Swedish Council on Health Technology Assessment (*Statens Beredning för medicinsk Utvärdering, SBU*)[255]. County councils (or regions) and municipalities can also promote and disseminate PS information to the general public (or target groups within the general population) within their areas of jurisdiction.

Collection of data and statistics. On a national level, the ***National Board of Health and Welfare*** and the ***Swedish Institute for Communicable Disease Control*** are assigned with the task of collecting data and statistics related to PS. SKL supports this national effort as well as data collection on a regional and local level, which is carried out by the county councils (or regions) and municipalities. As mentioned in Section A above, most data collection on part of the county councils (or regions) and municipalities is voluntary, although data collection for some registries (some PS related) are mandatory.[256]

SKL and the Centre for eHealth (*Center för eHälsa*) have developed the ***'Infection tool'*** (*Infektionsverktyget*). Launched in December 2011, this is a national IT-support for standardized and comprehensive documentation, feedback and follow-up of information regarding HCAI towards reducing the occurrence of HCAI and counteracting incorrect antibiotic prescriptions. The tool has been piloted at four hospitals so far and is expected to be rolled out nationally in 2014 and will be linked up with epSOS (and SepSOS, the Swedish part of the epSOS project).[257]

Surveillance of antimicrobial resistance and antibiotic use (in both human and veterinary medicine) is organized at a national level, with results published (by Strama and the Swedish Institute of Communicable Disease Control) in annual SWEDRES/SVARM reports.[258]

Monitoring and evaluation of policy implementation. The ***National Board of Health and Welfare*** has been assigned by the Government to develop of a system of indicators to monitor and follow-up on PS measures at county level. Supported by SKL, the National Board of Health and Welfare and the Swedish Institute for Communicable Disease Control are the primary entities responsible for the monitoring and, to some extent, the evaluation of PS policy implementation.

While there is no obligation on part of individual healthcare providers or care givers to submit their 'patient safety accounts' to any authority, the National Board of Health and Welfare carries out ***spot-checks*** with regard to these accounts on around 10% of all relevant institutions. This provides an indication of what has been done and what will be done (i.e. is planned).

Finally, also with regard to PS, relevant 'open comparisons' by SKL and the National Board of Health and Welfare can serve as an indirect monitoring instrument.

Apart from Strama (see above), the Ministry of Health and Social Affairs has just initiated the establishment of an ***inter-sectoral coordination mechanism (ICM)*** for activities promoting the fight against HCAI and antimicrobial resistance. The National Board of Health and Welfare will coordinate this function together with the Swedish Board of Agriculture (*Jordbruksverket*)[259].

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[255] www.sbu.se

[256] The National Board of Health and Welfare has also carried out a study (in 2002 and 2003) to estimate the incidence, nature and consequences of adverse events: Soop, Michael et al. 'The incidence of adverse events in Swedish hospitals: a retrospective medical record review study', *Int J Qual Health Care* 2009; 21(4), 285–291.

[257] www.cehis.se/vardtjanster/infektionsverktyget

[258] 'Report from the ECDC Visit in Sweden to Discuss Antimicrobial Resistance, 25-29 January 2010'.

[259] Government authority specialized in matters of agro-food policy and responsible for the agricultural and horticultural sectors. www.sjv.se

Details on its exact composition and functions are yet to be defined, but the mechanism is expected to be in place by the end of 2012.

3. Main Difficulties in Implementation

The only major difficulty with regard to implementation raised during the Study regards the coordination with education authorities for the inclusion of PS in curricula (namely the basic medicine curriculum for doctors). Minor issues presenting some implementation difficulties include legal issues and inadequate enforcement system with regard to blame-free reporting and enforcement (the *Lex Maria* mechanism is not entirely blame-free as reporting individuals might suffer sanctions). Nevertheless, as also stressed by the new PS law, PS-related 'thinking' and activities are moving away from seeking to solely identify individuals bearing responsibility for adverse events towards developing routines, processes and structures that prevent such events from occurring in the first place. It is suggested that a functional system for reporting and handling deviations or adverse events incidents (*avvikelsehantering*) is crucial for both county councils (or regions) and municipalities, not in order to punish or find 'the guilty', but in order to enhance learning and thereby prevent injuries and increase PS (which eventually will reduce the number of reported events). Financial constraints, shortage of qualified staff and the capacity of relevant entities are not considered to hinder the adoption or implementation of EU's PS policy in Sweden.

Table 3.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Financial constraints	Not an issue
Shortage of qualified staff	Not an issue
Legal issues (e.g. regarding the blame-free reporting)	Minor issue
Relevant entities capacity (especially non-hospital facilities)	Not an issue
Inadequate enforcement system (e.g. name-blame systems, which disincentive open reporting of adverse events)	Minor issue
Complex coordination with education authorities for the inclusion of PS in curricula	Major issue

4. Available Indicators

The ***National Board of Health and Welfare***, upon a Government assignment, is currently ***in the process of developing of a system of indicators to monitor and follow-up on PS measures*** at county level.

A group of researcher at the University of Linköping has been assigned the role of evaluating SKL's PS initiative (which is a direct consequence of the PS policy and law) up until 2014 (part of the evaluation includes yearly surveys among PS expert within the county councils).[260]

[260] Swedish Association of Local Authorities and Regions. 'Patient safety activity report for 2011' (*Patientsäkerhet, Verksamhetsberättelse för 2011*), March 2012.

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.4	Alignment of Data Classification Systems to Standardised Given Procedures	A national 'term bank' exists with standardized classifications exists for measurable and comparable data. The Swedish system generally includes internationally used classifications. The National Board of Health and Welfare has also developed, together with other Nordic counterparts and for the Nordic Council of Ministers, a Nordic standard and framework for quality measurements.[261] The indicator is deemed: **definitely valid**; **highly feasible** (to be used as indicator in the national monitoring system).
2	ANA.1	Adoption of a Methodology/Problem Definition in line with international standard	National definitions are based on international standards (for credibility), but adopted to national circumstances. Generally in line with international standards, with some national (Nordic) adaptations or additions – a separate definition of 'healthcare injury' (*vårdskada*), or adverse injury, has for example been developed. The indicator is deemed: **fairly valid**; **highly feasible** (to be used as indicator in the national monitoring system).
3	OUT.1	Specific Outcome Indicator for the Stated Objective	National outcome indicators still under development, but, with the exception of those referring to obstetric trauma, SE will not use the OECD ones. With the exception of the two obstetric trauma indicators 6&7, SE is not adopting the OECD indicators – the other indicators (1 through 5) are not relevant because so much goes under-reported (they indicate only what is reported, not what actually happens). Data/information collected, on a ward level, by caregivers (public and private hospitals, clinics, health centres) through the 'Infection Tool' (*Infektionsverktyget*) and 'point prevalence measurements' (*punktprevalensmätningar*). The indicator is deemed: **definitely valid** (Outcome indicators are certainly relevant, but not necessarily the OECD ones); **highly feasible** (Outcome indicators to be included in the national monitoring system. Data already now collected at a local (hospital and ward) level and will also be collected at a national/regional level once the 'Infection Tool' (*Infektionsverktyget*) has been rolled out completely).
4	PROG.1	Establishment of a PS Strategy / Programme / Action Plan covering the Whole Population	A complete national PS strategy is under development, while the strategies of counties (and private hospitals, clinics, health centres and individual practitioners) are represented by the 'patient safety accounts' (*patientsäkerhetsberättelser*). The indicator is deemed: **fairly valid** (However, what is really the definition of a strategy or action plan? This has to be specified clearly – for example, while SE does not yet have an official and outlined PS strategy, PS is a clear priority with a new law, a recent agreement on numerous efforts between the government and SKL, etc. Need to look at substance, i.e. what actually is taking place, and not only on apparent strategy/action plan);

[261] 'Nordisk kvalitetsmåling i sundhedsvæsenet', TemaNord 2010:572, Nordic Council of Ministers: www.norden.org/da/publikationer/publikationer/2010-572

	Code	Indicator	Notes
			fairly feasible (Not to be used as indicator in the national monitoring system, but the 'patient safety accounts' (*patientsäkerhetsberättelser*) can provide data/information in this regard).
5	PROG.2	Number of RE with Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	The indicator is deemed: **fairly valid** (Considered as relevant, but perhaps not so important. Again, they believed it to be more relevant to look at what has actually been done and what concretely will be done on a regional/local level than looking at just strategies/action plans); **highly feasible** (To be used as indicator in the national monitoring system and information available through the 'patient safety accounts' (*patientsäkerhetsberättelser*). However, it might be more difficult to collect this information in larger decentralized countries).
6	PROG.3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	Same as above (PROG.2).
7	PROG.RES	Preparation of a Specific Programmes, such as (but not only) Research Projects, on PS-related Subject	There is no national research programme specifically targeting PS issues, but there are several PS-related research activities (data/information on these is, however, apparently not collected). Institutions carrying out PS-related research include the Royal Institute of Technology (*Kungliga Tekniska Högskolan, KTH*), Medical Management Centre (MMC) at *Karolinska Institutet (KI)*, etc. The indicator is deemed: **fairly valid** (Considered relevant, but not so important); **not feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected – it is very difficult to have an overview of what is actually going on with regard to PS-related research). <u>Proposed change</u>: Rather than looking for entire research 'programmes' in the PS field (which might not exist), the indicator should address research 'activities/initiatives' related to PS (both commissioned and voluntary research). For example, there are several research efforts related to 'pressure wounds' (decubitus ulcers), but they are not necessarily part of a specific PS research programme (hard to define – where do you draw the line?). Who really prepares such research 'programmes'? Calls for a specific budget line from the government and for an independent research institution? Rather look at the 'number of institutions' that carry out PS-related research (KTH, KI, etc.)
8	PART.2	Involvement of Advocacy NGOs in the Policymaking Process (incl. RE level)	Advocacy NGOs (interest groups) are frequently involved in the process (depending on the issue at hand as most NGOs represent very specific and special interests). The indicator is deemed: **of dubious validity** (NGOs commonly drive only very specific and special interests and the involvement of interest groups does not necessarily improve PS; for example, the so called Amalgam group scared rather than properly informed the process – fillings should not be removed as they then release the toxic substance); **hardly feasible** (Not be used as indicator in the national monitoring system and data/information apparently not collected).

	Code	Indicator	Notes
9	PART.3	Provision of Support to Advocacy NGOs active in the Given Policy Field (incl. RE level)	Support (financing) is given to some interest groups, but this sort of data/information is, however, apparently not collected. The indicator is deemed: **of dubious validity** (same as above, PART.2); **hardly feasible** (Not be used as indicator in the national monitoring system and data/information apparently not collected – would be too time consuming).
10	RES.1	Existence of Research Programmes in the PS Field	There is no national research programme specifically targeting PS issues, but there are several PS-related research activities (data/information on these are, however, apparently not collected). The indicator is deemed: **definitely valid** (If the wording is changed, see proposed change below, this indicator was considered more relevant than PROG.RES in order to show the existence of some kind of competence in the field); **fairly feasible** (Not to be used as indicator in the national monitoring system, but data/information could be collected). Proposed change: Again, look at 'activities/initiatives' rather than entire 'programmes'. Perhaps also look at the involvement of patients in research (now supported by the new PS law in SE for example) – additional indicator?
11	RES.2	Resources Made Available by MS to Research Programmes in the PS Field in Either Absolute or Relative Terms	The indicator is deemed: **fairly valid** (However, there was some concern over how one can actually measure and compare this; it needs to be standardised and requires that resources/funds are available at a national level); **hardly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected; would require some time to check allocation of government grants to this area).
12	RES.3	Number of Studies/ Publications Produced by Research Programmes in PS Policy Field	The indicator is deemed: **of dubious validity** (A study or publication says very little about the actual PS situation, or policy, in a country. This was not considered a good indicator since MS can do a good PS job even without producing studies/publications. Furthermore, most research is international; not necessarily only by Swedish institutions or researchers, but rather published in collaboration (internationally) - so how do you measure this?); **hardly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected. It would be fairly time consuming to search for studies / publications related to the various PS related research activities/initiatives and would require detailed instructions on how to search for such studies/publications by Swedish authors).
13	RES.4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature	Same as above (RES.3).
14	AWA.1	Information/Awareness Raising Campaigns on PS issues in a Given Year (period)	Various such initiatives are carried out (mostly on a county level), but data/information on the number, content, etc. is apparently not currently collected (maybe SKL?). The indicator is deemed: **fairly relevant** (Considered to possibly be a relevant indicator, as a 'concrete measure', even if campaigns usually

	Code	Indicator	Notes
			cost a lot of money and do not necessarily have an impact on awareness. Similarly, even if there are no campaigns in a given year, actual awareness might be high in any case. It is hence more important to consider actual level of awareness, (see AWA.2), even if it is hard to measure); **hardly feasible** (To be used as indicator in the national monitoring system, but data/information currently not collected., Data/information can be collected on a national level and should be retrievable from the counties/municipalities as well, but it would be time consuming.
15	AWA.2	Level of Awareness about PS issues among the Population	A Nordic patient information and satisfaction survey (with some PS-related questions), developed by a working group of the Nordic Council of Ministers, has been carried out and might contain some information on level of awareness. The indicator is deemed: **definitely valid**; **fairly feasible** (Apparently to be used as indicator in the national monitoring system, even if data/information is apparently not yet collected. Feasibility depends on whether a whole survey mechanism is actually in place – requires quite a machinery. Furthermore, surveys are costly and their actual effectiveness, or objectivity, is dubious, according to some). <u>Proposed change</u>: More relevant to talk specifically about awareness of 'risks' than of general PS 'issues' – i.e. what kind of risks am I facing as a patient if I do this or that procedure and what can I myself do to reduce that risk?
16	AWA.3	Trend in the Level of Awareness about PS issues among the Population	Same as above (AWA.2).
17	AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target	The indicator is deemed: **of dubious validity** (The population does not necessarily have an effect); **not feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected - difficult to quantify and would involve a time consuming search).
18	FUND.1	Total Budgeted Funds to Specifically Implement PS Policy in Absolute or Relative Terms	The indicator is deemed: **definitely not valid** (Everything does not necessarily cost money. It is more about doing things right, following the correct procedures, not necessarily about spending money. Furthermore, PS-related funds cannot be defined or measured objectively); **not feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected. It would be time consuming to collect data/information on amount of funds as PS-related issues are not budgeted for separately).
19	FUND.2	Total Public Expenditure to Specifically Implement PS Policy in Absolute or Relative Terms	Same as above (FUND.1).
20	FUND.3	Total dedicated infection control	The indicator is deemed:

	Code	Indicator	Notes
		staff (absolute terms or per 1000 beds)	**of dubious validity** (This indicator is not considered relevant as 'dedicated' infection/hygiene control staff might actually work also on other, 'normal', issues; even if staff is assigned as infection control, they might work 80% in 'normal' capacity – hard to know); **hardly feasible** (Apparently not to be used as indicator in the national monitoring system, but still under discussion within the Swedish Institute for Communicable Disease Control, and data/information is apparently not yet collected. It would not be so easy and very time consuming to collect data on number of staff at various hospitals, etc.).
21	ORG.1	Identification of a Body Responsible for Policy Coordination / a Focal Point	SKL and the National Board of Health and Welfare function as such focal point(s). Countries like SE, without national control/management (hierarchy), work more on building networks between various entities and SKL can for example provide a platform for this. The indicator is deemed: **definitely valid** (It is very important to have a national entity that can support interpretation of methods, issue guidelines, etc. in cooperation with decentralised entities. However, there might be no formal such body, but in practice this role is in any case carried out well informally – refine definition of such a body; see proposed change below). **fairly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected, but can be done; also at local level). Proposed change: In a country like SE, with local self government, it is not useful to talk about a body 'responsible' for policy coordination, etc., but rather a body that 'provides support'.
22	ORG.2	Routine Interaction with European Institutions on PS by Means of a Well-identified Institution	The National Board of Health and Welfare carries out this role, part of networks (also through the Nordic Council of Ministers). The indicator is deemed: **fairly valid** (even MS are all so different in the ways they work on PS-related issues); **fairly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected, but, if specifications are made on how to measure 'routine interaction', it would be feasible – see proposed change below). Proposed change: What does 'routine interaction' actually involve? – needs to be specified/quantified.
23	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices in PS Area	SKL aims to provide this type of support. The indicator is deemed: **fairly valid** (However, while it is very important that best practice support exists, it does not necessarily have to be in the form of a 'centre of expertise'. There might be several entities with different instruments for disseminating best practices, so maybe the indicator could be rephrased per proposed change below. Again, MS are all structured in different ways); **fairly feasible** (even if not to be used as indicator in the national monitoring system and data/information is apparently not collected at county/local level).

	Code	Indicator	Notes
			Proposed change: There are some concerns over the wording ('centre of expertise') – it can maybe be rephrased to 'knowledge banks'. It is important that this kind of support exists, but not how it is organised (it is irrelevant if there is a separate centre of expertise since such support can also be provided by another type of entity).
24	NET.1	Creation of a Network of Institutions to Implement the PS Policy	SKL can be seen to have this role since the counties (primary implementing entity) collaborate through it. Regarding the prudent use of antimicrobial agents, there are the Strama network and the local Strama groups. The indicator is deemed: **of dubious validity** (While it is important to have an overall PS strategy and objective in place, it is not considered necessary to measure how the implementation is organised by such a specific indicator); **hardly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected. It would also be hard to measure and be like "comparing apples with oranges" since countries organise the implementation of their PS strategies differently).
25	DEL.2	Number of RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents	Current status / Possible data sources: 2 - Blame-free reporting: *Lex Maria* (an active reporting system for 'abnormalities' - even if not completely blame free since it could involve sanctions). 3 - HCAI surveillance system: the 'Infection Tool' (*Infektionsverktyget*) and 'point prevalence measures'. 1, 4 & 5 - Other modalities: information retrievable only on specific hospital/clinic, or even ward, level. The indicator is deemed: **definitely not valid** (This indicator was considered as too specific since the national guidelines, which might or might not take the EU guidelines into account, should be what the RE should follow. Furthermore, some of the evidence shows that, while compliance might be relevant with regard to features 1,2 & 3, it is not with regard to features 4 & 5. Number of single rooms (4) is not a valid measure because double rooms might be used on a single basis when necessary. Increased use of alcohol handrub products (5) is not a good measure since needs to be properly used (when, etc.) – basic hand hygiene practice is a better measure; to be part of the SE list of indicators – see proposed change below); **fairly feasible** (even if very time consuming and complicated to collect relevant data for some modalities - ICT systems, # of single rooms, use of alcohol handrub products – as one needs to go to individual hospital/clinic, or even ward, level. Adaptations of 1, 2 & 3 will be used as indicators in the national monitoring system, but 4 & 5 will not be used). Proposed change: Adherence to basic hand hygiene practice is a better measure than increased use of alcohol handrub products – needs to be properly defined though (this indicator is currently under development in SE).
26	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken to Specifically Deliver Policy	The indicator is deemed: **of dubious validity** (The indicator was considered as too vague as irrespectively of the size it is difficult to establish to what extent a certain initiative deliver sthe the policy). **hardly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected – hard to measure).
27	TRAI.1	Implementation of Training Courses on PS-related Subject for Healthcare Personnel (incl.	The indicator is deemed: **of dubious validity** (It is not necessary to implement specific courses – PS issues can be dealt with and integrated into normal management and quality assurance processes);

	Code	Indicator	Notes
		RE level)	**not feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected - hard to measure as there are probably also plenty of private course offerings related to PS issues). Proposed change: In case need to specify what kind of training – part of basic, specialist or further training curricula?
28	TRAI.2	Total Number of Trained Healthcare Workers on PS-related Subject	Same as above (TRAI.1).
29	TRAI.3	Resources Made Available for Training in PS-related subject in Absolute or Relative Terms	Same as above (TRAI.1 and TRAI.2).
30	TRAI.4	Introduction of PS in Relevant Curricula (incl. RE level)	PS not yet part of standard curricula (medicine studies); discussions to introduce an obligatory PS course is currently ongoing. The indicator is deemed: **valid** (if you look only at the basic curricula for becoming a doctor - medicine studies); **highly feasible** (if you look only at the basic curricula for becoming a doctor - medicine studies; even if not to be used as indicator in the national monitoring system and data/information is currently not collected).
31	EVAL.1	PS policy evaluation (i.e. regular review of practices and standards)	Some relevant official government inquiries (*statens offentliga utredningar*, *SOU*) as well as potential (future) evaluations by the Swedish Agency for Health and Care Services Analysis. The indicator is deemed: **definitely valid**; **highly feasible** (To be used as indicator in the national monitoring system even if data/information currently not collected in a systematic manner).
32	EVAL.2	Change of PS Policy as a result of the above evaluation	The indicator is deemed: **fairly valid**; **hardly feasible** (Not to be used as indicator in the national monitoring system and difficult to measure; how do you standardise this? Possible data sources could be relevant official government inquiries, (*statens offentliga utredningar*, *SOU*), which include proposals for change in policy (or law) and government bills).
33	EVAL.3	Establishment of a System of Indicators to Monitor Policy Implementation	Indicators system currently being developed by the National Board of Health and Welfare. All indicators will not be followed-up all through the national level (i.e., some indicators will only be valid at the individual hospital/clinic, or even ward, level, while others are relevant only at the county level). There are also the 'open comparisons' (*öppna jämförelser*) between counties (and municipalities). The indicator is deemed: **definitely valid**; **highly feasible** (To be used as indicator in the national monitoring system and partly done already through the 'open comparisons' (*öppna jämförelser*) between counties).
34	EXC.1	Contribution by the MS of its Policy Experiences to the *PS*	The indicator is deemed: **fairly valid** (Considered relevant, as it is good that MS follow suit also internationally, but not so important);

	Code	Indicator	Notes
		and Quality of Care Working Group *Not mere participation but presentation of national / regional policy*	**fairly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected. Once identified the data/source, the measurement is relatively easy).
35	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	The indicator is deemed: **of dubious validity** (Generally not considered a good measurement. The reasons for MS not complying with reporting requirement might vary; not necessarily because they have not done anything with regard to PS, but because of lack of resources or time or other more urgent priorities than complying with reporting requirements); **hardly feasible** (Not to be used as indicator in the national monitoring system and data/information is apparently not collected).

***RE**=Relevant Entity

Proposed additional indicators

Indicator	Comments
Outcome indicator: occurrence of 'healthcare injuries' (*vårdskador*), or adverse events.	This is the most important outcome indicator currently under development in SE – need to properly and specifically define how to measure/quantify it (type, intensity, etc.).

D – Cancer Screening (CS)

1. Legal, Policy and Institutional Framework

The first important step towards defining a specific CS policy in SE are the 2007 national guidelines for breast, colorectal and prostate cancer (*nationella riktlinjer för bröst-, kolorektal- och prostatacancer*) and the 2009 national cancer strategy (*en nationell cancerstrategi för framtiden*). Within the framework of the latter, in February 2012, the National Board of Health and Welfare put forward a proposal for a recommendation of a national model for the implementation, assessment and monitoring of national screening programmes (with regard to breast, cervical and colorectal cancer).

The national cancer strategy foresaw the creation of ***Regional Cancer Centres*** (*Regionala Cancercentra, RCCs*) in each of the six 'healthcare regions' for the coordination and development of the regional resources for cancer related healthcare services (covering everything from prevention and early diagnosis – including screening - to treatment and follow-up as well as palliative care) towards providing more equal cancer care throughout the country. The six RCCs are now in place and are responsible for the planning and monitoring of regional CS programmes as well as for the regional cancer/tumour registries. They should also be in charge of the continuous evaluation of results of applied interventions. Finally, and more generally, the RCCs should be actively involved in the development of national guidelines for cancer related areas.

Table 1.1 - Legal, policy and programming framework

Year	Type	Authority	Title	Comment
2006	Official government inquiry	Ministry of Health and Social Affairs	'Patient data law' (*Patientdatalag*), SOU 2006:82	Includes an assessment of whether a special statutory regulation is required for the regional cancer registries (but not directly screening registries).
2008	Law	Government / Parliament	'Patient data law' (*Patientdatalag*), SFS 2008:355	A new patient data law, adopted on 28 May 2008, which leaves room (perhaps depending on interpretation) for establishing national/regional screening registries over healthy people, but the debate is still ongoing.
2007	Guide-lines	National Board of Health and Welfare	'National guidelines for breast, colorectal and prostate cancer' (*Nationella riktlinjer för bröst-, kolorektal- och prostatacancer*)	Include guidelines for breast cancer and colorectal screening. A further update of the national guidelines is currently being prepared and a new preliminary version is expected for 2013.
2008	Policy bill	Government	'Renewed National Public Health Policy' (*En förnyad folkhälsopolitik*), Prop. 2007/08:110	The policy (adopted by Parliament on 5 June 2008) particularly recognises the challenges of non-communicable diseases, including cancer (even if screening is not specifically addressed – in this regard it refers to the then ongoing official government inquiry's proposal for a national cancer strategy).
2009	Official govern-ment inquiry	Ministry of Health and Social Affairs	'National cancer strategy' (*En nationell cancerstrategi för framtiden*), SOU 2009:11	The strategy addresses population-based screening of cervical cancer, breast cancer, colorectal cancer, prostate cancer and hereditary cancers as important tools in preventive care. In this regard, the proposal especially points to the importance of increasing participation in already existing as well as forthcoming screening programmes

Year	Type	Authority	Title	Comment
				and highlights the lack of yearly follow-up/monitoring and data of participation levels on a national level. Finally, it calls for increased investments in preventive care as well as for improved prevention knowledge creation and sharing.
2011	Open compa-rison	National Board of Health and Welfare and SKL	'Open comparisons of the quality and effectiveness of cancer care' (*Öppna jämförelser av cancersjukvårdens kvalitet och effektivitet*)	These comparisons address breast and colorectal cancer, but not cervical cancer. Even if screening related indicators *per se* are not (perhaps yet) included, other indicators (related to diagnosis) can feed back to preventive care.
2012	Pro-posal for recom-menda-tion	National Board of Health and Welfare	'Model for the introduction of national cancer screening programmes' (*Modell för införande av nationella screeningprogram på cancerområdet*)	Proposal for a recommendation of a model for the implementation, assessment and monitoring of national screening programmes (with regard to breast, cervical and colorectal cancer) developed within the framework of the national cancer strategy. The proposal discusses the possibility of law-binding regulation of CS in the future, but this calls for further inquiry and takes time (in the meantime, the Board opts for a recommendation since it can be issued in the near future).

2. Governance

Regulation. In general terms, the state is responsible for formulating overall policies and establishing basic principles. The ***Ministry of Health and Social Affairs*** is responsible for drafting proposals for decrees (*förordningar*) or acts (*lagar*), which are both law binding once presented by the Government and approved by the Parliament. The ***National Board of Health and Welfare*** can issue directions (*föreskrifter*), which are binding, and recommendations (*rekommendationer*) or guidelines, which are not binding.

With specific regard to CS, very little national regulation currently exists apart from the screening guidelines for breast and colorectal cancer. However, in a 'Model for the introduction of national cancer screening programmes' (*Modell för införande av nationella screeningprogram på cancerområdet*), the National Board of Health and Welfare[262] makes a proposal for a recommendation to county councils and municipalities for a model for the implementation, assessment and monitoring of national screening programmes (with regard to breast, cervical and colorectal cancer). The proposal will be further anchored through consultation with municipalities, county councils and other organisations before a final recommendation is formulated. The model will also be developed further in collaboration with SKL based on more detailed information.

Finally, as foreseen by the 2009 national cancer strategy, the RCCs will also be actively involved in the development of national guidelines for cancer related areas, including screening.

Strategic planning. While responsibility for actual and practical strategic planning with regard to CS lies with the county councils (or regions), supported by the RCCs with regard to regional strategic planning, the ***National Board of Health and Welfare provides a national strategy***

[262] Based on consultations with SKL, SBU, relevant professionals, patient associations, head of the county councils, etc.

framework for CS activities (as presented by the 2012 proposal for a model for national CS programmes).

Implementation of programmes/initiatives. Responsibility for the implementation of CS programmes and related activities lies entirely with the county councils (or regions). The RCCs will play a central role in supporting the county councils (or regions) in the implementation of screening programmes.

The current national screening guidelines with regard to ***breast*** cancer recommend the full 40-74 year age range on a nation-wide level. Nevertheless, in practice, some county councils differ slightly with regard to both the age of the target group and the screening intervals.[263] In 2011, the cooperation group of the RCCs established a working group for mammography that will: (i) work for regional and national coordination; (ii) outline basic definitions; (iii) develop regional action plans for increasing participation; and (iv) develop a national quality register.

National ***cervical*** CS guidelines are presently being revised (a first proposal for recommendation was made in 1998) as screening methods have not yet been established. In the meantime, the cooperation group of the RCCs has set up a working group also for the prevention of cervical cancer. This group shall: (i) ensure a clear structure/organisation for screening efforts; (ii) outline collective basic definitions and quality indicators; (iii) develop a national quality register, and (iv) propose a concrete strategy for future measures. SKL will put forward a proposal for a national randomised screening study to be carried out before a recommendation is drafted.

The roll-out of nationwide, population-based screening programmes regarding both breast cancer (for women between 40 and 74 years of age) and cervical cancer (for women between 23 and 60 years of age) was complete already in 2007.[264]

While ***colorectal*** CS guidelines exist, population-based screening programmes are currently carried out (piloted) only by the Stockholm county council and Gotland. In January 2012, SKL put forward a proposal (prepared by the national working group for colorectal CS, as set up by the cooperation group of the RCCs) for a national randomised screening study to be carried out.

SKL provides support to county councils (or regions) in the implementation of CS activities. It is currently (2010-2012) undertaking a project to increase participation in the national screening programmes for breast and cervical cancer. More specifically, the project seeks to achieve: (i) a coverage ratio of at least 85% for cervical screening tests; (ii) a participation rate of at least 80% for mammography; and (iii) a more equal participation in screening activities (with regard to socio-economic and ethnic factors).

Promotion and dissemination. County councils (or regions), supported by the RCCs, are responsible for promotion and dissemination activities related to CS and targeted at the general public (or target groups within the general population). SKL could also, based on agreements, carry

[263] See also an account of the Stockholm county council's breast CS program: Lind, Helena, Gunilla Svane, Levent Kemetli, and Sven Törnberg. 'Breast Cancer Screening Program in Stockholm County, Sweden – Aspects of Organization and Quality Assurance', *Breast Care* (Basel). 2010;5(5), 353–357.

[264] European Commission, DG for Health and Consumers and the International Agency for Research on Cancer. 'Cancer Screening in the European Union: Report on the implementation of the Council Recommendation on cancer screening - First Report', 2008. Commission Report (2008)882final on the 'Implementation of the Council Recommendation of 2 December 2003 on cancer screening', 22 December 2008.

out such a function towards relevant entities and professionals (county councils, regions, healthcare workers, etc.).

Collection of data and statistics. The ***National Board of Health and Welfare is currently responsible for the national cancer registry*** (and possibly the national CS registry, if set up) for which data collection and reporting is mandatory on part of county councils (or regions). The six RCCs will be responsible for the regional cancer/tumour registries (and possibly the regional CS registries, if set up) – see also sub-section 3 below.

Monitoring and evaluation of policy implementation. While the ***National Board of Health and Welfare*** plays an important role as a national 'supervisor', the six RCCs will be responsible for the monitoring of regional CS programmes. They are also to be in charge of the continuous evaluation of results of applied interventions.

The Swedish Organised Service Screening Evaluation Group (SOSSEG), a scientific group of researcher with the University Hospital (*Akademiska Sjukhuset*) in Uppsala, carries out evaluations of CS initiatives.

In 2010, upon request by the government (Ministry of Education), the Swedish Research Council (*Vetenskapsrådet*)[265] was assigned the task of evaluating investments in strategic research areas, including cancer (even if CS is not specifically mentioned in the evaluation assignment, it is one of the research areas for which the Council provides funding).

Finally, 'open comparisons' can represent an indirect monitoring mechanism. These comparisons can in fact assist in the implementation of policy since no county council wants to be the "poorest student of the class". To encourage enforcement of policy, disseminating the outcomes of the open comparison is considered to be very important.

3. Main Difficulties in Implementation

It appears that the primary factors most negatively influencing the adoption and implementation of EU's CS policy to be legal and political/cultural issues regarding the setting up of CS registries (and linking these to cancer and/or mortality registries). Apart from the more concrete legal privacy issues (even if the new the patient data law seems to, depending on interpretation, open up to the possibility of screening registries,), there is substantial political/cultural concern over including healthy people in registries. The debate is still ongoing, even if the general acceptance of keeping records over healthy people appears to be growing. Resource constraints (both financial and human) and technical and organisational issues connected to the complexity of nationwide screening programmes were only considered as minor issues affecting implementation. Factors not believed to influence Sweden's adoption or implementation of EU's CS policy include timing issues (i.e. that results and impacts might materialise only after a much longer period) and the potential lack of a sound efficiency assessment of CS.

[265] A government agency that provides funding for basic research of the highest scientific quality in all disciplinary domains. Besides research funding, the agency works with strategy, analysis, and research communication. www.vr.se

Table 3.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Financial constraints (human and financial)	Minor issue
Timeframe, the results and impacts will materialise after a much longer period	Not an issue
Lack of a sound efficiency assessment of CS	Not an issue
Technical and organisation issues connected to the complexity of CS nationwide programmes (issues of capacity, training of staff, management and service delivery etc.)	Minor issue
Legal issues in setting up registries as requested, and linking them to mortality databases (e.g. issues of personal data management)	Major issue
Cultural and political issues (e.g. political sensitivity of the matter in certain cultural environment, political difficulties to maintain a long-term commitment in this area etc.)	Major issue

4. Available Indicators

Great need was felt to monitor and follow-up adherence to CS guidelines and alike. There are currently no collective, standardised routines for the monitoring or assessment/evaluation of national population-based CS programmes. The National Board of Health and Welfare has been assigned by the Government to develop a model for monitoring routines and presented a proposal in February 2012.[266] This can be considered a first step in setting up a proper monitoring system. The proposal specifically calls for the setting up of a national health data register covering the individuals to whom the CS programmes will be directed. Currently there is no national register for breast CS, but some county councils (or regions) have monitoring systems in place (even if with different designs, IT-solutions and variables). County council quality registers for cervical CS exist throughout the county and, through the cooperation of the RCCs, a national quality register is under development. With regard to evaluation, the Swedish Organised Service Screening Evaluation Group (SOSSEG), a scientific group of researcher with the University Hospital (*Akademiska Sjukhuset*) in Uppsala, carries out evaluations of CS initiatives.

[266] 'Model for the introduction of national national cancer screening programs' (*Modell för införande av nationella screeningprogram på cancerområdet*), National Board of Health and Welfare, February 2012.

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.2	Compliance with Data Comparability Criteria based on Expert Assessment	The indicator is deemed: **definitely valid**; **highly feasible** (Not yet used as indicator in SE, but currently under development. Data/information to be collected by the Regional Cancer Centres, RCCs).
2	HAR.3	Establishment of Special Registries (centralised data systems for the management and assessment of CS data)	The indicator is deemed: **definitely valid**; **highly feasible** (Not yet used as indicator in SE, but currently under development (problem with including healthy people in a registry). Data/information to be collected by the RCCs).
3	HAR.4	Alignment of Data Classification Systems to Standards defined by the *European Network of Cancer Registries*	The indicator is deemed: **fairly valid** (Considered as relevant, but not so important); **highly feasible** (Not yet used as indicator in SE, but currently under development. Data/information to be collected by the RCCs).
4	ANA.1	Formal Adoption of the EU CS Guidelines (incl. RE* level) *Clearly distinguish b/w breast, cervical and colorectal CS*	National guidelines for breast, colorectal and prostate cancer (*Nationella riktlinjer för bröst-, kolorektal- och prostatacancer*) include guidelines for screening: (i) breast CS guidelines are in line with EU guidelines; and (ii) colorectal CS guidelines are currently not in line with EU guidelines (population-based screening programmes piloted in two counties). National cervical cancer guidelines presently being revised, but current screening practices are in line with EU guidelines. The indicator is deemed: **fairly valid** (even if it is more relevant that the national guidelines are followed. The national guidelines might however include or use the EU, and other, guidelines as support); **fairly feasible** (Not used as indicator in SE, but the RCCs might be able to provide data/information).
5	ANA.2	Evidence of a Significant Debate in the Scientific Literature of the MS about CS methodology and specifically the EU Guidelines	2012 report of the Cancer Fund refers to the EU guidelines. Significant current debate in Nordic scientific literature doubting/questioning mammography. The indicator is deemed: **definitely not valid** (This would be particularly hard for smaller countries and research is also not really nationally confined anymore); **not feasible** (Not used as indicator in SE and data/information apparently not collected – impossible to monitor).
6	ANA.3	Effective Outreach Level of the EU Guidelines in the MS (downloads, web pages visited) in Absolute or Relative Terms (% of the target population) *Clearly distinguish b/w breast, cervical and colorectal CS*	EU guidelines are available on various web sites (SKL, etc.). The indicator is deemed: **of dubious validity** (It is believed that it would be more relevant that the EU guidelines are reflected in the national guidelines and that they are made available; how many times they are downloaded, etc. were not deemed important); **fairly feasible** (Not used as indicator in SE, but data/information could be collected).
7	OUT.1	Specific Outcome Indicator for the Stated Objective	The indicator is deemed: **definitely valid**;

	Code	Indicator	Notes
			highly feasible (Not yet used as an indicator in SE, but currently under development. Data/information to be collected by the RCCs).
8	IMP.1	Specific Impact Indicator for the Stated Objective	The indicator is deemed: **definitely valid** (It is important to specify what you wish to reach, but perhaps with adaptation; by 2030?); **highly feasible** (even if not used as an indicator in SE, but data/information possibly to be collected by the RCCs. Furthermore, it might also be hard to assess those caught in the interval between one screening and another, i.e. what does the screening catch and what does it not catch?).
9	PROG.1	Establishment of a CS Strategy / Programme / Action Plan covering the Whole Population *Clearly distinguish b/w breast, cervical and colorectal CS*	2009 proposal for a national cancer strategy (*en nationell cancerstrategi för framtiden*). 2012 model for the introduction of national cancer screening programmes (*modell för införandet av nationella screeningprogram på cancerområdet*). The indicator is deemed: **definitely valid** (It is definitely important to set national goals); **highly feasible** (Apparently to be used as indicator in SE and data/information possibly to be collected by the RCCs.
10	PROG.2	Number of RE with CS Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered) *Clearly distinguish b/w breast, cervical and colorectal CS*	Screening programmes are in place in all counties with regard to breast and cervical cancer. SKL could collect information on this through the 'open comparisons' (*öppna jämförelser*) between counties (and municipalities). Only Stockholm and Uppsala counties currently have pilot programmes for population-based screening of colorectal cancer. The indicator is deemed: **fairly valid** (It is important that national goals are followed through on regional and local level, but perhaps not so important (superfluous) an indicator; more interesting in case to know % of target population reached); **fairly feasible** (Not yet used as an indicator in SE, but maybe under development. Data/information possibly to be collected by the RCCs).
11	PROG.3	Number of RE with a CS Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only *Clearly distinguish b/w breast, cervical and colorectal CS*	Population-based screening programmes for colorectal cancer being piloted in Stockholm and Uppsala counties. The indicator is deemed as above (PROG.2).
12	LEG.1	Adoption of appropriate data protection legislation	Debate over privacy issues is still ongoing in SE, but there is a growing acceptance of including healthy people in registries. New patient data law in 2008. The indicator is deemed: **fairly valid** (even if not so important; not a key issue); **fairly feasible** (even if not used as indicator in SE and possibly hard to measure in some countries).
13	LEG.2	Appropriate data protection legislation Discussed but Not Yet Adopted	Same as above (LEG.1).

	Code	Indicator	Notes
14	LEG.3	Appropriate data protection legislation Still under Preparation and in its Drafting Stage	Same as above (LEG.1 and LEG.2).
15	AWA.1	Information/Awareness Raising Campaigns on CS in a Given Year (period)	The indicator is deemed: **of dubious validity** (if dissemination of EU GL is included); **not feasible** (Not used as indicator in SE and data/information is currently not collected; possibly to be collected by the RCCs. There so many initiatives and it would be hard to count them all). Proposed change: Perhaps the wording can change from 'campaign's to 'activities' – not always necessary to launch full scale campaigns, but targeted information leaflets in the appropriate places might be enough in some cases.
16	AWA.2	Level of Awareness about CS issues among the target Population	The indicator is deemed: **of dubious validity**; **not feasible** (Not used as indicator in SE and data/information is apparently not collected. Hard to measure – only by surveys).
17	AWA.3	Trend in the Level of Awareness about CS issues among the target Population	Same as above (AWA.2).
18	AWA.4	Estimate of Population Reached by Information Initiatives on EU guidelines in Absolute Terms or Relative to the Potential Target	The indicator is deemed: **not valid** (National interpretations and guidlines are most important, even if they commonly are based upon EU recommendations); **not feasible** (Not used as indicator in SE and data/information apparently not collected – it would be too time consuming to count them all).
19	FUND.1	Total Budgeted Funds to assure appropriate organisation and quality control of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is deemed: **of dubious validity** (Funds are not considered really important to assure improved processes); **not feasible** (Not used as indicator in SE and data/information is apparently not collected. It would be impossible to monitor in a decentralised system).
20	FUND.2	Total Public Expenditure to assure appropriate organisation and quality control of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	Same as above (FUND.1). The indicator is deemed: **of dubious validity** **not feasible**
21	FUND3	Total dedicated staff to implement and assure quality of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is deemed: **of dubious validity** (Number of staff not considered really important to assure improved processes); **not feasible** (Not used as indicator in SE and data/information is apparently not collected. It would be impossible to monitor in a decentralised system).

	Code	Indicator	Notes
22	DEL.1	Population Reached by CS Programmes in the country, in Absolute or Relative Terms (out of the target population) *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is deemed: **definitely valid**; **highly feasible** (once the RCCs work properly. Not yet used as an indicator in SE, but currently under development. Data/information to be collected by the RCCs).
23	DEL.2	Compliance with the Relevant Features of CS Implementation Modalities Stated in the EU Documents (incl. RE level)	The indicator is deemed: **fairly valid** (Indicator considered relevant even if (i) the total number of screened individuals is what is really important and (ii) the national guidelines are more important. There might also be modalities that should not be recommended); **hardly feasible** (Not used as indicator in SE. Difficult to measures even if data/information could possibly be collected by the RCCs). Proposed change: No need to distinguish between types of screening (population-based or opportunitistic); the total figure of people screened is what is important (choice of methods depends on what goals you set and on the situation).
24	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken, i.e. CS programmes set up *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is deemed: **of dubious validity** (Not considered important. There are plenty of initiatives, but there is no need to map them. And some are effective, while others not. The important is the general process, not the specific initiatives); **hardly feasible** (Not used as indicator in SE even if data/information could possibly be collected by the RCCs).
25	CAP.1	Compliance with Given Equipment Technical Standards and Operational Procedures	The indicator is deemed: **of dubious validity** (Considered too detailed; there is no need to control the specifics or technicalities if the process is in place); **hardly feasible** (Not used as indicator in SE and data collection and verification would be time consuming even if information could possibly be collected by the RCCs).
26	PRO.1	Introduction of a Given Procedure in CS Routine Operations (incl. RE level)	The indicator is deemed: **definitely valid** (It is important for proper screening and for procedures to be comparable); **fairly feasible** (Not yet used as an indicator in SE, but currently under development. Data/information possibly to be collected by the RCCs). Proposed change: 'Given' procedures need to be further specified; too vague like this.
27	PRO.2	Number of Relevant Institutions Complying with Procedure (incl. RE level)	Some monitoring is already done through the 'open comparisons' (*öppna jämförelser*) between counties (and municipalities). The indicator is deemed: **fairly valid** (Considered relevant, but not so important. In the case of SE, compliance will be resolved by itself through 'open comparisons' (*öppna jämförelser*) between counties (and municipalities); "no one wants to be the poorest student in the class"); **fairly feasible** (Not used as indicator in SE even if data/information could possibly be collected by the RCCs).

	Code	Indicator	Notes
28	TRAI.1	Implementation of Training Courses on CS for Healthcare Personnel (incl. RE level)	The indicator is deemed: **definitely not valid** (Not considered eloquent); **not feasible** (Not used as indicator in SE and data/information apparently not collected – it would be too complicated to monitor and impossible to answer).
29	TRAI.2	Total Number of Trained Healthcare Workers on CS	Same as above (TRAI.1).
30	TRAI.3	Resources Made Available for Training on CS in Absolute or Relative Terms	Same as above (TRAI.1 and TRAI.2).
31	EVAL.1	Evaluation of data from tests, assessments and diagnosis	The indicator is deemed: **definitely relevant**; **fairly feasible** (Not used as indicator in SE, but data collection, through the RCCs, would be feasible once the CS registries are all in place).
32	EVAL.2	Change of CS Policy as a result of the above evaluation	The indicator is deemed: **of dubious validity** (Evaluation results are considered most important; changes in policy will come spontaneously and hence do not need to be measured). **not feasible** (Not used as indicator in SE and data/information is apparently not collected. Difficult to measure - how would a change in policy be measured? Surveys?).
33	EVAL.3	Regularly Monitor CS Implementation and Outcome *Clearly distinguish b/w breast, cervical and colorectal CS*	The indicator is deemed: **definitely relevant**; **highly feasible** (once the process, through the RCCs is in place. Not yet used as an indicator in SE, but currently under development. Data/information to be collected by the RCCs and some monitoring is already done through the 'open comparisons' (*öppna jämförelser*) between counties[267]).
34	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	The indicator is deemed: **of dubious validity**; **hardly feasible** (Not used as indicator in SE and data/information is apparently not collected. It could be considered feasible only if the reporting requirements involved only a basic summary (print-out) of information that can be retrieved from the regional and national registries).
35	REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing CS Containing Information Not Shared with the EU	The indicator is deemed: **of dubious validity**; **hardly feasible** (Not used as indicator in SE and data/information is apparently not collected. It would be cumbersome to collect such reports at various levels/places).

***RE**=Relevant Entity

[267] 'Open comparisons' of the quality and effectiveness of cancer care (*Öppna jämförelser av cancersjukvårdens kvalitet och effektivitet*) could possibly include screening related indicators as well.

Proposed additional indicators

Indicator	Comments
Existence of some sort of ‘knowledge centre’.	An additional measure could be if there is an entity through which best practices are shared (for example, where can RE learn from what others, both at home and abroad, have done to increase participation in screening programmes?).

ANNEX E – CASE STUDY REPORT: POLAND

A – Overall Health Strategy (White Paper)

1. Legal, Policy and Institutional Framework

Table 1.1 - Legal and Policy Framework

Year	Type	Authority	Title	Comment
1997	Law	Parliament	Law on universal health insurance system (*Ustawa o powszechnym ubezpieczeniu zdrowotnym*)	Enacts adequate provision of various types of care and public health activities.
2004	Law	Parliament	Law on publicly funded healthcare services financed (*Ustawa o świadczeniach zdrowotnych finansowanych ze środków publicznych*)	Defines obligations of regional and local self-governments with respect to healthcare.
2004	Decree	Ministry of Health	National Health Plan 2004-2013 (*Narodowy Plan Zdrowia na lata 2004-2013*)	The most important document aimed to improve the health of the Polish population. The list of strategic objectives concentrates on prevention and treatment of main diseases with the goal of decreasing mortality.
2007	Decree	Ministry of Health	National Health Programme 2007-2015 (*Narodowy Program Zdrowia na lata 2007-2015*)	The main objective of the National Health Programme is to decrease social and territorial differences in the health status of the population.
2011	Law	Parliament	Law on medicalactivity (*Ustawa o działalnościmedycznej*)	Defines rules for medical activity, including monitoring and registration as a medical professional.

The Policy Background. The healthcare system in its current shape in Poland is a result of the reform process that took place over the past 15 years. The reforms undertaken were shaped by a number of ***laws aimed at creating a health insurance system***, with adequate provision of various types of care as well as public health activities. Public health in Poland is organised into a quasi-centralised system, with regulatory and decision-making competences at the central level of administration and decentralisation of policy implementation[268]. As regards public health, an important mechanism was created by the ***2004 Law on publicly funded healthcare services***, whereby obligations of regional and local self-governments with respect to healthcare were defined. The Ministry of Health has been working on a draft ***law on public health*** in recent years. The goal of the new law would be to create a system of management of public health at the central and local levels of administration. The project foresees "soft" management based on existing public health programmes: ***National Health Plans*** and the ***National Health Programme***. The concept of "soft" management should respond to the structure and share of responsibilities as in use within public administrations, with transfer of responsibilities to regional and local governments for the implementation of various public health activities and programmes. The project has been reportedly influenced by some foreign models – especially Finland. The project proposes new financing mechanisms by creation of funds dedicated to specific public health policies. The project is still at a

[268] Aluttis, C. et al. 2012: Review of Public Health Capacity in the EU. Supplementary document to the final report. Maastricht/The Netherlands, March 2012

very early stage of preparation; it has not been presented to the Parliament yet nor has it been subjected to so-called 'social consultations'.

Implementation of some public health activities has shifted to regional competence, based on the above mentioned ***Law on publicly funded healthcare services*** and on the ***laws regulating actions and obligations of regions, counties and local governments***. Regional administrations in Poland are divided into **governmental administrations** and **self-governmental administrations**.

With respect to public health, their share of responsibilities is as follows:

- ***Regional governments*** (*Urząd Wojewódzki*) monitor implementation of health policy in the region, the core of which is defined by the National Health Programme, and stimulate activities of regional and local self-governments with respect to health policy. Regional governments create an annual Action Plan addressing the main health problems and lines of action to be undertaken, but they do not translate the proposed policies into a specific health strategy.
- ***Regional self-governments*** (*UrządMarszałkowski*), as well as county and local self-governments (*powiat* and *gmina*) bear responsibility for actual implementation of health policy actions. Some public health activities are assigned to the regional and local self-governments by the rule of law (i.e. actions against alcohol consumption) with financial resources allocated to them. While regional governments do not have any financial resources for specific health policy actions, regional self-governments and local self-governments have the power to implement actions with the financial resources assigned to them. Some regional self-governments create a complete public health Action Plan in the form of a regional strategy, to a large extent based on the National Health Programme. However, this practice is uncommon. It is common sense that actions undertaken at regional and local levels should be responsive to local needs. However, monitoring of the National Health Programme implementation shows that most of the actions undertaken at local level do not always take these needs into account and focus mostly on actions related to alcohol consumption. Local initiatives are also often undertaken in response to specific temporary needs. In such cases, they are conceived as short-term initiatives, and do not constitute elements for any long-term public health strategy.

The main policy documents in the field of public health and prevention include:

- ***National and Regional Health Plans for 2004-2013***[269]. The National Health Plan is by far the most important document aimed to improve the health of the Polish population. The list of strategic objectives concentrates on prevention and treatment of main diseases (cardiovascular system diseases, cancers, etc.) with the goal of decreasing mortality. It creates a framework for Regional Health Plans and requires the monitoring the population health status. It is also linked with health programmes targeting specific diseases, i.e. POLKARD (cardiovascular system diseases prevention and treatment programme), and the National programme of cancers prevention. The other mechanism was introduction of inter-sectoral approach, with supervision of the Steering Commitee.

- ***National Health Programme for 2007-2015***[270]. The main objective of the National Health Programme is to decrease social and territorial differences in the health status of the population. Specifically, the programme proposes various policy actions to target age cohorts at greater health risk (i.e. the youth and the elderly), actions to tackle behavioural health risks (smoking, alcohol consumption), and to increase the accessibility of prevention and medical services. The National Health Programme is a guideline for activities in the field of prevention for the

[269] http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/narodowy_plan_zdrowia_30042004.pdf
[270] http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/zal_urm_npz_90_15052007p.pdf

Regional Public Health Centres, regional governments, regional and local self-governments and the local healthcare units. The policy draft was discussed with experts in each of the proposed fields of action. These experts were supervised by the Ministry of Health and came from a variety of specialised institutions including, *inter alia*, the Centre of Oncology, the Institute of Labour Medicine, the National Institute of Public Health and the National Centre for Quality Assessment in Healthcare. After consulting these institutions for specific policy goals, all the elements were combined into a final draft of the Programme. The main challenge was to persuade the experts from each institution that the Programme would tackle first and foremost prevention and health promotion issues, and no so much medical treatment. Another feature of the Programme is that it endorsed intersectoriality by introducing a Steering Committee; *de facto*, however, cross-cutting cooperation is still at an early stage.

Regulation and Strategic Planning. The Council of Ministers is responsible for overall public health strategy legislation, while specific acts are prepared by the Ministry of Health. The Ministry can cooperate with the Public Health National Consultant, an additional advisory partner. Proposals of any new legal act have to be approved by both parliamentary chambers and by the President. The Parliament is endowed with a Health Commission which can make amendments to the proposed law, and so can any other MP.

At regional level, both types of regional government can be involved in strategic planning. Typically, the regional government (*urząd wojewódzki*) prepares short-term (one year) policies and points out main directions for actions, while the regional self-government is responsible for long-term strategic planning, and is in charge of allocating financial resources.

2. Governance

Various institutions are responsible for implementation of concrete public health programmes and initiatives:

- The ***Ministry of Health*** is responsible for the overall management of the healthcare sector, including public health. The main departments responsible for policy are the ***Health Policy Department*** and ***Public Health Department***. The former coordinates implementation of the National Health Plan and sectoral action plans therein (e.g., Polkard and National programme on cancer prevention), while the latter coordinates the implementation of the National Health Programme.
- The ***National Health Fund*** contracts out medical services that are foreseen to be provided, also within health plans (i.e. screenings). It has a payer function, managing financial resources from the health insurance contributions.
- ***Medical services providers*** are responsible for provision of services as contracted with the National Health Fund.
- ***Regional self-governments*** are responsible for implementation of activities within the National Health Plan and the National Health Programme. They are also owners of medical facilities, what means that indirectly they are responsible for planning managing provision of services (i.e. by decision on types and number of medical providers in a given area, assurance of access to appropriate medical infrastructure, etc.). The latest National Health Programme suggested that the implementation of public health activities should be highly decentralised; this bottom-up approach has given a greater margin of manoeuvre to the regional administrations and encouraged local initiatives.

Promotion and dissemination of policy directions, strategic plans and actions is the responsibility of:

- The ***Ministry of Health*** outlines the strategic plans on public health and promotes them via public campaigns by assuring appropriate financial resources. The Ministry of Health directly supervises promotion and information policy in some areas (e.g. cancer screening).
- The ***Public Health National Consultant*** can be involved in the promotion and media information campaigns; it can also lobby for some solutions or public health policies in the Parliament.
- The ***National Public Health Institute*** is responsible for producing knowledge-based policies, such as conferences, seminars and international projects (i.e. EuroHealthNet), and for promoting relevant research projects.
- The ***regional governments and self-governments*** directly promote policies with respect to public health reaching directly target groups. They do organise information campaigns, activities such as leaflets distribution, sending invitation letters to target groups, etc.

3. Data Collection, Evaluation and Monitoring of Policy Implementation

Data Collection. There are various institutions responsible for data and statistics collection; some are specific registers (i.e. National Cancer Register), while some others are repositories of broader types of information. These include:

- The ***Ministry of Health*** that collects data on activities within the health sector, ranging from pharmaceutical to financial and public health data;
- The ***National Institute of Public Health*** collects and publishes data and reports on the health status of the Polish population, prevention policy (i.e. vaccinations), public health policy (monitoring the National Health Programme);
- The ***National Health Fund*** collects and publishes financial data from the health insurance system; and
- The ***Centre for Information Systems in Healthcare*** is responsible for digitalisation of healthcare system institutions and creates the most comprehensive databases. This is still in the process of implementation.

Monitoring and Evaluation. *Monitoring* of policy implementation is the responsibility of:

- The ***Ministry of Health***, with respect to the overall health policy;
- The ***Public Health National Consultant***, with respect to public health (this is an advisory body, consulted also in cases of medical malpractice);
- The ***National Institute of Public Health*** monitors the implementation of the National Health Programme on an annual basis; and
- The ***regional governments*** monitor actions undertaken in the framework of the National Health Programme in their respective regions.

The process of baseline assessment started in 2005 and lasted for approximately one year. The previous edition of the National Health Programme[271] was monitored with respect to health outcomes and health status of the population. A baseline assessment included an overview of the health status of the Polish population and progress made over the Programme years.

Also a separate survey was conducted by the Polish Society of Hygiene among public health experts. The survey asked what priorities in public health and risk factors should be addressed by the new policy given the current socio-economic situation in the country. The survey showed that

[271] The previous edition of the National Health Programme was established for the period 1995-2005 with the strategic goal of improvement of health and quality of life3 of the society.

there was a concern with health inequalities, lifestyle-related health determinants (smoking, alcohol consumption) and the need was shown to address the health risks of the most sensitive groups, namely the youth, the elderly and the disabled.

Based on the above assessment the priorities for the 2007-2015 Programme were drafted. These priorities were then discussed in focus groups consisting of representatives of medical institutes supervised by the Ministry of Health, including the Oncology Centre, the Centre for Psychiatry and Neurology, the TBC and Lung Diseases Institute, the Institute of Cardiology and the Institute of Mother and Child. The *evaluation* of policy outcomes and impact assessment is the responsibility of the Ministry of Health, but with respect to public health no evaluation has been conducted.

4. Overall EU Health Policy Adoption/Implementation

Although EU recommendations in public health have been well received in Poland, the level of uptake could be much greater. The country is presently faced with a number of bottlenecks that slow down policy adoption. Such bottlenecks range from gaps in human resources, to financial constraints to a patchy level of awareness of select public health issues across the country.

Table 4.1 – Assessment of possible factors affecting the adoption and implementation of EU policy

Obstacles/drivers	Comments
Institutional architecture (since uptake might be more difficult in more decentralised systems)	This is deemed a considerable barrier due to different sensitivities in the regions.
The different nature of the soft law instrument chosen by the EU, i.e. whether Recommendations, Council Conclusions, or Commission Communications (since MS may attribute a different level of priority or deal with them in a different way)	There is not an issue as long as the Ministry of Health is open in line of principle to ideas promoted at the EU level irrespective of the nature of the soft-law instrument. These however are poorly circulated. Recommendations maybe are however *de facto* slightly better known.
Prior adequate discussion / consultation period before the adoption of a EU Policy (since this may facilitate adoption)	Policy implementation has never been hindered by an insufficient previous consultation process. The system of consultation and consensus building on specific issues is well organised by the EC.
Other aspects of legislative techniques adopted to put pressure on recipients (such as the inclusion in the text of deadlines for compliance or explicit reporting requirements)	This is considered a problem, caused mainly by financial constraints that strained the policy making process in Poland. So any instrument to further strengthen the EU policy message is welcome including scoreboards.
Issues of national ownership (since policy items put forward in the European agenda by individual MS may encounter resistance in other MS due to national experiences, cultural factors, traditions or technical obstacles to transposition)	There are no issues of ownership at the national level. But awareness of public health problems greatly varies between counties, which might cause some problems and diverging sensitivities; however, this difficulty can definitely be overcome over time.
Adequate maturity, i.e. existence of sufficient evidence ('pilot' experiences, evaluations, scientific studies) supporting the inclusion of a given policy approach in the European agenda	There is often a lack of sufficient domestic supportive evidence to judge on the degree of maturity for the national agenda. The system of public health registers is highly insufficient in Poland and it is not consistent with the Eurostat standards and recommendations. This area needs further attention and substantial strengthening.
Programming capacity (since some MS could find it difficult to cope with the total number of programmes, action plans, strategies requested by the EU in a given period. Not only for internal capacity constraints, but also for the duration of the political approval process)	So far the institutional capacity of the Polish government to deal with and integrate EC programmes has been insufficient due to lack of resources and staff. Many hope that with the introduction of the new law on public health it will be possible to overcome this barrier.

Obstacles/drivers	Comments
Clear prioritisation of actions (since the inclusion of too many European items in the policy making agenda might be ultimately detrimental for most urgent priorities, particularly in times of financial crisis)	Prioritisation of public health as such in Polish policy making is a huge problem. In result financial resources devoted to public health are insufficient, and also human capital in this field in insufficient. In these conditions there is room for only a very few real priorities where resources can be concentrated.
Existence of relevant OMC / JA mechanisms on the subject at the European level and the MS participation therein (since this may facilitate adoption)	The Polish presidency proposed networking with other MS as a policy tool to overcome gaps; there is support for this idea as an effective way to develop a national public health strategy.
Pressure from stakeholders' groups or lack thereof (since this may ultimately influence uptake)	This does not seem to be a major issue. The influence of NGOs is limited

B – Health in All Policies

1. Legal, Policy and Institutional Framework

Table 1.1 – Legal and Policy Framework

Year	Type	Authority	Title	Comment
2007	Decree	Council of Ministers	National Health Programme for 2007-2015 (*Narodowy Program Zdrowia na lata 2007-2015*)	The main HIAP-inclusive public health document. It is the only policy document that targets health inequalities due to social differences. With the institution of the Steering Committee it attempts to introduce intersectoral policy analysis and management.

The Policy Background. Looking for evidence of a HIAP policy making process would be far-fetched, as there is no dedicated policy in this field. However, steps taken to introduce the HIAP concept in Poland can be summarised as follows. The most important document on Health in All Policies in Poland is the ***Rome Declaration*** signed by the Representative of the Polish government on 18 December 2007 and promoted by the EU Finnish Presidency[272]. With the exception of the ***National Health Programme***, there are no laws or policy documents directly incorporating the HIAP concept. The Programme is the main public health document, implemented in approximately 20% of territorial local self-governments (*gmina*). At the central level of administration, the Programme is managed by a ***Steering Committee*** chaired by the Prime Minister, typically represented by the Ministry of Health, and it also includes high officials from all Ministries, and representatives of other institutions (such as the Agency for the Prevention of Alcohol Abuse, the Chamber of Physicians and various NGOs). The Programme is therefore the main HIAP instrument in Poland. The idea of establishing the Steering Committee is inspired to the Rome Declaration, although the Declaration is not mentioned anywhere in the Programme document. Typically, as it meets the Steering Committee discusses future programming and the contents of the National Health Programme implementation reports. While meetings should stimulate intersectoral activity, this is hardly the case, in actual practice, so that it is rare that any health-related initiative is taken by Ministries other than the Health Ministry.

Another initiative promoting the HIAP approach –might be a new law on public health, currently under preparation. HIAP should be promoted by the new law not only at national, but also at regional level and at the administrative level of territorial self-governments. The new law should incorporate the Health Impact Assessment (HIA) mechanism. This information was confirmed by the National Consultant on Public Health, who began to work on the draft of this policy together with the Parliamentary Health Commission and the Ministry of Health. Still, the preparation of the new law is at an early stage.

While at the national level the impact of the HIAP approach is limited, some initiatives are undertaken at the regional or even at the level of localised territorial administration. For instance, the National Institute of Public Health is often informed of cooperation between regional self-government Health departments and Educational and Transport departments.

[272] Stahl T., Wismar M., Ollila E., Lahtinen E., Leppo K., (2006), Heath in All Policies, Prospects and Potentials, Ministry of Social Affairs and Health, Finland

Examples of HIAP-related initiatives undertaken in Mazowieckie region are:

- Establishment of a committee working on HIV/AIDS awareness and prevention involving the regional government and self-government administration, NGOs and social services authorities;
- Inclusion of educational and social policy institutions in the implementation of the National Health Programme;
- A Working Group on mental health problems consisting of representatives from the Ministry of Health, regional government and self-government administration and social services authorities;
- A programme on the promotion of organ transplantation based on common agreements between, *inter alia*, healthcare service providers, the Ministry of Health, the National Chamber of Physicians, churches and schools;
- Support for the programme of "Schools promoting health" designed by the Ministry of Education. The programme includes, among others, promotion and information activities on healthy nutrition, prevention of obesity, dental health projects.

Regulation and Strategic Planning. Since HIAP implementation is erratic, it is difficult to point out to a HIAP governance structure and to a HIAP policy process as such. However, based on the evidence at hand (specifically, the Programme), it can be said that HIAP regulation is the responsibility of the Council of Ministers and the Ministry of Health. They are in the process of drafting and presenting a proposal of the aforementioned new public health law to the Parliament. Also, a Public Health National Consultant participates in the process and should closely cooperate in this field with all parties involved (the Council of Ministers, the Ministry of Health and the Parliament).

At the same time, planning of specific activities that incorporate HIAP would the competence of the National Health Programme Steering Committee, although this rarely happens in actual practice. Typically, the Steering Committee accepts reports on the National Health Plan monitoring, but does not usually propose new initiatives.

2. Implementation and Promotion

While policy coordination at the central level is not effective, it often takes place at the regional or even local levels of administration. ***Regional governments*** and regional, county and local ***self-governments*** participate in intersectoral initiatives combining public heath activities with educational and social policy institutions. It was noted that at the regional level ***NGOs*** have proven important partners in the implementation of public health policy. In the ***Mazowieckie Region***, for instance, representatives of the regional governmental and self-governmental administrations, the central administration and NGOs are brought together in a *Health Forum*. This successfully promotes and implements programmes on a variety of public health themes: prevention of smoking, organ transplantation, and so forth.

The National Institute of Public Health organises basic HIAP promotional activities and organises the meetings of the National Health Programme Steering Committee. The Institute is also involved in research on HIAP in other countries and is a partner in EuroHealthNet[273], an European initiative of networking policy makers, experts and professionals from various fields, to promote and implement knowledge-based, intersectoral activities in public health. At regional level, governmental and self-governmental administrations promote their own public health activities, including those that are intersectoral and/or involving third sector organisations (NGOs).

[273] Marinetti C., Stegeman I., Kuipers I., Crossing bridges. Developing methodologies and building capacity to advance the implementation of HiAP and achieve health equity. Project overview. EuroHealthNet, 2011 http://ec.europa.eu/health/social_determinants/docs/ev_20110405_co08_en.pdf

3. Data Collection, Evaluation and Monitoring of policy implementation

No activities on data collection or overall policy evaluation with respect to HIAP have been identified. Similarly, **t**here is no direct monitoring of HIAP implementation, with the exception of National Health Programme monitoring, which is undertaken on an annual basis, and for which regional level administration often meet. Such meetings can be considered inter-sectoral in as far as representatives of regional departments other than Public Health participate. To sum up, there has been no evaluation or monitoring of HIAP uptake and/or implementation. The main reason is that the policy is hardly implemented, although some elements are planned to be implemented in the future. Also, there is currently no relevant promotion of HIAP implementation and monitoring from the EC (i.e. no proposal of specific policy measures or monitoring indicators).

4. Policy Implementation and Indicators

Table 4.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comment
Lack of a clear legal framework for HIA use in the public administration	This factor is thought to have had a moderate/quite relevant impact on policy implementation.
Availability of sufficient epidemiological information as a precondition / privacy issues	This factor is thought to have had a moderate impact on policy implementation.
Availability of a sufficient number of professionals trained in the subject matter	There is disagreement on the impact this factor has had. Some consider it a major issue, others not an issue.
Lack of a centre of expertise	There is disagreement on the impact this factor has had. Some consider it a major issue, others not an issue.
Political resistances in principle (e.g. to considering income distribution also a health equity issue)	This factor is thought to have had a major impact on policy implementation.
Lack of a technical secretariat responsible for coordinating intersectoral cooperation / HIA	This factor is thought to have had a major impact on policy implementation. Such a secretariat would be needed and should be established by the Ministry of Health.
Lack of active dissemination of HIAP principles at all Government levels	This factor is thought to have had a major impact on policy implementation.
Resource constraints	This factor is thought to have had a major impact on policy implementation.
Lack of convincing evidence coming from other Countries' experiences	This factor is thought to have had a moderate/major impact on policy implementation.

Table 4.2 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	ANA.1	Formal Adoption of EU HIAP definition and HIA methodology (incl. RE* level)	This indicator would be relevant but it is not currently in use. Information could be made available from the National Institute of Public Health. The indicator is deemed: **highly feasible** **fairly valid**
2	ANA.2	Evidence of a Significant Debate in the Scientific Literature about HIAP	Same as above. The indicator is deemed: **highly feasible** **fairly valid**
3	PRI.1	Existence of Health Policy Documents Including a Commitment to HIAP Principle (incl. RE level)	This indicator would be relevant but it is not currently in use. Information could be made available from the National Institute of Public Health. The indicator is deemed: **highly feasible** **fairly valid**
4	PRI.2	Reporting to International Organisations of Commitment to HIAP Principle (for instance in the WHO Healthy Cities programme)	Same as above. The indicator is deemed: **highly feasible** **fairly valid**
5	PRI.3	Strategies/Programmes/Action Plans Specifically focusing on HIAP (incl. RE level)	This indicator would be relevant but it is not currently in use. Information could be made available from the National Institute of Public Health, as it coordinates the National Health Programme. The indicator is deemed: **highly feasible** **fairly valid**
6	PART.1	Existence of Advocacy NGOs Active in the HIAP Field	Identifying NGO activities would be very difficult. According to information from the Mazowieckie region, NGOs are very active, but it is hard to collect actual information on cooperation with them. The indicator is deemed: **not feasible** **of dubious validity**

	Code	Indicator	Notes
7	PART.2	Involving of Advocacy NGOs in the Policymaking Process (incl. RE level)	Same as above. The indicator is deemed: **not feasible** **of dubious validity**
8	RES.2	Resources Made Available by MS to Research Programmes in HIAP Field in Either Absolute or Relative Terms	This is not considered a relevant or a feasible indicator, given that there is no HIAP strategy in Poland. The indicator is deemed: **not feasible** **of dubious validity**
9	ORG.1	Identification of a Body Responsible for HIAP Coordination / a Focal Point	This indicator would be relevant but it is not currently available. Information could be made available from the Ministry of Health. The indicator is deemed: **highly feasible** **definitely valid**
10	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices on HIAP (including HIA methodology)	This indicator would be relevant but it is not currently in use. Information on HIAP conferences could be made available from the Ministry of Health and the National Institute of Hygiene. This information may start to be collected in the future. The indicator is deemed: **fairly feasible** **definitely valid**
11	PRO.1	Introduction of HIA in Routine policy-making process (incl. RE level)	This indicator would be relevant but it is not currently in use. Information could possibly be made available from the National Institute of Public Health. The indicator is deemed: **not feasible** **fairly valid**
12	PRO.2	Number of Relevant Institutions Complying with the above Procedures (incl. RE level)	Same as above. The indicator is deemed: **not feasible** **fairly valid**
13	EVAL.1	Implementation of Evaluations / Cost Effectiveness Assessments of their Policies (incl. RE level)	This indicator would be relevant but it is not currently in use, nor is related information available. The indicator is deemed: **not feasible** **definitely valid**

	Code	Indicator	Notes
14	EVAL.2	Streamlining / modification of Policy as a Result of an Evaluation Exercise / Cost Effectiveness Assessment (incl. RE level)	Same as above. The indicator is deemed: **not feasible** **definitely valid**
15	EVAL.3	Setting up of a System of Indicators to Monitor HIAP uptake / Implementation (incl. RE level)	This indicator would be relevant but it is not currently in use. Information could possibly be made available from the National Institute of Public Health. The indicator is deemed: **highly feasible** **definitely valid**

***RE**=Relevant Entity

C - Patient safety

1. Legal, Policy and Institutional Framework

Patient safety as such is not prioritised in the Polish public health agenda. Poland is one of the three EU countries ***without a national patient safety strategy or even a policy document*** (European Commission 2012). There is also not even an official patient safety definition agreed on that could serve as the basis for national policy formulation[274].

However, there are various institutions involved in assuring quality of care, sanitary conditions and safety of citizens. Their activities are anchored in a number of legal acts, which are referred to in Table 1.1 below. Some of the laws refer to goals much broader than patient safety (e.g. citizen safety), introduce laws that have an impact on quality of services in healthcare (i.e. law on food and feeding safety, law on Chief Sanitary Inspectorate). The most relevant piece of legislation in terms of patient safety and quality assurance in healthcare are the ***Law on Accreditation in Healthcare*** and the ***Law on Patients' Rights and Patients' Ombudsmen***. The former defines standards for accreditation of medical facilities (mainly hospitals), taking into account quality of services provided and patients' safety. Accreditation is awarded to a medical facility by the Ministry of Health, based on the opinion of the accreditation institute – the ***National Centre for Quality Assessment in Healthcare***. The patients' rights law defines patients' rights, rules for access to medical documentation, obligations of medical facilities towards patients' right, competencies of Patients' Rights Ombudsmen and procedures to be undertaken if patients' rights are not respected.

Table 1.1 - Legal, Policy and Programming Framework

Year	Type	Authority	Title	Comment
1985	Law	Parliament	Law on Chief Sanitary Inspectorate (*Ustawa o Państwowej Inspekcji Sanitarnej*,– unified document)	Amended in 1985, 1998, 2006.
2006	Law	Parliament	Law on food and nutrition safety (*Ustawa o bezpieczeństwie żywności i żywienia*,– unified document)	Amended in 2010.
2008	Law	Parliament	Law on prevention and treatment of infectious diseases (*Ustawa o zapobieganiu oraz zwalczaniu zakażeń i chorób zakaźnych u ludzi*)	
2008	Law	Parliament	Law on accreditation in healthcare (*Ustawa o akredytacji w ochronie zdrowia*)	Amended in 2009 (Dz.U.09.76.641)
2008	Law	Parliament	Law on Patients' Rights and Patients' Ombudsment (*Ustawa o prawach pacjenta i rzeczniku praw pacjenta*,)	Amended in 2011

[274] Somekh, D., Working package 2: Mapping exercise of activities related to patient safety in EU countries London: ESQH Office for Patient Safety, 2007

Responsibility for patient safety is shared by various institutions, including the Ministry of Health, healthcare providers and further institutions involved in public health activities that address some aspects of patient safety and patients' rights. Bearing overall responsibility for patient safety, the Ministry of Health, however, does not have a specific department dealing with patient safety issues. This responsibility has *de facto* shifted to the ***National Centre for Quality Assessment in Healthcare*** (*Centum Monitorowania Jakości w Ochronie Zdrowia*).

Institutions otherwise involved in monitoring safety but with no implementation role also include (i) the ***Association of Patients' Rights Ombudsmen*** which intervenes whenever patients' rights are encroached on, (ii) the ***Chief Sanitary Inspectorate*** which is responsible for monitoring sanitary conditions in medical facilities. ***Regional authorities*** (*wojewoda*) bear some responsibilities with respect to monitoring conditions for registering medical facilities that can provide services to the public. While there has been ***no national incident reporting system***[275], patients can assert their rights via various mechanisms, some of them introduced only as late as in 2012. Patients can report incidents related to medical malpractice to the Patients' Rights Ombudsmen, but they can also report the case to the judicial authorities or to the Chamber of Physicians. Either way, the case is analysed and the hospital is fined accordingly if evidence shows that the physician has made a mistake[276]. Procedurally speaking, action has been taken to increase reporting on adverse events by healthcare workers. For instance, Poland has a learning and reporting system which is differentiated from disciplinary systems and procedures for healthcare workers, in order to ensure non-punitive context of reporting. In practice, however, no information is available as to the reporting of adverse events by health professionals.

The former system to process incident reports was dated and often ineffective, especially due to the length of the compensation process. It has been replaced with an institution processing claims for ***financial compensation*** in case of malpractice. This reform was adopted by the regional governments and enacted in 2011 with an amendment to the ***Law on Patient's Rights and Patients' Ombudsmen***. The new institutions are ***regional commissions for judging medical incidents*** (*wojewódzka komisja do spraw orzekania o zdarzeniach medycznych*). These commissions consist of 16 members; 14 of them are legal representatives (i.e. judges, advocates) and medical practitioners appointed by the regional government (*urząd wojewódzki*), joined by a Ministry of Health official and one member of the Patient's Rights Ombudsmen Association. Since this body has only been recently activated, it has only been processing incidents reported in 2012. Once again due to its recent inception, it is not yet possible to opine on its scope and effectiveness.

Overall, institutions' involvement in patient safety has led to practical actions to prevent complications and adverse events in the following areas: (i) Medication related events; (ii) Complications during or after surgical interventions; (iii) Complication and adverse events during and after blood/blood components transfusion; (iv) Complication and adverse events during and after tissue transplantation; (v) Complication and adverse event during and after organ transplantation; and (vi) Complication and adverse event during and after organ living donation.

Finally, a number of NGOs have been involved in patient safety. By far the most active, *Primum non Nocere* assists individuals in (i) protecting their rights, (ii) bringing the patient safety cases to court (or other judicial body), and (iii) lobbying for the establishment of the Patient's Safety

[275] Somekh, D., Working package 2: Mapping exercise of activities related to patient safety in EU countries London: ESQH Office for Patient Safety, 2007

[276] Sowa A. (2002), Upodmiotowienie pacjenta (Patient's empowerment) in: Ochrona zdrowotna w Polsce po reformie (Health care in Poland following the reform), Golinowska S., Czepulis-Rutkjowska Z., Sitek M., Sowa A., Sowada Ch., Włodarczyk C., CASE Report no 52/2002, Warsaw

Ombudsmen Association[277] (the 2008 Law enacting the Association was amended in 2011 because the 2008 provisions were too narrow). While most likely other organisations in the field of patient safety exist, it is difficult to collect information on their activities. They are often perceived as too informal to become official partners to the governmental institutions and their messages are often uncomfortable to the public officials[278]. In terms of *patients' involvement*, Poland healthcare institutions report having in place mechanisms to deliver information to the patient; they also provide patients with the list of accredited healthcare institutions.

2. Governance

Regulation and strategic planning. The central government is responsible for establishing new regulations and strategic planning in the field of patient safety. In practice, such responsibilities are shared between the Council of Ministers and the Ministry of Health.

Implementation of concrete programmes and initiatives. Several institutions responsible for implementation of specific programmes that have could have an intended or unintended impact on patient safety can be identified. There are no overlaps between them and their responsibilities are streamlined as follows:

- **National Centre for Quality Assessment in Healthcare** - responsible for the implementation of quality measures in hospital care (via accreditation mechanism);
- **Chief Sanitary Inspectorate** - responsible for inspecting sanitary conditions in workplaces, including facilities providing medical care;
- **National Medicines Institute** - responsible for inspecting the impact of medical products and pharmaceuticals on patients' health. Moreover, the inspectorate is responsible for public health in terms of monitoring hygiene in various settings, ***preventing infections and infectious diseases***, assuring environmental hygiene, as well as water and food safety;
- **National Food and Nutrition Institute** - responsible for assessing the health quality and hygiene of food supplied by mass catering institutions, including hospitals. Activities of the institute target the whole population, but have an impact particularly on the health status of patients and their food safety. The Institute is also responsible for the dissemination of knowledge of hygienic and nutritional standards, as well as for health promotion through nutrition.

The above institutions are supervised by the Ministry of Health and are called on to advise on prevention questions, although they are not directly involved in programme implementation.
The institutions in charge of upholding patients' rights in case of maltreatment are (i) ***the Patients' Rights Ombudsmen*** and (ii) the ***regional commissions evaluating medical malpractice*** (*Wojewódzka Komisja ds. Orzekania o Zdarzeniach Medycznych*).

Promotion and dissemination. There is no single institution strictly responsible for the promotion of patient safety. However, each of the above institutions is active in areas of expertise with a direct or indirect impact on patient safety as a by-product of their activity.

Conversely, the ***Polish Society for Quality in Healthcare*** stands out for it is closely implicated in patient safety issues. This is an association that since the early 1990s promotes patient safety and advocates for turning it into a stand-alone policy priority. The association is very active in raising awareness of patient safety and quality of care issues. Through trainings, workshops and

[277] Sowa, A., Upodmiotowienie pacjenta (Patient's empowerment) in: Ochrona zdrowotna w Polsce po reformie (Health care in Poland following the reform), Golinowska S., Czepulis-Rutkjowska Z., Sitek M., Sowa A., Sowada Ch., Włodarczyk C., CASE Report no 52/2002, Warsaw, 2002
[278] Somekh, D., Working package 2: Mapping exercise of activities related to patient safety in EU countries London: ESQH Office for Patient Safety, 2007

conferences, it addresses medical practitioners, managers of healthcare units, policy makers and other relevant stakeholders. The association also participates in international patient safety discussion panels. Furthermore, the association regularly collaborates with the National Centre for Quality Assessment in Healthcare. The Centre also liaises with the European Commission, OECD and WHO on the subject of patient safety, though it is not involved in the national policy making process. The Centre, together with the Polish Society for Quality in Healthcare organises conferences, often involving international audiences and speakers, where participants can exchange experiences, on occasion also on intersectoral mechanisms bringing together various institutions on patient safety.

Finally, there is hardly any activity in the *monitoring and evaluation of policy implementation and policy outcomes*. Since there is no policy on the subject, no monitoring and evaluation activity has ever taken place, nor is there an established mechanism to report on policy implementation by way of supplying data sets or statistics.

Healthcare-associated infections (HAI). There is no national or regional strategy for the prevention and control of healthcare associated infections, but one is reportedly under preparation. Similarly, as other Member States have adopted HAI Action Plan, describing what actions are needed and what institutions should take the lead to achieve the prevention and control objectives, Poland has set out to prepare its own. Simultaneously, the country is in the process of developing indicators to assess implementation of its future HAI strategy and Action Plan. At the time of writing, the main document regulating hygiene requirements and procedures with respect to HAIs is the law on prevention and treatment of infectious diseases.

Hand hygiene campaigns and updated guidelines are under preparation; meanwhile, healthcare workers' compliance with the existing guidelines has already been assessed. Hygiene in healthcare units, including hand hygiene, is supervised and regularly monitored by the Chief Sanitary Inspectorate.

A ratio for the number of ***infection control nurses*** (full time equivalent) according to healthcare institution activity had been agreed in Poland, where there are legal requirements for this (the ratio should be greater than one infection control nurse per 250 beds). The same ratio is in use for nursing homes managed by hospitals. Similarly, Poland has set a legal ratio also for the number of ***infection control doctors*** (full time equivalent) according to healthcare institution activity.

3. Difficulties in Implementation

Once adopted, patient safety policy is very likely to face a number of easily imaginable problems ranging from financial constraints to difficult coordination with the education system. However, for the time being the major bottleneck is the lack of awareness among politicians of the importance of the subject; also, insufficient resources are available to the professional societies and NGOs that could effectively work towards raising the rank of patient safety. The country cannot bypass formulating policy on quality of care before fully assimilating the importance of patient safety.

Table 3.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comment
Financial constraints	Until now all these factors have worked against the adoption and implementation of patient safety policy in Poland.
Shortage of qualified staff	
Legal issues (e.g. regarding the blame-free reporting)	
Relevant entities capacity (especially non-hospital facilities)	
Inadequate enforcement system (e.g. name-blame systems, which disincentive open reporting of adverse events)	
Complex coordination with education authorities for the inclusion of PS in curricula	
Unaware politicians and decision makers with respect to problems of public health and the need to have a coherent policy in the field	All factors above represent major obstacles, but this is arguably the most serious of all.

4. Available Indicators

Patient safety policy in Poland is still at a seminal stage, lacking an overarching strategy or any plan to introduce it. Therefore, little use is made of indicators for monitoring purposes in this field; the only monitoring activities undertaken have been few and highly dispersed, with no common objective. To end with, patient safety is not expected to climb up the agenda of national priorities any time soon.

There has been no evaluation of patient safety policy in Poland. The only review was undertaken to reply to the EC questionnaire on the development stage of patient safety policy. A quasi-evaluation can be found in the revision of the hospital accreditation standards after 10 years from their implementation. As a result of this revision, an updated list of accreditation standards and quality requirements was introduced; importantly, this list included the introduction for the first time of the term “adverse effect”. The indicators’ review was conducted by the National Centre for Quality Assessment in Healthcare at healthcare service provider level.

The concept of patient safety is poorly understood. “Patient safety” as such was introduced in Polish policy making only in 2002/2003. One-time research in this field was conducted in those years by the Polish Society for Quality in Healthcare in cooperation with the Danish Patient Safety Society. The research surveyed levels of awareness of medical malpractice among healthcare professionals. That was the first and one of the few researches on that subject. Besides, there are various indirect monitoring activities in specific fields related to patient safety; sanitation, prevention of infectious diseases, specific standards for providing medical services etc. In each of these fields standards are set, monitored and regularly updated. These patient safety standards, however, are only recommended, not mandatory. The National Health Fund, for instance, sets standards for all medical procedures; it then monitors and updates them on an annual basis during the contract procedure as fulfilling them is a prerequisite for signing a contract with the National Health Fund.

Table 4.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.4	Alignment of Data Classification Systems to Standardised Given Procedures	This indicator would be feasible and relevant. Data could be drawn from the National Medicines Institute. However, this indicator is not currently in use. The indicator is deemed: **highly feasible** **definitely valid**
2	ANA.1	Adoption of a Methodology/Problem Definition in line with international standard	This indicator would be feasible and relevant. Data could be drawn from the National Medicines Institute. The indicator is deemed: **highly feasible** **fairly valid**
3	OUT.1	Specific Outcome Indicator for the Stated Objective	No data are systematically collected through outcome indicators, although they would be relevant. Such indicators are not in use and doubts exist on their feasibility. Poland has reported being involved in the EC co-financed project on healthcare quality indicators, led by the OECD. The indicator is deemed: **not feasible** **fairly valid**
4	PROG.1	Establishment of a PS Strategy / Programme / Action Plan covering the Whole Population	This is not considered a relevant nor a feasible indicator, given that there is no PS strategy in Poland. However, if one such indicator existed it could put a spotlight on the absence of a PS strategy, and could therefore be a propeller for setting up a national PS policy. The indicator is deemed: **not feasible** **definitely not valid**
5	PROG.2	Number of RE with Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	The indicator is not adequately formulated considering that sub-national organisations in Poland are only entrusted with very limited authority over patient safety. The indicator is deemed: **not feasible** **of dubious validity**
6	PROG.3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	Same as above. The indicator is deemed: **not feasible** **of dubious validity**
7	PROG.RES	Preparation of a Specific Programmes, such as (but not	This would be a relevant indicator but it is not currently in use. As of now it is not considered feasible, and existing information is only collected on occasion, mostly for PhD research.

	Code	Indicator	Notes
		only) Research Projects, on PS-related Subject	The indicator is deemed: **hardly feasible** **fairly valid**
8	PART.2	Involvement of Advocacy NGOs in the Policymaking Process (incl. RE level)	This would be a relevant indicator but it is not currently in use. It would be feasible considering that the Polish Society for Quality in Healthcare keeps track on NGO involvement and could easily provide this information. The indicator is deemed: **fairly feasible** **fairly valid**
9	PART.3	Provision of Support to Advocacy NGOs active in the Given Policy Field (incl. RE level)	This seems pretty irrelevant as an indicator and is not currently in use. Not feasible as no organisation collects any related data. The indicator is deemed: **not feasible** **of dubious validity**
10	RES.1	Existence of Research Programmes in the PS Field	Same as above. The indicator is deemed: **not feasible** **fairly valid**
11	RES.2	Resources Made Available by MS to Research Programmes in the PS Field in Either Absolute or Relative Terms	This indicator is not adequately formulated for the Polish context, given that the offer of research programmes in this field is limited. The indicator is deemed: **fairly feasible** **of dubious validity**
12	RES.3	Number of Studies/ Publications Produced by Research Programmes in PS Policy Field	This would be a relevant indicator but it is not currently in use. Not feasible as no organisation collects any related data. The indicator is deemed: **not feasible** **definitely valid**
13	RES.4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature	Same as above. The indicator is deemed: **not feasible** **definitely valid**
14	AWA.1	Information/Awareness Raising Campaigns on PS issues in a Given Year (period)	This would be a relevant indicator but it is not currently in use. Some information would be available from the National Centre for Quality Assessment in Healthcare and the Polish Society for Quality in Healthcare, but it might be incomplete. More data would require some important effort.

	Code	Indicator	Notes
			The indicator is deemed: **hardly feasible** **definitely valid**
15	AWA.2	Level of Awareness about PS issues among the Population	This would be a relevant indicator but it is not currently in use. It could be measured among healthcare professionals, as the National Centre for Quality Assessment in Healthcare collects information through surveys on (i) number of accreditation visits, (ii) number of participants in patient safety trainings. The indicator is deemed: **highly feasible** **definitely valid**
16	AWA.3	Trend in the Level of Awareness about PS issues among the Population	Same as above. The indicator is deemed: **highly feasible** **definitely valid**
17	AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target	See AWA.1 The indicator is deemed: **fairly feasible** **fairly valid**
18	FUND.1	Total Budgeted Funds to Specifically Implement PS Policy in Absolute or Relative Terms	This would be a relevant indicator but it is not currently in use. Information would be available from various sources, such as the national budget and the National Health Fund, so in principle the indicator is feasible. The indicator is deemed: **fairly feasible** **fairly valid**
19	FUND.2	Total Public Expenditure to Specifically Implement PS Policy in Absolute or Relative Terms	Same as above. The indicator is deemed: **fairly feasible** **fairly valid**
20	FUND.3	Total dedicated infection control staff (absolute terms or per 1000 beds)	This would be a relevant indicator but it is not currently in use. Information would be available from the National Medicines Institute and the Chief Sanitary Inspectorate, so in principle the indicator is feasible. The indicator is deemed:

	Code	Indicator	Notes
			fairly feasible **fairly valid**
21	ORG.1	Identification of a Body Responsible for Policy Coordination / a Focal Point	This would be a relevant indicator but it is not currently in use. Information would be available from the National Centre for Quality Assessment in Healthcare, so in principle the indicator is feasible. The indicator is deemed: **highly feasible** **definitely valid**
22	ORG.2	Routine Interaction with European Institutions on PS by Means of a Well-identified Institution	Same as above. The indicator is deemed: **highly feasible** **definitely valid**
23	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices in PS Area	Same as above. The indicator is deemed: **highly feasible** **definitely valid**
24	NET.1	Creation of a Network of Institutions to Implement the PS Policy	This would be a relevant indicator but it is not currently in use. Information could be obtained (with difficulty, due to scarce cooperation between the few relevant bodies), from (i) an existing network of accredited hospitals and (ii) the Association of Hospitals with Accreditation in Starachowice. The indicator is deemed: **fairly feasible** **fairly valid**
25	DEL.2	Number of RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents	The indicator is not adequately formulated considering that sub-national organisations in Poland are only entrusted with very limited authority over patient safety. The indicator is deemed: **not feasible** **definitely not valid**
26	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken to Specifically Deliver Policy	This is not considered a relevant or feasible indicator, given that there is no PS strategy in Poland. The indicator is deemed: **not feasible** **definitely not valid**
27	TRAI.1	Implementation of Training Courses on PS-related Subject	This would be a relevant indicator but it is not currently in use. Information would be available from the National Centre for Quality Assessment in Healthcare and the Polish Society for Quality in Healthcare, so in principle the

	Code	Indicator	Notes
		for Healthcare Personnel (incl. RE level)	indicator is feasible. The indicator is deemed: **fairly feasible** **definitely valid**
28	TRAI.2	Total Number of Trained Healthcare Workers on PS-related Subject	Same as above. The indicator is deemed: **fairly feasible** **definitely valid**
29	TRAI.3	Resources Made Available for Training in PS-related subject in Absolute or Relative Terms	Same as above. Non-sponsored continuing specialised training was mandatory for infection control doctors and for Infection Control Nurses. The indicator is deemed: **fairly feasible** **definitely valid**
30	TRAI.4	Introduction of PS in Relevant Curricula (incl. RE level)	This would be a relevant indicator but it is not currently in use. The only information currently available is that obtained from thematic conferences and that a process is under way to develop a curriculum inclusive of core competencies in PS. None is available otherwise, so this indicator is not feasible for the time being. The indicator is deemed: **not feasible** **definitely valid**
31	EVAL.1	PS policy evaluation (i.e. regular review of practices and standards)	This would be a relevant indicator but it is not currently in use. Not feasible given that in the absence of a Polish PS strategy, no evaluation has been conducted. The indicator is deemed: **hardly feasible** **definitely valid**
32	EVAL.2	Change of PS Policy as a result of the above evaluation	Same as above. The indicator is deemed: **hardly feasible** **definitely valid**
33	EVAL.3	Establishment of a System of Indicators to Monitor Policy Implementation	This would be a relevant indicator but it is not currently in use nor feasible, since there is not a Polish PS policy. Doubts exist as to what such indicators should measure (number of PS initiatives, quality of such initiatives, other). The indicator is deemed: **hardly feasible**

	Code	Indicator	Notes
			definitely valid
34	EXC.1	Contribution by the MS of its Policy Experiences to the *PS and Quality of Care Working Group*	It is not clear what the usefulness of this indicator and would be. Related information could be found if one wanted to), but not currently in use. The indicator is deemed: **fairly feasible** **of dubious validity**
35	REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies	This would be a relevant indicator but it is not currently in use nor feasible, since there is not a Polish PS policy. The indicator is deemed: **hardly feasible** **fairly valid**

***RE**=Relevant Entity

D – Cancer Screening

1. Governance, Legal and Policy Framework

The Policy Background. The main legal document on cancer screening was established in 2005 when the ***National Programme on Cancer Prevention*** was constituted. The programme is multiannual; the planning of the various activities included in the Programme has to be agreed by the Council of Ministers. Financial resources are appropriated out of the central government budget. The law establishing the Programme was introduced in 2005 and amended in 2008, establishing that no less than 10% of the annual resources available for the Programme is to be devoted to cancer screening, including breast, cervical and colorectal cancer screening (Art. 3, pt. 2 of the law[279]).

The Law states out the main goals of the Programme, which are as follows:

- reduction of cancer morbidity;
- alignment with average European indicator levels of cancer early detection;
- alignment with average European indicators levels of cancer treatment;
- establishment of the conditions for the use of advanced knowledge of cancer prevention and treatment techniques; and
- creation of a system of regular nationwide and regional monitoring of cancer prevention.

The Programme operates since 1 January 2006. It has adopted the population-based approach to programme implementation recommended by the Council of the European Union. In 2007 the Programme shifted from a non-population-based to a population-based approach with personal invitation. It concentrates on various activities, including (i) prevention of cancers attributable to lifestyles (i.e. smoking), (ii) prevention of breast, cervical and colorectal cancers, (iii) increasing the quality of treatment and public awareness of cancer. The last Programme was approved in February 2012 and it lasts from 2012 through 2014. The plan includes:

- prevention and screening programmes, with special attention given to (i) educational activities and promotion of the European Code Against Cancer, promotion of healthy life-style; (ii) prevention and screening of cervical cancer; (iii) prevention and screening of breast cancer; (iv) prevention and screening of colorectal cancer; and (v) care for families with higher cancer risk rates;
- prescription of investment in the purchase of diagnostic equipment and cutting-edge radiotherapy equipment;
- improvement in diagnosis and cancer treatment, and specifically: (i) improvement in lung cancer treatment; (ii) improvement in diagnosis of leukaemia among adults, incorporation of EC recommendations in this field and cooperation with European Leukaemia net; (iii) improvement in diagnosis and treatment of cancers among children; (iv) quality control of leukaemia treatment among children; (v) preventing disability among children with bone cancers; and (vi) quality control in treatment of solid cancers among children.
- educational programmes, especially medical staff trainings; and
- other programmes, including improvement of cancer registries.

[279] Activities of the Programme include specifically: (...), 2. Implementation of cancer screening for cervical, brast and colorectal cancer and specific cancers among children.

Table 1.1 - Legal, Policy and Programming Framework

Year	Type	Authority	Title	Comment
2005	Law	Ministry of Health	Law of 1 July 2005 establishing the multiannual "National programme on cancer prevention" (*Ustawa z dnia 1 lipca o ustanowieniu programu wieloletniego „Narodowy program zwalczania chorób nowotworowych"*)	The law was amended on 7 February 2008 (*Ustawa z dnia 7 lutego o zmianie ustawy o ustanowieniu programu wieloletniego "Narodowy program zwalczania chorób nowotworowych"*). The amendment stated that the annual budget devoted to cancer screening cannot be lower than 10% of the total budget of the Programme.

Regulations and Strategic planning. Regulations with respect to cancer screening policy are made on an annual basis by the ***Council of Ministers*** which establishes an ***Action Plan*** every year, based on the financial resources that are available for this purpose in the annual national budget. Strategic planning is a responsibility shared among the ***Ministry of Health***, the ***Council of the Ministers*** and the ***Council of Cancer Prevention***. The latter was enacted by the 2005 Law and is composed of experts in oncology, representatives of the Ministry of Health and the National Health Fund. Problems that should be tackled by the annual Action Plan and concrete actions that should be undertaken can be proposed to the Council of Cancer Prevention by any group of interest in that field, including the Ministry of Health itself. Then, when appropriate, the Council can recommend specific action items to the Council of the Ministers.

2. Implementation

Policy implementation. *Policy coordination and implementation* of concrete programmes within the work plan approved by the Council of Ministers is primarily a responsibility of the ***Health Policy Department*** of the Ministry of Health. The Department coordinates actions undertaken in the framework of different sectoral health plans (i.e. cardiovascular diseases prevention health plan), among which cancer prevention is a priority. The National Cancer Programme is the only health plan for which specific pieces of legislation have been created and resources are granted out of the central budget. The Department is responsible for managing the overall National Cancer Programme, while the implementation of concrete programmes and initiatives lies within the regional/local governments and healthcare service providers who bid with their own programmes for screenings contracts with the National Health Fund. Financial resources for specific healthcare services are allocated by the National Health Fund.

Coordination of cancer screening programmes is the responsibility of the ***National Coordination Centre***. All types of cancer screening are supervised by the Director; additionally, there are coordinators of site-specific screening programmes (breast, cervical and colorectal cancer screening), supported by the Regional Coordination Centres that operate through the regional branches of the National Health Fund.

Cancer screening *promotion and information dissemination* are coordinated by the ***Health Policy Department***, together with the ***National and Regional Coordination Centres***. The Department approves promotional leaflets and information on screening distributed to various target groups.

Data collection. Two systems are used for the collection of data on cancer prevalence and screenings:

A. ***National Cancer Register*** (*Krajowy Rejestr Nowotworów*), supervised by the Centre of Oncology (*Centrum Onkologii*) in Warsaw.

B. ***Information System of Prevention Monitoring*** (*System Informatyczny Monitorowania Profilaktyki*/**SIMP**), supervised by the National Health Fund together with its branches of National and Regional Coordination Centres.

There are no registers of *primary prevention* data (i.e. vaccinations preventing cervical cancer). SIMP covers *secondary prevention* collecting nationwide information on prevention of cardiovascular system diseases, prevention of cervical cancer and prevention of breast cancer. SIMP was established in 2006 and has been operating since 2007. Being integrated with other National Health Fund registers and allowing for personal identification, it allows for time trend analysis. SIMP data are collected on a regular basis by the Health Policy Department of the Ministry of Health. *Tertiary prevention* (treatment) is registered by the **National Cancer Register** where all the cases of diagnosed cancer are included. Data are collected at the regional level and then transferred to the Centre of Oncology in Warsaw. Yet, there is some evidence that the registers are not fully compliant with the EC Guidelines on prevention information systems[280].

3. Monitoring of policy implementation

Monitoring of activities undertaken as part of the National Programme, including cancer screening, is again a responsibility of the ***Health Policy Department*** of the Ministry of Health. Information from the National Coordination Centre is collected by the Department every month. Monitoring concentrates not only on outputs (number of screening programmes or individuals covered with screenings), but also controls quality of screenings and trainings are organised, if needed. Monitoring of cancer screening is based on collection of statistical data from the SIMP database including information on the number of screening per type of screening. According to the information released by the Department of Health Policy, responsible for the supervision and *overall evaluation* of screenings, the main concern is low turnout in screening rounds. Turnout for cervical cancer screening in 2010 was 27% and 40% for breast cancer screening[281]. Comparable turnout figures are reported in the case of breast cancer screening in a 2011 analysis of screening in the Lower Silesia Region[282].

Information on the various steps of the policy process is presented in Table 3.1 below.

[280] 'Rekomendacje kompleksowych zmian w obszarze profilaktyki raka szyjki macicy w Polsce", Polska Koalicja na Rzecz Walki z Rakiem Szyjki Macicy, Warsaw 2012.

[281] Ministry of Health, Sprawozdanie z realizacji Narodowego Programu Zwalczania Chorób Nowotworowych w 2010 (Report on implentation of the National Programme on Cancer Prevention in 2010) http://www.mz.gov.pl/wwwfiles/ma_struktura/docs/sprawozdanie_npzchn_12122011.pdf

[282] Matkowski R, Szynglarewicz B., First report of introducing population-based breast cancer screening in Poland: experience of the 3-million population region of Lower Silesia, Cancer Epidemiol. 2011 Dec;35(6):e111-5, 2011

Table 3.1 - The policy-making process

Step	Description
Baseline Assessment	Poland has a long track record of statistical data, used to monitoring cancer prevalence. Starting in 1960, information on cancer incidence has been collected by the Centre of Oncology in Warsaw[283] . Indicators used in these studies were compliant with international guidelines, and indicators collected in recent years are compliant with the Lisbon guidelines on cancer monitoring. Thus there are various and long-standing studies on cancer incidence in Poland. A broad cancer screening programme was introduced in several areas as part of a World Bank project in the early 2000s. A 2003-2004 study[284] documented national and regional colorectal cancer screening programmes in Poland and listed the institutions involved in this field at the time (Centre of Oncology, National Public Health Institute and Ministry of Health).
Development and discussion of draft policy	The current cancer prevention programme was developed in response to the WHO Recommendations (Strategies to Improve and Strengthen Cancer Control Programmes in Europe) by the Ministry of Health in cooperation with experts in oncology. Cancer prevention policy was created in order (i) to streamline and coordinate a number of disparate activities in the field of cancer prevention undertaken by different stakeholders (National Health Fund, regional governments, healthcare service providers) and (ii) to secure appropriate resources for them in the long run.
Adoption of the policy	

4. Policy Implementation and Indicators

Evaluation of cancer prevention and cancer screening programmes is performed on an annual basis by the ***Health Policy Department*** of the Ministry of Health which prepares annual reports on implementation of the National Programme on Cancer Prevention. The report is subsequently presented to the Parliament and published on the Programme's website. However, the report covers only financial information (i.e. resources invested in various programmes during a given year) and includes only basic indicators. The data and information included in the report do not follow up on patients' health status over time, their treatment records nor does it provide any information on health the health impact of treatment.

These annual reports are the single nationwide monitoring mechanism for cancer screening implementation in Poland. They are based on the SIMP data, collected by the National Health Fund and the Central and National Cooperation Centre. The ***SIMP database*** covers information on prevention of cardiovascular system diseases, as well as on cervical and breast cancer prevention. The database covers the whole country and integrates basic ***National Health Fund data***, composed of (i) the central register of health insurance and (ii) a database of medical services provided. The database is set up on the basis of individual records of the those participating in the screening rounds. The database is available to medical doctors, the National Health Fund and the Ministry of Health. SIMP data are continuously collected, but only a select series of summary statistics are published once a year in the annual report mentioned above.

[283] One of the first publication on this subject are: „Cancer in Poland, City of Warsaw and Selected Rural Areas 1963-1972", Koszarowski T., Gadomska H., Wronkowski Z., Romejko M., Polish Medical Publishers, Warsaw 1977; "Nowotwory złośliwe w Polsce w latach 1952-1982, Koszarowski T., Gadomska H., Wronkowski Z., Romejko M., Centre of Oncology, Warsaw 1987.

[284] Benson VS, Patnick J, Davies AK, Nadel MR, Smith RA, Atkin WS, on behalf of the International Colorectal Cancer Screening Network (2008) Colorectal cancer screening: A comparison of 35 initiatives in 17 countries Int J Canc 122: 1357-1367

Another type of register is the ***National Cancer Register***. It does not include information of cancer screening, but provides detailed information on cases of diagnosed cancer. The database includes the following information: type of disease, sex, age and residence. Summary statistics of these data are published on an annual basis. The database also includes detailed information on treatment and date of death; the latter, however, is not publicly available. The database is operated by the Centre of Oncology in Warsaw, while the reports are produced for the use of the Ministry of Health within the National Programme on Cancer Prevention.

To conclude with, both databases include statistics to a large extent available the public, with summaries published every year. The registers' information is subsequently fed to Eurostat and WHO.

Fieldwork data gathering produced a rather general assessment of the factors that may have had an impact on implementation of EU policy. By and large, however, they did not attribute utmost importance to any of the issues in the list but "financial resources could always be higher". In general, with respect to cancer screening all other issues listed were found of none or minor importance.

Table 4.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	Comments
Financial constraints (human and financial)	These were identified as an obstacle; financial resources could be greater.
Timeframe, the results and impacts will materialise after a much longer period	Not perceived as an issue.
Lack of a sound efficiency assessment of CS	Not perceived as an issue.
Technical and organisation issues connected to the complexity of CS nationwide programmes (issues of capacity, training of staff, management and service delivery etc.)	Not perceived as an issue.
Legal issues in setting up registries as requested, and linking them to mortality databases (e.g. issues of personal data management)	Not perceived as an issue.
Cultural and political issues (e.g. political sensitivity of the matter in certain cultural environment, political difficulties to maintain a long-term commitment in this area etc.)	Not perceived as an issue.

5. Policy Implementation and Indicators

Table 5.1 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.2	Compliance with Data Comparability Criteria based on Expert Assessment	The indicator would be relevant but it is not currently in use in the country. Information could be obtained from the National Institute of Public Health Data. The indicator is deemed: **highly feasible** **definitely valid**
2	HAR.3	Establishment of Special Registries (centralised data systems for the management and assessment of CS data)	The indicator would be relevant but it is not currently in use in the country. Information could be obtained from the National Health Fund. It is believed that the indicator could already be collected but there is not sufficient political will to do so. The indicator is deemed: **highly feasible** **definitely valid**
3	HAR.4	Alignment of Data Classification Systems to Standards defined by the	This information is relevant and already collected through the existing databases (notably the National Cancer Register and SIMP), which were aligned with existing classifications at the time of their design. The indicator is deemed: **highly feasible** **definitely valid**
4	ANA.1	Formal Adoption of the EU CS Guidelines (incl. RE* level)	The indicator would be relevant but it is not currently in use in the country. Related information is not available anywhere. The indicator is deemed: **not feasible** **fairly valid**
5	ANA.2	Evidence of a Significant Debate in the Scientific Literature of the MS about CS methodology and specifically the EU Guidelines	The indicator would be relevant but it is not currently in use in the country. Related information is very dispersed. The indicator is deemed: **hardly feasible** **fairly valid**
6	ANA.3	Effective Outreach Level of the EU Guidelines in the MS (downloads, webpages visited) in Absolute or Relative Terms (% of the target population)	The indicator would be relevant but it is not currently in use in the country. Possible source of information may be interviews and ad hoc research projects. Only some part of the Guidelines are available in Polish, which is a major obstacle to their dissemination to wider audiences. The indicator is deemed:

	Code	Indicator	Notes
			fairly feasible **fairly valid**
7	OUT.1	Specific Outcome Indicator for the Stated Objective	This indicator is used by the Ministry of Health to prepare annual screening reports. Information is collected from National Health Fund and the Ministry of Health (SIMP). The indicator is deemed: **fairly feasible** **fairly valid**
8	IMP.1	Specific Impact Indicator for the Stated Objective	The Ministry of Health plans to collect this information from five-year datasets on mortality rates of the screened population. These datasets will be provided shortly by the National Health Fund and the Ministry of Health (SIMP) combined with National Cancer Register. The indicator is deemed: **hardly feasible** **fairly valid**
9	PROG.1	Establishment of a CS Strategy / Programme / Action Plan covering the Whole Population	A strategy is in place, so information for this indicator could be collected. Full text of the relevant Acts are available from the Ministry of Health Internet site. The indicator is deemed: **fairly feasible** **fairly valid**
10	PROG.2	Number of RE with CS Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	The National Health Fund monitors screening contracts. Information is collected by the National Health Fund from the SIMP database, and published by the Ministry of Health in annual reports. The indicator is deemed: **highly feasible** **fairly valid**
11	PROG.3	Number of RE with a CS Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	Not relevant because a strategy is already in place. The indicator is deemed: **definitely not valid**
12	LEG.1	Adoption of appropriate data protection legislation	Data protection legislation is adopted and allows both screening registries and cancer registries The indicator is deemed: **fairly feasible** **fairly valid**
13	LEG.2	Appropriate data protection legislation Discussed but Not Yet	See above.

	Code	Indicator	Notes
		Adopted	The indicator is deemed: **fairly feasible** **fairly valid**
14	LEG.3	Appropriate data protection legislation Still under Preparation and in its Drafting Stage	See above. The indicator is deemed: **fairly feasible** **fairly valid**
15	AWA.1	Information/Awareness Raising Campaigns on CS in a Given Year (period)	This indicator would be relevant but it is not currently in use. Related information is available from the Ministry of Health and National Coordination Centre, Polish Union of Oncology. The indicator is deemed: **fairly feasible** **definitely valid**
16	AWA.2	Level of Awareness about CS issues among the target Population	It would be relevant but it is not currently in use. The only information available is dated (the most recent dates back to 1990). The indicator is deemed: **not feasible** **definitely valid**
17	AWA.3	Trend in the Level of Awareness about CS issues among the target Population	Same as above. The indicator is deemed: **not feasible** **definitely valid**
18	AWA.4	Estimate of Population Reached by Information Initiatives on EU guidelines in Absolute Terms or Relative to the Potential Target	This indicator would be relevant but it is not currently in use, nor is there any information available. The indicator is deemed: **not feasible** **fairly valid**
19	FUND.1	Total Budgeted Funds to assure appropriate organisation and quality control of CS programmes	It would be relevant but it is not currently in use. The only information available is on public funding available. The indicator is deemed: **not feasible** **fairly valid**
20	FUND.2	Total Public Expenditure to assure appropriate organisation	Information on the National Programme can be drawn from the National Health Fund, the sub-national governments and the annual national budget.

	Code	Indicator	Notes
		and quality control of CS programmes	The indicator is deemed: **fairly feasible** **of dubious validity**
21	FUND3	Total dedicated staff to implement and assure quality of CS programmes	This indicator would be relevant but it is not currently in use. Information would be difficult to collect (the National Health Fund has information on medical units, but not on employees). The indicator is deemed: **not feasible** **fairly valid**
22	DEL.1	Population Reached by CS Programmes in the country, in Absolute or Relative Terms (out of the target population)	This indicator is currently used; information is obtained from the annual reports of the Ministry of Health based on SIMP database. The indicator is deemed: **highly feasible** **definitely valid**
23	DEL.2	Compliance with the Relevant Features of CS Implementation Modalities Stated in the EU Documents (incl. RE level)	This indicator would be relevant but it is not currently in use, although information could be easily collected by a study designed for that purpose. The indicator is deemed: **highly feasible** **definitely valid**
24	DEL.3	Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken, i.e. CS programmes set up	This indicator is currently used; information is obtained from the annual reports of the Ministry of Health based on SIMP database. The indicator is deemed: **highly feasible** **definitely valid**
25	CAP.1	Compliance with Given Equipment Technical Standards and Operational Procedures	This indicator seems not fully relevant and is not currently in use, although information could be provided by the Ministry of Health. The indicator is deemed: **fairly feasible** **of dubious validity**
26	PRO.1	Introduction of a Given Procedure in CS Routine Operations (incl. RE level)	This indicator would be relevant but it is not currently in use, although information could be provided, in part, by the Ministry of Health based on the SIMP database. If the EC Guidelines were fully adopted, this aspect would be regularly monitored. The indicator is deemed:

	Code	Indicator	Notes
			hardly feasible **fairly valid**
27	PRO.2	Number of Relevant Institutions Complying with Procedure (incl. RE level)	This indicator is not currently in use, although information could be provided by the Ministry of Health. The indicator is deemed: **fairly feasible** **of dubious validity**
28	TRAI.1	Implementation of Training Courses on CS for Healthcare Personnel (incl. RE level)	This indicator is currently used; information is obtained from the annual reports of the Ministry of Health. The indicator is deemed: **highly feasible** **fairly valid**
29	TRAI.2	Total Number of Trained Healthcare Workers on CS	Same as above. The indicator is deemed: **highly feasible** **fairly valid**
30	TRAI.3	Resources Made Available for Training on CS in Absolute or Relative Terms	Same as above. The indicator is deemed: **highly feasible** **fairly valid**
31	EVAL.1	Evaluation of data from tests, assessments and diagnosis	This indicator is currently used; information is obtained from the National Health Fund and the Ministry of Health based on the SIMP database and the National Cancer Register. However, it is noted that there is no information on the population that refused to participate in the screening programmes. The indicator is deemed: **highly feasible** **definitely valid**
32	EVAL.2	Change of CS Policy as a result of the above evaluation	This indicator would be relevant but it is not currently in use. Partial information could be made available from the Ministry of Health. The indicator is deemed: **fairly feasible** **definitely valid**
33	EVAL.3	Regularly Monitor CS Implementation and Outcome	This indicator is currently used; information is obtained from the annual reports of the Ministry of Health. The indicator is deemed: **highly feasible** **definitely valid**

	Code	Indicator	Notes
34	REP.1	Full or Partial Compliance with the Reporting Requirements on the Progress Reached in the Implementation of the EU Policy	This indicator would be relevant but it is not currently in use, nor is there any information available. The indicator is deemed: **not feasible** **fairly valid**
35	REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing CS Containing Information Not Shared with the EU	This indicator would be relevant but it is not currently in use, nor is there any information available. The indicator is deemed: **not feasible** **fairly valid**

***RE**=Relevant Entity

Proposed additional indicators

Indicator	Comments
People's perception of cancer screening; esp. regarding the accountability of these programmes (does public financing increase transparency/accountability?) and people's attitude (do people fear being screened, and if so, why?)	It is believed that this indicator would be very helpful in planning cancer screening programmes and in increasing their cost effectiveness.

ANNEX F - INDICATIVE SHORT-LIST OF POSSIBLE INDICATORS PER POLICY AREA

This table provides an indicative example of how the indicator selection mechanism identified in table 4.3 of volume I can translate into a concrete shortlist of six indicators for concise reporting purposes. The number of the indicators has been chosen as a compromise between different needs: 1) to have a limited set of indicators for strategic reporting purposes; 2) to report indicators as homogeneous as possible across the various policy areas; 3) to include both primary and secondary indicators. This framework of indicators can be tailored to specific information needs and shortened or lengthened accordingly. The emphasis on the various aspects to be highlighted may also vary depending on different internal validation. Whenever it is unclear whether an agreement has been reached on how to measure the achievement of the relevant objective a question mark has been added to the OBJ indicator.

Policy area	Indicators					
Shared Health Values[285]	Number of M S whose health policy documents recognise the common principles (PRI.1)	Expert opinion on degree of harmonisation reached in the provision of indicators on health inequalities (HAR.2)	*Total structural fund financing committed to reduce health inequalities (STR.FUND)*	*Number of studies published on health inequalities by MS (ANA.2)*	*Number of accesses to the EU health inequalities portal by MS (ANA.3)*	*Number of MS that have contributed their relevant policy experiences to the EU data base (EXC.2)*
Health is the Greatest Wealth	Cumulated savings from investing in health prevention policies and implementing the EU health strategy (OBJ?)	Number of MS that have carried out cost-effectiveness studies in the areas encompassed by the strategy (EVAL.1)	*Number of MS that have contributed the results of their cost-effectiveness studies to the relevant EU policy exchange mechanism (EXC.1)*			
Health in All Policies	Number of MS whose health policy documents recognise HiAP (PRI.1)	Number of MS that Have Identified a Technical Secretariat for Intersectoral Coordination (ORG.1)	Number of MS that have Identified a Centre of Expertise to Disseminate Best Practice (ORG.3)	Number of MS/RE with strategies, programmes. action plans specifically dealing with HIAP (PRI.3)	Number of MS/RE That have adopted HIA Guidelines (ANA.1)	Number of MS that have evaluated their HIAP policies (EVAL.1)
Global Heath	Number of MS that Have Appointed a Global Health Coordinator (ORG.2)	Number of Policy Areas where a common position between MS is routinely reached in international fora (OBJ?)	Number of health professionals drawn out from developing countries (OBJ?)	Number of MS that evaluate their global health programmes (EVAL.1)	*Number of MS that have committed to the WHO global code on health personnel recruitment (PRI.2)*	*Number of MS that have contributed their programs and evaluations to the relevant EU exchange platform (EXC1)*
Health of Older People	Number of MS that have drafted a strategy,	Number of MS that have developed and contributed	Number of MS that have evaluated their Alzheimer	*Total funding made available through the Public Health*	*Number of MS that have contributed their*	

[285] OBJ is also a possible primary indicator here, but work is still in progress on how to measure the reduction in health inequalities.

	programme on Alzheimer (PROG.1)	comparable indicators on Alzheimer (HAR.1)	strategies (EVAL.1)	*Programme (PHP.FUND)*	*programs and evaluations to the relevant EU exchange platform (EXC1)*	
Tobacco	Number of MS that have managed to reduce the number of smokers in the population (OBJ?)	Number of MS that have introduced comprehensive smoke-free laws (LEG.1)	Number of MS that Have developed comprehensive control strategies to reduce secondary exposure from tobacco (PROG.1)	Number of MS that Have Established a Focal Point on Tobacco Policies (ORG.2)	Number of MS that have developed a coherent and comparable framework of indicators on tobacco consumption (HAR.2)	Number of MS that Have evaluated their smoking cessation and tobacco prevention programmes (EVAL.1)
Nutrition	Number of MS that have managed to reverse the increasing obesity trend (OBJ?) Number of MS that have managed to decrease their salt consumtpino by 16% (OBJ?)	Number of voluntary commitments made in the MS (LEG.VOL)	Number of initiatives implemented in the various policy areas. E.g share of the target population who have received free of subsidised meals or share of the population who has access to attractive structures for physical activities (DEL)	Number of MS that contribute harmonised data to the WHO database (HAR)	Number of MS that have put in place an indicator and monitoring system on nutrition and obesity (EVAL.3)	*Number of MS that have made available their pledges in a website (EXC.2)*
Alcohol[286]	Number of MS that have introduced regulation self-regulation on selling alcohol to minors or adevertising or BAC levels for drivers (LEG.1)	Number of MS that Have developed comprehensive control strategies to reduce harmful and hazardous alcohol (PROG.1)	Number of MS that have identified centres of expertise on how to inform and educate consumers on alcohol (ORG.3)	Number of MS that can provide on harmonised data on harmful alcohol consumption in the age group over 60 (HAR.1)	Number of MS that evaluate their alcohol harm-reduction polices (EVAL.1)	*Number of items that MS have Reported on their Policy Results to the Commission (REP.1)*
Mental Health	Number of MS that have developed strategies programmes on Mental Health (PROG.1)	*Total Structural Funds financing committed for mental health purposes (STR.FUND)*	Number of MS that have introduced or improved their monitoring systems on mental health (EVAL.3)	Number of MS that have evaluated their Mental Health policies (EVAL.1)	*Number of MS that have contributed their programs and evaluations to the relevant EU exchange platform*	

[286] OBJ indicators have not been included here because of preliminary evidence of possible disagreements on how the health strategy priority themes should be measured.

					(EXC1)	
Illicit Drugs	Number of MS that have developed strategies programmes on illicit drugs (PROG.1)	*Number of MS that have developed information strategies (PROG.AWA)*	Share of drug offenders who have access to alternatives to prison (DEL)	Number of MS that monitor their alternative treatment programs (EVAL.3)	Number of MS that Have Improved Compliance with the Five Harmonised Indicators (HAR.2)	*Number of MS that communicate their best practice to the EU database (EXC.2)*
Cancer	Number of MS that have developed comprehensive cancer strategies by 2013 (PROG.1)	Number of MS that Have Reduced Cancer Mortality Inequalities (OBJ?)	Share of the Population Receiving Cancer Screening (DEL)	*Structural Funds financing committed for cancer policy purposes (STR.FUND)*	*Number of Cancer Registries in Operation (HAR.3)*	*Number of downloads of the EU Cancer Screening Guidelines (ANA.3)*
Rare Diseases[287]	Number of MS that have developed an action plan on rare diseases (PROG.1)	Proportion of Rare Diseases identified in the ICD (ANA.1)	Number of people identified as affected by rare diseases (DEL)	*Number of laboratories certified for genetic testing (CAP/NET)*	Number of Registries or Databases for Rare Diseases Established at the MS level (HAR.3)	Number of Health Technology Assessments carried out to measure the efficacy of treatments for rare diseases (EVAL.1)
Organ Donation	Number of MS that have put in place or revised a National action plan (PROG.1)	Number of MS that have increased their national donation rates (OBJ?)	Number of transplant coordinators per million inhabitant (DEL)	*Number of Transplant Procurement Hospitals (NET.1)*	Number of MS that have established registers of living donors and organ recipients (HAR.3)	Number of MS that Have established a system of indicators to monitor their organ donation and transplantation activities (EVAL.3)
Injuries	Number of MS that have set up national plans on injuries (PROG.1)	Number of MS that have established a technical secretariat responsible for intersectoral coordination (ORG.1)	Degree of comparability of the indicators on injuries (HAR.2)	Number of MS that have put in place a monitoring system on injuries (EVAL.3)	Number of MS that have evaluated the effects of their prevention measures and modified their polices accordingly (EVAL.2)	*Number of MS that have contributed their evaluations to the relevant EU exchange platform (EXC1)*
HIV-AIDS	Number of MS that have established mid-term planning (PROG.1)	*Structural funds financing committed for HIV-AIDS (STR.FUND)*	Share of the patient population who has access to ARV treatments (DEL)	Number of MS that can provide harmonised epidemiological indicators (HAR.1)	Number of MS that Have Developed a System of Indicators to Monitor their Actions (EVAL. 3)	*Number of items MS Report to ECDC on Progress On Dublin, Vilnius and Bremen Declarations*

[287] OBJ indicators have not been including here because reported in the impact assessment but it is not clear to what extent there is consensus on their being linked to the contents of the Recommendation.

						(REP.1)
Vaccination	Number of MS that Have adopted action plans/policies on vaccination (PROG.1)	Number of MS that have harmonised their policies to ECDC definitions of older age groups and risk groups (ANA.1)	Share of older age groups and risk groups vaccinated (DEL)	Number of MS that have evaluated the causes for poor uptake and modified their policies accordingly (EVAL.2)	*Number of MS that Regularly Report to the Commission on their Vaccination Programs (REP.1)*	
Preparedness Programs	Number of MS that Have Prepared Generic Preparedness Plans (PROG.1)	Number of MS that have established a body responsible for coordinating preparedness programmes (ORG.1)	Number of MS that have appointed a body for liaising with European institutions on preparedness programmes (ORG.2)	*Number of MS that Have introduced or Improved Communication Procedures with Professionals and the Public (PRO.1)*		
CRBN	Number of MS that Have Prepared CRBN Plans (PROG.1)	Number of MS complying with minimum requirements on sampling, detection, etc (ANA.1)	Number of MS that have established a body responsible for liaising on CRBN matters (ORG.2)	*Number of laboratories included in networks specialised in high risk biological networks and toxins (NET)*	Number of exercises carried by MS (DEL.3)	*Number of MS that Have Developed Guidelines on Suspicious Transactions (PRO)*
Antimicrobial Resistance	Number of MS that have developed national programs for hospital hygiene and infection control (PROG.1)	Number of MS that Have Established a Technical Secretariat to Ensure Intersectoral Cooperation (ORG.1)	Share of health establishments with infection control committees and infection nurses (DEL)	Number of MS that can provide harmonised data on antimicrobial resistence (HAR.1)	*Number of MS that have developed guidelines on prevention and control of antimicrobial resistance (PRO)*	Number of MS that have put in place monitoring systems of their antimicrobial resistance programmes (EVAL.3)
Patient Safety	Number of Member States that make recourse to harmonised terminology (ANA.1)	Number of MS that have established programmes or action plans on Patient Safety (PROG.1)	Number of MS that have Designated Competent Authorities (ORG.1)	Share of the Population who have access to blame-free reporting systems (DEL)	Number of MS that can provide harmonised OECD patient safety indicators (HAR.1)	*Number of MS that contribute their policy experiences to the relevant EU platform (EXC.1)*
Telemedicine	Number of MS that Have submitted their action plans (PROG.1)	*Number of MS that have contributed their best practices to the relevant platform (EXC.2)*				

ANNEX G – DRAFT OUTLINE FOR CASE STUDY REPORTS

A – Overall Health Strategy (White Paper)

1. Legal, Policy and Institutional Framework

- Indicate the main legal/policy documents defining the overall public health strategy in your country (including examples of sub-national acts, e.g. regional action plan etc., as needed). Where appropriate, describe how these documents fit into the overall policy-making process of the public health strategy in your country.

Table 1.1 - Legal and Policy and Framework

Year (1)	Type (2)	Authority (3)	Title (4)	Comment (5)

Notes:

(1) Year – For policy/strategy documents focus on items published after 2000.

For legal documents also items published before 2000 should be mentioned if strictly relevant.

(2) Type – Indicate the nature of the act, e.g. Law, Decree, Action Plan, etc.

(3) Authority – Indicate not only the authority formally adopting the act, but – when relevant – also the body that developed its content (e.g. some Ministerial acts may simply ratify agreements undertaken by joint committees involving different authorities).

(4) Title – provide the title of the act both in national language and the translation in English.

(5) Comment – Use this field to clarify the salient points of the act when these are not clearly understandable from the title (e.g. to specify the key provisions included in more general acts). Use this field also to provide information on subsequent amendments of the original act.

- Briefly illustrate the institutional and the policy governance framework for public health policy in your country. Please describe how roles and responsibilities are distributed among the various levels (national, regional, local), particularly in terms of strategic planning, implementation of programmes/initiatives, collection of data and statistics and monitoring and evaluation of policy implementation and outcome. While it is not necessary that all these areas are equally covered, the overview should be as comprehensive as possible.

2. EU added-value

- Briefly discuss to what extent the EU policy (especially the White Paper: Together for Health) was conducive to the establishment and/or improvement of public health strategy/plan in your country. Two types of evidence should be used:
  - (i) possible references to the White Paper in relevant national/sub-national acts (i.e. those listed in Table 1.1)
  - (ii) the interviewees' responses.

- Summarise respondents' views on specific policy areas of possible EU added value with respect to the overall public health strategy/action plan, referring to the policy areas listed in Table 2.1.

Table 2.1 - EU added value

Policy area	***Comments***
Political 'pressure' contributing to the adoption of certain principles and the	

Policy area	*Comments*
prioritisation of certain objectives (as indicated in the White Paper)	
Advisory/technical support through instruments such as the Joint Actions and the OMC mechanisms	
Support to convergence of strategic approaches adopted by MS / 'gap' reduction among MS	
Other (specify)	

3. Overall EU Health Policy Adoption/Implementation

- Discuss in detail the potential obstacles/drivers that possibly had an influence in the adoption and/or the overall implementation of the EU health policy (i.e. not only the "White paper" but the entire body of EU 'soft laws' on public health). Reference can be made to the items listed below.

Table 3.1 – Assessment of possible factors affecting the adoption and implementation of EU policy

Obstacles/drivers	*Comments*
Institutional architecture (since uptake might be more difficult in more decentralised systems)	
The different nature of the soft law instrument chosen by the EU, i.e. whether Recommendations, Council Conclusions, or Commission Communications (since MS may attribute a different level of priority or deal with them in a different way)	
Prior adequate discussion / consultation period before the adoption of a EU Policy (since this may facilitate adoption)	
Other aspects of legislative techniques adopted to put pressure on recipients (such as the inclusion in the text of deadlines for compliance or explicit reporting requirements)	
Issues of national ownership (since policy items put forward in the European agenda by individual MS may encounter resistance in other MS due to national experiences, cultural factors, traditions or technical obstacles to transposition)	
Adequate maturity, i.e. existence of sufficient evidence ('pilot' experiences, evaluations, scientific studies) supporting the inclusion of a given policy approach in the European agenda	
Programming capacity (since some MS could find it difficult to cope with the total number of programmes, action plans, strategies requested by the EU in a given period. Not only for internal capacity constraints, but also for the duration of the political approval process)	
Clear prioritisation of actions (since the inclusion of	

Obstacles/drivers	***Comments***
too many European items in the policy making agenda might be ultimately detrimental for most urgent priorities, particularly in times of financial crisis)	
Existence of relevant OMC / JA mechanisms on the subject at the European level and the MS participation therein (since this may facilitate adoption)	
Pressure from stakeholders' groups or lack thereof (since this may ultimately influence uptake)	

B - Patient safety (PS)

1. Legal, Policy and Institutional Framework

- Indicate the main legal/strategic documents on patient safety (including HCAI prevention and control) as well as the main specific programmes/initiatives implementing PS policy in your country (including examples of sub-national acts, e.g. regional action plan etc., as needed). Where appropriate, describe how these documents fit into the PS policy making process in your country.

Table 1.1 - Legal, Policy and Programming Framework

Year (1)	Type (2)	Authority (3)	Title (4)	Comment (5)

Notes:

(1) Year – For policy/strategy documents focus on items published after 2000.

For legal documents also items published before 2000 should be mentioned if strictly relevant.

For programmes/initiatives focus on items published after 2005.

(2) Type – Indicate the nature of the act, e.g. Law, Decree, Action Plan, Programming document etc.

(3) Authority – Indicate not only the authority formally adopting the act, but – when relevant – also the body that developed its content (e.g. some Ministerial acts may simply ratify agreements undertaken by joint committees involving different authorities).

(4) Title – provide the title of the act both in national language and the translation in English.

(5) Comment – Use this field to clarify the salient points of the act when these are not clearly understandable from the title (e.g. to specify the key PS-related provisions included in more general acts). Use this field also to provide information on subsequent amendments of the original act.

- Briefly illustrate the institutional and the policy governance framework for PS in your country. Please describe how roles and responsibilities are distributed among the various levels (national, regional, local), particularly in terms of strategic planning, implementation of programmes/initiatives, collection of data and statistics and monitoring and evaluation of policy implementation and outcome. While it is not necessary that all these areas are equally covered, the overview should be as comprehensive as possible.

2. EU added-value

- Briefly discuss to what extent the EU policy (especially the Recommendation but also the previous EC Communication and the Public Consultation on HIA) was conducive to the establishment and/or improvement of a PS strategy in your country. Two types of evidence should be used:
  - (i) possible references to EU policy in relevant national/sub-national acts (i.e. those listed in Table 1.1)
  - (ii) the interviewees' responses.

- Summarise respondents' views on specific areas of possible EU added value with respect to PS policy, referring to the policy areas listed in Table 2.1.

Table 2.1 - EU added value

Policy area	*Comments*
Political 'pressure' contributing to the prioritisation of PS issues	

Policy area	*Comments*
Support to the dissemination of strategies and approaches that were already a priority in your country	
Advisory/technical support through instruments such as the Joint Action (PASQ) and the Patient Safety and Quality of Care Working Group	
Support to convergence of strategic approaches adopted by MS / 'gap' reduction among MS	
Other (specify)	

3. Policy Implementation and Indicators

- Indicate whether an evaluation of PS policy implementation has ever been conducted in your country and by whom (public authority, academic institute, NGO…). If not, clarify whether it is planned for the near future.

- Indicate whether your country has established a structured monitoring system for PS policy implementation. If so, specify: (i) the bodies responsible for the design, implementation, analysis and reporting of data, (ii) the types of data being collected, collection method and frequency, and (iii) the usage of data (internal discussion, reporting to international organisation, e.g. WHO, etc.).

  If not, explain possible reasons for this (as reported by interviewees).

- Briefly summarise the level of adoption and implementation of the EU PS policy in your country and provide an overview of the possible factors that might have affected it. Reference can be made to the items listed below.

Table 3.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	*Comments*
Financial constraints	
Shortage of qualified staff	
Legal issues (e.g. regarding the blame-free reporting)	
Relevant entities capacity (especially non-hospital facilities)	
Inadequate enforcement system (e.g. name-blame systems, which disincentive open reporting of adverse events)	
Complex coordination with education authorities for the inclusion of PS in curricula	

- Finally, summarise the evidence collected (through desk research and interviews) on the proposed indicators. Indicators shall be assessed, when possible, by reference to the criteria of **validity/relevance**, **availability** (i.e. the corresponding data are or may be collected) and **feasibility** (i.e. the corresponding data may be collected at reasonable costs and within a relatively short timeframe). Please duly report all proposals for revision of the proposed indicators voiced by the interviewees.

Table 3.2 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.4	Alignment of Data Classification Systems to Standardised Given Procedures *Ref to – the ECDC indicators*	
2	ANA.1	Adoption of a Methodology/Problem Definition in line with international standard *Ref to – e.g. the WHO taxonomy and ECDC work on HCAI*	
3	OUT.1	Specific Outcome Indicator for the Stated Objective *Ref to – No EU outcome indicators. Test the OECD ones:* *1. Catheter-related bloodstream infection* *2. Postoperative pulmonary embolism (PE) or deep vein thrombosis (DVT)* *3. Postoperative sepsis* *4. Accidental puncture or laceration* *5. Foreign body left in during procedure* *6. Obstetric trauma – vaginal delivery with instrument* 7. *Obstetric trauma – vaginal delivery without instrument*	
4	PROG. 1	Establishment of a PS Strategy / Programme / Action Plan covering the Whole Population	
5	PROG. 2	Number of RE with Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	
6	PROG. 3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	

	Code	Indicator	Notes
7	PROG. RES	Preparation of a Research Programme on PS-related Subject	
8	PART.2	Involvement of Advocacy NGOs in the Policymaking Process (incl. RE level)	
9	PART.3	Provision of Support to Advocacy NGOs active in the Given Policy Field (incl. RE level)	
10	RES.1	Existence of Research Programs in the PS Field	
11	RES.2	Resources Made Available by MS to Research Programmes in the PS Field in Either Absolute or Relative Terms	
12	RES.3	Number of Studies/ Publications Produced by Research Programs in PS Policy Field	
13	RES:4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature	
14	AWA.1	Information/Awareness Raising Campaigns on PS issues in a Given Year (period) *Ref to citizens/wider public* *- incl. a specific focus on hand-hygiene campaign (as per ECDC indicator)*	
15	AWA.2	Level of Awareness about PS issues among the Population *See above (e.g. by means of surveys)*	
16	AWA.3	Trend in the Level of Awareness about PS issues among the Population *See above (e.g. by means of surveys)*	

	Code	Indicator	Notes
17	FUND. 1	Total Budgeted Funds to Specifically Implement PS Policy in Absolute or Relative Terms	
18	FUND. 2	Total Public Expenditure to Specifically Implement PS Policy in Absolute or Relative Terms	
19	FUND. 3	Total dedicated infection control staff (absolute terms or per 1000 beds) *Ref* *- as per ECDC indicator*	
20	ORG.1	Identification of a Body Responsible for Policy Coordination / a Focal Point	
21	ORG.2	Routine Interaction with European Institutions on PS by Means of a Well-identified Institution	
22	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices in PS Area	
23	NET.1	Creation of a Network of Institutions to Implement the PS Policy *Ref to – the establishment of intersectoral mechanism collaborating with or integrated into the existing mechanism on the prudent use of antimicrobial agent*	
24	DEL.2	Number of RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents *Ref to:* *1. Development of tools/systems (incl. the use of ICT)* *2. blame-free reporting and learning system on adverse events*	

	Code	Indicator	Notes
		3. active surveillance system for HCAI *4. increase of number of single rooms (per beds or per rooms) as per ECDC indicator* *5. increase in the use of alcohol handrub products (as per ECDC indicator)*	
25	DEL.3	Number of Initiatives Undertaken to Specifically Deliver Policy *See above*	
26	TRAI.1	Implementation of Training Courses on PS-related Subject for Healthcare Personnel (incl. RE level)	
27	TRAI.2	Total Number of Trained Healthcare Workers on PS-related Subject	
28	TRAI.3	Resources Made Available for Training in PS-related subject in Absolute or Relative Terms	
29	TRAI.4	Introduction of PS in Relevant Curricula (incl. RE level)	
30	DISS.1	Number of dissemination initiatives on PS policy (to HC organisations, professional bodies and educational institutions)	
31	DISS.2	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target *Ref – not the general public (already covered by AWA)*	
32	EVAL. 1	PS policy evaluation (i.e. regular review of practices and standards)	
33	EVAL. 2	Change of PS Policy as a result of the above evaluation	
34	EVAL. 3	Establishment of a System of Indicators to Monitor Policy Implementation	

	Code	Indicator	Notes
35	EXC.1	Contribution by the MS of its Policy Experiences to the *PS and Quality of Care Working Group* *Not mere participation but presentation of national / regional policy*	
36	REP.1	Full or Partial Compliance with the Reporting Requirements on the Progress Reached in the Implementation of the EU Policy *Ref to* – *reporting to the EC under the REC annual (internal) reporting on the implementation of infection control programme (as per ECDC indicator)*	

***RE**=Relevant Entity

Proposed Additional indicators

Indicator	Comments

C – Cancer Screening (CS)

1. Legal, Policy and Institutional Framework

- Indicate the main legal/strategic documents on cancer secondary prevention (in particular breast, cervical and colorectal screening), as well as the main specific programmes/initiatives implementing CS policy in your country (including examples of sub-national acts, e.g. regional programmes etc., as needed). Where appropriate, describe how these documents fit into the CS policy making process in your country.

Table 1.1 - Legal, Policy and Programming Framework

Year (1)	Type (2)	Authority (3)	Title (4)	Comment (5)

Notes:

(1) Year – For policy/strategy documents focus on items published after 2000.

For legal documents also items published before 2000 should be mentioned if strictly relevant.

For programmes/initiatives focus on items published after 2005.

(2) Type – Indicate the nature of the act, e.g. Law, Decree, Action Plan, Programming document etc.

(3) Authority – Indicate not only the authority formally adopting the act, but – when relevant – also the body that developed its content (e.g. some Ministerial acts may simply ratify agreements undertaken by joint committees involving different authorities).

(4) Title – provide the title of the act both in national language and the translation in English.

(5) Comment – Use this field to clarify the salient points of the act when these are not clearly understandable from the title (e.g. to specify the key CS-related provisions included in more general acts). Use this field also to provide information on subsequent amendments of the original act.

- Briefly illustrate the institutional and the policy governance framework for CS in your country. Please describe how roles and responsibilities are distributed among the various levels (national, regional, local), particularly in terms of strategic planning, implementation of programmes/initiatives, collection of data and statistics and monitoring and evaluation of policy implementation and outcome. While it is not necessary that all these areas are equally covered, the overview should be as comprehensive as possible.

2. EU added-value

- Briefly discuss to what extent the EU policy (especially the Guidelines but also Recommendation 878) was conducive to the establishment and/or improvement of a CS strategy in your country. Two types of evidence should be used:
  - (i) possible references to EU policy in relevant national/sub-national acts (i.e. those listed in Table 1.1)
  - (ii) the interviewees' responses.

- Summarise respondents' views on specific areas of possible EU added value with respect to CS policy, referring to the policy areas listed in Table 2.1.

Table 2.1 - EU added value

Policy area	Comments
Political 'pressure' contributing to the prioritisation of CS issues	

Policy area	Comments
Support to the dissemination of strategies and approaches that were already a priority in your country	
Advisory/technical support through instruments such as the Guidelines and / or the Joint Action (AAC Partnership)	
Support to convergence of strategic approaches adopted by MS / 'gap' reduction among MS	
Other (specify)	

3. Policy Implementation and Indicators

- Indicate whether an evaluation of CS policy implementation has ever been conducted in your country (further to the EC periodical evaluation of Recommendation 878) and by whom (public authority, academic institute, NGO…). If not, clarify whether it is planned for the near future.

- Indicate whether your country has established a structured monitoring system for CS policy implementation. If so, specify: (i) the bodies responsible for the design, implementation, analysis and reporting of data, (ii) the types of data being collected, collection method and frequency, and (iii) the usage of data (internal discussion, reporting to international organisation, e.g. WHO, etc.)

  If not, explain the possible reasons for this (as reported by interviewees).

- Briefly summarise the level of adoption and implementation of the EU CS policy in your country and provide an overview of the possible factors that might have affected it. Reference can be made to the items listed below.

Table 3.1 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	***Comments***
Financial constraints (human and financial)	
Timeframe, the results and impacts will materialise after a much longer period	
Lack of a sound efficiency assessment of CS	
Technical and organisation issues connected to the complexity of CS nationwide programmes (issues of capacity, training of staff, management and service delivery etc.)	
Legal issues in setting up registries as requested, and linking them to mortality databases (e.g. issues of personal data management)	
Cultural and political issues (e.g. political sensitivity of the matter in certain cultural environment, political difficulties to maintain a long-term commitment in this area etc.)	

- Finally, summarise the evidence collected (through desk research and interviews) on the proposed indicators. Indicators shall be assessed, when possible, by reference to the criteria of

validity/relevance, **availability** (i.e. the corresponding data are or may be collected) and **feasibility** (i.e. the corresponding data may be collected at reasonable costs and within a relatively short timeframe). Please duly report all proposals for revision of the proposed indicators voiced by the interviewees.

Table 3.2 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	HAR.2	Compliance with Data Comparability Criteria based on Expert Assessment *Ref to – screening data which are required to be processed through centralised data systems*	
2	HAR.3	Establishment of Special Registries (centralised data systems for the management and assessment of CS data)	
3	HAR.4	Alignment of Data Classification Systems to Standards defined by the *European Network of Cancer Registries*	
4	ANA.1	Formal Adoption of the EU CS Guidelines (incl. RE* level) *Clearly distinguish b/w breast, cervical and colorectal CS*	
5	ANA.2	Evidence of a Significant Debate in the Scientific Literature of the MS about CS methodology and specifically the EU Guidelines	
6	ANA.3	Effective Outreach Level of the EU Guidelines in the MS (downloads, webpages visited) in Absolute or Relative Terms (% of the target population) *Ref to – possible publication of the EU Guidelines on MS websites at national / regional level* *Clearly distinguish b/w breast, cervical and colorectal CS*	

	Code	Indicator	Notes
7	OUT.1	Specific Outcome Indicator for the Stated Objective *Ref to -* *100% population coverage of screening for breast, cervical and colorectal cancer by 2013; (125 million examinations per year).* *[As per AAC objectives]*	
8	IMP.1	Specific Impact Indicator for the Stated Objective *Ref to -* *15% reduction by 2020 (510 000 new cases)* *[As per AAC objectives]*	
9	PROG.1	Establishment of a CS Strategy / Programme / Action Plan covering the Whole Population *Clearly distinguish b/w breast, cervical and colorectal CS*	
10	PROG.2	Number of RE with CS Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered) *Clearly distinguish b/w breast, cervical and colorectal CS*	
11	PROG.3	Number of RE with a CS Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	

	Code	Indicator	Notes
		Clearly distinguish b/w breast, cervical and colorectal CS	
12	LEG.1	Adoption of appropriate data protection legislation *Ref to – screening registries and possible link to mortality registries*	
13	LEG.2	Appropriate data protection legislation Discussed but Not Yet Adopted	
14	LEG.3	Appropriate data protection legislation Still under Preparation and in its Drafting Stage	
15	AWA.1	Information/Awareness Raising Campaigns on CS in a Given Year (period) *Ref to – info actions to inform participating pop about benefits and risks, and actions to promote participation*	
16	AWA.2	Level of Awareness about CS issues among the target Population	
17	AWA.3	Trend in the Level of Awareness about CS issues among the target Population	
18	FUND.1	Total Budgeted Funds to assure appropriate organisation and quality control of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	
19	FUND.2	Total Public Expenditure to assure appropriate organisation and quality control of CS programmes	

	Code	Indicator	Notes
		Clearly distinguish b/w breast, cervical and colorectal CS	
20	FUND3	Total dedicated staff to implement and assure quality of CS programmes *Clearly distinguish b/w breast, cervical and colorectal CS*	
21	DEL.1	Population Reached by CS Programmes in the country, in Absolute or Relative Terms (out of the target population) *Clearly distinguish b/w breast, cervical and colorectal CS*	
22	DEL.2	Compliance with the Relevant Features of CS Implementation Modalities Stated in the EU Documents (incl. RE level) *Ref to:* *-population-based vs. 'opportunistic' screenings* *-compliance with best practices included in the EU guidelines*	
23	DEL.3	Number of Initiatives Undertaken, i.e. CS programmes set up *Clearly distinguish b/w breast, cervical and colorectal CS*	
24	CAP.1	Compliance with Given Equipment Technical Standards and Operational Procedures *Ref to:* *-set up of a call/recall system & centralised data system* *-standard defined by the European Network of Cancer Registries*	

	Code	Indicator	Notes
25	PRO.1	Introduction of a Given Procedure in CS Routine Operations (incl. RE level) *Ref to:* *-introduction of quality assurance procedures* *- provision of adequate follow-up to positive cases* *- introduce new tests only when scientific evidence is available* *- assess the cost-effectiveness of new tests before their introduction* *-manage and evaluate data on tests, assessment and final diagnosis*	
26	PRO.2	Number of Relevant Institutions Complying with Procedure (incl. RE level)	
27	TRAI.1	Implementation of Training Courses on CS for Healthcare Personnel (incl. RE level)	
28	TRAI.2	Total Number of Trained Healthcare Workers on CS	
29	TRAI.3	Resources Made Available for Training on CS in Absolute or Relative Terms	
30	DISS.1	Number of Information/Communication Initiatives to disseminate the EU guidelines *Clearly distinguish b/w breast, cervical and colorectal CS guidelines*	
31	DISS.2	Estimate of Population Reached by Information Initiatives on EU guidelines in Absolute Terms or Relative to the Potential Target	

	Code	Indicator	Notes
		Clearly distinguish b/w breast, cervical and colorectal CS guidelines	
32	EVAL.1	Evaluation of data from tests, assessments and diagnosis	
33	EVAL.2	Change of CS Policy as a result of the above evaluation	
34	EVAL.3	Regularly Monitor CS Implementation and Outcome *Clearly distinguish b/w breast, cervical and colorectal CS*	
35	REP.1	Compliance with the EC reporting requirement	
36	REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing CS Containing Information Not Shared with the EU	

***RE**=Relevant Entity

Proposed Additional indicators

Indicator	Comments

D – Health in All Policies (HiAP)

1. Legal, Policy and Institutional Framework

- Indicate the main legal/strategic documents on HiAP in your country. In particular, indicate the main policy items related to the adoption of Health Impact Assessment (HIA) methodologies, as well as to mechanism for the intersectoral coordination. Where appropriate, describe how these documents fit into the HiAP policy making process in your country.

Table 1.1 – Legal and Policy Framework

Year (1)	Type (2)	Authority (3)	Title (4)	Comment (5)

Notes:

(1) Year – For policy/strategy documents focus on items published after 2000.

For legal documents also items published before 2000 should be mentioned if strictly relevant.

(2) Type – Indicate the nature of the act, e.g. Law, Decree, Action Plan, etc.

(3) Authority – Indicate not only the authority formally adopting the act, but – when relevant – also the body that developed its content (e.g. some Ministerial acts may simply ratify agreements undertaken by joint committees involving different authorities).

(4) Title – provide the title of the act both in national language and the translation in English.

(5) Comment – Use this field to clarify the salient points of the act when these are not clearly understandable from the title (e.g. to specify the key HiAP-related provisions included in more general acts). Use this field also to provide information on subsequent amendments of the original act.

- Briefly illustrate the institutional and the policy governance framework for HiAP in your country. Please describe how roles and responsibilities are distributed among the various levels (national, regional, local), particularly in terms of strategic planning, implementation of programmes/initiatives, collection of data and statistics and monitoring and evaluation of policy implementation and outcome. While it is not necessary that all these areas are equally covered, the overview should be as comprehensive as possible.

2. EU added-value

- Briefly discuss to what extent the EU policy conducive to the uptake of HiAP principles and to the establishment and/or improvement of specific HiAP approaches and methodologies in your country. Two types of evidence should be used:
  - (i) possible references to EU policy in relevant national / sub-national acts (i.e. those listed in Table 1.1)
  - (ii) the interviewees' responses.

- Summarise respondents' views on specific areas of possible EU added value with respect to HiAP policy, referring to the policy areas listed in Table 2.1.

Table 2.1 - EU added value

Policy area	***Comments***
Political 'pressure' contributing to the prioritisation of HiAP in the health agenda	
Adoption of methodologies developed at the	

Policy area	*Comments*
EU level by PHP projects	
Support to the dissemination of HiAP approaches and methods that were already a priority in your country	
Advisory/technical support	
Support to convergence of strategic approaches on HiAP adopted by MS / 'gap' reduction among MS	
Other (specify)	

3. Policy Implementation and Indicators

- Briefly summarise the level of uptake/implementation of Council Conclusions on HiAP in your country, with reference to the different priorities indicated in table 3.1.

Table 3.1 – Uptake and implementation of HiAP priorities

Priorities	*Uptake/implementation*
Develop the knowledge base on health and its determinants, associated trends, and trends in health inequalities;	
In national policy formulation and implementation, take into account the added value offered by cooperation between government sectors, social partners, the private sector and the non-governmental organisations for public health;	
Undertake, where appropriate, health impact assessments of major policy initiatives with a potential bearing on health;	
Pay special attention to the impact which major government policies have on equity in health, including mental health, and guarantee necessary efforts to tackle health inequalities;	
Focus on capacity building in policy analysis and development for improved intersectoral policies.	

- In connection with the above indicate specific programmes / initiatives possibly demonstrating the uptake/implementation of HiAP in your country. Please make explicit reference to the development and use of HIA and intersectoral coordination mechanism.

Table 3.2 – HiAP programmes and initiatives

Year (1)	*Type (2)*	*Entities involved (3)*	*Title (4)*	*Description (5)*

Notes:

(1) Year –Start and end year. Focus on initiatives implemented after 2005 (or earlier in case of particularly important initiatives).

(2) Type – Indicate the nature of the action (pilot project, comprehensive programme, info&comm. initiative etc.)

(3) Authority – Indicate the implementing body, the financing authority, and other entities directly involved.

(4) Title – provide the title of the act both in national language and the translation in English.

(5) Description– Use this field to provide a succinct description of the salient features of the initiative. Geographical coverage, concrete actions, outcomes. In particular, specify whether HIA and/or intersectoral coordination mechanism were envisaged, and if so provide implementation details.

- Indicate whether an evaluation of HiAP uptake/implementation has ever been conducted in your country and by whom (public authority, academic institute, NGO…). If not, clarify whether it is planned for the near future.

- Indicate whether your country has established a structured monitoring system for HiAP. If so, specify: (i) the bodies responsible for the design, implementation, analysis and reporting of data, (ii) the types of data being collected, collection method and frequency, and (iii) the usage of data (internal discussion, reporting to international organisation, e.g. WHO, etc.)

  If not, explain the possible reasons for this (as reported by interviewees).

- Briefly report stakeholders' view (and other evidence) on the following factors having possibly affected the uptake/implementation of HiAP in your country. Reference can be made to the items listed below.

Table 3.3 – Assessment of possible factors influencing the adoption and implementation of EU policy

Factors	***Comments***
Lack of a clear legal framework for HIA use in the public administration	
Availability of sufficient epidemiological information as a precondition / privacy issues	
Availability of a sufficient number of professionals trained in the subject matter	
Lack of a centre of expertise	
Political resistances in principle (e.g. to considering income distribution also a health equity issue)	
Lack of a technical secretariat responsible for coordinating intersectoral cooperation / HIA	
Lack of active dissemination of HiAP principles at all Government levels	
Resource constraints	
Lack of convincing evidence coming from other Countries' experiences	

- Finally, summarise the evidence collected (through desk research and interviews) on the proposed indicators. Indicators shall be assessed, when possible, by reference to the criteria of **validity/relevance**, **availability** (i.e. the corresponding data are or may be collected) and **feasibility** (i.e. the corresponding data may be collected at reasonable costs and within a relatively short timeframe). Please duly report all proposals for revision of the proposed indicators voiced by the interviewees.

Table 3.4 – List of potential policy implementation indicators

	Code	Indicator	Notes
1	ANA.1	Formal Adoption of EU HiAP definition and HIA methodology (incl. RE* level)	
2	ANA.2	Evidence of a Significant Debate in the Scientific Literature about HiAP	
3	PRI.1	Existence of Health Policy Documents Including a Commitment to HiAP Principle (incl. RE level)	
4	PRI.2	Reporting to International Organisations of Commitment to HiAP Principle (for instance in the WHO Healthy Cities programme) *To become members of the Healthy Cities European network municipalities must declare commitment to HiAP principles. (Watch out National and European networks are different entities subject to different rules*	.
5	PRI.3	Strategies/Programmes/Action Plans Specifically focusing on HiAP (incl. RE level)	
6	PART.1	Existence of Advocacy NGOs Active in the HiAP Field	
7	PART.2	Involving of Advocacy NGOs in the Policymaking Process (incl. RE level)	
8	RES.2	Resources Made Available by MS to Research Programmes in HiAP Field in Either Absolute or Relative Terms	
9	ORG.1	Identification of a Body Responsible for HiAP Coordination / a Focal Point	
10	ORG.3	Existence of a Centre of Expertise Entrusted with Disseminating Best Practices on HiAP (including HIA methodology)	
11	PRO.1	Introduction of HIA in Routine policy-making process (incl. RE level)	

	Code	Indicator	Notes
12	PRO.2	Number of Relevant Institutions Complying with the above Procedures (incl. RE level)	
13	EVAL.1	Implementation of Evaluations / Cost Effectiveness Assessments of their Policies (incl. RE level)	
14	EVAL.2	Streamlining / modification of Policy as a Result of an Evaluation Exercise / Cost Effectiveness Assessment (incl. RE level)	
15	EVAL.3	Setting up of a System of Indicators to Monitor HiAP uptake / Implementation (incl. RE level)	

***RE**=Relevant Entity

Proposed Additional indicators

Indicator	Comments

ANNEX H – LIST OF INTERVIEWEES

ITALY

Policy area	Institution	Name and position of interviewee within the institution	Interview status
Overall country health strategy	**Ministry of Health** (Ministero della Salute)	Giovanni Nicoletti – Director of Office III for Quality Assurance and Evaluation Systems, Prevention and Communication Department	CONDUCTED ON 27/04/2012
		Roberta Merlotti, Prevention and Communication Department	
		Stefania Masselli, Directorate for Prevention and Coordination	
		Silvia Arcà, Director of Office II for Health Planning, DG Health Planning	
		Dott.ssa Milazzo, DG European and International Relations	
Patient Safety	**Ministry of Health** (Ministero della Salute)	Alessandro Ghirardini, Director of Office III for Quality of Service, DG Health Planning	CONDUCTED ON 27/04/2012
		Maria Grazia Pompa, Office V for Infectious Diseases, Prevention Department	CONDUCTED ON 21/05/2012
	National Agency for Regional Health Services (Age.Na.S. – Agenzia nazionale per i servizi sanitari regionali)	Giovanni Caracci • Director of Quality and Accreditation Unit • Member of the Regional Technical Committee on Patient Safety	CONDUCTED ON 10/05/2012
		Barbara Labella, Good Clinical Practice Unit	
Cancer Screening	**Ministry of Health** (Ministero della Salute)	Antonio Federici, Scientific officer at national centre for disease prevention and control (CCM), Prevention and Communication Department	CONDUCTED ON 10/05/2012

Policy area	Institution	Name and position of interviewee within the institution	Interview status
	Veneto Region Cancer Institute (IOV - Istituto Oncologico Veneto)	Manuel Zorzi, Member of Italian Working Group on Colorectal Cancer Screening (GISCoR)	CONDUCTED ON 19/04/2012
	Piemonte Region Centre for Epidemiology and Cancer Prevention (CPO - Centro per l'epidemiologia e la prevenzione oncologica)	Livia Giordano, Member of Italian Working Group on Breast Cancer Screening (GISMa)	CONDUCTED ON 26/04/2012
Health in All Policies	**Ministry of Health** (Ministero della Salute)	Daniela Galeone – Director of Office II for Planning, Prevention and Communication Department	CONDUCTED ON 27/04/2012
		Maria Teresa Menzano, Office II for Planning, Prevention and Communication Department	CONDUCTED ON 27/04/2012
		Liliana La Sala – Director of Office IV for Environmental Security and Prevention, DG Prevention	CONDUCTED ON 10/05/2012
	Piemonte Region Centre for Epidemiology (Servizio di Epidemiologia Piemonte)	Giuseppe Costa – Team leader of project "Salute in Tutte le Politiche" (Health in All Policies)	CONDUCTED ON 26/04/2012
	Emilia-Romagna Regional Government (Regione Emilia-Romagna)	Marinella Natali, Department of Health – point person of two HIA projects	CONDUCTED ON 17/04/2012
	University of Parma (Università degli studi di Parma)	Carlo Signorelli, Department of Public Health, Hygiene Unit - Author of 'The role of Health Impact Assessment (HIA) in the decision-making'	CONDUCTED ON 18/04/2012
	Istituto Superiore di Sanità (leading technical and scientific public body of the Italian National Health Service)	Giovanni Marsili, Senior Researcher	CONDUCTED ON 09/05/2012
	WHO Italian Healthy Cities Network (Rete Italiana Città Sane OMS)	Simona Arletti, National President of the Network	CONDUCTED ON 15/05/2012

FRANCE

Policy area	Institution	Name and position of interviewee within the institution	Interview status
Overall country health strategy	**Ministry of Health/General Directorate of Health** (DGS - Direction générale de la santé)	Alexandre De la Volpilière, Head of European and International Affairs	CONDUCTED ON 25/04/2012
	High Council of Public Health (HCSP - Haut conseil de la santé publique)	Catherine Le Galès • Head of HCSP International Relations • Former DGS Scientific Advisor	CONDUCTED ON 26/05/2012
	Île-de-France Regional Health Agency (ARS - Agence Régionale de Santé)	Laurent Chambaud, Directeur de la Santé Publique	CONDUCTED ON 10/05/2012
Patient Safety	**Ministry of Health/General Directorate of Health Care Supply** (DGOS - Direction générale de l'offre de soins)	Valérie Salomon • Programme officer of quality and security of care • Former performance indicators project officer (HAS) • Former HCAI policy officer (MoH)	CONDUCTED ON 25/04/2012
	High Council of Public Health (HCSP - Haut conseil de la santé publique)	Bruno Grandbastien, President of the HCSP Patient Safety Committee	CONDUCTED ON 24/04/2012
		Philippe Michel, Vice-president of the HCSP Patient Safety Committee	CONDUCTED ON 10/05/2012
Cancer Screening	**Ministry of Health/General Health Directorate** (DGS - Direction générale de la santé)	Rosemary Ancelle-Park, Directorate for Health Promotion and Chronic Disease Prevention	CONDUCTED ON 25/04/2012
		Alexandre De la Volpilière, Head of European and International Affairs	CONDUCTED ON 25/04/2012
	French National Cancer Institute (INCa – Institut National du Cancer)	Jérôme Viguier, Head of Screening Department	CONDUCTED ON 09/05/2012
	International Agency for Research on Cancer (IARC)	Lawrence Von Karsa, Lead author of the first report: "Cancer screening in the European Union. Report on the implementation of the Council Recommendation on cancer screening"	CONDUCTED ON 11/05/2012

Policy area	Institution	Name and position of interviewee within the institution	Interview status
Health in All Policies	**School of Higher Education in Public Health** (EHESP - Ecole des hautes études en santé publique)	Antoine Flahault, Professor in Epidemiology and Dean of EHESP	CONDUCTED ON 11/05/2012
	WHO French Healthy Cities Network (Réseau Français Villes Santé OMS)	Zoë Heritage, Network Project Officer	CONDUCTED ON 16/05/2012
	National Institute for Public Health Surveillance (InVS – Institut de veille sanitaire)	George Salines, Director of Department Environment and Health	CONDUCTED ON 26/05/2012
		Ellen Imbernon, Director of Department Occupational Health	CONDUCTED ON 24/05/2012

SWEDEN

Policy area	Institution	Name and position of interviewee within the institution	Interview status
Overall country health strategy	**Ministry of Health and Social Affairs** (Socialdepartementet)	Lovisa Strömberg, Advisor, Unit for public health and healthcare	CONDUCTED ON 16/05/2012
	National Board of Health and Welfare (Socialstyrelsen)	Bosse Pettersson, Senior Public Health Advisor	CONDUCTED ON 03/05/2012
	Swedish National Institute of Public Health (FHI - Statens folkhälsoinstitut)	Ann-Cristine Jonsson, Public health planning officer	CONDUCTED ON 14/05/2012
	Swedish Agency for Health and Care Services Analysis (Myndigheten för vårdanalys)	Fredrik Lennartsson, Director and Head (former Head of the Unit for EU and international coordination with the Ministry of Health and Social Affairs)	CONDUCTED ON 04/05/2012
	Swedish Association of Local Authorities and Regions (SKL - Sveriges Kommuner och Landsting)	Erik Svanfeldt, International coordinator, Health and social care division	CONDUCTED ON 02/05/2012
Patient Safety	**National Board of Health and Welfare** (Socialstyrelsen)	Michael Soop, Advisor, Department of supervision	CONDUCTED ON 03/05/2012
	Swedish Association of Local Authorities and Regions (SKL - Sveriges Kommuner och Landsting)	Eva Estling, Patient safety project manager	CONDUCTED ON 04/05/2012
		Agneta Andersson, Officer, Patient safety/patient involvement officer	
		Petra Hasselqvist, Patient safety officer	
Cancer Screening	**National Board of Health and Welfare** (Socialstyrelsen)	Arvid Widenlou Nordmark, Cancer national guidelines coordinator	CONDUCTED ON 03/05/2012
	Swedish Association of Local Authorities and Regions (SKL - Sveriges Kommuner och Landsting)	Maria Prigorowsky, Cancer screening project manager	CONDUCTED ON 03/05/2012
Health in All	**National Board of Health and**	Bosse Pettersson, Senior Public Health Advisor	CONDUCTED ON

Policy area	Institution	Name and position of interviewee within the institution	Interview status
Policies	**Welfare** (Socialstyrelsen)		03/05/2012
		Maria Danielsson, Assistant project manager	
	Swedish National Institute of Public Health (FHI - Statens folkhälsoinstitut)	Anita Linell, Director, Department of society and health (HIA)	CONDUCTED ON 09/05/2012
		Ann-Cristine Jonsson, Public health planning officer	CONDUCTED ON 14/05/2012

POLAND

Policy area	Institution	Name and position of interviewee within the institution	Interview status
Overall country health strategy	**Department of Public Health, Ministry of Health** (Departament Zdrowia Publicznego, Ministerstwo Zdrowia)	Piotr Dąbrowski, Department Director	CONDUCTED ON 27/04/2012
	Ministry of Health (Ministerstwo Zdrowia)	Bolesław Samoliński - National Consultant on Public Health - expert position appointed by the Ministry of Health (Krajowy Konsultant Zdrowia Publicznego, Ministerstwo Zdrowia)	CONDUCTED ON 26/04/2012
	Department of Public Health, National Institute of Public Health/National Institute of Hygiene (Departament Zdrowia Publicznego, Narodowy Instytut Zdrowia/Państwowy Instytut Higieny)	Rafał Halik, Project Coordinator – National Health Programme	CONDUCTED ON 27/04/2012
	Department of Public Health at the regional administration in Mazowieckie voivodship (Departament Zdrowia Publicznego, Mazowiecki Urząd Wojewódzki)	Elżbieta Nawrocka, Department Director	CONDUCTED ON 14/05/2012
Patient Safety	**Center for Monitoring Quality in Health Care** (Centrum Monitorowania Jakości w Ochronie Zdrowia)	Barbara Kutryba, Audit Officer, Expert of the Ministry of Health	CONDUCTED ON 08/05/2012
Cancer Screening	**Department of Health Policy, Ministry of Health**	Agnieszka Strzemieczna, Department Deputy Director	CONDUCTED ON 09/05/2012
	Department of Public Health at the regional administration in Mazowieckie voivodship (Departament Zdrowia Publicznego,	Elżbieta Nawrocka, Department Director	CONDUCTED ON 14/04/2012

Policy area	Institution	Name and position of interviewee within the institution	Interview status
	Mazowiecki Urząd Wojewódzki)		
	Departament of Prevention of Civilization Diseases, National Institute of Public Health /National Institute of Hygiene (Departament Prewencji Chorób Cywilizacyjnych, Narodowy Instytut Zdrowia Publicznego/Państwowy Instytut Higieny)	Magdalena Bielska-Lasota, Project Coordinator, Expert	CONDUCTED ON 20/04/2012
Health in All Policies	**National Institute of Public Health/National Institute of Hygiene** (Narodowy Instytut Zdrowia Publicznego/Państwowy Zakład Higieny)	Mirosław Wysocki, Director of the Institute	CONDUCTED ON 02/05/2012
	Department of Public Health, Ministry of Health (Departament Zdrowia Publicznego, Ministerstwo Zdrowia)	Piotr Dąbrowski, Department Director	CONDUCTED ON 27/04/2012

ANNEX I – BIBLIOGRAPHY

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