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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 I – MAIN TEXT

submitted by

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

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Main Abbreviations and Acronyms

CBRN	Chemical Biological Radiological Nuclear
COM	Commission Communication
CONC	Council Conclusions
CS	Cancer Screening
DG SANCO	Directorate General for Health and Consumers
EBCCN	European Cervical Cancer Screening Network
EC	European Commission
ECDC	European Centre for Disease Control
ECHI	European Community Health Indicators
ECN	European Cancer Network
EMCDDA	European Monitoring Centre for Drugs and Drug Addictions
ENCR	European Network of Cancer Registries
EPAAC	European Partnership on Action Against Cancer
ERN	European Reference Network
EU	European Union
EUNICE	European Network for Information on Cancer
IA	Impact Assessment
IARC	International Agency for Research on Cancer
HC	Healthcare
HAI	Healthcare Associated Infection
HCAI	Healthcare Associated Infection
HCQI	Healthcare Quality Indicator
HEIA	Health Equity Impact Assessment
HFA	Health For All
HIA	Health Impact Assessment
HIAP	Health in All Policies
HSIA	Health System Impact Assessment
HS	Health Strategy
IA	Impact Assessment
ICPS	International Classification for Patient Safety
IR	Implementation Report
IT	Information Technology
MS	Member State
N.A.	Not Available
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
PHP	Public Health Programme
PS	Patient Safety
RE	Relevant Entity
REC	Council Recommendations
WAPS	World Alliance on Patient Safety
WHO	World Health Organisation

MAIN TEXT

EXECUTIVE SUMMARY

1. Introduction

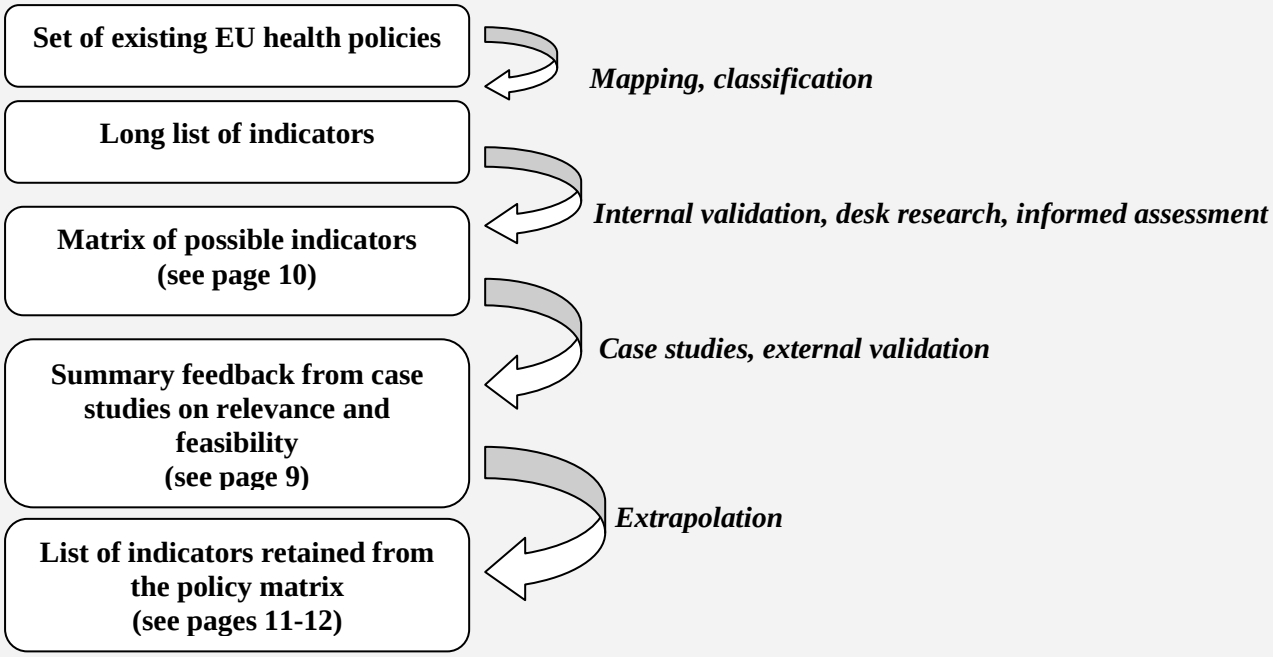
The quest for indicators on policy implementation. Policy makers need to be able to check if implementation of policies is 'on track' and the extent to which any given policy is achieving its objectives. When a policy is not achieving its intended objectives, it is important to know whether this depends on problems with the policy design or with implementation, including possible weak administrative capacity. Indicators provide valuable information in this regard and Commission impact assessment practice already envisages arrangements to have core indicators for the main policy objectives in place. Indicators must serve a clear purpose, i.e. measuring to what extent a policy has been properly implemented and its objectives achieved. Another important factor in choosing indicators is the ease with which data can be collected; collecting data should not be more costly than the value of the information they provide. Finally, indicators should be perceived as legitimate by all the stakeholders concerned.

In the public health field substantial work has been carried out over the last few years at the European level in reaching consensus about health outcome and health impact indicators. In parallel, also structural and process indicators have increasingly been developed as tools to measure the governance process through which any policy can be implemented and changed over time and spot reasons for success or problem areas. While in some health policy areas these process indicators have already entered into Commission practice and been incorporated in the related impact assessment reports and monitoring systems, no systematisation of the indicators variously proposed from different sources to come to a more coherent framework for broader strategic internal monitoring purposes has ever been attempted.

This *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* has covered more than twenty different EU health policies implemented in the 2005-2011 period and lying within the framework of the EU Health Strategy 2008-2013. It was aimed at the identification of a common analytical framework containing homogenous categories of indicators that could eventually be applicable to other health policy areas in the future. This framework was preliminarily tested and validated by means of case studies in three different policy areas (Health in All Policies, Cancer Screening and Patient Safety) in four Member States (France, Italy, Poland and Sweden).

The methodology used included a combination of desk research and external validation by means of case studies, as well as interviews with stakeholders and policy specialists. The set of existing EU Health Policies was first mapped and classified. This led to a first long list of indicators and to a matrix of policy areas to which these indicators could be applied as a product of an internal validation process based on desk research and expert assessments. The validity and feasibility of the various possible indicators was then cross-checked through a selected number of pilot case studies. The methodology is briefly summarised in the flowchart below (see Box A).

Box A - Methodology Flowchart



2. Summary of Main Findings

Policy indicators are valuable but scarce. At present there is no common system of indicators available for monitoring the uptake of EU Health Policies at Member State level. Instead, there are a number of scattered and fragmented sources poorly systematised and largely conceived quite independently from one another. These include the indicators already proposed within the framework of the EU Health Strategy's Interim Evaluation Report (TEP 2011), and those proposed by the preparatory studies and the impact assessment reports carried out for the different specific policies. However, these indicators have not been systematically implemented or followed up. Some policy initiatives have envisaged their own monitoring systems and called for related implementation reports, some on a strictly voluntary basis. Only in relatively few cases indicators have been explicitly included in the texts of the EU policies. In such cases, the indicators envisaged are typically outcome or impact indicators, and are meant for use only with respect to population health status, while they are hardly ever concerned with progress in policy implementation or uptake. In other cases, indicators have been for expert groups or the MS themselves to identify; the very fact that on occasion these have been actually identified has been considered *per se* as an indicator of commitment to the policy.

Policy indicators measuring the degree of policy uptake can be defined. A total of twenty different categories of process indicators have been identified as representative of five distinct stages of the policymaking process. These include indicators describing the policy definition stage that can be further subdivided into (i) a problem identification phase and (ii) consensus building phase. The policy implementation process can be then described in both (iii) institutional and (iv) operational terms. Finally, appropriate indicators represent the essence of (v) the policy feedback and learning mechanisms. An outline of these categories is presented in the box below (see Box B).

Box B - Categories to measure the degree of policy uptake

Policy Definition – Problem Identification

- Agreeing Analysis (ANA): Adopt/transpose/promote policy based on a common problem definition, or common analytical methodologies and/or guidelines, or inspired to common principles.
- Setting Objectives (OBJ): Aim to a certain specific policy objective irrespective of the concrete modalities with which it has to be achieved.
- Drafting Programmes (PROG): Define strategies, programmes and action plans at all the relevant levels of Government (national, regional, local) in a given policy area. A subset of this programming activity concerns the specific identification of research needs with an aim for their eventual coordination at the EU level (PROG.RES).
- Introducing Legislation (LEG): Introduce/modify enforceable legislation/self-regulation. Self-regulation can be represented by voluntary commitments to change behaviour from single economic agents (LEG.VOL).

Policy Definition – Consensus Building

- Committing to Principle (PRI): Commit all policymakers to a given horizontal health policy principle.
- Involving Partners (PART): Promote participatory policymaking by involving stakeholders' groups and patient organisations.
- Investing in Research (RES): Fund research to spur interest in the subject in the scientific community.
- Raising Awareness (AWA): Raise awareness through informational/educational campaigns[1].

Policy Implementation – Institutional Aspects

- Funding Policies (FUND): Make adequate resources available to implement policies/programmes. A subset of this may include specific suggestions to use the EU Structural Funds and the Health Programme as a source of financing.
- Establishing Organisations (ORG): Establish a body clearly responsible for policy coordination and/or a focal point entrusted with data collection and policy reporting at the EU level. Establish a lead agency/centre of expertise to disseminate policy.
- Building Networks (NET). Build networks of institutions and ensure the necessary communication among them.
- Introducing Procedures (PRO): Introduce given procedures.

Policy Implementation – Operational Aspects

- Policing /Enforcement (POL): Policing compliance with regulation/self-regulation by means of administrative or judicial controls.
- Delivering Actions (DEL): Deliver concrete activities in compliance with a given set of implementation modalities or for certain population targets (this can be at the national, regional and local level).
- Ensuring Technical Capacity (CAP): Ensure the availability of the necessary technical means or equipment.
- Training (TRAI): Train personnel.

Feedback on Policy and Learning Mechanisms

- Harmonising Data (HAR): Establish a harmonised set of indicators concrete to the policy area and the national framework to describe the policy problem to allow data comparisons at the European level. Adopt a common set of definitions and modify national data recording accordingly.
- Evaluating Results (EVAL): Monitor and evaluate the effectiveness/cost-effectiveness of policies.
- Exchanging Information (EXC): Exchange best practices and policy results at European level.
- Reporting on Implementation (REP): Report to the Commission on implementation and results achieved.

Source: Consultant's own elaboration.

The matrix below (see Table I) is the result of a mapping of policy actions recommended to the Member States by various EU health policy initiatives and analysis of the indicators proposed, based on a review of the relevant Commission policy documents and an internal expert validation process. Table I shows that the system presented in Box B is robust and internally consistent; the categories identified can measure the process of policy implementation in all the cases reviewed. Moreover, the list of categories is structured not to rule out the possibility of adding new policies in the future, should this be needed. Therefore the system is satisfactorily scalable.

[1] This category results from the merging of three previously identified categories on 1) the awareness about the policy problems; 2) dissemination and communication campaigns about the policy content; and 3) educational campaigns specifically targeting schools.

Table I - Matrix of EU Policy Areas and Categories of Applicable Indicators

	ANA	OBJ	PROG	LEG	PRI	PART	RES	AWA	FUND	ORG	NET	PRO	POL	DEL	CAP	TRAI	HAR	EVAL	EXC	REP
Shared Health Values	●	○			●			○	○								●		●	
Health is the Greatest Wealth							●		●									●	●	
Health in All Policies	●				●	○	○			●		●						●		
Global Health		●			○				○	●		●						●	○	
Health of Older People			●	○		●	●	●								●	○	●		●
Tobacco		●	●	●				●	○	●			●				○	●		●
Nutrition		●		●	○	●		●		○		●		●			●	●	●	○
Alcohol		●	●	●		○	○	●		○			●			●		●	●	●
Mental Health					○	○		○	○					●		●	●	●	●	
Illicit Drugs	●		●			●		●						●			●	●	●	●
Cancer	●	●	●	○				●	●			○		●		●	●			●
Rare Diseases	●		●			●	●		●		●	●				●	●	○	●	●
Organ Donation & Transplantation	○	●	●					●				●		●		●	●	●	●	
Injuries			●		○							○				●	●	●		
HIV/Aids			○			○	○		●					●			●	●	●	
Vaccination	○		●				●	●						●				●		●
Preparedness Planning		●	●						○		○	●			●				●	
CBRN	●									○	●	●		●	●		○		●	
Antimicrobial Resistance		●	●		○			●	○	●		●			○		●			
Patient Safety	●		●			●	●	●	○	●	●			●		●	●	○	●	●
Telemedicine			●	●									●						●	
RELEVANCE	9/2	9/1	14/1	6/2	7/5	9/4	8/3	12/2	11/7	8/3	4/1	10/2	3/0	9/0	3/1	8/0	14/3	15/2	14/1	9/1

Legend: *See box B above for the classification of indicators. Cases of relevance are highlighted with the symbol •. Cases of possibly limited relevance are highlighted with the symbol ○. The ratio in the last row should be understood as the total number of policy areas in which the category would have relevance (limited or not) (numerator), over the cases of possibly limited relevance (denominator). For further details on the rationale behind see volume II, Annex A.*

During the internal validation process, not all the categories of indicators have appeared in the expert's opinion as equally relevant in all cases; in fact, there were several categories for which a number of indicators, while feasible on paper, proved of limited interest to EU policymakers. This was often the case of indicators that were indeed included in the relevant policy documents, but were far from the core of the related policy messages, or concerning secondary aspects. These indicators were classified as of possibly limited relevance in Table I, based on informed assessment. This leaves room for simplification and streamlining of this framework in a manner tailored to the specific information needs of the DG SANCO services concerned.

The concrete feasibility of the analytical framework in Box B was then tested by means of pilot case studies in view of its implementation in concrete, real-world conditions. The table below (see Table II) summarises the results of the case studies. Most categories of indicators have appeared as both valid and feasible, while others have generated some validity and feasibility issues. A thorough inspection of their characteristics eventually led to a final reclassification of the indicators as 'primary', 'secondary' and 'not retained for the time being but to be reconsidered in the future'.

Table II – Summary Feedback from Case Studies on Validity and Feasibility of Indicators

Indicator	Patient Safety		HIAP		Cancer Screening	
	Validity	*Feasibility*	*Validity*	*Feasibility*	*Validity*	*Feasibility*
ANA	+	++	+	++	0	+
OBJ	0	+			+	0
PROG	+	0			+	+
LEG					+	+
PRI			+	++		
PART	0	-	-	-		
RES	+	-	-	--		
AWA	+	0			+	--
FUND	-	--			0	--
ORG	++	++	++	++		
NET	0	+				
PRO			-	0	0	0
DEL	--	--			+	+
CAP					0	+
TRAI	+	-			-	-
HAR	++	++			++	++
EVAL	++	+	++	+	++	++
EXC	-	+				
REP	-	-			0	0

Legend: (++) highly valid / feasible; (+) fairly valid/feasible, (-) hardly valid/feasible; (--) definitely not valid/feasible. (0) stands for diverging inconclusive judgements. See box B above for the categories of indicators.

A common framework of policy indicators is a realistic option. Following this comprehensive exercise, it appeared that a logical and consistent system of policy indicators could be identified and that indicators could be clustered in a limited, and thus manageable, number of homogenous categories. Similarities across various aspects of health policy were sufficiently pervasive and consistent, and the number of outliers was limited enough that the system could be reasonably considered adaptable. All in all, the resulting categorisation proved satisfactory for the Commission's internal monitoring purposes, as it could be transposed to other health policy areas and fine-tuned at the user's convenience. The system's current setup does not exclude the possibility of making further additions, should the need to do so arises in the future. The box below (see Box C) summarises the results of the external validation process and provides a first classification of the indicators that for the time being can be considered primary or secondary, as well as of those that can be retained in special cases only.

Box C - Indicators Retained from the External Validation Process

Primary Indicators

The case studies carried out within the framework of this exercise have confirmed the relevance of indicators on (i) the adoption or transposition of policy definitions or methodologies (ANA), (ii) data harmonisation (HAR), (iii) the existence of dedicated programmes or strategies in a given policy area (PROG), (iv) the allocation of organisational responsibility (ORG), and (v) the availability of evaluation reports (EVAL). All in all, these indicators, which we have been named 'primary' indicators, represent on their own a good proxy of the level of commitment to any given policy. Examples include, among others:

- number of MS or other relevant entities formally adopting a given methodology/problem definition - wholly or in part (ANA);
- number of MS that have established a strategy / programme / action plan covering the whole population (PROG);
- number of MS that have identified a body responsible for policy coordination / a focal point (ORG);
- number of MS for which a centre of expertise entrusted with disseminating best practice in a given policy area can be officially identified (ORG);
- number of MS providing homogeneous data to the relevant EU Health Indicator database (HAR);
- number of MS that have put in place special registries when requested / number of registries established (HAR);
- number of MS or other relevant entities that have carried out evaluations / cost effectiveness assessments of their policies (EVAL); and
- number of MS or other relevant entities that have put in place a system of indicators to monitor policy implementation (EVAL).

Secondary Indicators

Other categories of indicator can be retained as secondary indicators for complementary information purposes. They are not generally considered as valid and feasible as primary indicators and are subject to a number of limitations, but can nevertheless address special purposes and information needs. These include, among others:

- bibliographic indicators such as number of MS with evidence of a significant debate in the scientific literature about a methodology / policy problem (ANA);
- indicators on EU funding such as total structural fund financing committed to implement a given health policy (STR.FUND);
- indicators on the number of MS reporting commitment to a given policy principle to international organisations or the EU (PRI);
- indicators on the number of MS that have submitted their policy experiences to the relevant European Coordination Mechanism / Working Group or dedicated database / portal (EXC);
- indicators on the number of MS that have complied with their reporting requirements when relevant (REP).

Indicators to Be Considered on an Ad Hoc Basis
Indicators on introducing legislation or self-regulation (LEG) and on policing and enforcing it (POL), as well as those on building networks (NET) and ensuring related technical capacity (CAP) and on introducing given procedures (PRO) have been retained for special cases only to be considered on an ad hoc basis.

Indicators not Currently Retained but Worth Reconsidering in the Future
Awareness raising and communication (AWA), policy participation (PART), research (RES), and policy funding (FUND) indicators have not been retained partly because of disagreement among stakeholders on their relevance in the specific country context, partly because of severe feasibility problems. At any rate, they remain worth considering in the future, should the current limitations be overcome and an agreement found on their relevance in light of well-defined benchmarks in terms of compliance with relevant EU guidelines.

Main limitations. Further progress in the definition of a more concise and streamlined framework of process indicators to monitor the uptake of the EU Health Policies is hindered by some inherent limitations, and in particular:

- the benchmark for reference is represented by a rather heterogeneous set of policy documents;
- the existence of very few horizontal principles that can consistently be applied *across all* the various policy areas;
- also as a consequence of this, the lack of consensus among stakeholders on major categories of indicators; and
- the fact that the proposed system can measure convergence towards certain common aims, but it is of limited help in solving the problem of attributing the progress achieved to the specific influence of EU policies (the so called problem of attribution) and measure the *specific contribution of EU inputs* ('EU added value') to the policymaking process.

3. Conclusions

The exercise has demonstrated that a common framework of indicators to monitor uptake of EU health policies in Member States for the Commission's internal strategic monitoring purposes is feasible and sufficiently robust to be transposable in the future to cover also other health policy areas, with only minor needs for adjustment. The system is flexible enough to lend itself to be fine-tuned according to the specific information needs of the different Services concerned. Evidence from the case studies shows that the framework can be an effective tool to measure the progress achieved in the different areas and highlight obstacles or instances of best practice. It can also be used as a tool for internal Commission stocktaking and decision-making in the allocation of resources to the most effective policy interventions or means, in the interest of having European investment absorbed and have the greatest impact. Additional steps towards the implementation of the indicator system above would require further validation from the concerned DG SANCO Services, together with the fine-tuning of the most relevant indicators for their specific information purposes and, where possible, further testing in other countries and aspects of EU health policy. In the future any further streamlining and consolidation of the proposed framework of indicators into a more coherent set with smaller room for disagreement, would depend on two conditions: 1) the benchmark for reference to measure progress in the uptake of the EU health strategy could be more clearly focused in a shorter set of predefined shared principles valid across the various policy areas; e.g. on enhancing the value for money of the resources spent (at present the issue is dealt with as a horizontal principle in the 2007 strategy document but hardly incorporated in concrete terms in the sectoral policy documents) or on reaching a common agreement on what elements should be evaluated of the various policies and how; and consequently 2) greater emphasis should be given to a better defined European added value dimension. Evidence from the case studies shows that this would involve:

1. concentrating on a smaller number of long-term priorities. At present there is a feeling that the EU action is diluted into too many priorities, proposed over a too short period of time and

therefore difficult to follow, which ultimately causes the loss of any sense of real prioritisation and of the momentum built with the success of previous initiatives;

2. gradually moving away from sectoral policy documents towards framework recommendations that can be applied across policy areas, e.g. by defining common formats for evaluating policies and share related results;
3. identifying areas of clear European added value where action should be focused (economies of scale were the clear example for rare diseases, but other sources of European added value can be identified) and providing guidance on common governance/stewardship principles including organisational aspects;
4. building consensus on ways to generate common policy intelligence at the European level so that the debate on harmonising data can be expanded to needs for applied research and on how to take into consideration the broader socio-economic contextual factors;
5. defining common principles to ensure accountability (e.g. by improving reporting requirements and agreeing publishing or data dissemination rules or common quality assurance principles);
6. better defining common policy evaluation frameworks and related methodological guidance to facilitate exchange of experiences as part of a broader effort in reaching consensus on intelligence needs; and
7. addressing areas of disagreement or limited implementation by establishing partnerships or defining financial incentives or sanctions (some interviewees suggested that a share of the Public Health Programme could be made conditional on progress achieved).

In particular, further progress in tackling the problem of attribution and better assessing the role played by the EU would require a better definition of the main components of European added value. At present, with a few notable exceptions, European added value is mainly identified with exerting soft policy influence on Member States by means of recommendations and other consensus building mechanisms, which is hardly measurable in quantitative terms but with recourse to subjective expert opinions. If the role of the Commission were seen as that of "steward of stewards" within the framework of the stewardship principle agreed by the Member States with the charter of Tallinn[2] and common lines were identified on the best way to (i) maintain the strategic direction of policy development and implementation; (ii) detect and correct undesirable trends; (iii) articulate the case for health in development; (iv) interact with a wide range of stakeholders; (v) define effective accountability mechanisms and (vi) steer the role of regional and local authorities were provided, it would be possible to come to a more precise measurement of the specific contribution of the EU actions to policy convergence.

[2] Tallinn Charter adopted at the 2008 WHO European Ministerial Conference on Health Systems: "Health Systems, Health and Wealth". See the WHO Europe conference document EUR/RC58/Conf.Doc./4 Stewardship/Governance of health systems in the WHO European Region, and the working document EUR/RC58/9 Stewardship/Governance of health systems in the WHO European Region.

1. BACKGROUND

1.1 The Aim and Scope of the Exercise

Aim. Policy makers need to be able to check if implementation is 'on track' and the extent to which any given policy is achieving its objectives. When a policy is not achieving its intended objectives it is important to know whether this depends on problems with the policy design or with implementation, including possible weak administrative capacity. Indicators provide valuable information in this regard and Commission impact assessment practice already envisages arrangements to have core indicators for the main policy objectives in place. Indicators must serve a clear purpose, i.e. measuring to what extent a policy has been properly implemented and its objectives achieved. Another important factor in choosing indicators is the ease with which data can be collected; collecting data should not be more costly than the value of the information they provide. Finally indicators should be perceived as legitimate by all the stakeholders concerned.

The Terms of Reference for this exercise consist of the development of a methodological study supporting the assessment of EU health policy uptake and implementation in Member States. The assignment is to complement the recently completed mid-term evaluation[3] of the EU Health Strategy 2008-2013[4] (hereafter abbreviated to the EU Health Strategy), with a particular focus on the identification and analysis of indicators capable of measuring the degree of adoption and implementation of EU health policy at the national, regional and local levels. This in turn should contribute to the monitoring and assessment of the overall added value of EU action, as well as of its ultimate impact on the achievement of medium- and long-term health policy targets.

In particular, the three specific objectives of the work are:

- Objective #1 - elaborating a set of appropriate and robust policy implementation indicators that may be used by DG SANCO to assess progress and monitor the implementation and achievements of EU health policy in the 2005-2011 period;
- Objective #2 - providing support to DG SANCO in its effort to establish an indicator-based approach for the evaluation of EU health policy post-2013 (i.e. after the end of the current period covered by the Health Strategy), including the Health for Growth Programme;
- Objective #3 - contributing to the monitoring and evaluation of the current degree of implementation of the EU health policy in MS and of the interactions between EU-level health policy and MS-level health policies.

In particular, it was noted that the Commission often has limited access to 'bottom-up' information on how EU-level policies translate into concrete MS-level initiatives and on the possible causes of implementation gaps or enhancing factors. Hence, the importance of focusing on policy implementation process indicators. In the context of this Study, it was instead deemed not relevant to develop indicators to measure in detail the degree of success of MS-level initiatives.

The set of indicators eventually sought would have to include to the extent possible 'high-level'/general indicators common to all policy areas, and to a minor extent indicators relating to particular policy aspects, selecting in these cases only the most informative ones. Process indicators would be generated so as to be applicable in all MS, transcending the idiosyncrasies the policy governance and health system organisation in individual MS. The Study would be based on a combination of extensive desk research, and a limited number of case studies for both information and validation purposes, selected by the relevant Commission services.

[3] PHEIAC, "Mid-Term Evaluation of the EU Health Strategy 2008-2013", Final Report, August 2011.
[4] COM(2007) 630 final, "Together for Health: A Strategic Approach for the EU 2008-2013", Brussels 23.10.2007.

Scope. The analysis has covered the policies issued in the *2005-2011 period*, but in a few cases, references had to be made to policy documents released before that date, because these remain the reference policy framework of all subsequent developments that took place in the period under consideration[5]. The analysis would take into consideration a number of possible aspects, including (i) the extent to which the EU policy is referenced in MS policy documents; (ii) the concrete initiatives taken in MS connected to the EU policy; and (iii) the structural and organisational factors affecting the capacity of MS to concretely implement the EU health policy. The proposed set of indicators would take into account the different levels (national, regional, local) at which EU policy may be implemented by MS, thus reflecting the different configurations of health policy-related governance and health systems.

During the Inception Phase, it was agreed that the Study should focus on non-legislative policy items (such as recommendations, communications etc.), since there exists already mechanisms to adequately track the implementation of regulatory ones (in particular regulations and directives). For this reason, the Consultant performed an initial mapping exercise, covering a variety of EU policy documents issued in the 2005-2011 period. The areas that have remained outside the scope of this mapping exercise are therefore most EU policy on communicable diseases and related early warning systems - that is mainly regulated by means of Commission Decisions - as well as of the entire EU *acquis* on safety and health at work and blood, tissue, cells and organs, with the notable exception of the two recent Communications on Organ Donation and Transplantation[6]. Table 1.1 below reports the complete matrix of the policy documents reviewed by policy area[7]. This can be considered as reasonably representative of the policy actions undertaken at the EU level, although not fully exhaustive especially, as concerns Council Communications. As can be seen, in the period concerned the number of EU soft law instruments aimed at steering MS actions has been steadily increasing from 2005 till 2009 when it peaked, and slowly subsided from then on.

There are differences in the degree of policy development reached in the various policy areas. In some areas, the EU policy is articulated in a very detailed list of requests made to MS concerning specific actions and relatively easily verifiable outputs. This is generally the case of Council Recommendations, often preceded by a Commission Communication outlining the main underlying principles and by an extensive consultation process. This is the legislative technique that was followed in the areas of tobacco, rare diseases, injuries, influenza vaccination, and patient safety; these are the policy areas in which EU soft law, while still remaining non-binding, has gained maximum leverage. In other policy areas, the existence of a Commission Communication can be accompanied or not by a parallel Council Conclusion[8] reinforcing the underlying policy message in terms of political commitment. However the two are not strictly related in terms of timing and strategic orientations. In fact, there can be cases where the Communications and Conclusions differ to some extent in their contents, and focus on different priorities. This reflects the fluid nature of

[5] So, for instance, the three Guidelines released on cancer screening still draw from the seminal 2003 Recommendation on Cancer Screening. DG SANCO monitoring of the EU policy on Illicit Drugs is still based on the 2003 Council Recommendation on the Prevention and Reduction of Health-related Harm associated with Drug Dependence, as well as information on antimicrobial resistance is still retrieved based on the provisions of the 2003 Recommendation on the Prudential Use of Antimicrobial Agents in Human Medicine.

[6] Namely, *Organ Donation and Transplantation: Policy Actions at EU Level* SEC (2007) 704 and *Action Plan on Organ Donation and Transplantation: Strengthened Cooperation between Member States* SEC (2008) 2956

[7] The distinction between vertical and horizontal policies is not as clear-cut as the matrix would make it appear. For instance policy documents on obesity and nutrition also include substantial Health-in-All-Policies elements in their formulation, and the same applies to mental health and injuries. Similarly, Recommendations on health inequalities are spread across several policy areas, and the same can be said of the "Health is the Greatest Wealth" principle.

[8] Conclusions are political statements by the Council that enable (and legitimate) cooperation between two or more MS; this cooperation between MS may involve changes in practices or in the national legislation and allows them to undertake joint operational action. Conclusions also set out the direction of policies to be pursued when the European Commission initiates a proposal. The European and national parliaments have no say regarding their content.

documents released at stages when policy is still in its making. It follows that requests made to MS are also typically not formulated with the same level of detail as in Recommendations. They can be expressed in ways more open to interpretation, and not as easily verifiable. When a European policy has just been outlined in its basic principles, or MS are requested to take preliminary or preparatory steps, Commission Communications are usually the policymaking instrument of choice. Finally, there are policy areas (e.g. alcohol, organ donation and transplantation, etc.) where requests to MS are expressed mainly in terms of objectives to be achieved in the given local context, thereby leaving considerable room for manoeuvre as regards concrete implementation modalities and verifiable outputs.

Table 1.1 - Policy Actions Undertaken by the EU (2005-2011)

Policy Area	2005	2006	2007	2008	2009	2010	2011
Shared Health Values					Solidarity in health: reducing health inequalities in the EU		A EU Framework for National Roma Integration Strategies
Health is the Greatest Wealth.						*EPC- Commission Joint Report on health systems in the EU*	
Health in All Policies		*Health in All Policies*					
Strengthening the EU Voice in Global Health		Programme to Tackle the Critical Shortage of Health Workers in Developing Countries				The EU Role in Global Health	
Health of Older People				*Public Health Strategies to Combat Neurodegenerative Diseases*	European initiative on Alzheimer's Disease and Other Dementias *On a research joint programming initiative on combating neurodegenerative diseases*		
Tobacco					**Smoke-free environments**		
Nutrition	*Council Conclusions on Obesity, Nutrition and Physical Activity*		A Strategy for Europe on Nutrition Overweight and Obesity Related Health Issues *Council Conclusions on Strategy on Obesity, Nutrition and Physical Activity*			*Council Conclusions on Salt Action*	
Alcohol		An EU Strategy to Support Member States in Reducing Alcohol-related Harm			*On Alcohol and Health*		

Policy Area	2005	2006	2007	2008	2009	2010	2011
Mental Health	Green Paper on Mental Health Action Plan *Council Conclusions on Mental Health Action Plan*			European Mental Health Pact			*Council Conclusions on European Mental Health Pact*
Illicit Drugs				*EU Drugs Action Plan 2009-2012*			
Cancer		European guidelines for quality assurance in breast cancer screening and diagnosis		European guidelines for quality assurance in cervical cancer screening. *On reducing the burden of cancer*	On Action Against Cancer: European Partnership	European guidelines for quality assurance in colorectal cancer screening and diagnosis *Action Against Cancer*	
Rare Diseases				On Rare Diseases: Europe's challenges	**On an Action in the Field of Rare Diseases**		
Organ Donation & Transplantation			Organ Donation & Transplantation: Policy Actions at EU Level *On organ donation and transplantation*	Action plan on Organ Donation & Transplantation (2009-2015): Strengthened Cooperation between Member States			
Injuries		On Actions for a Safer Europe	**On the Prevention of Injury and the Promotion of Safety**				
HIV/Aids					Combating HIV/AIDS in the European Union and neighbouring countries, 2009 -2013		
Vaccination					**On Seasonal Influenza Vaccination**		

Policy Area	2005	2006	2007	2008	2009	2010	2011
Preparedness Planning	On Strengthening Coordination on Generic Preparedness Planning for Public Health Emergencies at EU Level On Pandemic Influenza Preparedness and Response Planning in the European Community						
CBRN					On Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union *An EU CBRN Action Plan*		
Antimicrobial Resistance .				*Council Conclusions on Antimicrobial Resistance*			Action Plan against the Rising Threats from Antimicrobial Resistance
Patient Safety				On Patient Safety, including the Prevention and Control of Healthcare-associated Infections (HCAI)	**On Patient Safety, including the Prevention and Control of Healthcare associated Infections**		
Telemedicine.			On Telemedicine for the Benefit of Patients, Healthcare Systems and Society				

Legend: Recommendations are in **bold**; Council Conclusions in *italics.* Source: Consultant's own elaboration of data.

1.2 The Current Situation – Indicators Available for the EU Health Policies

The EU Health Strategy. The EU health policy framework remained relatively fragmented until the issuance in 2007 of the EU Health Strategy (HS), which has attempted to integrate the rationale, aims and priorities of EU action in the field of health into a comprehensive document. The HS identifies four fundamental horizontal principles underpinning EU action: 1) Shared health values; 2) Health is the Greatest Wealth; 3) Health in All Policies (HIAP); 4) Strengthening EU's voice in global health. The strategy is articulated into three objectives grouping a number of vertical policies. Based on a classification of the soft EU *acquis* on health of some relevance to the *three objectives* outlined in the *EU Health Strategy 2008-2013*, a total of seventeen vertical policies have been identified and retained for further analysis as reported in Table 1.2 below[9].

Table 1.2 - EU Health Policies Classification Scheme

Four Principles	Objective One: Fostering Good Health in an Ageing Europe	Objective Two: Protecting Citizens from Health Threats	Objective Three: Supporting Dynamic Health Systems and New Technologies
1. Shared Health Values 2. Health is the Greatest Wealth 3. Health in All Policies 4. Strengthening the EU Voice in Global Health	5. Health of Older People 6. Tobacco 7. Nutrition 8. Alcohol 9. Mental Health 10. Illicit Drugs 11. Cancer 12. Rare Diseases 13. Organ Donation & Transplantation	14. Injuries 15. HIV/Aids 16. Vaccination 17. Preparedness Planning 18. CBRN 19. Antimicrobial Resistance 20. Patient Safety	21. Telemedicine

Source: Consultant classification based on the EC Health Strategy 2008-2013, SEC (2007) 1374.

Results from the Mid-Term Evaluation. The EU Health Strategy has recently undergone a mid-term evaluation showing mixed results in how it has influenced, guided, and encouraged different actors in the public health arena to adopt, adapt, or revise policies, and to undertake concrete action. Its main strengths appear to be related to its coherence and ability to provide a guiding framework; however, with regard to its impact and uptake in MS, the evaluator has concluded that the HS has possibly only provided a minor, indirect contribution. However, a precise assessment was made difficult by the so-called 'attribution problem,' i.e. the extent to which various outcomes registered at the MS level can be attributed to the causal effect of EU intervention (EU added-value). The evaluation exercise was largely based on subjective experts' opinions collected through surveys and interviews, and a system of agreed indicators and targets against which to measure HS implementation progress and achievements. In this respect, the present Assignment can be considered complementary to the mid-term evaluation as it contributes to the completion of the HS implementation assessment and the establishment of a solid and methodologically sound evaluative framework for future evaluation of the overall EU health policy. A limited set of twenty-one indicators for strategy monitoring purposes had been proposed within the framework of the mid-term evaluation exercise. These are reported in Table 1.3 below.

[9] All policies mentioned in the Health Strategy have been have been reviewed, irrespective of the fact that primary responsibility for implementation and monitoring lies with DG SANCO or with other DGs, as can be the case for instance with illicit drugs and CBRN (DG JLS), with actions in the field of global health (DG DEV) or with the health inequality dimension of actions aimed at the Roma population.

Table 1.3 - List of indicators proposed by the EU Health Strategy mid-term evaluation to help monitor future progress in policy uptake

Principle 1: A Strategy based on shared values	1. Number of MS whose national EU Health Strategy documents (post-2007) explicitly recognise the following principles: • Universality, access to good quality care, equity and solidarity of healthcare systems. • Citizens' empowerment: facilitate participation and competence development. • Reducing health inequalities.
Principle 2: Health is the greatest wealth	2. 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.
Principle 3: Health in All Policies	3. Number of MS with an overarching national EU Health Strategy / policy plan that includes an explicit reference to HIAP. 4. Number of MS that are referred to in publications in relation to the HIAP principle). 5. Number of MS that have developed specific tools / guidelines for health IA.
Principle 4: Strengthening the EU's voice in global health	6. 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). 7. 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.
Objective 1: Fostering health in an ageing Europe	8. Tobacco: Number of MS that have introduced comprehensive smoke-free laws in line with their international obligations under the WHO FCTC.
	9. Tobacco: Number of MS that have introduced flanking tobacco control measures, including: • pictorial warnings on tobacco packs. • subsidised support for smokers to quit. 10. Alcohol: Number of MS that have developed or revised their alcohol policy. 11. Alcohol: Number of MS that have implemented new measures to protect young people, children and the unborn child from harm from alcohol (before / after the adoption of the HS). 12. Cancer: No of MS implementing cancer screening programmes according to Council Recommendation (2003/878/EC). 13. Rare diseases: Number of MS that have adopted an action plan on rare diseases, on the basis of Council Recommendation (2009/ C 151/02). 14. Organ donation / transplantation: Number of MS that have adopted / revised National Action Plans on the basis of the Commission's 2008 Action Plan.
Objective 2: Protecting citizens from health threats	15. Health Threats. Number of MS that have national or regional health information tools to monitor health threats and the type of threats covered by the devices. 16. Communicable diseases: Number of MS that have national influenza pandemic preparedness plans in line with EU recommendations (before / after the adoption of the HS). 17. CBRN: Number of MS that have developed national CBRN preparedness and response plans. 18. Climate change: Number of MS that have adopted a specific strategy to deal with / mitigate the likely effects of climate change on human health. 19. Patient safety: Number of MS that have fully implemented the 2009 Council recommendation on patient safety (2009/C 151/01).
Objective 3: Supporting dynamic health systems and new technologies	20. Number of MS with programmes / initiatives at national and/or regional level for eHealth or other new technologies, e.g. eHealth initiatives like developing electronic records or having a website for citizens treatment, and support a shift from hospital care to prevention and primary care." 21. Number of MS that have a specific national / regional budget allocated to eHealth or other new technologies.

1.3 The Current Situation – Indicators Available from Other Sources

Indicators Proposed in other EU Documents. As reported in Table 1.4 overleaf and as will be better detailed in the specific mapping factsheets of selected EU policies in 2005-2011 (Annex A), a number of indicators, including process indicators to measure policy uptake at the MS level, have already been used or proposed by various sources and consulted for the purposes of this study. These include:

(i) preparatory studies[10] carried out for the preparation of impact assessments or, in a few cases, utilised as background documents by the various EU Presidencies in the conferences held to propose the introduction of new EU policy agenda items;
(ii) impact assessment reports;
(iii) the implementation reports prepared to monitor the progress achieved in policy implementation or in the attainment of the various objectives; and
(iv) the text of the various Recommendations or Communications themselves.

In particular, Impact Assessments (IA) have usually, though not always, proposed a set of indicators for subsequent monitoring. When IA did not explicitly suggest indicators, they often provided for MS to develop their own, on a voluntary basis. However, only in very few cases were the proposed indicators actually employed to produce quantitative measurements in IA analyses; the result is that, even if indicators could have been used, for instance to generate baseline data, in reality they have been underutilised. The mapping and classification exercise has been based on existing official documents and has not covered databases eventually established in the single policy areas to follow developments in policy implementation[11]. When available, information on their existence was included in the preliminary comments on the sources available.

Monitoring Mechanisms and Reporting Requirements. It is worth noting that not all EU health policy initiatives have formal reporting requirements attached, whereby MS would have to inform of progress made in implementation. Such requirements can usually be found in more articulated and complex documents (typically Recommendations), but can be missing, at least in an explicit form, in the relatively less developed policy areas. There can be intermediary cases (e.g. HIV/AIDS) where it is explicitly stated in the text of the policy document that MS can report on the progress reached in implementation on a purely voluntary basis. A rather varied situation concerns monitoring mechanisms and related indicators. In a few cases, indicators to be used for monitoring by the MS have already been included in the text of the policy document. However, these usually are outcome or impact indicators with reference to the population health status, and not process indicators reflecting progress in implementation and degree of policy uptake in MS.

In other cases, developing indicators was one task assigned to either a European expert group or to MS; this was, for instance, the case of antimicrobial resistance and organ donation and transplantation. Past experience with antimicrobial resistance shows that when MS were left free to develop their own indicators, they either created rather heterogeneous lists of outcome and process indicators, or did not develop any indicators at all. Finally, in the notable case of HIV/AIDS policy the very fact that MS identify and select implementation indicators for subsequent monitoring was proposed in the IA report as an indicator of the degree of MS commitment to policy implementation.

[10] Preparatory studies of various types are generally available for all the policy areas. Specifically, attention has been paid here to preparatory studies focusing on indicators and monitoring aspects.
[11] For instance in the field of nutrition and obesity information on policy uptake is collected through the NOPA database managed by WHO Europe. See http://data.euro.who.int/nopa/

Table 1.4 - List of sources on EU Health Policies indicators consulted for this study

	Preparatory Studies	EU Communications or Recommendations	Impact Assessment Reports	Implementation Reports	Mid Term EU Health Strategy Evaluation
Shared Health Values			•		•
Health is the Greatest Wealth					•
Health in All Policies					•
Strengthening the EU Voice in Global Health		•			•
Health of Older People			•		
Tobacco	•	•	•		•
Nutrition			•		
Alcohol	•	•		•	•
Mental Health					
Illicit Drugs		•		•	
Cancer		•		•	•
Rare Diseases			•		
Organ Donation & Transplantation	•		•		•
Injuries					
HIV/Aids			•		
Vaccination					
Preparedness Planning					
CBRN					
Antimicrobial Resistance		•		•	
Patient Safety	•		•	•	•
Telemedicine					

2. INDICATORS OF POLICY UPTAKE

Introduction. This chapter is divided into six sections. The first section provides an overview of the methodological approach and the rationale underpinning the proposed system of indicators and related robustness and relevance criteria. Then the proposed indicators are reviewed in more detail in five dedicated sections; each of these also reports the consolidated results of the indicators' validation process *vis à vis* their suitability for internal DG SANCO monitoring purposes. Each paragraph summarises information on relevance of the proposed indicators for the different policy areas, their availability from secondary sources, the results of the validation process - as far as indicators' validity and feasibility are concerned - and a summary judgment.

2.1 Overview of the Methodological Approach

Criteria for Indicator Robustness and Relevance. As seen earlier, the EU Health Strategy is composed of both horizontal principles and priority areas. The horizontal principles are 'cross-sectoral', i.e. apply – when relevant - to the entire body of specific health policies, whilst priority areas define the strategic framework to which existing and perspective sectoral policies are supposed to connect. A system of indicators aimed at measuring the degree of overall policy uptake in MS should take into account this peculiar aspect of the subject matter, including the need to cope with the evolving nature of the specific policies encompassed by the overall strategy. Moreover, it is important that proposed indicators are not simply defined in *abstracto*, but they should also undergo an adequate internal and external validation process before their use is recommended. The criteria that have been used in the framework of this Study to verify the robustness and the relevance of the proposed system of indicators can be summarised as follows:

- **Logical consistency –** indicators should be logically sound and well-founded, and ensure consistency with known causal relationships on determinants of policy uptake;
- **Applicability/scalability –** the definition of indicators should be generic enough to be potentially relevant for all the horizontal principles and the priority areas concerned. Additionally, it should remain valid over time and ideally scalable to eventually include also other sectoral policies or principles in the future;
- **Validity –** indicators should be relevant across the different categories of stakeholders concerned, including the Commission, MS policymakers and experts directly involved in policy implementation or otherwise familiar with the subject, in different institutional contexts;
- **Feasibility -** finally, indicators should not only be *in theory* a good measure of policy uptake, but it should be possible *in practice* to use them, and with a reasonable effort.

The application of the abovementioned criteria were not simultaneous but followed a two-step sequence: (i) initial conceptualisation phase, consisting in identifying a theoretical logical model supporting the definition of a long-list of indicators compliant with criteria #1 and #2; (ii) validation process based on pilot testing and extrapolation of results (in line with criteria #3 and #4), leading to the preparation of a short-list of recommended indicators. This process is described succinctly in the following paragraphs.

Logical consistency. Conventionally, any policymaking cycle can be divided into three elementary stages, which are connected in a continuously circular process:

(i) a policy definition phase encompassing the analytical identification of the policy problem and the building of consensus on its causes, and actions needed to address it;

(ii) a policy implementation phase in which these actions are actually undertaken which is composed of institutional, organisational and operational aspects; and

(iii) a policy feedback phase in which, based on a discussion of the results achieved and any subsequent evidence that may have become available in the meantime, the validity of the analytical phase is verified and lines of action fine-tuned as needed.

This basic structure has been used as the theoretical model to further break down the policy process into a discrete number of standard categories of activities connected to each stage. The exercise was based on the detailed review and mapping of the EU health policy documents issued in the 2005-2011 period (i.e. the Commission Communications, Recommendations and Council Conclusions listed in Table 1.1 above). The review showed that all requests for action made to the MS could be reclassified in 20 analytical categories, which jointly cover the entire spectrum of the policymaking process. The categories identified may therefore be used as the reference framework for the evaluation of progress in policy uptake in MS for any of the EU health policy/principles under consideration. These categories (reported in Box 2.1 below) have been gathered in five groups broadly corresponding to the standard stages of the policymaking process, with the caveat that the first (policy definition) and the second step (policy implementation) have been further split in two subsets. All categories in the list have been also 'coded' for easier reference in the Report.

Box 2.1 – Stages and standard categories of activities in the policymaking cycle

Policy Definition – Problem Identification

- Agreeing Analysis (ANA): Adopt/transpose/promote policy based on a common problem definition, or common analytical methodologies and/or guidelines, or inspired to common principles.
- Setting Objectives (OBJ): Aim to a certain specific policy objective irrespective of the concrete modalities with which it has to be achieved.
- Drafting Programmes (PROG): Define strategies, programmes and action plans at all the relevant levels of Government (national, regional, local) in a given policy area. A subset of this programming activity concerns the specific identification of research needs with an aim for their eventual coordination at the EU level (PROG.RES).
- Introducing Legislation (LEG): Introduce/modify enforceable legislation/self-regulation. Self-regulation can be represented by voluntary commitments to change behaviour from single economic agents (LEG.VOL).

Policy Definition – Consensus Building

- Committing to Principle (PRI): Commit all policymakers to a given horizontal health policy principle.
- Involving Partners (PART): Promote participatory policymaking by involving stakeholders' groups and patient organisations.
- Investing in Research (RES): Fund research to spur interest in the subject in the scientific community.
- Raising Awareness (AWA): Raise awareness through informational/educational campaigns[12].

Policy Implementation – Institutional Aspects

- Funding Policies (FUND): Make adequate resources available to implement policies/programmes. A subset of this may include specific suggestions to use the EU Structural Funds and the Health Programme as a source of financing.
- Establishing Organisations (ORG): Establish a body clearly responsible for policy coordination and/or a focal point entrusted with data collection and policy reporting at the EU level. Establish a lead agency/centre of expertise to disseminate policy.
- Building Networks (NET): Build networks of institutions and ensure the necessary communication among them.
- Introducing Procedures (PRO): Introduce given procedures.

Policy Implementation – Operational Aspects

- Policing /Enforcement (POL): Policing compliance with regulation/self-regulation by means of administrative or judicial controls.
- Delivering Actions (DEL): Deliver concrete activities in compliance with a given set of implementation modalities or for certain population targets (this can be at the national, regional and local level).
- Ensuring Technical Capacity (CAP): Ensure the availability of the necessary technical means or equipment.

[12] This category results from the merging of three previously identified categories on 1) the awareness about the policy problems; 2) dissemination and communication campaigns about the policy content; and 3) educational campaigns specifically targeting schools.

- Training (TRAI): Train personnel.

Feedback on Policy and Learning Mechanisms

- Harmonising Data (HAR): Establish a harmonised set of indicators concrete to the policy area and the national framework to describe the policy problem to allow data comparisons at the European level. Adopt a common set of definitions and modify national data recording accordingly.
- Evaluating Results (EVAL): Monitor and evaluate the effectiveness/cost-effectiveness of policies.
- Exchanging Information (EXC): Exchange best practices and policy results at European level.
- Reporting on Implementation (REP): Report to the Commission on implementation and results achieved

Source: Consultant's own elaboration

Applicability/scalability. The Policy Matrix in Table 2.1 illustrates the concept of 'applicability' of the abovementioned logical categories across the various horizontal and vertical EU health policy areas. After cross-checking with the evidence provided by the mapping exercise and the reclassification of the actions envisaged therein, it has appeared that these categories can be considered relevant in several policy areas, which further confirms the internal consistency and robustness of the model proposed. In other words, each of the EU policy documents reviewed contained requests for actions that could be classified according to the categories put forward in Box 2.1. Based on the same analysis, it was also possible to extrapolate from already proposed indicators and by means of analogical considerations and other similarity criteria a long list of possible families of indicators. The families of indicators in the long list (Table 2.2) were classified according to the categories in Box 2.1 and then assigned serial numbers, in case of multiple families per category (e.g. ANA.1, ANA.2, etc.). These families of indicators could be applied to one or more policy areas, where similar types of actions were envisaged. The families applied to the single policy areas are the individual indicators.

The indicators were then phrased in sufficiently generic terms to be applicable to all EU Health Policies and therefore could even be aggregated horizontally[13]. Sectoral specificities have been limited to (i) indicators of specific policy deliverables ('policy outputs') and their compliance with given requirements or standards[14]; (ii) policy outcome (OUT) and policy impact (IMP) indicators. The latter two are not process indicators, so they have only been indirectly considered when reviewing the OBJ category.

Moreover, the indicators were formulated in such a way as to cover policy areas that may be added at a later point in time. During the mapping exercise, it emerged that the long-list of indicators had already become quite stable after the review of a portion of policy items, with limited need for further additions as long as further policy items were reviewed. This suggests that the inclusion of further policy items in the future would not require any significant revision of the proposed system of indicators but possibly only some minor refinements, if any. In other words, the evidence from the analysis indicates that the proposed list is substantially scalable.

[13] Some indicators could theoretically be aggregated across policies as number of output-units (e.g. 'number of reporting items') delivered in the period. Others can be reported in terms of 'degree of compliance with a reference standard or a given benchmark' and aggregated by recourse to weighting mechanisms (e.g. the indicator 'number of existing EC implementation reports on Cancer Screening' stands to show the number of MS compliant with certain qualitative criteria); alternatively, indicators have to be reported analytically (e.g. based on the WHO/EU indicators on injuries, scores are attributed to the degree of effectiveness of the interventions implemented by the given MS).

[14] Indicators to measure the degree of compliance with given reference standards can be theoretically developed for any typology of action, irrespective of the specifics of the policy area they relate to, if any. In other words, indicators can be easily produced not only about as concerns the existence of given programmes in a certain MS, but also on their programme compliance with certain given criteria. This was notably the approach followed by both the ECDC and the WHO in selecting indicators to report on the degree of MS uptake of influenza preparedness plan policy.

Table 2.1 - Matrix of EU Policy Areas and categories of applicable indicators

	ANA	OBJ	PROG	LEG	PRI	PART	RES	AWA	FUND	ORG	NET	PRO	POL	DEL	CAP	TRAI	HAR	EVAL	EXC	REP
Shared Health Values	●	○			●			○	○								●		●	
Health is the Greatest Wealth							●		●									●	●	
Health in All Policies	●				●	○	○			●		●						●		
Global Health		●			○				○	●		●						●	○	
Health of Older People			●	○		●	●	●								●	○	●		●
Tobacco		●	●	●				●	○	●			●				○	●		●
Nutrition		●		●	○	●		●		○		●		●			●	●	●	○
Alcohol		●	●	●		○	○	●		○			●			●		●	●	●
Mental Health					○	○		○	○					●		●	●	●	●	
Illicit Drugs	●		●			●		●						●			●	●	●	●
Cancer	●	●	●	○				●	●			○		●		●	●			●
Rare Diseases	●		●			●	●		●		●	●				●	●	○	●	●
Organ Donation & Transplantation	○	●	●					●				●		●		●	●	●	●	
Injuries			●		○							○				●	●	●		
HIV/Aids			○			○	○		●					●			●	●	●	
Vaccination	○		●				●	●						●				●		●
Preparedness Planning		●	●						○		○	●			●				●	
CBRN	●									○	●	●		●	●		○		●	
Antimicrobial Resistance		●	●		○			●	○	●		●			○		●			
Patient Safety	●		●			●	●	●	○	●	●			●		●	●	○	●	●
Telemedicine			●	●									●						●	
RELEVANCE	9/2	9/1	14/1	6/2	7/5	9/4	8/3	12/2	11/7	8/3	4/1	10/2	3/0	9/0	3/1	8/0	14/3	15/2	14/1	9/1

Legend: *See box 2.1 above for the categories of indicators. Cases of relevance are highlighted with the symbol •. Cases of possibly limited relevance are highlighted with the symbol ○. The ratio in the last row should be understood as the total number of policy areas in which the category would have relevance (limited or not) (numerator), over the cases of possibly limited relevance (denominator). For further detail on the rationale behind see volume II, Annex A.*

Table 2.2 – Draft long list of proposed indicators

Code	Indicator
ANA.1	Number of MS/RE formally Adopting a Given Methodology/Problem Definition (wholly or in part)
ANA.2	Number of MS with Evidence of a Significant Debate in the Scientific Literature about a Methodology / Policy Problem
ANA.3	Circulation Reached by Relevant Methodological Documents (downloads, webpages visited) in Absolute or Relative Terms (% of the target population)
OUT.1	Specific Outcome Indicator for the Stated Objective in a Given MS/Instance
IMP.1	Specific Impact Indicator for the Stated Objective in a Given MS/Instance
OBJ.1	Number of MS / Instances in which the Given Stated Objective Has Been Reached
PROG.1	Number of MS that Have Established a Strategy / Programme / Action Plan Covering the Whole Population
PROG.2	Number of RE with of Strategies/Programmes/Action Plans Implemented at the Subnational Level (% of population covered)
PROG.3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only
PROG.RES	Number of MS that Have Prepared Specific Programme on Given Areas/ Subject, such as (but not only[15]) Research Projects
LEG.1	Number of MS/RE where Given Legislation/Self-Regulation Has Been Adopted
LEG.2	Number of MS/RE where Given Legislation/Self-Regulation Has Been Discussed but Not Yet Finally Agreed Upon
LEG.3	Number of MS/RE where Given Draft Legislation/Self-Regulation is Still under Preparation and in its Drafting Stage
LEG.VOL	Number of Voluntary Commitments taken in a Given MS
PRI.1	Number of MS/RE whose Health Policy Documents Include a Commitment to a Given Horizontal Principle
PRI.2	Number of MS that Report to International Organisations Commitment to a Given Horizontal Policy Principle
PRI.3	Number of MS/RE with Strategies/Programmes/Action Plans Specifically Tackling a Horizontal Policy Problem
PART.1	Number of MS Reporting the Existence of Advocacy NGOs Active in a Given Policy Field
PART.2	Number of MS/RE Actively Involving Advocacy NGOs in their Policymaking Process
PART.3	Number of MS/RE Providing Support to Advocacy NGOs active in the Given Policy Field
RES.1	Number of MS Reporting the Existence of Research Programmes in the Given Policy Field
RES.2	Resources Made Available by MS to Research Programmes in the Given Policy Field in Either Absolute or Relative Terms
RES.3	Number of Studies/ Publications Produced by Research Programmes in a Given Policy Field
RES.4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature
AWA.1	Number of MS/RE Carrying On Information/Awareness Raising Campaigns on a Given Health Problem in a Given Year (period)
AWA.2	Level of Awareness about a Given Policy Problem among the Population of a Given MS
AWA.3	Trend in the Level of Awareness about a Given Policy Problem among the Population of a Given MS[16]
AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target
FUND.1	Total Budgeted Funds in a Given MS to Specifically Implement a Given Policy in Absolute or Relative Terms
FUND.2	Total Public Expenditure to Specifically Implement a Given Policy in Absolute or Relative Terms
FUND 3	Human Resources dedicated to Specifically Implement a Given Policy in Absolute or Relative Terms
PHP.FUND.	Total Public Health Programme Financing Committed to Implement a Given Health Policy
STR:FUND	Total Structural Fund Financing Committed to Implement a Given Health Policy
ORG.1	Number of MS that Have Identified a Body Responsible for Policy Coordination / a Focal Point

[15] There can be for instance specific requests to have information strategies on communication campaigns, or programmes to train personnel.

[16] AWA.3 is conceptually very close to AWA.2 but is retained here for those situations (as was the case with illicit drugs in the past) where it substantially matters that the level of awareness dynamically keeps increasing over time, irrespective of the starting point. There can be cases, on the contrary, where it is important to reach (and maintain) a minimum level of awareness.

Code	Indicator
ORG.2	Number of MS that Routinely Interact with European Institutions on a Given Policy by Means of a Well Identified Institution
ORG.3	Number of MS for which a Centre of Expertise Entrusted with Disseminating Best Practice in a Given Policy Area Can be Officially Identified
NET.1	Number of MS that Have Created a Network of Institutions to Implement a Policy
NET.2	Number of MS Networks Participating to ERN
NET.3	Number of MS Entities Included in Networks in Absolute or Relative Terms
PRO.1	Number of MS/RE that Have Officially Introduced a Given Procedure in their Routine Operations
PRO.2	Number of Relevant MS/RE Institutions Complying with Procedure
POL.1	Number of Controls Made in a Given MS on Specific Legislation / Self Regulation in Absolute or Relative Terms
POL.2	Share of Positive Controls of Regulatory Infringement on Total Number of Controls on a Given Policy Area in a Given MS
POL.3	Share of the Population Agreeing to Being Subjected to Controls for Health Policymaking Purposes
DEL.1	Population Reached by Policy Delivery Mechanisms in a Given MS in Absolute or Relative Terms
DEL.2	Number of MS/RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents
DEL.3	Number of Significant Initiatives (i.e. above a certain value threshold) Undertaken to Specifically Deliver Policy
CAP.1	Number of Entities Compliant with Given Equipment Technical Standards and Operational Procedures in a Given MS
CAP.2	Number of MS/RE in a Position to Ensure Sufficient Availability of Consumables to Enforce Policies
TRAI.1	Number of MS/RE that Have Carried Out Training Courses on a Given Subject for Their Healthcare Personnel
TRAI.2	Total Number of Trained Healthcare Workers on a Given Subject
TRAI.3	Resources Made Available for Training in a Given Field in Absolute or Relative Terms
TRAI.4	Number of MS/RE that Have Introduced a Subject in Relevant Curricula
HAR.1	Number of MS Providing Homogeneous Data to the Relevant EU Health Indicator Database
HAR.2	Number of MS Deemed Compliant with Data Comparability Criteria based on Expert Assessment
HAR.3	Number of MS that Have Put in Place Special Registries When Requested / Number of Registries Established
HAR.4	Number of MS that Have formally Aligned Their Data Classification Systems to Standardised Given Procedures[17] (e.g. ICD10, etc.)
EVAL.1	Number of MS/RE that Have Carried Out Evaluations / Cost Effectiveness Assessments of their Policies
EVAL.2	Number of MS/RE where Policy Has Been Streamlined / Modified as a Result of an Evaluation Exercise / Cost Effectiveness Assessment
EVAL.3	Number of MS/RE that Have Put in Place a System of Indicators to Monitor Policy Implementation
EXC.1	Number of MS that Have Contributed their Policy Experiences to the Relevant European Coordination Mechanisms / Conference / Working Group
EXC.2	Number of MS that Have Submitted Examples of their Best Practices / Pilot Actions to the Relevant European Database /Portal
REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies
REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing a Policy Containing Information Not Shared with the EU

Validity and Feasibility. The second main methodological step of the work consisted in the validation of the long-list of indicators. This included at first an internal validation exercise based on the Consultant's own expert judgment and cross-verification with available secondary sources; and secondly an external validation process based on in-the-field case studies in a limited number of policy areas in four different Member States.

[17] This indicator is very similar to HAR2, but while HAR2 focuses on ultimate outcome, HAR4 limits itself to procedural aspects, irrespective of how they have been actually implemented.

- ***Internal Validation.*** Internal validation has been carried out by means of the Consultant's expert judgment and cross-verification with the indicators already proposed in the past as identified in the mapping exercise. So, for instance, in the cases where the impact assessment of the Commission Communication of the European initiative on Alzheimer's disease and other dementias envisaged the monitoring of the coverage and content of strategies and plans established by the MS on dementias, this was considered as a validation of a PROG indicator. In other words, the fact that an indicator had already been proposed has been taken as a first indication of its possible validity. As this could seem an exceedingly restrictive criterion, given the varying quality and degree of detail of the reference documents above, this analysis was complemented by the Consultant's identification of a number of additional indicators that could seem *prima facie* relevant and logically linked to the underlying actions (often identified as missing indicators in the mapping exercise). These were not mentioned in any of the reference documents, yet they seemed to be particularly consistent with the EU policy documents. The result consisted in the long-list of indicators and the matrix of applicability across policy areas already described in Table 2.1 and 2.2 above.

- ***External Validation.*** External validation has been carried out through the use of four case studies in three selected policy areas (HIAP, cancer screening and patient safety). In particular:
  - Health in All Policies (HIAP) is a horizontal principle envisaged in the EU Health Strategy that has been analysed in two main respects: the establishment of intersectoral coordination mechanisms to ensure that the health dimension of all policies is taken into consideration before policy adoption, and recourse to formal Health Impact Assessments (HIA) in the ordinary policymaking process;
  - Cancer screening has long been a EU priority and a major component of EU cancer policies. Through the three released guidelines, respectively on breast cancer, cervical cancer and colorectal cancer, the largest European body of technical and methodological recommendations was produced, which could also serve as a reference to judge on the degree of policy uptake;
  - Patient safety and healthcare associated infections are a more recent addition to the set of EU policies and have been recently given great emphasis also because of their economic impact and social relevance. They represent an area where the great level of MS interest in taking action faces resistance due to methodological and terminological differences and comparability issues.

To ensure the strongest possible robustness of results, the four Countries were selected so to give a fairly representative sample of cross-country variations. Thus, the sample includes old and new Member States located in the North and South of Europe, with differing population sizes, and featuring different health systems and policymaking processes. Specifically:

- **Italy**, which has a three-layer public health and governance system: national, regional and local, of which the regional one is constitutionally prominent, but where major strategic programming tasks are also left to the central level and the bulk of policy implementation lies with the Local Healthcare Enterprises;
- **France**, which has an insurance-based health system that has experienced over the last few decades a two-pronged evolution, i.e. (i) a concentration of strategic governance responsibilities in the hands of the central State administration, which has taken over various health insurance competences, and (ii) a regionalisation process, especially as far as policy implementation aspects are concerned;
- **Sweden**, which is another publicly funded system where the bulk of governance lies at the local level and the Central Government retains a limited coordination role; and

- **Poland**, where the strongly centralised health system based on the Semashko model was replaced with a decentralised system of mandatory health insurance complemented by financing from State and territorial self-government budgets.

The case studies included a total 57 interviews with key informants (officials of national and regional authorities, public health agencies and advisory bodies, senior academic experts, and representatives of stakeholders' organisations). The interview programme was complemented by in-depth desk research, covering both conventional and grey literature. In particular, the sources ranged from national and regional policy and programming documents (regulations, strategies, action plans, programmes, guidelines, etc.), evaluation and monitoring reports, scientific literature, as well as further sources of policy-specific data and indicators used on a national basis for monitoring purposes. In accordance with the pilot-like nature of the exercise, the case-study approach allowed to cover the vast majority but not all the potential indicators of the long-list. The indicators not covered by the case-studies underwent the abovementioned internal validation process, supported, when available, by additional evidence sought from impact assessments, implementation reports and preparatory studies.

The validation process was guided by the two criteria of 'validity' and 'feasibility'. In particular, the validity criterion encompasses judgments on indicator meaningfulness (i.e., contents are sensible and informative) for the stakeholders concerned, as well as on their apparent plausibility (i.e. their link with policy uptake is plausible and unambiguous). Moreover, it also considered their sensitivity, i.e. their capacity of showing small changes over time. Feasibility has been defined as a combination of (i) availability and (ii) amount of effort required in terms of resources needed for data gathering and analysis.

Within the case studies, the 'tested' indicators were assigned overall validity and feasibility scores consistent with the judgement criteria spelled out below. The scores were assigned on the basis of the preparatory desk work and the interviews conducted. Since the system of indicators is meant to be applied to strategy-level policymaking with the smallest possible level of effort, the Consultant has assigned higher scores to indicators that had already been published or made otherwise available than indicators that, although theoretically feasible, have never been used or proposed in the past.

- ***Validity***: the indicator is logically linked to the matter being measured, and is perceived as useful for policy purposes. The definition of validity used here combines expert assessment and policy-makers' opinion validation. In other words, a valid indicator is not only an indicator that can be used (i.e. it is coherent with the subject matter), but is also deemed recommendable in a policy monitoring perspective. The operational assessment of the proposed indicators with respect to the validity criterion therefore lumps together expert judgment and degree of consensus among practitioners and political actors (see Table 2.3 below).

Table 2.3 – Definition of validity ratings

Rating	Definition
Definitely valid (++)	The validity is not only ascertained by expert assessment, but it is also confirmed by strong consensus of the concerned key actors. A sufficient but not necessary condition for an indicator to be considered definitely valid is that it is already (or is planned to be) used by the competent authority for policy monitoring purposes.
Fairly valid (+)	The indicator is deemed valid on the basis of expert assessment of its logical link to the subject matter. The results of testing do not raise any significant doubt on its relevance and/or usefulness for policy-making purposes; however, key actors' feedback may sensibly call for slight refinements.

Of dubious validity (-)	At a closer look, the coherence of the proposed indicator with the judgment criteria it measures poses problems and/or its usefulness is limited. Dubious validity may characterise also situations of highly polarised and irreconcilable views among different actors. A profound reformulation of the indicator would be necessary to make it usable.
Definitely not valid (--)	The analysis and testing of the indicator reveal important irresolvable incoherencies and/or key actors unanimously rejected it as logically-flawed or inappropriate. There seems to be no room to correct these issues and reformulate the indicator in a valid manner.

- ***Feasibility***: the second step concerns the assessment of the practical feasibility, i.e. the degree to which the indicator is not only a good measure of the subject matter, but it can also be measured with no more than reasonable effort. The parameters for the operational application of this criterion to the proposed indicators are essentially three: (i) the availability of information, (ii) the reliability of the information, and (iii) the level of effort (financial and time resources) required to collect and process the information. With respect to availability, it is important to underline that the same rating is attributed to instances where the information is already available and others where it is expected that it will be available in the near future, e.g. since it is foreseen in the legislation. In these cases, full compliance with the legal/policy provisions is inferred (see Table 2.4 below).

Table 2.4 – Definition of feasibility ratings

Rating	Definition
Highly feasible (++)	This is the case where the indicator is already used / is planned to be used soon by competent authorities, and monitoring data of good quality (i.e. complete and reliable) are/are expected to be easily available (i.e. published and easily retrievable or directly communicated to the EC) and no further treatment of data is required.
Fairly feasible (+)	Using the indicator is largely feasible, however some attention should be paid in its application and/or there are minor feasibility issues that can be overcome in a relatively easy way, such as (i) the indicator is already / is expected to be measured but on a pilot basis and/or only by a portion of relevant authorities (e.g. in the case of regionalised systems); (ii) the indicator is / is expected to be measured but it is not / is not expected to be published; (iii) the indicator is / is expected to be measured but its reliability must /will have to be duly verified (e.g. due to methodological issues, inconsistencies in measurement by different regional/local authorities etc.); (iv) the indicator is available but not updated and/or its measurement timetable does not match with the EC evaluation schedule; (iv) the indicator is not measured but raw data or proxy data of good quality (complete, reliable, updated) are easily available (i.e. published or available on demand) which - if duly processed with reasonable financial and HR inputs - would allow a solid measurement of the indicator.
Hardly feasible (-)	The indicator is not / is not planned to be measured. In theory, it would be possible to measure it through an ad hoc study starting from raw data / proxy data but there exists significant difficulties related to (i) the reliability of available data (e.g. raw data are incomplete or of dubious quality and/or extrapolation from proxies poses serious methodological issues); (ii) the level of effort required to acquire and/or process the information (i.e. excessive financial/HR inputs needed).
Not feasible (--)	The indicator is / is not planned to be measured and is not methodologically feasible, or it is unreasonably onerous to carry out an ad hoc study to generate the evidence needed for its measurement.

Approach to the analysis of proposed indicators. Sections 2.2-2.6 present the analytical work performed to assess indicators included in the long-list above (Table 2.2), with a view to compiling a short-list of validated, robust indicators for EU health policy evaluation. The text is structured into five sub-sections corresponding to the five main stages of the policymaking cycle and further subdivided into a number of categories of indicators corresponding to the classification already conveyed in Box 2.1 above. Each category is further broken down into families of indicators, where each family measures a specific aspect of its respective category.

The indicators were assessed and category-wide narratives provided for the following parameters: (i) *Indicators' relevance for EU Health Policies*, (ii) *Concrete Examples of Availability from Secondary Sources*, (iii) *Evidence from the Case Studies on Validity and Feasibility*. To finish with, a *Summary Judgment* recollects the outstanding features of the category under consideration, often supplemented by family-specific commentaries. Beyond reiterating salient *validity* and *feasibility* features of the various categories and, on occasion, of the individual families, in the summary judgment indicators are also qualified according to their *sensitivity*, i.e. their ability to accurately reflect changes in their areas of application.

Throughout the text, the indicators are also assessed based on their descriptive and predictive potential. In particular, *lagging* indicators, once collected, can be used to retrace policy developments. They confirm long-term trends but cannot predict them. Conversely, *lead* indicators can aptly be used to predict or give prior information on future policy developments.

Additionally, for the purpose of monitoring the uptake of the policies associated with the EU Health Strategy 2008-2013, indicators may qualify as *primary* or *secondary*. The former attribute refers to indicators so called "*of choice*". These indicators appear to be feasible and particularly informative for broad strategic purposes; for this reason they should be retained for future use. Conversely, secondary indicators can provide complementary information or replace primary indicators, when needed. However valid and feasible, secondary indicators have a narrower dimension and focus on more specific policy aspects. The primary/secondary classification served as the basis for the compilation of a final shortlist of indicators. Retained ones are primary and secondary indicators, while the remaining ones were dropped. The final shortlist is presented in the last chapter of this report.

2.2 Policy Definition – Problem Identification

Problem Identification may require the adoption/transposal of policy concepts or methodologies. Following the indicators in the ANA category, there are three ways to measure adoption/transposal: (i) by tracing down the availability of relevant policy documents in the various MS where the policy problem is explicitly acknowledged, (ii) by measuring the impact that these documents may have had, indirectly, on the MS public health literature, or (iii) by surveying the physical circulation of these documents. Policy uptake in the Policy Definition phase can be assessed through various other means. Formal hierarchical policymaking mechanisms may envisage references to the existence of given policymaking documents (PROG indicators) or regulations (LEG indicators) or, more specifically, to the existence of formal statements or commitments therein (PRI). Policy Definition can be framed in terms of objectives to be achieved (OBJ) and these are often expressed as outcome or impact indicators.

2.2.1 ANA – Indicators about the Adoption of Common Analytical or Methodological Tools

ANA.1	Number of MS/RE formally Adopting a Given Methodology/Problem Definition
ANA.2	Number of MS with Evidence of a Significant Debate in the Scientific Literature about a Methodology / Policy Problem
ANA.3	Circulation Reached by Relevant Methodological Documents (downloads, webpages visited) in Absolute or Relative Terms (% of the target population)

Indicators of convergence towards common analytical and methodological approaches have been grouped into three families. The first directly focuses on the formal adoption of European guidelines or the transposal in official national guidelines and other methodological documents of problem definitions and technical benchmarks agreed at the European level (ANA.1). The second indirectly measures the impact of the above on the relevant scientific literature of the MS concerned

(ANA.2) and the third (ANA.3) - also belonging to the family of indirect indicators - finally aims at providing evidence about the circulation eventually reached by the relevant European reference documents.

Relevance for EU Health Policies. All ANA indicators are typically found in EU policies in their early development stages when agreement on methodological issues or common definitions is still actively sought after. Instances of ANA.1 indicators have been proposed in the past, for instance, in the field of illicit drugs, antimicrobial resistance, patient safety and healthcare related infections. In other cases a request for the MS to carry out ANA-type actions was included in the relevant EU Policy Documents (e.g. vaccination) but related indicators were never officially proposed, as if this type of information were not deemed particularly relevant for policy uptake monitoring purposes. Cancer and cancer screening was also an area where the adoption of the EU Guidelines was never proposed as a process indicator[18]. Both ANA.2 and ANA.3 indicators have been relatively less frequent and mainly proposed for the monitoring of the uptake of horizontal principles, such as the reduction of health inequalities or Health in All Policies. In only one case was an ANA.2 indicator proposed in a preparatory study on tobacco policy, but the idea was eventually dropped.

Concrete Examples of Availability from Secondary Sources. ANA.1 indicators have already been routinely collected in implementation reports on antimicrobial resistance, patient safety and illicit drugs. On the contrary, hardly any indicators of the ANA.2 and ANA.3 families have been operationalised thus far. Nevertheless, following the related impact assessment, they remain the logical reference standards for the monitoring of the Public Health Programme.

Evidence from the Case Studies - Validity. ANA indicators revealed valid and unproblematic in the areas of patient safety and Healthcare Associated Infections (HAI). This is unsurprising, if one considers that these were the areas for which ANA indicators were originally formulated. ANA.1 was broadly validated also in areas such as cancer screening, where European Guidelines were not expressly conceived for formal adoption. That said, ANA.1 is arguably a more useful indicator at the European than at the national level. Findings on ANA.2 were divergent, with some reservations on data plausibility for small countries whose researchers are more likely to publish for international teams and an abstract concern that too strong a link with a PHP criterion might further strengthen the academic bias of projects, while being of limited use to policymakers. However, when concretely tested on cancer screening, the validity of ANA.3 applied to a concrete PHP output was not reported as particularly problematic.

Evidence from the Case Studies - Feasibility. In those policy areas where data collection itself was envisaged as an indicator for policy monitoring purposes, this poses little problem and the ANA.1 is highly feasible. Transposal of ANA.1 to other policy areas can be more problematic, especially when responsibility for policy implementation is decentralised and within the remit of local-level operators. Similarly, there are different feasibility patterns for ANA.2 and ANA.3, depending also on country size and language barriers. Bibliographic searches are more complex when the nationality of the individual authors has to be identified, as opposed to the country of origin of the journal; equally, searches are hindered when local publications are not routinely indexed in the main bibliographic databases or are only locally circulated.

Summary Judgment. ANA indicators are particularly appropriate when expressly mentioned in the underlying EU policy documents, and linked to well-identifiable outputs. Their main drawback is

[18] The EU Health Strategy considers the release of the Guidelines as a Commission's task in itself, independent of any further request for action made to MS. So, formally, the EU Guidelines on Cancer Screening are only intended for 'release' and not for adoption, strictly speaking. Guidelines-related indicators were therefore tested out of analogy and for the sake of transposing them to all MS.

that they can easily provide false positives when the same terminology is used with a different meaning than envisaged in the related EU policy documents and this would require some qualitative analysis and data qualification. Moreover, "formal adoption" is somewhat ambiguous given that it lends itself to different interpretations; in fact, MS have in some cases different means of formal endorsement in policymaking. However, with some caution, they can nonetheless represent a reasonable compromise for monitoring the uptake of broad policy concepts, especially when supported by parallel PHP projects, provided that the geographical level of the analysis remains very broad; in fact, the indicator tends to lose validity and feasibility when moving from the national to the regional level. Provided a minimum level of diligence, ANA indicators are relatively feasible. Their main drawback is their limited sensitivity and the fact that their limited range of possible values do not necessarily correlate with sequential changes in the degree of policy uptake over time. ANA.1 is by definition a lagging indicator; the way it is designed does not allow to measure sequential/chronological changes on a linear and continuous basis. It is therefore not suitable to measure trends but only to portray discrete points in time. Finally, for different reasons both ANA.2 and ANA.3 are likely to peak at the time of policy adoption/document release and then subside. To sum up, ANA1 is worth retaining as a primary indicator, while ANA.2 and ANA.3 are considered as secondary ones.

2.2.2 OBJ – Indicators about Setting and Eventually Verifying Certain Policy Objectives

OUT.1	Specific Quantified Outcome Indicator for the Stated Objective in a Given MS/Instance
IMP.1	Specific Quantified Impact Indicator for the Stated Objective in a Given MS/Instance
OBJ.1	Number of MS / Instances in which a Given Objective Has Been Stated

There can be three different policymaking techniques, as far as the definition of policy objectives is concerned; specifically, policy objectives (i) can be stated in qualitative terms, (ii) they can be quantified in terms of the expected targets related to the outcome of policy actions or (iii) they can be quantified in terms of their ultimate impact on health. There has been an increasing trend over the last few years in the EU policy documents towards quantifying policy objectives by means of target indicators. So, for instance, in the field of cancer objectives have been expressly stated with reference to a targeted reduction of inequalities in cancer mortality or the population reached by the screening programmes. However, in most policy areas objectives remain stated in qualitative terms and the measurement of their attainment is left to proxy output- or impact-indicators, identified separately in impact assessment documents or other implementation reports.

Relevance for EU Policies. Quantitative or qualitative objectives to be reached have been identified for a number of polices spanning global health, alcohol, mental health, illicit drugs, health threats, preparedness planning, telemedicine and organ donation and transplantation. The number of related outcome or impact indicators proposed is even higher and covers also nutrition and obesity, rare diseases, HIV/AIDS, antimicrobial resistance.

Concrete Examples of Availability from Secondary Sources. The identification of outcome or impact indicators has not been the primary goal of this exercise which, conversely, focused on policy processes; these are nevertheless found to be fairly widespread and available for a variety of policy areas, although with major sectoral differences. The latter are often due to a lack of methodological harmonisation.

Evidence from the Case Studies - Validity. OBJ indicators could not be tested as the Study did not cover the areas for which OBJ indicators were envisaged; however, output and impact indicators that seemed to be best suited to measure policy success were used as proxies. These were generally deemed fairly valid indicators, with the notable exception of one country which aims at measuring the outcomes of its patient safety policy through its own definitions.

Evidence from the Case Studies - Feasibility. Feasibility problems with the proposed indicators were reported in around one third of cases, the majority of which were considered as rather serious.

Summary Judgment. Although judgment based on the degree of attainment of the stated objectives can safely be considered the 'golden rule' in the measurement of policy uptake, there are two main limitations to consider. Quite often there are serious feasibility issues that make it difficult to put in place even the simplest indicators, such as "the number of MS that have met their stated objectives"; additionally, there may disagreement on whether output or impact indicators provide plausible measurements in given policy contexts. That said, when the indicator is feasible and agreement is reached on its relevance, it is a very sensitive, and possibly lagging indicator; therefore it can also be considered as a primary indicator.

2.2.3 PROG – Indicators about Defining Programmes of Activities

PROG.1	Number of MS that Have Established a Strategy/Programme/Action Plan Covering the Whole Population
PROG.2	Number of RE with Strategies/Programmes/Action Plans Implemented at the Subnational Level (% of population covered)
PROG.3	Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only, or Covering only a Given Share of Requested Items
PROG.RES	Number of MS that Have Prepared Research Programme on a Subject[19]

The existence of strategies, programmes or action plans in a given policy area can be assessed along three different dimensions, namely (i) as an indication of compliance with a formal request, i.e. a request that the MS put in place a strategy/programme/etc. (PROG.1); (ii) in terms of the share of population actually covered by these instruments in those MS that have decentralised programming systems at the regional/local level that complements or substitutes a national strategic framework (PROG.2); and (iii) the level of development of the underlying provisions which can range from experimental to full-fledged policies (PROG.3). Additionally, there can be requests to have in place subject-specific programmes, typically research programmes (PROG.RES).

Relevance for EU Health Policies. This is one of the most frequently mentioned policy process indicator in the relevant EU documents. Under various denominations, similar indicators have already been proposed for EU policies on Alzheimer, alcohol, mental health, cancer, illicit drugs, organ donation and transplantation, rare diseases, injuries, HIV/AIDS, preparedness planning, CBRN, antimicrobial resistance, patient safety (and particularly HAIs), and telemedicine. Some emphasis on the specific contents of these programming documents and, in particular, the need to investigate existing research programmes, can be found in the field of Alzheimer and rare diseases, although this has not yet translated into a dedicated indicator. The importance of the geographical reach of these programmes has been highlighted for influenza. In other areas, qualitative details on the minimum acceptable contents of these documents can be found.

Concrete Examples of Availability from Secondary Sources. Information on programme availability can usually be found in the EU implementation reports or in the dedicated WHO repositories whenever these exist, although with different levels of completeness and reliability. Data gathering at the regional and sub-regional level is much scarcer and more fragmented than at national level

[19] The emphasis here is on the fact that the applied research is specifically programmed by the relevant policy makers as a top-down tool to meet their information needs as a part of broader policy programming process and with dedicated resources. In this sense, PROG.RES differs from RES indicators, as the latter simply ascertain the existence of generic research programmes on a subject, often managed by other entities, broader in scope and in competition with other subjects so that the allocation of resources can be estimated only ex post.

and so is also the information on the contents of sector-specific Plans available from secondary sources.

Evidence from the Case Studies – Validity. The validity of PROG indicators has hardly been challenged except in countries where public health policy is not rolled out on a sector-by-sector basis, but rather by means of general, all-encompassing programmes and budgets. In the majority of cases, PROG.2 and PROG.3 are deemed comparatively less meaningful and sensible than data on actual implementation, although still valid from the standpoint of generating a preliminary appreciation of policy progress.

Evidence from the Case Studies – Feasibility. While PROG.1 is generally straightforward, the implementation of PROG.2, PROG.3 or PROG.RES indicators can be more problematic in terms of data availability because country-wide repositories of regional/local implementation documents are not always available, and because of the (often underestimated) difficulty in locating such documents. Moreover, PROG.RES adds an extra layer of complexity, given that it is not always possible to classify research programmes according to the clear-cut categories suited for policymaking.

Summary Judgment. PROG.1 remains among the easiest and quickest means of monitoring a minimum degree of policy uptake and institutional capacity in the Policy Definition phase. PROG.1 would require an affordable amount of data gathering effort, as long as there is a common understanding on what qualifies[20] these documents as strategies, programmes or action plans. It can be considered as a primary indicator. The more sophisticated PROG.2 and PROG.RES aptly allow for a more detailed assessment of the level of prioritisation the policy has reached in the MS overall agenda; however, they are considered as less feasible and their effectiveness in providing stimulus for conducting evaluation exercises remains to be seen on a case-by-case basis; they can be deemed as secondary indicators.

These indicators have limited sensitivity and high inertia, meaning that the data they collect cover long-term periods and cannot be segmented more finely. In fact, on paper, they could capture major evolutions in policy uptake over relatively long periods of time and *de facto* tend to be lagging indicators. Two points are therefore worth mentioning: (i) these indicators do not account for smaller changes, occurring in the period intervening between two measurements; and (ii) validity may outlive the end date of some programmes, and as a consequence data can be easily misunderstood if not processed by individuals familiar with the subtleties of the different legal systems.

2.2.4 LEG - Indicators about Introducing Norms by Means of Legislation, Codes of Self-Conduct or Self-Regulations

LEG.1	Number of MS/RE where Given Legislation/Self-Regulation Has Been Adopted
LEG.2	Number of MS/RE where Given Legislation/Self-Regulation Has Been Discussed but Not Yet Finally Agreed Upon
LEG.3	Number of MS/RE where Given Draft Legislation/Self-Regulation is Still under Preparation and in its Drafting Stage
LEG.VOL	Number of Voluntary Commitments taken in a Given MS/ Number of MS where voluntary commitments have been taken

There can be requests in EU soft law policy documents that MS enforce legislation or codes of conduct / voluntary commitments in a given policy area. Examples of such instances typically

[20] Particularly in terms of required level of official endorsement.

include: (i) policies for which adaptation to local conditions is appropriate because of the strong influence of local cultural factors on health behaviours or (ii) pieces of legislation generated as by-products of EU-wide Directives with a harmonising value but whose contents are too generic and require adaptation to the local legal systems. These documents may be analysed according to (i) their stage of development (draft, discussion, adoption); (ii) their nature (mandatory, publicly enforced/ privately enforced codes of conduct); and (iii) their number, in the case of actions based on voluntary commitments.

Relevance for EU Health Policies. Indicators of this type have obviously been proposed for health policies directly interlinked with regulated markets (tobacco, alcohol) and, given that they largely target to health determinants, they are relevant also in the fields of nutrition and obesity. Additionally, there are a number of cases where there can be a need for legislative intervention/clarification to remove regulatory obstacles to policy implementation. Personal data protection hampering the development of cancer registries, and the normative barriers to telemedicine are two cases in point. In the latter cases, however, no LEG indicator has ever been formally proposed. A test was made of LEG validity and feasibility in the field of cancer, where the problem of regulatory obstacles is widely reported, although EU soft law documents do not require MS to take any specific action.

Concrete Examples of Availability from Secondary Sources. Data on health-related legislative initiatives in regulated markets are widely reported and available. Difficulties were experienced with the establishment of databases of voluntary commitments, particularly when related policy implementation was envisaged at all levels from national to local. WHO sources have listed data on regulatory barriers in telemedicine based on subjective expert assessment.

Evidence from the Case Studies – Validity. When tested in the field of cancer, LEG indicators have generally appeared as fairly valid, although probably not very high in the ranking of relevance at the national level. It was not possible to directly test LEG.VOL, but in some countries similar indicators were proposed as proxies for the level of commitment to HIAP principles.

Evidence from the Case Studies – Feasibility. In the countries surveyed, these indicators pose little feasibility problems and would simply require to maintain regular contact with in-country point persons who would be responsible for reporting on implementation. Availability appeared to be a major issue according to a number of respondents.

Summary Judgment. LEG is a category of indicators typically used in regulated markets, where it can be extremely relevant, and are primary indicators. If extended to other policy areas, they could represent a rather indirect proxy for the overall level of political commitment to a given policy area (bearing in mind that a full picture can only be drawn after taking into account the weight that these legislative measures carry compared to the rest of the country-specific juridical apparatus). At any rate, qualitative evaluation exercises are better suited to capture these aspects. Their sensitivity is also rather limited, given that they could only account for outstanding cases of policy reversal. They also tend to be lagging indicators.

2.3 Policy Definition – Consensus Building

Alternative bottom-up approaches to policy definition can be based on policymaking by consensus. This can be measured by ascertaining commitments to stated principles, and how the latter may have echoed in MS policy documents. Evidence of consensus may also be traced, at MS level, in the existence and effective involvement of stakeholders' groups aligned with EU health policy aims, which prove capable of influencing the policymaking mechanisms through participatory means.

Other criteria can include the level of awareness about the policy problem among the population at large or the stakeholders concerned, or the commissioning of research activities to increase the knowledge basis on a subject and involve the research community, including related funding.

2.3.1 PRI - Indicators about Commitment to a Given Policy Principle

PRI.1	Number of MS/RE whose Health Policy Documents Include a Commitment to a Given Horizontal Principle
PRI.2	Number of MS/RE that Report to International Organisations Commitment to a Given Horizontal Policy Principle
PRI.3	Number of MS/RE with Strategies/Programmes/Action Plans Specifically Tackling a Horizontal Policy Problem

Indicators aimed at capturing MS commitment to devise policies based on certain shared values or given policy principles represent a challenge for any monitoring system based on process indicators. This is largely due to the intrinsically *qualitative* nature of the subjects in question which hardly lend themselves to be measured in quantitative terms. Therefore the possible process indicators would only cover (i) formal adherence to principles in policymaking documents, (ii) participation to international initiatives inspired to the same principles, and (iii) existence of strategies/action plans - or part thereof - specifically devoted to the implementation of such principles.

Relevance for EU Policies. It is little surprise that PRI indicators have been proposed so far only with reference to four horizontal principles of the EU Health Strategy, and in particular as regards health inequalities and Health in All Policies. Commitment to given values can be implicitly found in a number of other policy areas (Alzheimer, illicit drugs, HIV/AIDS, to mention but a few), but MS have hardly ever been formally requested to adhere or inspire their policies to any values; accordingly, no indicator has ever been proposed in this respect.

Concrete Examples of Availability from Secondary Sources. On an interim or ex-post basis, such indicators have been practically tested out only within the framework of the interim evaluation of the EU Health Strategy. Examples (for instance PRI.2 in the field of HIAP) can be found more frequently in preparatory studies preceding the launch of EU initiatives.

Evidence from the Case Studies – Validity. PRI indicators have appeared as generally valid and as good descriptors of actual policy uptake, with the notable exception of PRI.2. The latter, in fact, has often proven of dubious plausibility, hardly reliable, and subject to possible manipulations. On occasion, PRI.3 has appeared as intrinsically more valid and reliable than PRI.1; it was also suggested that the number of standalone strategies/programmes may be more meaningful than the counts of strategies/programmes that are part of wider documents.

Evidence from the Case Studies – Feasibility. These indicators are generally considered feasible; difficulties may arise only when the indicators are implemented at the programme level (PRI.3) or in decentralised systems with regional and local layers of programming. Such difficulties can however be solved with minimum effort through recourse to informants familiar with the health system under consideration.

Summary Judgment. PRI indicators have been confirmed as the easiest and quickest means to monitor the uptake of horizontal principles, provided that a common understanding is reached on what are the minimum requirements for these documents to qualify as strategies or action plans and related level of official endorsement. Some reservations exist on the validity of PRI.2 indicators. The latter, however, have a greater potential to accurately reflect marginal changes over time, i.e. they are more ‘sensitive’ and with a somewhat higher potential to be “lead” indicators.

2.3.2 PART - Indicators about Participatory Policymaking

PART.1	Number of MS Reporting the Existence of Advocacy NGOs Active in a Given Policy Field
PART.2	Number of MS/RE Actively Involving Advocacy NGOs in their Policymaking Process
PART.3	Number of MS/RE Providing Support to Advocacy NGOs active in the Given Policy Field

EU policymaking in the health field has increasingly envisaged recourse to participatory techniques aimed at eliciting NGO and civil society organisations' involvement in policy definition. This can be monitored by three families of indicators: (i) those ascertaining the existence of NGOs active in a given policy field (PART.1); (ii) those explicitly targeted at monitoring NGO involvement in the policymaking process, be it in the policymaking or policy implementation phase (PART.2); and (iii) those about the active support providing support to sector-specific NGOs (PART.3).

Relevance for EU Policies. Indicators about the involvement of patient organisations have already been proposed in the field of rare diseases and HIV/AIDS, and related actions envisaged in policy documents on mental health, nutrition, obesity and patient safety. Rare diseases is probably the policy area where the scope of this provision has been most far-reaching, because MS are formally requested to actively promote patients' organisations activities.

Concrete Examples of Availability from Secondary Sources. No example was found with regard to this category of indicators as being actively monitored and published in existing secondary sources. Also recent EU implementation reports on patient safety and healthcare associated infections include relatively scanty information on the subject, specifically as regards the involvement of patient organisations. For instance, twenty MS patient organisations were formally invited to take part in the development of patient safety policy; in 14 of them, patient organisations are required by law or administrative decisions to play a part in policy development. Some MS openly acknowledged contributions made by patient organisations and citizens' networks in disseminating information and patient safety measures.

Evidence from the Case Studies – Validity. For the purpose of this exercise, PART indicators were tested in both patient safety and HIAP. This choice was justified by the fact that these policy areas call for cultural change and beg to introduce new policy concepts; these are two aspects where the added value of external NGO support is likely to be felt the most. There are fairly diverging views about the overall plausibility and meaningfulness of these indicators, particularly when 'NGOs' are not qualified. It should also be noted that the current formulation of these indicators assumes that NGOs or patient organisations' agendas are aligned with EU policy initiatives. If this were the case, they would be supportive of EU policy uptake, as it were, by default. In reality, however, there are several NGOs whose orientations differ substantially from EU ones; therefore the indicator can be highly misleading and inappropriate.

Evidence from the Case Studies – Feasibility. These indicators are hardly collected nowadays and, with the notable exception of PART.1, are not generally considered as easily feasible and would, by and large, require considerable analytical and data gathering efforts (e.g. in the form of *ad hoc* case studies).

Summary Judgment. PART indicators appear among the most controversial ones as far as the policy definition process is concerned. To some extent, they mirror different national traditions of participatory policymaking and NGO involvement. Additionally, they shed light on the difficulty of attributing significance values to strictly quantitative health policy information. If there is broad consensus that involvement of civil society organisations may in certain circumstances represent a fairly powerful mechanism to push through reforms, there is also a concern that the underlying related nuances can be very poorly captured by quantitative indicators that are liable to be highly

misleading and whose sensitivity is questionable. In the best of cases, they would end up providing a ballpark picture of the level of development of civil society organisations in the different MS. These indicators would require very careful phrasing and formulation and, at any rate, in many cases the level of effort required for their feasibility appears comparable to that of a small case study. So for the time being, they cannot be recommended as primary indicators for EU Health Strategy monitoring purposes, although they could have some potential to capture subtle changes in policy uptake over time and to some extent even represent a lead indicator.

2.3.3 RES - Indicators about the Involvement of the Scientific and Research Community

RES.1	Existence of Research Programmes in the Given Policy Field
RES.2	Resources Made Available by MS to Research Programmes in the Policy Field in Either Absolute or Relative Terms
RES.3	Number of Studies/ Publications Produced by Research Programmes in the Given Policy Field
RES.4	Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature

Although EU Health Policies are usually mainly concerned with concrete and applied policymaking, there have been instances of provisions reaching out to the field of research, particularly to fill the knowledge gaps as needed to better inform evidence-based policymaking. The involvement of the scientific and research communities can be broadly measured by four main types of indicators: indicators about the existence of dedicated research programmes (RES.1) and the amount of resources invested therein (RES.2), indicators about the outputs produced by such programmes (RES.3), and indicators about the impact that these research projects have had on the scientific debate (RES.4).

Relevance for EU Policies. The need to further strengthen research also by means of national research programmes and disseminate research findings has been highlighted in the field of Alzheimer, nutrition, alcohol, HIV/AIDS, rare diseases and patient safety. However, hardly ever has this been accompanied by proposals for dedicated indicators, as if the subject was not deemed worth monitoring. A notable exception in this regard is represented by rare diseases for which an indicator on the level of funding made available for research purposes at the national level has been proposed; another exception is HIV/AIDS whose impact assessment recommended introducing an indicator to measure the progress achieved in research in identified fields where knowledge gaps persist.

Concrete Examples of Availability from Secondary Sources. Information on national research initiatives established for given policy purposes was collected in the first implementation report on antimicrobial resistance, intended for information dissemination only, while there was not an explicit request of MS to act along these lines in the underlying recommendation.

Evidence from the Case Studies – Validity. When tested as a possible substitute/complement of ANA indicators in the field of HIAP, RES indicators have caused some concerns about their possibly limited validity because of perceived difficulties in defining their scope. Indeed, HIAP is still a fluid and not yet rigorously defined policy area; due to this reason, there is a need to investigate in detail the contents of the single projects for classification purposes. In more consolidated policy areas, this family of indicators is generally considered valid, although with some reservations on aspects such as the risk that citation-based indicators such as RES.4 may overstate the academic value of research to the detriment of its potential use for policymaking purposes.

Evidence from the Case Studies – Feasibility. The concrete feasibility of these indicators appears limited due to the widespread lack of available data and the difficulties in tracking down projects

often spread across different programmes, which would require a level of effort comparable to that of a dedicated study.

Summary Judgment. RES can be considered as a fairly valid family of indicators but are currently fraught with major feasibility problems, which in turn reveal the degree of control policymakers often exert on the research agenda. Actually, one may be tempted to conclude that the very fact that the indicator can be used is in itself an indication of the link between the research agenda and policymaking needs. Strategically, this is an area which future versions of the EU Health Strategy and EU policy recommendations may find it worthwhile to emphasise, especially considering that this family of indicators potentially have a high sensitivity to quickly capture changes in the level of policy uptake over time and are considered by some as lead indicators.

2.3.4 AWA - Indicators about the Level of Awareness about a Policy Problem

AWA.1	Information/Awareness Raising Campaigns on Given Policy Issues in a Given Year (period)
AWA.2	Level of Awareness about policy issues among the Population
AWA.3	Trend in the Level of Awareness about policy issues among the Population
AWA.4	Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target

One of the mainstay of EU policies in the health field is that healthy behaviours descend from awareness about health risks and related informed choices. Moreover, the level of awareness among the population can also be a powerful factor in shaping the policy agenda and influence decision-makers. Accordingly, once a policy is in place, its impact can partly depend on how successfully it is communicated and made known to the public. Educational programmes have traditionally been deemed particularly effective in this respect. There are well-known indicators to measure these phenomena across all policies. These include (i) indicators collecting data on active information and awareness-raising campaigns (AWA.1), (ii) indicators monitoring the level of awareness in the population and related trends by way of surveys (AWA.2 and AWA.3, respectively), and (iii) indicators that estimate the outreach of information and dissemination activities regarding both the policy problem and associated policy initiatives, formulated in terms of potentially targeted population[21].

Relevance for EU Policies. Indicators about the level of awareness or the number of awareness-raising and communication campaigns have been traditionally proposed for policies concerning voluntary unhealthy behaviours such as tobacco and alcohol consumption, as a complement to other regulatory approaches. They have also been proposed for areas such as vaccination, antimicrobial resistance, patient safety and healthcare-related infections where citizens' behaviour is considered a powerful lever for prevention. The number of policy areas where MS have been requested to carry out awareness raising campaigns is actually wider and include nutrition and obesity, rare diseases, organ donation and even the horizontal principle of health inequalities.

Concrete examples of Availability from Secondary Sources. Detailed information on awareness raising campaigns carried out at the national level has been gathered by the EU in the field of alcohol and was published by the WHO on tobacco. Data on awareness raising campaigns on

[21] Indicators on educational activities can be considered a subset of the indicators above specifically targeting school-age children. Out of analogy, related indicators could then be: (i) the existence of the subject in school curricula (EDU.1); (ii) the population actually reached in absolute terms (EDU.2); and (iii) the population actually reached in relative terms (EDU.3). Educational activities have been envisaged in EU policies on nutrition and obesity, alcohol and injuries, but have not materialised in any proposed indicator so far. No example of data for such indicators can be found in the review of secondary sources carried out for this exercise, but elements of AWA indicators specifically related to youth can be found in Eurobarometers on specific health problems.

antimicrobial resistance have been collected and published in this policy implementation report; in this context, health professionals were the only targeted category. Generic data on the level of awareness about a given policy problem are published in the Eurobarometers, but the sample size is usually not sufficient to make data statistically significant at the MS level.

Evidence from the Case Studies – Validity. There are reservations concerning the validity of the indicators on awareness raising or information campaigns (AWA.1) due to the potentially heterogeneous nature of the underlying data; the risk so incurred is that indicators so broadly defined would group together highly different initiatives, though all labelled as campaigns. Considerable differences exist, for instance, between initiatives at the national, regional, or local level. The indicators are not formulated in a way that reflects these differences. The same can be said for figures on the population reached, so AWA.4 faces similar validity problems. There is more consensus on the validity of the indicators concerning the level of awareness (AWA.2) and related trends (AWA.3), although doubts exist on whether these indicators can apply to areas whose specific information requirements can hardly be captured by means of a survey. It is believed that careful qualitative analysis would be required in these cases.

Evidence from the Case Studies – Feasibility. There are also fairly diverging patterns about the feasibility and availability of such data. Indeed, some MS invest heavily in the collection and analysis of these data, while others do not consider this task as a policy priority part, and therefore take little action, if any.

Summary Judgment. Indicators on communication and dissemination activities are not considered particularly reliable for monitoring policy uptake and represent a poor substitute for more qualitative and in-depth case studies that would be better able to provide a realistic description of developments. Indicators about level of awareness among the population are more extensively employed and deemed useful for policymaking purposes, but require a comprehensive package of data, cross-checking between different subsets of respondents and different control questions, in order to come to robust conclusions. Moreover, they pose notable feasibility problems in a number of countries where substantial efforts would be needed to collect the relevant data. That said, they have a potential to signal the evolution of policy uptake over time (high sensitivity), and can reasonably be considered as lead, although can be misleading if delivered only as figures, with no further qualification. In conclusion, these types of indicators can be extremely valid for relevant policy monitoring purposes, but only if analysed in combination with an appropriate set of complementary information.

2.4 Policy Implementation – Institutional Aspects

Indicators about the actual policy implementation phase can be divided into two main groups: (i) indicators about institutional and organisational aspects that look at the preconditions for policy action; and (ii) operational indicators strictly speaking. Assessing whether the basic conditions for policy delivery are in place is possible through a combination of indicators about the actual funding of policies [FUND indicators]; other relevant judgment criteria is conveyed by the existence (i) of lead agencies acting as a multiplier of relevant methodological information across the health system and/or (ii) of entities entrusted with coordinating policy implementation nationwide and acting as a focal point for European institutions. Other indicators on the existence and size of relevant networks or on the introduction of procedures may also be relevant.

2.4.1 FUND - Indicators about Funding of Policies

FUND.1	Total Budgeted Funds in a Given MS to Specifically Implement a Given Policy in Absolute or Relative Terms
FUND.2	Total Public Expenditure to Specifically Implement a Given Policy in Absolute or Relative Terms
PHP.FUND	Total Public Health Programme Financing Committed to Implement a Given Health Policy
STR:FUND	Total Structural Fund Financing Committed to Implement a Given Health Policy

One of the horizontal principles of the EU Health Strategy is the economic dimension of health policies, and in particular their positive economic returns on society. Indicators about the funding of health policies make these assessments possible. Such indicators can be of two main categories: the first on commitments and budgeted funds (FUND.1) and the second on actual expenditure (FUND.2). *Ad hoc* categories can be introduced per origin of funds. So specific indicators may be developed on, for instance, the amount of EU structural funds devoted to a given policy area, on the policy-specific shares of Public Health Programme funds or any other specific programme considered relevant.

Relevance for EU Policies. Indicators about the funding of health policies to monitor MS commitment to policy uptake remain so far an exception and have been recently proposed mainly in the field of rare diseases, HIV/AIDS, and alcohol. Indications for MS to increase the use of the funding opportunities offered by the EU cohesion and structural funds have been given repeatedly in several EU policy documents on health inequalities, mental illness and cancer, but have never materialised in a dedicated indicator, except in the case of health inequalities. Generic requests to ensure the availability of funding have been formulated also in other areas (e.g. antimicrobial resistance).

Concrete Examples of Availability from Secondary Sources. For the time being, there are limited OECD data available on the national funding of policies with a sufficiently detailed breakdown by sector; difficulties arise, *inter alia*, due to data classification and comparability problems. Data on the breakdown of EU structural funds by broad policy areas is recorded by DG REGIO. Data on the PHP national and sectoral breakdown can be made easily available by DG SANCO.

Evidence from the Case Studies – Validity. When tested in both the field of cancer and patient safety, some reservations arose on the validity of funding as an indicator of policy uptake; common concerns revolve around plausibility issues (i.e. it would be difficult to make a clear-cut distinction of funding assigned exclusively to a given area) and significance (e.g. low monetary values would tend to penalise those who use resources more efficiently). More specific and better focused indicators such as STRU.FUND could be slightly more valid; if reformulated, they could convey at least a rough idea of administrative and absorption capacity.

Evidence from the Case Studies – Feasibility. The feasibility of these indicators appears somewhat limited due to the widespread lack of available data and the difficulties in classifying expenditure on a policy basis, and allocating the cost of human resources and overheads accordingly. In countries where this was attempted, dedicated studies were carried out on a sample basis and variance in results is far from giving anything similar to standard costs.

Summary Judgment. For the time being, FUND can still be considered as a potentially misleading and not sufficiently sensitive family of indicators, marred by some feasibility problems and as such their ranking is rather low in the hierarchy of possible priority indicators for the EU Health Policies. A more positive assessment is currently possible for some of the policy-specific declinations of these indicators (e.g. STR.FUND), although their relevance is still limited; overall, they can be retained as secondary indicators. In prospective terms, however, should their future availability

under the OECD programmes improve and should data be more systematically accompanied by cost-effectiveness or efficiency evaluations, FUND could represent primary indicators to monitor changes in policy uptake over time. In strategic terms this could be an area deserving expansion in future versions of this framework for indicators and in related EU policy recommendations.

2.4.2 ORG - Indicators about Clearly Defined Institutional Responsibilities

ORG.1	Number of MS that Have Identified a Body Responsible for Policy Coordination / a Focal Point
ORG.2	Number of MS that Routinely Interact with European Institutions on a Given Policy by Means of a Well Identified Institution
ORG.3	Number of MS for which a Centre of Expertise Entrusted with Disseminating Best Practice in a Given Policy Area Can be Officially Identified

From an organisational and institutional viewpoint, policy coordination can have three main dimensions: (i) there can be a body clearly responsible for strategic planning and for overseeing policy implementation at national or other relevant level; (ii) in highly decentralised systems, there can be at least one focal point responsible for interacting with EU and international institutions and for collecting data from and disseminating information to relevant regional and local entities; and (iii) there can be a technical body playing the role of the centre of expertise and disseminating best practices in a given policy area across the health system.

Relevance for EU Policies. EU policy documents so far have rarely had an explicit institutional or organisational component. There have been requests to designate a national coordinator for global health matters, to establish national focal points for tobacco consumption control, and to designate competent authorities for patient safety. A generic request to focus on capacity building was formulated in the field of HIAP.

Concrete Examples of Availability from Secondary Sources. The WHO regularly monitors compliance with the requirement to establish a focal point and the EU implementation report on antimicrobial resistance provides data on organisational issues. Various studies on HIAP have explored the importance of the governance dimension in the dissemination of best practices.

Evidence from the Case Studies – Validity. Due to its potential relevance across the board of all EU health policies, ORG indicators have been tested in both HIAP and patient safety and have been found extremely valid. Main reservations related to ORG.3 indicators because any such mandate could go against competition in the provision of consulting services; while other reservations also concerned the fact that ORG.1 might be understood as an endorsement of a given organisational model.

Evidence from the Case Studies – Feasibility. ORG indicators have been found easily feasible and, at most, only in need of some terminological clarification on what should count as centres of expertise.

Summary Judgment. Although with some qualifications on the terminology to be used, ORG indicators can be considered as extremely valid and representative of the underlying policy development stage. In this respect they could be considered as primary indicators, given that they are a good proxy of policy uptake that could eventually be extended to all policy areas. In particular, ORG.2 could be a good proxy for the value EU policy documents may add in shaping the policy debate at the MS level. It was found that this tends to correlate with the existence of institutions and procedures to disseminate information across the health system from the national level, responsible for interacting with EU institutions, to the regional and local administrations. If complemented with data on the availability of human resources or funds, these indicators could

have some good sensitivity in tracking changes in the level of policy uptake and could possibly be considered as lead indicators.

2.4.3 NET - Indicators about Networks and Networking

NET.1	Number of MS that Have Created a Network of Institutions to Implement a Policy
NET.2	Number of MS Networks Participating to a European Network
NET.3	Number of MS Entities Included in Networks in Absolute or Relative Terms

The network dimension and related economies of scale can be one of the major components of European added value in the field of health policy. This can be roughly measured along three dimensions: (i) the existence at the MS level of networks in a given policy area (NET.1); (ii) participation of such networks to broader European networks (NET.2); and (iii) the size of such networks in terms of the number of relevant entities involved in absolute or relative terms (NET.3).

Relevance for EU Policies. Network indicators so far have been marginally used and have been proposed in those policy areas where the search for economies of scale is more evident such as rare diseases and organ donation and transplantation and for health surveillance systems that require adequate networks of antennae on the territory to be able to function at full capacity and effectively (e.g., CRBN, patient safety, etc.).

Concrete Examples Available from Secondary Sources. There is information easily available on health surveillance networks. Some secondary data can be indirectly available on networks financed under the PHP programmes in the same areas (NET.2), and actually MS participation in European networks is an indicator envisaged in the PHP impact assessment as a proxy for the capacity of the programme to involve as many MS as possible.

Evidence from the Case Studies - Validity. Because of their limited diffusion, NET indicators could be tested in the area of patient safety only. The assessment of the indicator's validity is rather neutral and concerns have been raised on the limited significance of the term "network" per se, which can lend itself to several interpretations, and on the fact that it could be fairly easy to find formally existing networks, although in practice a number of them may not be truly operational; as a consequence, they would have little or no impact on policy uptake and implementation.

Evidence from the Case Studies – Feasibility. If broadly understood, the indicator poses hardly any problem with its feasibility. It is noted that if stricter and more precise definitions of networks were given, the indicator would become more difficult to measure and compare because of the resulting lack of homogeneity. However, this only limitedly concerns the information needs at a strategic level.

Summary Judgment. These indicators can partly describe a policy dimension such as that of network. Networking, however, requires a more in-depth qualitative assessment of its concrete operational aspects and hardly allows to be measured in purely quantitative terms. The indicators could at best provide some preliminary idea of compliance with minimum policy implementation requirements (e.g. the existence of surveillance network entities) or at best be used as secondary indicators for very specific cases to measure the coverage of target population. Their sensitivity is however limited, as well as their potential as lead indicators.

2.4.4 PRO - Indicators about Introduction of Procedures

PRO.1	Number of MS/RE that Have Officially Introduced a Given Procedure in their Routine Operations
PRO.2	Number of Relevant MS/RE Institutions Complying with Procedure

There can be some cases in which EU policy uptake can be measured in terms of adoption of administrative or operational procedures. In an extremely simplified form, this can translate in two possible families of indicators on (i) whether procedures have been introduced (PRO.1), and (ii) whether these are being complied with (PRO.2).

Relevance for EU Policies. Examples of procedures relevant for EU health policy purposes so far have mainly consisted of relatively minor operational issues such as quality programmes and communication protocols with the notable exception of intersectoral cooperation in the fields of HIAP, injuries, antimicrobial resistance and patient safety. So far a PRO indicator (the introduction of a quality programme) has been proposed just once in the field of rare diseases.

Concrete Examples of Availability from Secondary Sources. For the time being, examples of PRO indicators can be found mainly in the field of studies about HIAP, with specific reference to the existence of procedures to ensure intersectoral cooperation between different administrations.

Evidence from the Case Studies – Validity. PRO indicators on HIA procedures have been tested in the case study on HIAP, and an attempt has been made to see whether this could be extended to operational procedures in the field of cancer screening. Feedback on validity has been mixed, but mainly with reference to substantive matters of the underlying policies than to the indicator per se. The overall usefulness of PRO indicators seem limited for strategic purposes; they rather appear more suited for performance reviews.

Evidence from the Case Studies – Feasibility. As expected, while PRO.1 appeared all in all fairly feasible, PRO.2 indicators face the need to establish a benchmark against which compliance is assessed. Classification issues inevitably ensue.

Summary Judgment. These appear as rather marginal indicators both in terms of policy areas to which they can potentially be applied to and of significance within the single policy areas. They can be secondary indicators in very special cases where, for instance, the adoption of a common communication protocol is a significant part of the European added value and in this respect they could complement the NET indicators above. However, generally speaking, PRO can be considered only hardly relevant for Health Strategy purposes and qualitative studies would be needed to capture the nuances of more complex situations, such as intersectoral cooperation where concrete behaviours are not necessarily formalised in official procedures and common indicators would suffer from substantial definition problems. Moreover, they are poorly sensitive and tend to be lagging.

2.5 Policy Implementation – Operational Aspects

The assessment of the degree of policy uptake in operational terms can be fairly straightforward and can be judged through a combination of the existence of certain policy delivery mechanisms in a given country, and information on the population actually reached by the intervention [DEL indicators]. When regulations are at stake, indicators should investigate the level of enforcement [POL indicators]. Other judgement criteria can be represented by the availability of sufficient technical means and equipment [CAP indicators], or investment in human capital as the share of the relevant healthcare workforce undergoing training on any given subject [TRAI indicators].

2.5.1 POL - Indicators on Enforcing Compliance with Regulatory Provisions

POL.1	Number of Controls Made in a Given MS on Specific Legislation / Self Regulation in Absolute or Relative Terms
POL.2	Share of Positive Controls of Regulatory Infringement on Total Number of Controls on a Given Policy Area in a Given MS
POL.3	Share of the Population Agreeing to Being Subjected to Controls for Health Policymaking Purposes

As a complement to the indicators on modifying behaviours by means of legislation or codes of self-conduct, there are obviously indicators on how these provisions are actively policed and their impact on the population subject to controls. These may include indicators on the total number of controls carried out (POL.1) or on the number of positive controls (POL.2) or on consensus about these policing activities in the total potential target population (POL.3).

Relevance for EU Policies. Needless to say, such indicators have been mainly proposed in the past in the field of tobacco and alcohol consumption and related data that are often published in the related implementation reports. Eurobarometers are sources of information on POL.3 at the European level.

Concrete Examples of Available Indicators. Existing reports on both tobacco and alcohol extensively elaborate on POL indicators, although not necessarily with homogeneous degree of coverage and usually with very limited data on POL.3.

Evidence from the Case Studies. None of the case studies selected for this exercise lent itself to testing POL indicators.

Summary Judgment. POL appears second best when compared to others, the main reason being the qualitative differences in how controls are performed; these differences would add to the pre-existing specifics of the national regulatory provisions, so that POL.1 and POL.2 indicators could hardly be made comparable across MS. However, they lend themselves well to complement, as secondary indicators, the LEG indicators above as they provide lagging but quite sensitive information on how the degree of policy uptake has varied over time. Their relevance as standalone indicators for overall strategic monitoring purposes, however, appears rather limited.

2.5.2 DEL - Indicators on Delivering Specific Policy Actions

DEL.1	Population Reached by Policy Delivery Mechanisms in a Given MS in Absolute or Relative Terms
DEL.2	Number of MS/RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents
DEL.3	Number of Significant Initiatives Undertaken to Specifically Deliver Policy

These indicators concern the sector specific actions MS are requested to implement in the different policy fields. It is worth noting that EU policies do not call for concrete actions in all policy areas, either because policies are still at an early development stage and focus on research, principles or institutional aspects, or because they are defined in terms of objectives to be achieved in terms of health outcomes and impacts, and the definition of the most appropriate actions in the given context is left to the MS themselves. Being sector specific, DEL indicators are inevitably highly heterogeneous and can be grouped into three main categories: (i) indicators on the population reached/covered by the requested action (DEL.1); (ii) compliance of actions with qualitative features outlined in the EU policy documents, if any (DEL.2); and (iii) the number of initiatives undertaken, if applicable (DEL.3).

Relevance for EU Policies. Specific DEL indicators have already been proposed in a number of policy areas, including health of the elderly, illicit drugs, patient safety, cancer, organ donation-and transplantation, vaccination, alcohol and antimicrobial resistance. However, the number of policy areas envisaging the delivery of specific policy actions is actually higher and includes also nutrition and obesity, mental health, HIV/AIDS and CBRN.

Concrete Examples of Available Indicators. DEL indicators are extensively dealt with in all relevant EU implementation reports. Their availability as secondary sources basically depends on whether and when an implementation report is due. There can be problems of consistency over time if underlying definitions change even slightly.

Evidence from the Case Studies – Validity. DEL indicators have been tested with reference to both patient safety and cancer screening. Feedback based on testing in these two policy areas has brought to diverging results. While DEL.1 unambiguously appears as a highly valid indicator, the validity of DEL.2 and DEL.3 seems to depend on the degree to which the underlying policy is perceived as actually standardised according to well-defined benchmarks or still requires substantial qualification of related implementation modalities.

Evidence from the Case Studies – Feasibility. Since validity of DEL indicators appears to depend on consensus on definitions and benchmarks, the amount of effort required to make them available varies accordingly, as controversial definitions would require substantial reclassification efforts and research work. So when DEL indicators appear not valid they are also generally considered as poorly feasible.

Summary Judgment. DEL indicators when available and agreed upon should be considered as primary indicators to report on policy implementation at the strategic level, also because of their ability and sensitivity to track progress in implementation over time, although they remain in this respect lagging indicators. When they are not available this can be considered as an indication of lack of consensus on implementation aspects and in such cases qualitative studies and evaluations are better equipped to capture real progress in policy uptake.

2.5.3 CAP - Indicators on Ensuring Technical Capacity

CAP.1	Number of Entities Compliant with Given Equipment Requirements and Technical Standards in a Given MS
CAP.2	Number of MS/RE in a Position to Ensure Sufficient Availability of Consumables to Enforce Policies

CAP is to capture specific technical capacity requirements that can be variously articulated in terms of needs for equipment, compliance with given technical standards (CAP.1) or availability of a sufficient quantity of consumables to allow smooth operations (CAP.2). CAP indicators are basically a combination of FUND, NET and PRO indicators in their declinations specifically concerned with technical or operational issues.

Relevance for EU Policies. This is a rarely used category of indicators, introduced to reflect provisions often found in health threats-related documents (e.g. preparedness planning, CBRN, antimicrobial resistance) concerning the availability of laboratory capacity, procedures or materials. However, a similar indicator has not yet been put forward by any EU document.

Concrete Examples of Available Indicators. No example of data for such indicators could be found in the review of secondary sources carried out for this exercise.

Evidence from the Case Studies – Validity. CAP was tested with reference to the technical procedures envisaged in the cancer screening Guidelines, which gave fairly neutral results because of the Guidelines' non-mandatory nature; some reservations exist on the usefulness of this information for policy monitoring purposes.

Evidence from the Case Studies – Feasibility. Monitoring the level of compliance with technical standards and requirements appears fairly straightforward and generally poses little feasibility problems, when reference benchmarks are clearly available.

Summary Judgment. When technical standards and requirements are clearly spelled out, the CAP.1 is probably worth maintaining and merging in the NET category as a lagging and secondary indicator with some sensitivity. CAP.2 appears ambiguous if not linked to a benchmark and, at any rate, it should be supplemented with qualitative expert assessment.

2.5.4 TRAI - Indicators on Training Activities

TRAI.1	Number of MS/RE that Have Carried Out Training Courses on a Given Subject for Their Healthcare Personnel
TRAI.2	Total Number of Trained Healthcare Workers on a Given Subject
TRAI.3	Resources Made Available for Training in a Given Field in Absolute or Relative Terms
TRAI.4	Number of MS/RE that Have Introduced a Subject in Relevant Curricula

A number of well-established indicators have been developed to monitor training activities. For the purpose of this exercise, four main aspects can be highlighted: (i) whether training courses targeted to healthcare personnel are provided (TRAI.1); (ii) whether it is possible to track down the total number of personnel receiving training on a subject (TRAI.2); (iii) the amount of resources made available for training (TRAI.3); and (iv) whether a given subject has been included in educational curricula (TRAI.4).

Relevance for EU Policies. So far, TRAI indicators have been proposed in the field of antimicrobial resistance and patient safety where healthcare personnel skills are key for policy success. However, the number of EU policies with a training component is much higher and includes Alzheimer, tobacco, alcohol, mental health, illicit drugs, cancer, rare diseases, injuries, HIV/AIDS, vaccination, CBRN and telemedicine.

Concrete Examples of Already Available Indicators. Information on training programmes has been included in the implementation report on antimicrobial resistance.

Evidence from the Case Studies – Validity. The indicator was tested on both patient safety and cancer screening and its validity appeared correlated to the perceived importance of the overall training component on ultimate policy success. It was suggested that the indicator could be biased, putting too much emphasis on specialised courses to the detriment of more general courses dealing with a number of different specific subjects.

Evidence from the Case Studies – Feasibility. In a number of countries the health training system is so decentralised that the feasibility of TRAI indicators is not to be taken for granted unless a major data gathering effort is undertaken.

Summary Judgment. TRAI indicators can be very valid and appropriate in specific policy areas thanks to their good sensitivity and lead nature but generally pose feasibility problems and should be commissioned on an *ad hoc* basis. They can be justified when a data gathering system is already in place for specific policy monitoring purposes, but are otherwise unpractical and not particularly recommendable as broader EU Health Policies indicators.

2.6 Feedback on Policy and Learning Mechanisms

Compliance with data harmonisation requirements [HAR indicators] is a precondition for any evidence-based cross-contamination of experiences at the European level and it allows for mutual learning to take place. Harmonisation can be judged either with reference to the number of MS in a position to feed data to the relevant EU indicator database, or by means of an expert judgment on the degree of compliance reached combining qualitative and quantitative analysis. Availability of the relevant registries in the different MS and the fact of having in place consistent classification mechanisms would be a precondition for harmonisation. Progress reached in processing feedback on policy and related learning mechanisms can be judged through a combination of criteria ranging from the availability of evaluation reports [EVAL indicators] on a given policy subject or of a fully-fledged evaluation programme funded with adequate resources, to the capacity of contributing to the existing European policy cross-contamination initiatives by proactively providing relevant examples of best practices and information [EXC indicators], to compliance with reporting requirements envisaged in the EU policy documents [REP indicators].

2.6.1 HAR - Indicators on Data Harmonisation

HAR.1	Number of MS Providing Homogeneous Data to the Relevant EU Health Indicator Database
HAR.2	Number of MS Deemed Compliant with Data Comparability Criteria based on Expert Assessment
HAR.3	Number of MS that Have Put in Place Special Registries When Requested / Number of Registries Established
HAR.4	Number of MS that Have formally Aligned Their Data Classification Systems to Standardised Given Procedures[22] (e.g. ICD10, etc.)

One of the preconditions for exchange of best practices and policy discussion between MS is that the underlying data on the given policy issue are sufficiently harmonised to represent a common basis for comparisons. Depending on the policies, this data harmonisation requirement can be measured across several dimensions. A possible indicator is the number of MS that can provide harmonised data to a common database (HAR.1), or failing that, the number of MS that can provide data complying with commonly agreed standards based on accepted expert opinion (HAR.2). Data harmonisation may require that registries are established based on common standards (HAR.3), or that national classification schemes are modified according to predefined standards (HAR.4).

Relevance for EU Policies. Unsurprisingly, given the prevailing nature of European added value in EU health policies, HAR-type actions have been identified in a number of EU policy areas ranging from tobacco, alcohol, and mental health to illicit drugs, cancer, and rare diseases and encompassing also organ donation and transplantation, injuries, HIV/AIDS, antimicrobial resistance and patient safety. However, HAR indicators have been explicitly proposed so far in a much more limited number of cases and basically only in the fields of Alzheimer, illicit drugs – indeed, developing comparable indicators has represented a substantial part of past policy efforts in this area –, HIV/AIDS and rare diseases.

Concrete Examples of Already Available Indicators. Implementation and EMCDDA reports on illicit drugs and drug policies have probably represented the best available sources of such indicators in the period under consideration and can represent a benchmark of how they can be implemented.

[22] This indicator is very similar to HAR.2, but while the latter focuses on ultimate outcomes, HAR.4 limits itself to procedural aspects, irrespective of how they have been actually implemented.

Evidence from the Case Studies – Validity. HAR indicators have been tested in both patient safety and cancer screening and have generally been recognised as highly valid indicators.

Evidence from Case Studies - Feasibility. HAR indicators appear to pose little feasibility problems as they are generally based on easily available benchmarks.

Summary Judgment. HAR indicators aptly lend themselves to capture a key component of European added value in policies based on exchange of best practices; as such, they appear relatively underutilised in current Commission practice. Given their relative feasibility, they can be considered primary indicators for EU strategy monitoring purposes, but they have also some limited sensitivity capacity to track down small changes in policy over time; they are lagging indicators as they can be used for data collection on past policy developments.

2.6.2 EVAL - Indicators on Monitoring and Evaluation Practice

EVAL.1	Number of MS/RE that Have Carried Out Evaluations / Cost Effectiveness Assessments of their Policies
EVAL.2	Number of MS/RE where Policy Has Been Streamlined / Modified as a Result of an Evaluation Exercise / Cost Effectiveness Assessment
EVAL.3	Number of MS/RE that Have Put in Place a System of Indicators to Monitor Policy Implementation

Another key element of European added value based on the exchange of best practices is that MS can monitor and evaluate their own policies and eventually modify them based, *inter alia*, on learning from evaluation results. This can be sketched out in three categories of indicators: (i) indicators on MS ability to evaluate the effectiveness and cost-effectiveness of their own policies (EVAL.1); (ii) indicators on the existence of evidence that these results have been fed back into the policymaking process and informed subsequent policymaking, by means of formal documents and Government reports or the like (EVAL.2); and (iii) indicators on the existence of a domestic monitoring system able to track policy development by means of a set of indicators that can be commonly agreed at the EU level or devised on a national basis (EVAL.3).

Relevance for EU Policies. Monitoring and evaluation requirements have been included in a number of EU policies, such as HIAP, tobacco, nutrition and obesity, alcohol, mental health, organ donation and transplantation, injuries and HIV/AIDS. However, a specific EVAL indicator has been proposed only in the field of rare diseases with a narrowly defined scope and purpose (i.e. health technology assessments carried out to measure the efficacy of treatments) and in the field of HIV/AIDS.

Concrete Examples of Already Available Indicators. DG SANCO provisions have never envisaged that the evaluation of European policies should be accompanied by evaluations carried out at the national level, and therefore such indicators are not usually available. In certain areas (e.g. antimicrobial resistance) data exist on MS that have put in place a system of indicators and therefore presumably also a monitoring system. Data on the existence of monitoring systems can otherwise be indirectly inferred from the availability of DEL indicators (e.g. geographical coverage of cancer screening).

Evidence form the Case Studies – Validity. Needless to say, EVAL indicators have generally appeared as highly valid proxies for the level of commitment to a given policy in the different countries, there are reservations on the fact that a feedback mechanism as that envisaged in EVAL.2 can be captured by a quantitative indicator, as it might require a more qualitative and nuanced assessment.

Evidence from Case Studies - Feasibility. EVAL indicators appear as highly feasible with the notable exception of EVAL.2 for the reasons explained above. EVAL.2 would require a considerable research effort.

Summary Judgment. EVAL indicators appear particularly valid and, together with HAR indicators, can capture a key component of European added value in policies based on exchange of best practices. As such, they also appear relatively underutilised in the current Commission practice, considering that they have an untapped potential to report on changes in the degree of policy uptake (although with limited sensitivity and only over quite long periods of time and with some delay). In this respect, they can be considered as lagging indicators. Given their relative feasibility, they can be considered indicators of first choice for EU strategy monitoring purposes. The suggestion of expanding the link with Health Technology Assessments is worth exploring for the monitoring of future strategy documents.

2.6.3 EXC - Indicators on Sharing and Exchange of Policy Experiences

EXC.1	Number of MS that Have Contributed their Policy Experiences to the Relevant European Coordination Mechanisms / Conference / Working Group
EXC.2	Number of MS that Have Submitted Examples of their Best Practices / Pilot Actions to the Relevant European Database /Portal

Exchange of policy experiences in European fora can typically take place through conferences, working groups and other coordination mechanisms (EXC.1), or by submission of examples of best practices to databases and dedicated portals (EXC.2).

Relevance for EU Policies. Indicators about sharing and exchange of experiences have not been proposed yet, although related provisions are explicitly mentioned in most EU policy areas, both horizontal ("shared health values", "health is the greatest wealth" and "global health"), as well as vertical (Alzheimer, health of the elderly, tobacco, nutrition, illicit drugs, cancer, rare diseases, HIV/AIDS, preparedness planning, CBRN, patient safety and telemedicine). For practical purposes, EXC could even be considered an implicit provision of all policy areas.

Concrete Examples of Already Available Indicators. Although in a number of cases the underlying data could be easily available, none of these indicators was found published in the sources reviewed for this exercise.

Evidence form the Case Studies – Validity. EXC indicators could be tested only once and appeared of limited validity. The main point is that they do not necessarily measure the degree of uptake of a given policy in an MS, but rather the overall functioning of the transmission mechanisms of the body of knowledge developed at the national basis to the other EU partners. In this sense, EXC indicators represent good counterparts of ORG.2, if the former were focused on measuring whether there are any procedures envisaged to communicate EU priorities to the national health systems.

Evidence from Case Studies - Feasibility. EXC indicators appear as relatively feasible and would require very limited research effort.

Summary Judgment. EXC indicators may eventually represent secondary indicators, as they measure the level of commitment to the open method of coordination[23] thus providing an indirect

[23] The open method of coordination (OMC) is a relatively new and intergovernmental means of governance in the European Union, based on the voluntary cooperation between MS. It relies on a combination of guidelines and indicators, benchmarking and sharing of best practices. OMC effectiveness relies on a form of peer pressure and naming

measurement of policy uptake in a broad sense. EXC indicators are relatively feasible. According to desk sources, their sensitivity to capture trends in commitment to policy uptake over time is however limited and they are lagging, rather than leading.

2.6.4 REP - Indicators on Reporting on Policy Implementation

REP.1	Number of Required Items on which MS adequately Report to the EC about the Progress Reached in the Implementation of Their Policies
REP.2	Availability of Reports or parts thereof on the Progress Reached in Implementing Policies Containing Information Not Shared with the EU

Not all EU health policy documents include explicit provisions requiring MS to report back on policy implementation, but if such a requirement exists, the number of complying MS (REP.1) is a possible policy uptake indicator. The exercise also brought to light the possibility of testing the validity and feasibility of indicators on the existence of policy monitoring information, commonly used for internal purposes and therefore not routinely shared at the European level (REP.2)

Relevance for EU Policies. Although the existence of reporting provisions is frequently found in Commission policy documents (e.g. tobacco, alcohol, cancer, rare diseases and vaccination, to name but a few), indicators about compliance with this provision have not been proposed yet.

Concrete Examples of Already Available Indicators. REP.1 has never been published, but can be easily calculated based on the EU implementation reports that have been published so far. REP.2 is also not publicly avaialble

Evidence from the Case Studies – Validity. REP.1 appears as a fairly valid indicator, although it can become slightly ambiguous when data are provided only with a partial geographical coverage because they are not available at all regional or local levels. REP.2 would appear of more dubious validity and more liable to be interpreted subjectively.

Evidence from the Case Studies – Feasibility. REP.1 is highly feasible; the same can't be said of REP.2 which would require *ad hoc* research into the information shared and the sharing parties.

Summary Judgment. REP.1 can be used as a secondary indicator of limited sensitivity and lagging nature, with the caveat that the reasons for MS not complying with reporting requirements may be different. Failing to report is not necessarily due to the fact that nothing has been done with regard to a given policy area; alternative reasons may be resource or time constraints or the need to deal with and report on other more pressing matters. Unless a repository of MS monitoring reports is established, investment in REP.2 does not seem worth the effort.

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and shaming, as no MS wants to be seen as the worst-performing in a given policy area. Generally, the OMC works in stages. First, policy goals are agreed upon. Secondly, MS transpose guidelines into national and regional policies. Following transposition, specific benchmarks and indicators to measure best practice are agreed on. Finally, results are monitored and evaluated.

3. RESULTS OF THE CASE STUDIES

Introduction. This chapter summarises the findings of the three case studies on HIAP, Cancer Screening and Patient Safety. Each thematic section provides a summary background to the EU policy concerned, then reports factual evidence on the degree of policy uptake reached and the specific role played by the EU policy documents in the process. A review of the main implementation issues (i.e. perceived obstacles) follows. Finally, existing monitoring and evaluation provisions at the national level precede the presentation of validation results. These are described in more detail, indicator by indicator, in the Appendices to this volume, while Volume II – Annexes explore the Country case studies in full length.

3.1 Health in All Policies (HIAP)

3.1.1 Background – the EU Policy

The *core concept* of Health in All Policies (HIAP) is "*to examine determinants of health, which can be influenced to improve health but are mainly controlled by policies of sectors other than health"*[24], building on the 1978 WHO Alma Ata Declaration which had introduced the concept of *intersectoral interventions.* The subsequent Ottawa Charter (1986) introduced the notion of making policies accountable for health impact, leading to the development of *health impact assessments (HIA)* as a policy tool to measure impact. As of 2006, HIAP was integrated in mainstream European policies. The EU policy objectives in the field of HIAP were first spelled out in the 2006 Council Conclusions on HIAP urging MS to increase the visibility and value of health in the development of their legislation and policies also through health impact assessments. The HIAP agenda is expressed in terms of commitment to broad principles, rather than to concrete operational tasks. These principles include to:

- develop a *knowledge base* on health and its determinants, trends in them, and in health inequalities;
- reflect in policy formulation and implementation the *added value of 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 utmost attention to the impact major government policies have on *equity in health*, including mental health, and guarantee necessary efforts to tackle health inequalities; and
- focus on *capacity building* in policy analysis and development for improved intersectoral policies.

Furthermore, the *EU Health Strategy* includes a recommendation for MS to strengthen integration of health concerns into all policies, both at MS and regional levels, including use of Impact Assessment and evaluation tools. In the accompanying staff working paper this recommendation is further articulated in the following terms: "*HIAP approaches will be encouraged and promoted at all levels […] with the aim of supporting increased intersectoral cooperation in the field of health. The use of HIA and HSIA […] will be encouraged. The online Health Systems Impact Assessment Tool, which offers a methodology and background information on key policy areas in relation to their interaction with and impact on health systems, will be further developed. This will include*

[24] Sihto M, Ollila E, Koivusalo M. Principles and challenges of Health in All Policies. In: Ståhl T, Wismar M, Ollila E, Lahtinen E, Leppo K (eds), 'Health in All Policies: prospects and potentials'. Ministry of Social Affairs and Health and European Observatory on Health Systems and Policies, Helsinki, 2006, pp. 3–20.

adding further assessments of policy areas and disseminating the Tool at EC, national, regional and local levels to make it available to people assessing new initiatives which may have an impact on health systems. Opportunities for using post-hoc evaluation to support the integration of health into other policies will be explored[25]".

A solemn *Ministerial declaration* was then signed in *Rome* in 2007 to reiterate commitment to the HIAP principles (see Box 3.1 below).

Box 3.1 - The Rome Ministerial Declaration on Health in All Policies

The signatory EU Ministries declare their commitment to:

- Consider how to actively meet the challenge to implement health-conducive policies with a clear added value for the health of the people living in the European Union by conducting targeted projects and plans for action, thus exemplifying the benefits of Health in All Policies approaches, and to select for this purpose – and for exchange of best practice – topical areas with intersectoral interference and a high potential to improve health;
- Strengthening multi-sectoral approaches and processes at European, national, regional and local levels by which the public health impacts can be effectively taken into account in all policies;
- The intensification of collaborative efforts among themselves and, as appropriate with the European Commission and the World Health Organisation in order to speed up the elaboration and implementation of health-conducive policies in other sectors, including gender policies and equal opportunities;
- The strengthening of the use of HIA, where appropriate, and promoting the use of available methodologies at European, national, regional and local level, and integrating them in other already existing assessment frameworks.

Express their willingness to contribute to incorporating health concerns in other policies at all levels and to work together at European level in cooperation with the European Commission and with the WHO Europe to:

- Contribute to regular reporting about developments on Health in All Policies and consequences for improving the health status in all EU Member States and addressing health determinants. To this end, the feasibility of establishing an IT Network and other communication tools to share best practices in addressing health determinants and to monitor activities related to Health in All Policies should be considered;
- Encourage the use of health impact assessment of major policy initiatives;
- Consider the use of the on-line Health System Impact Assessment Tool which offers a methodology and background information on key policy areas in relation to their interactions with and impact on health systems, in order to make it widely accessible in Member States, and to do so with an interactive approach that would make possible the validation of this methodology;
- Undertake a major effort within member States and at EU level to effectively address health determinants, reaffirming their commitments to EU strategies and policies on tobacco control, nutrition and physical activity, alcohol-related harm, drug dependence, mental health, occupational health and safety, health and environment, health and migration, healthy ageing, preventing accidents and injuries, and addressing issues related to sexual health;
- Agree to improve further, at national and EU level, the research and information base for these activities, building upon the work undertaken in these areas in the public health and research fields;
- Agree to assess the possible need for strengthening of Health in All policy implementation, by considering the need for, *inter alia*, strengthening of public health expertise and national surveillance mechanisms, as well as common understanding across different sectors through intersectoral networks, processes and mechanisms;
- Commit to preparing analytical reports on key health determinants as well as good practices in intersectoral policies and approaches to address these determinants. These series of reports on health determinants so produced would support and help developing policy responses at EU and national levels,

[25] Commission Staff Working Document, Document accompanying the White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013', SEC(2007) 1376

and would also provide an invaluable database of good practice on policy options to address specific determinants;
- Establish a systematic and sustainable framework comprising skills and know-how development with the aim to increase the capacity of Ministries of Health to advocate, negotiate, implement and evaluate Health in All Policies approaches within given Country contexts. Close collaboration with the European Commission, the WHO Regional Office for Europe and other International Organisations relevant to this domain should be pursued to ensure efficiency and overall consistency of efforts.

3.1.2 Uptake of EU policy in MS

Key facts. Fieldwork findings would suggest that the HIAP approach has generally lost momentum since the EU Health Strategy was approved. Very little progress could be recorded in all MS concerned, and HIAP implementation has remained broadly characterised by *a series of localised experiences*, often fragmented and dissimilar in nature. In some countries there is also some evidence of HIAP having become a politicised issue with increasingly diverging views between political parties on its real usefulness and value for money, especially in the light of the time and resources needed for its implementation, and its allegedly disruptive effects on the policymaking process. Accordingly, in some cases HIAP changed its status from a positive to a negative priority following turnover in regional and national governments.

On the other hand, there are also *preliminary signs that HIAP could become increasingly institutionalised* in the policy debate of all four MS, and in particular:
- HIAP as a subject on its own has now entered the *draft 2011-2013 Italian Healthcare Plan*, the cornerstone health programming document in the country;
- in France the *National Committee on Public Health* has recently endorsed as part of its agenda the identification of possible ways to facilitate the assessment of possible impact on health of various government policies;
- a revival and further strengthening of the role of the *National Steering Group for Public Health* as a body responsible for HIAP coordination at the national level, has recently been proposed in Sweden;
- HIAP is reportedly one of the possible pillars of the coming *Polish Law on Public Health* that should become the reference law for reforming the Public Health system.

HIAP uptake in all four MS is characterised not by concrete operational achievements, but by declarations of commitment to HIAP at various stages of policy development. Policy declarations notwithstanding, reservations still exist on the actual effectiveness of HIAP, and in particular on the need to establish routine HIA procedures, in connection with concerns that the costs associated with this additional procedure may outweigh its benefits.

Finally, it is noted that proposals for the taxation of junk food or of sugar in drinks – that are deemed broadly in line with the HIAP philosophy – have been formulated and have entered the policy debate in some of the four MS considered, often without recurring to HIA or intersectoral cooperation procedures. Thus, some are concerned that HIAP could end up becoming a tool to focus on formal aspects of the debate only, while slowing down decision making on more concrete issues.

Intersectoral Cooperation. Examples of intersectoral cooperation were found in the framework of the implementation of *lifestyle-based policies* (e.g. health and nutrition). In other areas, the existence of such mechanisms also depends on the division of labour between the different ministries potentially concerned at the national level. However, a recognised framework for intersectoral policy coordination is usually *missing* even in the countries with a long-standing

engagement in HIAP (e.g. Sweden). Examples of grassroots initiatives on an *ad hoc* basis implemented at the local or regional level on various issues are much more widespread and easier to be found. But they generally fail to be incorporated in a clearly distinguishable institutional model or set of procedures as happens in Sweden.

Health Impact Assessment. HIA remains in the majority of cases an instrument linked to Environmental Impact Assessments (EIA) or at any rate implemented only at the *local project/programme level*, with very limited instances of transposition of this methodology to the policy level. Where intersectoral cooperation and HIA have been making a slow start, this is due to scarce familiarity with these instruments as routine components of the policymaking process in the MS considered.

Additionally, there are still substantial methodological uncertainties in a number of countries, hampering the use of HIA in domains not attaining to environmental policy. With one notable exception, the various non-EIA-related HIA-like exercises carried out at the regional/local level are characterised by a notable degree of methodological eclecticism and a lack of consolidated standards. This might further reinforce stakeholders' perceptions of HIA as a potentially arbitrary instrument still lacking the methodological requirements for it to be considered technically fit.

On the other hand, the prospects of the Health Equity Impact Assessment (HEIA) appear relatively brighter, as health inequalities already rank high on the agenda of several governments. This avoids the scorn of perceiving this policy priority as forcefully imposed from the outside. Support to HEIA is justified because this is perceived as an instrument of immediate applicability for the policymaking process. HEIA's popularity is also partly owed to the current joint actions on health inequalities, which are probably a more effective and far-reaching medium of communication, compared with the previous HIA-related PHP projects. The latter weren't generally considered suitable for concrete policymaking and their usage was restricted to small circles of experts.

The influence wielded by EU Policy. Fieldwork findings would suggest that the influence exerted by the EU for the adoption of this policy has been limited. In particular, a feature common to all the countries visited is the *very limited influence of the EU-funded methodological projects* and the very limited – not to say hardly existent - circulation related guidelines have had. HSIA, for instance, was either unheard of or rejected as unpractical in the four MS.

In perspective, a most useful information channel would be supplied if the Commission conducted an evaluation of its own HIA experience and disseminated the results of this exercise, combined with other evaluations at MS level. In performing this information and dissemination role, the EC would provide perhaps the most important element of European added value. Indeed, if results revealed positive, it would be easier to overcome the widespread *resistance and scepticism on the effectiveness and cost-effectiveness* of the HIA tool, currently the main barriers to implementation. The fieldwork allowed to gather some basic evidence on the extent and implications of EU influence wielded through different forms of support provided to MS. The key findings are summarised in Table 3.1 below.

Table 3.1 – EU influence on the policy area

Nature of EU support	*Key findings in selected MS*
Political 'pressure' contributing to the prioritisation of HIAP in the health agenda	In Italy, the EU White Paper contributed to raise the status of HIAP on the policy agenda, while in France there has not been any real pressure. The main hindrance in France is of a normative nature: adoption of the EU policy on HIAP is voluntary. The very nature of the legislation (i.e. soft) acts against prompt HIAP uptake in France, where the public health framework is highly regulated. In Sweden, pressure by EU institutions is thought to have contributed considerably to making of HIAP a priority in

Nature of EU support	*Key findings in selected MS*
	public health. In Poland it is felt that the Council Conclusions on HIAP have had an impact on experts' involvement in the field of health inequalities, but have not translated into any practical steps in the policy making process.
Adoption of methodologies developed at the EU level by PHP projects	In Italy and France most of the EU PHP HIA methodologies have gone largely unnoticed. Most of the local-level initiatives connected to varying degrees to HIAP that have been implemented in France so far are based either on customised methodologies or on methodologies borrowed from other countries (and especially Switzerland and Canada – Québec). Anecdotal evidence from fieldwork showed that better dissemination of the output of EU-funded projects at regional/local level would be greatly appreciated by policy-makers. In Poland, methodologies developed at EU level (notably HIA) are under discussion, but they have not been followed up on concretely. In Sweden, the share of HIAP methodologies that have been adopted by way of PHP projects is significant.
Support to the dissemination of HIAP approaches and methods that were already a priority in your country	The dissemination of jointly agreed HIAP approaches and methods has been slow in Italy. In France, the primary HIAP-related concern are health inequalities. In this respect, greater dissemination/promotion of EU work (especially HEIA) would be strongly aligned with French priorities. With respect to HIA, a relevant initiative to discuss approaches and methodologies and involving DG SANCO and the relevant ranks of the MoH was organised in 2010. The EU involvement definitely strengthened HIAP related initiatives that were already ongoing in Sweden.
Advisory/technical support	Italian regions have developed their own HIAP guidelines independently. In France, at local/regional level most of the advisory/technical support comes from networks e.g. the ESPT and the *Villes Santé*. EU technical support to HIAP is perceived as minimal with possibly the sole exception of the EU-funded project DETERMINE, in the field of health inequalities. In Sweden, EU added value varied according to the support mechanism it provided by area of activity. In Poland, advisory and technical support as well as exchange of experiences have not been sufficient. This is partly due to the fact that the relevant authorities have not been proactive. For instance, Poland has never requested any support from the EU in the HIAP field, and while health policy experts have identified interesting models in Finland and Britain, no step has been taken to replicate them.
Support to convergence of strategic approaches on HIAP adopted by MS / 'gap' reduction among MS	In Italy, prospects of convergence are more positive for HEIA than for HIAP. HEIA can be expedited by virtue of the fact that it already has a place in the Italian health policy agenda. In France, transnational cooperation and exchange for convergence have seemingly been more centred on bilateral projects. This is particularly true at local level where there are examples of regional health agencies or municipalities that have set up best practices and learning exchanges with foreign bodies or have hired foreign consultants to develop local HIA models. Convergence in Sweden has been crafted among MS on the subject of HIAP largely thanks to EU involvement and initiatives. In Poland, advisory and technical support as well as exchange of experiences have not been sufficient.

Implementation issues. Fieldwork findings have highlighted a number of obstacles to the implementation of HIAP in general, and of intersectoral cooperation and HIA in particular, in the four MS considered. In summary, the main factors identified can be broadly grouped into the categories below, divided between those inherent in the HIAP approach in general, in intersectoral cooperation and in HIA:

HIAP

- *Human and financial resources.* From the standpoint of human resources, in France the education and training programmes for health professionals are mostly centred on biological determinants, while transversal modules on social sciences and other disciplines are little developed in the curricula. This results in a shortage of personnel trained under a system that can effectively enable transforming the HIAP approach into practice. Formal application of a HIAP approach in Sweden is reportedly suffering primarily from a lack of human and financial resources.

Intersectoral cooperation

- *Lack of secretariat and centres of expertise.* In principle, intersectoral cooperation should be orchestrated by an in-country technical secretariat with coordinating functions. Such a body is missing from all four MS considered. This is unequivocally seen as a major barrier to implementation. In the absence of a full-fledged secretariat, the creation of a comparable centre of expertise has been a key priority of the *Haut Conseil de la Santé Publique* (HCSP) in France, but has not materialised yet. Its tasks would include to facilitate coordination among institutions at national and sub-national level, to support research, to develop the expertise and HEIA practices.
- *Invalidating institutional setup.* In some cases, the institutional architecture implies that the same organ covers a ranges of sectors that, if disconnected, would desirably be brought together through intersectoral cooperation. In Italy, where the Ministry of Health is responsible for a variety of horizontal policies (e.g. for health and the environment, or for health at labour, or for veterinary services), the very need/concept of intersectoral cooperation falls short.

HIA

- *Political expediency.* In some countries, various levels of government are reportedly reluctant to consider the implementation of HIAP principles (and in particular HIA procedures) in defence of their own political vantage. In Italy, several regional governments were found to oppose HIA/HIAP out of concern that their Health Departments, already in control of over 85% of the regional budgets, would be endowed with disproportionate resources compared to the rest of the regional administration. In addition to that, HIA has also suffered from being equalled to an instrument used to justify *controversial environmental projects*; as a consequence it came to be considered by some parties not as a neutral technical instrument but as a product of political contrivance. The origin of political resistance to HIA in France is different: political unwillingness to endorse HIAP in general, and HIA in particular, is connected with the traditional national approach on public health essentially focussed on care and only marginally on health prevention.
- *Insufficient evidence in support of HIA.* There is widespread concern that there is an insufficient body of knowledge to justify HIA as a procedure and to prove that HIA would not result in *costs and delays largely outweighing benefits* and in an additional unnecessary *administrative burden*, as feared by some of the stakeholders. In order to fill this evidence gap, it is noted that the EU could invest more in collecting this body of knowledge and making it available to all MS, while so far the lion's share of dissemination efforts consisted of investing in procedural guidelines of limited practical usefulness. This concern is common to Italy, France and Sweden.
- *Lack of evaluation culture.* 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. This is a predicament affecting in particular the Italian context.
- *Unclear legal framework.* The use of HIA in public administration is further undermined by the absence of clear legal frameworks and methodologies. In France there are no obligations for public administration entities to either use HIA systematically, or to adopt a standard definition of HIA. The absence of a clear national legal framework on HIA (and HIAP in general) has as a result that experiences at local level are quite fragmented and dissimilar. Both in Italy and France, although bodies designated for the dissemination of EU and international guidelines are in place (e.g. *Conferenza Stato-Regioni* in Italy), the transmission mechanisms are inefficient which ultimately fail to deliver coherent guidance. The above, however, does not apply to health impact assessments carried out as part of mandatory EIA in France, for which a

reference manual has been developed by InVS. The lack of a clear legal framework for the use of HIA within the public administration (most notably at the national level) is considered a major obstacle in Sweden, as well.

3.1.3 Monitoring and indicators

Monitoring at EU level. As already mentioned, the 2006 Study *Health in All Policies: Prospects and Potentials* set a baseline reference for HIAP implementation as of 2005, and of the related degree of institutionalisation across the EU. The report focused on two main areas: 1) incorporating health in the policymaking process through various means of intersectoral cooperation, and 2) more specifically the use and the degree of institutionalisation reached by the Health Impact Assessments (HIA) across Europe. Other relevant work carried out by the EU in the field includes:

- The Report on the Effectiveness of Health Impact Assessment, a project carried out by 21 teams from 10 countries between 2004 and 2007[26].
- The methodological work on Health Impact Assessment and Health Systems Impact Assessment of the Commission's High Level Reflection Group.
- The European Meeting on Health Impact Assessment and Health Systems Impact Assessment, organised by the Portuguese Presidency in 2007.
- A PHP Technical Assistance project on Health Impact Assessment in new MS, Accession and pre-Accession Countries (HIA-NMAC).

The study did not explicitly focus on identifying indicators for the measurement of policy implementation, but it did consider that the existence of a number of possible *policy dialogue mechanisms* could be used as proxies of the degree of coordination found at the various levels of Government. The existence of a technical secretariat responsible for coordinating these initiatives could be considered a further proxy of political endorsement of HIAP principles. Another important mechanism to demonstrate commitment to HIAP principles was to ascertain whether formal consultation procedures on, for example, legislation are in place. Finally, the Finnish presidency report made recourse to participation to the WHO Healthy Cities initiatives as a proxy for HIAP uptake at local level. Europe is therefore still lacking a comprehensive pan-European study on the approaches followed and the governance tools and frameworks for HIAP implementation. There are only a handful of recent studies that have comparatively analysed what governments in Europe are doing to integrate HIAP in their policies. In particular, a compilation by the Dutch Council for Health and Healthcare briefly reviewed country experiences and individual tools and demonstrated that the whole-of-government approach had been implemented in some countries (UK, FI, NL and SE) and regions (Wales, North Rhine–Westphalia). However most of the developments taking place at the regional and local level have remained unreported[27].

Health Impact Assessments. More quantified information was available for HIA. The aforementioned study recorded at least an overall tenfold increase in the number of Health Impact Assessments recorded as compared to a similar mapping exercise carried out in 2001. Overall, the situation at the time of the Finnish presidency report as regards the development of indicators to measure HIA implementation is summarised in Table 3.2 below, covering 18 MS plus Northern Ireland and Wales that have separated regulatory environments on health.

[26] Wismar M., Blau J., Ernst K. and Figueras J., 'The effectiveness of health impact assessment. Scope and limitations supporting decision-making in Europe', on behalf of the European Observatory on Health Systems and Policies, 2007.
[27] Some of these developments are reported by http://www.enrich-network.eu

Table 3.2 - Available Indicators of the Degree of Implementation of HIA across the EU in 2005 (N° of MS)

Indicator	No. of MS
Evidence of Methodological Standardisation / Guidelines	**n.a.**
Some Available Evidence of Implementation	**18/20**
Evidence of Frequent Implementation	**4/20**
Existence of a Lead Organisation	**n.a.**
National Reference Policies /Regulations	**10/20**
Regional Reference Policies /Regulations	**5/20**
Local Reference Policies /Regulations	**7/20**
Resources / Data Publicly Available	**10/20**
Dedicated Budgets[28]	**7/20**

Monitoring and evaluation at the national level. The results of fieldwork showed that further to EU level monitoring, there are hardly any local indicators and monitoring systems to supervise the implementation of national policy/programmes and related performance (more detailed information are provided in the case study reports in Volume II).

- ***Italy.*** The two most common indicators that could be currently used to monitor uptake of HIAP principles appear to be:
  - The number of regions indicating HIA as a priority in their Regional Prevention Plan, though noting that, even when indicated as a priority, the understanding of HIA in this context is much more limited in scope than envisaged in the EU policy initiative[29];
  - The physical indicators of implementation of the *Guadagnare Salute* ("Gaining Health") programme which remains to date the most important example of intersectoral cooperation in the Country.

  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 not implementing EU policies in this area.

- ***France.*** There is currently no monitoring system 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.

- ***Poland.*** There is no direct monitoring or evaluation system of HIAP implementation in place (the reason being that the policy is hardly implemented), with the sole exception of the National Health Programme monitoring, which is undertaken on an annual basis, and for which regional level administrations often meet. Such meetings can be considered intersectoral in as far as representatives of regional departments other than Public Health participate.

[28] Data were collected by a network of dedicated correspondents. However in one case a MS was reported to have no available evidence of any form of HIA implementation, but to have an official policy and a dedicated budget in place. It is unclear whether these had just been introduced at the time the study was performed.

[29] 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 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

- ***Sweden.*** No evaluation of HIAP uptake/implementation has been carried out to date on a national scale. Nevertheless, some local/regional HIA assessments have been carried out. 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). While the Swedish National Institute of Public Health (FHI) does not monitor HIAP uptake per se, it does carry out case studies of HIAs implemented at the county or municipal level. Furthermore, with regard to Public Health 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 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.

3.1.4 Summary results of indicator validation

The validation of indicators performed through in-depth interviews with key informants has given the following results (see Appendix 1 for details):

- ***ANA*** and ***PRI*** indicators can be considered fairly valid and easily feasible, although with some reservations linked to the fact that the same terminology can actually refer to different understandings of HIAP in the different countries; therefore, they may be misleading if not correctly qualified. Moreover, according to some, bibliographic indicators could also be intrinsically misleading and biased against small countries, and as such poorly representative.

- ***PART*** indicators are subject to so many qualifications that their gathering would require considerable qualitative judgment and are therefore liable to be ambiguous. They would appear at least questionable. All in all, there is limited consensus on their validity and feasibility.

- ***RES*** indicators would face major feasibility problems and are at any rate considered hardly significant and of dubious validity, in this specific field, by a majority of respondents.

- ***ORG*** indicators, although with some qualifications on the right terminology to be used, are generally considered as highly valid and easily feasible, as well as particularly representative of the underlying policy development stage.

- ***PRO*** indicators appear questionable in line of principle, especially to those that are more concerned that the implementation of HIAP principles by procedural administrative means could eventually result in a further administrative burden not really justified in terms of added value. So there is limited consensus on their validity. Feasibility is also uncertain in some cases.

- ***EVAL*** is generally considered as valid and particularly appropriate, as far as the availability of evaluation reports is concerned. Slightly greater reservations exist on the validity of having an indicator in place on the existence of monitoring systems on HIAP uptake because of uncertainties on items to be measured. Feasibility is generally assessed as fair, although with some reservations on data fragmentation.

3.2 Patient Safety

3.2.1 Background – the EU Policy

In the context of EU health policy, *patient safety (PS) is defined* as "*Freedom for a patient from unnecessary harm or potential harm associated with healthcare.*"[30] The cornerstone of the EU policy in the field of PS is represented by the 2009 Council Recommendation *on Patient Safety, including the Prevention and Control of HCAI*[31]. The Recommendation is structured in two main parts, the first dealing with general, systemic patient safety issues, while the second focuses specifically on prevention and control of healthcare associated infections, accounting for approximately 25% of all adverse events. The document includes *11 recommended actions* further articulated into *29 specific tasks* (see Table 3.3 below).

Table 3.3 - Recommended Action and Tasks

Recommendations on general PS Issues		Specific Tasks
1	Support the establishment and development of national policies and programmes on patient safety	• designating the competent authority / body responsible for PS • embedding PS as a priority issue in health policies and programmes • supporting the development of safer and user-friendly systems, processes and tools, including the use of ICT • regularly reviewing and updating safety standards and/or best practices • encouraging health professional organisations to have an active role in PS • including a specific approach to promote safe practices to prevent the most commonly occurring adverse events
2	Empower and inform citizens and patients	• involving patient organisations and representatives in the development of policies and programmes on PS • disseminating information to patients on PS standards, measures in place and complaints procedures / remedies available • considering the possibilities of development of core competencies in PS for patients
3	Support the establishment or strengthen blame-free reporting and learning systems on adverse events	• providing information on the extent, types and causes of errors, adverse events and near misses • encourage healthcare workers to actively report (taking into account MS disciplinary system for healthcare workers and legal issues) • provide opportunities for patients, their relatives and other informal caregivers to report their experiences • complement other safety reporting systems in, whilst avoiding multiple reporting
4	Promote, at the appropriate level, education and training of healthcare workers on PS	• encouraging multidisciplinary PS education and training • embedding PS in undergraduate and postgraduate education, on-the-job training and the continuing professional development of health professionals; • considering the development of core competencies in PS for dissemination to all healthcare workers and relevant management and administrative staff • providing and disseminating information to all healthcare workers on PS standards, risk and safety measures in place • collaborating with organisations involved in professional education in healthcare to ensure that PS receives proper attention in the curricula
5	Classify and measure patient safety at Community level, by working with each other and with the Commission	• to develop common definitions and terminology, taking into WHO's ICPS and the Council of Europe's work in this area • to develop a set of indicators to identify safety problems, to evaluate the effectiveness of interventions to facilitate mutual learning between MS (taking into account the work done at national level, at OECD level, and the ECHI project) • to gather and share comparable data and information on PS outcomes
6	Share knowledge, experience and best practice by working with each other and with the Commission and relevant European and international bodies	• sharing information on PS programmes, structures, policies, reporting and learning systems • sharing information on the effectiveness of PS interventions and solutions at the healthcare setting level • sharing information on major patient safety alerts in a timely manner
7	Promote research on PS	

[30] Council Recommendation of 9 June 2009 on Patient Safety, Including the Prevention and Control of Healthcare Associated Infections, *Official Journal of the European Union* (2009/C 151/01), 3.7.2009 EN, C 151/1.
[31] *Ibid.*

Recommendations on Prevention and Control of HCAI		Specific Tasks
8	Adopt and implement a strategy at the appropriate level for the prevention and control of healthcare associated infections	• implementing prevention and control measures at national or regional level to support the containment of HCAI and in particular: (i) implementing standard measures in all HC settings; (ii) promoting consistency of HCAI prevention and control measures; (iii) making guidelines available; (iv) using structure and process indicators. • enhance infection prevention and control at the level of HC institutions encouraging in particular: (i) adoption of appropriate programmes; (ii) adoption of appropriate organisational governance arrangements for implementation and monitoring • establish or strengthen active surveillance systems at national, regional and HC institutions levels • foster education and training of healthcare workers • improve the information to the patients by healthcare institutions: • support research
9	Consider the establishment of an inter-sectoral mechanism or equivalent systems collaborating with, or integrated into, the existing inter-sectoral mechanism on the prudent use of antimicrobial agents in human medicine	
Final Recommendations		
10	Disseminate the content of this recommendation to healthcare organisations, professional bodies and educational institutions	
11	Report to the Commission on the progress of the implementation	

3.2.2 Uptake of EU policy in MS

Three years after the adoption of the 2009 Recommendation, the Commission has summarised the main actions taken at MS and EU level on the basis of the information provided by the Member States on the implementation of the Recommendation. The Commission Report, including both parts (general patient safety and the prevention and control of HCAI) is currently under preparation and its adoption is planned for November 2012. The Report will be accompanied by a Commission Staff Working Document containing detailed information on the implementation of the Recommendation by Member States.

The case study was aimed at the external validation of the long list of indicators and at more directly addressing the problem of attribution, also with a view to eventually find the most suitable indicators and how these could reflect implementation obstacles and best practices. The rest of the section is devoted to briefly present the information gathered in the four MS covered, and particularly:

- key facts on PS policy and programmes enacted;
- extent of the influence of the EU PS policy and of the 2009 Recommendation on national policies and programmes;
- main implementation obstacles and best practices detected.

Key facts. In all the countries visited fieldwork evidence showed progress in uptake in a number of areas[32]. With the exception of Poland, the legal and institutional framework has evolved, in recent

[32] Some highlights include:
• In Italy, dedicated budgets are appropriated for the implementation of the regional Action Plans. This at least ensures that PS activities are adequately funded and the presence of qualified staff is guaranteed;
• In France, 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 on HAI. The availability of qualified staff in this area is therefore generally considered adequate. On the other hand, general PS training is comparatively less developed and more fragmented;
• Sweden has, since 2008, taken steps to effectively reduce the number of healthcare related injuries and adverse events by adopting packages of measures geared towards addressing different risk areas, to be implemented locally or regionally; and
• In Poland, action has been taken to increase reporting on adverse events by healthcare workers. Thus, the country's adverse events' learning and reporting system is differentiated from disciplinary systems and procedures for healthcare workers, in order to ensure non-punitive context of reporting.

years, in favour of integrating PS as a forefront issue in public health. Mainstay developments in this respect are: (i) the inclusion of PS among the core objectives of the 2003-2005 National Health Plan in Italy; (ii) the recent development of a general policy on patient safety (release expected by the end of 2012) in France; (iii) the enactment of the 2011 new Patient Safety Law in Sweden. Conversely, Poland is one of the three EU countries without a national patient safety strategy or even a policy document in place, yet.

The influence wielded by EU Policy. Results of fieldwork can be summarised as follows:

- In Italy, the incentive provided by the EU policy documents played a somewhat limited role in setting the agenda, particularly as regards patient safety, whose items had already been set long before but helped implementation at the regional level. The Public Health Programme (PHP) technical documents were extensively referred to in the work on HAI in Italy;
- In France, the EU Recommendation on patient safety is not explicitly referenced in any of the ministerial legal and policy documents currently framing the French PS policy. With respect to HAI, France developed its policy and implementation mechanisms (including indicators and information system) very early compared to the rest of the EU countries. The situation is radically different in the field of other PS issues, where France is relatively lagging behind as compared to other MS. Some influence of the EU policy on the national PS policy currently under development is however recognised, i.e. with respect to the adoption of an overall 'integrated risk management' approach;
- In Sweden, even if the EU soft legislation is not mentioned in official documents, EU PS policy is perceived to have played a somewhat supportive role in the overall development of the Swedish PS policy (in terms of keeping PS related issues on the agenda). However, with regard to the technicalities of specific policy areas (e.g. HCAI), the EU value added is estimated to be either low or nil since these areas have already been developed nationally;
- In Poland, there is no clearly stated patient safety strategy, nor does any reference EC documents, even though credit to EU public health policy is given by way of generic reference in laws or other public health documents.

More specifically, the fieldwork allowed to gather some basic evidence on the extent and implications of EU influence wielded through different forms of support provided to MS. The key findings are summarised in Table 3.4 below.

Table 3.4 – EU support to the policy area

Nature of EU support	*Key findings in selected MS*
Political 'pressure' contributing to the prioritisation of PS issues	EU policy documents played a limited role in agenda setting in both Italy and France, particularly as regards patient safety, whose items had already been set long before the earliest European legislation on the subject. In Sweden, EU political pressure is perceived to have played a supportive, however marginal, role. Common to both Sweden and Poland is the perception that EU pressure could have been higher.
Support to the dissemination of strategies and approaches that were already a priority in your country	Italy definitely benefited from the existence of a EU Communication in the pipeline; this allowed to coordinate and reach an institutional agreement on PS, as it propelled consensus between the relevant institutional bodies (the State and the Regions) on PS. Conversely, little benefit has accrued to France, Sweden and Poland from the few, if any, dissemination activities undertaken to analyse and discuss PS. Remarkably, Recommendation 2009/151 is deemed largely unknown to health professionals and experts in France. Scope for discussion is *per se* limited in Poland, given that the country has not transposed PS into a national strategy.
Advisory/technical support through instruments such as the Joint Action (PASQ) and the Patient Safety and Quality of Care Working Group	In Italy, there is plenty of evidence that the PHP technical documents were extensively referred to in the work on both HAI and patient safety in general. The reach of these instruments was found more limited in France, where a EU dimension could only be found in some reports and studies of bodies. In Sweden there is limited added value to the advisory and technical support initiatives so far undertaken. In Poland, while it is felt the EU offers enough technical support, there is limited political will to make effective

Nature of EU support	*Key findings in selected MS*
	use of it, mostly because the level of patient safety awareness is low.
Support to convergence of strategic approaches adopted by MS / 'gap' reduction among MS	Convergence has only partially materialised to date in Italy, given that involvement in PASQ has only recently started. In France, bilateral cooperation with other MS and European networks exceeds convergence as such. There is plenty of evidence of cross-contamination of European experiences on HCAIs and the ECDC acts as a catalyst for this. In Sweden and Poland, EU added value in support to convergence is thought to have been fairly limited. Some equaled it to almost nil, while advocating for a stronger EU role.

Implementation issues. It is possible to elaborate on the possible reasons for some of the implementation gaps in PS policy uptake and implementation by MS. In summary, the main factors identified can be broadly grouped into the seven categories below:

- ***Human and financial resources*** – by far the main obstacle to full implementation of patient safety strategies or programmes were reportedly the financial constraints. In some countries, such shortages are 'systemic' (e.g. in France, where overall budget allocations for PS have traditionally been limited); in several other cases, these arose as side-effects of the economic crisis on public finance, in consequence of which the allocation to PS control and prevention measures has reportedly been reduced in several countries. The elements of Part 1 of the Recommendation that have seemingly seen the larger reductions are (i) the setup of information systems, and (ii) citizens empowerment. As regards Part 2, the primary constraints apparently related to shortage of qualified personnel with the task of implementing the infection prevention and control programme (in many instances this task is added on the top of other tasks). The HR and financial constraints have especially hampered the strengthening of surveillance systems and the deployment of initiatives to inform patients about risks, safety measures in place, and practices that patients should follow. In addition, the availability of qualified PS personnel is hindered by the fragmented PS training offered to health professionals. In Sweden and France, for instance, resistance made by the educational authorities to integrate PS in standard curricula comes in for causing shortages in qualified personnel. Incidentally, financial shortages in Poland do not only have an impact on healthcare professionals, but also on the professional societies and NGOs that could effectively work towards raising the rank of patient safety in the country.
- ***Legal issues*** - some MS reported legal obstacles in implementing the Recommendation on the blame-free reporting system. Others, instead, have already put in place such a system (e.g. Germany), or reportedly have it in the pipeline (e.g. the UK and the Netherlands). In Italy, change in the area of reporting of adverse events is all the more difficult given that it is traditionally a legally contentious issue. 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. Given that due to the legal setup in the country personal data may be disclosed to justice at any point in time, thus trumping the patient safety protocol on the anonymous supply of information. Similarly, the overall constitutional and legal framework in France does not protect anyone reporting the occurrence of adverse events from juridical consequences. Sweden faces similar though lessen difficulties concerning the adequate enforcement system with regard to blame-free reporting (specifically, the *Lex Maria* mechanism is not entirely blame-free as reporting individuals might suffer sanctions).
- ***Organisational issues*** - in the field of HAI prevention and control, other organisational factors seem to have hindered the overall effectiveness of the strategy adopted, namely: (i) numerous HC interventions are increasingly being carried out in HC facilities other than hospitals (e.g. long-term care facilities, nursing homes, etc.), but these facilities have seldom qualified personnel and appropriate structures to deal with HAI; (ii) the repressive measures adopted in certain MS, such as 'name-blame' reporting or financial penalties over a certain threshold of HAI cases, may prove unfair (i.e. they need to be duly adjusted to take into consideration the

disparities in the types of HC services provided) and provide reverse incentives to HC managers to deal with HAI matters openly; (iii) the reimbursement schemes not anchored to the length of stay in hospital may also provide reverse incentives for hospitals to accept the responsibility for HAI events; (iv) responsibility for managing and dealing with PS issues is fragmented across a number of managing units, from regional to local. This is the case for France, Italy and Sweden and results in the lack of an integrated PS governance system affecting, *inter alia*, the learning process on PS.

- ***Training and Education*** - the implementation of provisions on the training and education of HC workers requires effective coordination with education authorities, which are typically responsible for the definition of curricula. In some cases, this has met academic resistances or insufficient inter-service cooperation. Accordingly, establishing a comprehensive PS curriculum has often proven challenging.
- ***Standardisation*** - Despite growing interest in PS, there are still significant disparities in the approaches adopted by competent authorities and HC institutions (e.g. Italy, France and Poland). This is due, *inter alia*, to the lack of a widespread standardisation of terminology for the definition, the measurement methods, and the reporting of adverse events. An important effort in this respect is currently being undertaken by WHO in the framework of the *International Classification for Patient Safety (ICPS)*[33] project, aimed at categorising PS information using standardised sets of concepts with agreed definitions, preferred terms and the relationships between them being based on an explicit domain ontology (e.g. patient safety). For the moment ICPS is not yet a complete classification, but a conceptual framework for an international classification which may provide a reasonable understanding of the world of PS and patient concepts to which existing regional and national classifications can relate[34].
- ***Reporting and Learning*** - capacity for reporting, analysing and learning from experience suffers from the methodological heterogeneity in the identification and measurement, inadequate adverse event reporting schemes, lack of data (in connection with data confidentiality and professional liability issues) and weak information systems. Therefore the understanding and knowledge of the epidemiology of adverse events are still limited, and successful initiatives for reducing their incidence often remain isolated examples that are not disseminated at the level of the entire health system. The scarcity and the fragmentation of the available baseline information on PS have been underlined also in the study commissioned by DG SANCO for the preparation of the impact assessment for the PS policy. The study findings revealed that PS data seldom exist at national level, but are collected at HC institution level, while in certain MS they seem to be unavailable at all.
- ***Timeframe and Prioritisation*** - PS uptake has suffered two other setbacks, namely: (i) the limited timeframe for implementation, resulting in insufficient time between the adoption of the Recommendation and the time of reporting; and (ii) the ranking of patient safety as a secondary issue, outdone by other items perceived as more pressing and thus resulting in low ranking of PS on the political agenda.

3.2.3 Monitoring and indicators

Monitoring at EU level. While Recommendation 2009/151 is composed of 29 specific tasks, all of them considered important to achieve the overall objectives of the EU policy, six items are particularly viewed as *priorities for policy implementation* by DG SANCO. One of them, under Part 2 of the Recommendation (i.e. the chapter on HCAI), refers to the definition and application of indicators to measure not only the degree of implementation of the above action plan, but also its

[33] WHO, Conceptual Framework for the International Classification for Patient Safety, Technical Report, January 2009

[34] The ICPS Technical Report has defined 48 key concepts and assigned preferred terms to facilitate understanding and transfer of information relevant to patient safety. These concepts represent the start of an on-going process of progressively improving a common international understanding of terms and concepts relevant to patient safety. *Ibid.*

effectiveness in terms of outcome. The European Centre for Disease Prevention and Control (ECDC) acted accordingly and in response to the Recommendation developed, in collaboration with Member States experts, a set of common structure and process indicators to measure the implementation of HCAI prevention and control strategies and programmes. ECDC indicators came in for partially filling the gap owed to the fact that the EU policy documents do not explicitly identify any indicators for the measurement of policy implementation.

Indicators relevant for Part 2 of the Recommendation (on HAI) that have been considered by DG SANCO for the coming implementation report are presented in Table 3.5 below.

Table 3.5 - Structure and Process Indicators surveyed in DG SANCO's implementation reports

Structure indicators	Process indicators
1. Human resources: number of full time equivalent (FTE) infection control staff per 1000 beds	4. Volume of alcohol handrub products used per year
2. Annual report on implementation of infection control programme	5. Campaign to improve hand hygiene
3. Number of single rooms (per number of beds or per number of rooms)	

Countries also monitor a number of other indicators, not originally included in DG SANCO's list, namely:

- ***Structure indicators***: proportion of beds with alcohol hand rub products at the point of care; proportion of beds with alcohol hand rub products in the room; proportion of hospitals with information system from the laboratory data; composite indicator on HAI organisation, activities and resources.
- ***Process indicators***:
  - related to hand hygiene (hand hygiene compliance, compliance to WHO hand hygiene recommendations, proportion of hospitals (or primary care areas) receiving basic training in hand hygiene, proportion of hospitals receiving training in the WHO Five Moments for Hand Hygiene, proportion of hospitals using WHO observational tools, proportion of hospitals reporting self-evaluation with WHO tools);
  - related to surveillance process (proportion of hospitals assessing HAI prevalence, HAI incidence, participation in surveillance activities, participation in national patient safety programme, proportion of hospitals having an alert system for selected microorganisms);
  - isolation procedures and measures;
  - antibiotic prescribing, antibiotic stewardship, antibiotic consumption surveillance, composite indicator assessing antibiotic stewardship;
  - environmental cleaning; endoscope reprocessing.

In addition to the above, in 2011 the OECD Health Care Quality Indicator (HCQI) Project published for the first time six indicators on patient safety: two related to obstetric trauma and four related to procedural and postoperative complications[35]. The stress of the HCQI project, however, is on outcome indicators rather than on process indicators.

Monitoring and evaluation at national level. The results of fieldwork showed that further to EU level monitoring some MS have set up their own indicators and monitoring systems to supervise the implementation of national policy/programmes and related performance. In some cases this extends to fully-fledged evaluation provisions.

[35] OECD (2011) Health at a Glance 2011: OECD Indicators, OECD Publishing. http://www.oecd.org/dataoecd/6/28/49105858.pdf

- ***Italy.*** Patient safety in Italy is monitored through a series of indicators of the Essential Levels of Assistance *(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[36]. 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*[37] 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 many healthcare agencies had just begun to actively promote the adoption of risk management policies.

  The country's overall patchy picture displays anecdotal evidence of substantial progress in monitoring PS also in regions traditionally lagging behind. For instance, in February 2011 Italy's National Agency for Regional Health Services (Age.Na.S.) hosted a joint conference[38] 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 MS ought to pursue to strengthen their respective health systems[39]. 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 included 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. Age.Na.S. has also recently 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 survey response rate was too low (33%), the results of this study have not been validated.

- ***France.*** The overall implementation of PS policy is monitored in France by the Ministry of Health (MoH), with the assistance of the various sectoral agencies and bodies and in coordination with the Regional Health Agencies (ARS). 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

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

[37] 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

[38] 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

[39] 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

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).

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, healthcare facilities report relevant events to their respective ARS, which in turn transmits the information to the competent institution at national level. However, ARSs have been created very recently, and a number of them have not yet been able to make the necessary organisational arrangements required to carry out all tasks assigned by the law.

At present, the information on healthcare-related adverse events comes essentially from a voluntary reporting system. The number of reports made by health professionals is however quite small, especially when compared to the nationwide epidemiological estimates. 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.

As regards *HCAI*, since 2001 a well-oiled network is in place that monitors and analyses HAI data (*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[40]. Regular assessments of incidence and prevalence of HAI are conducted by InVS on the basis of the RAISIN data[41].

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: (i) 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[42]; (ii) the HCSP *report on PS* «*Pour une politique globale et intégrée de sécurité des patients*»[43]; (iii) the *evaluation of the HAI programme 2005-2008*, which is included in the programme document for the 2009-2013 programme[44]. 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 soon[45].

- ***Sweden.*** The *National Board of Health and Welfare* has been assigned by the Government to develop a system of indicators to monitor and follow-up on PS measures at county level. 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

[40] http://www.invs.sante.fr/Dossiers-thematiques/Maladies-infectieuses/Infections-associees-aux-soins/Surveillance-des-infections-associees-aux-soins-IAS
[41] http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19408
[42] http://www.sante.gouv.fr/IMG/pdf/Rapport_Haut_conseil_de_la_sante_publique_-_Objectifs_de_sante_publique.pdf
[43] http://www.hcsp.fr/docspdf/avisrapports/hcspr20111021_politiquesecuritepatients.pdf
[44] http://www.sante.gouv.fr/IMG/pdf/circulaire_272_260809-2.pdf
[45] http://www.sante.gouv.fr/IMG/pdf/ACTES_colloque_iROGER.pdf

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.

- ***Poland***. Patient safety policy in Poland is still at a seminal stage, lacking an overarching strategy or action plan. Therefore, little use is made of indicators for monitoring purposes in this field; monitoring activities so far undertaken have been few and highly dispersed. There has been no evaluation of patient safety policy in Poland. The only review was undertaken to reply to the EC questionnaire with a view to the 2012 PS implementation report. A quasi-evaluation can be identified 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. The indicators' review was conducted by the National Centre for Quality Assessment in Healthcare. Research conducted in the early 2000s by the Polish Society for Quality in Healthcare in cooperation with the Danish Patient Safety Society surveyed levels of awareness of medical malpractice among healthcare professionals. 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.

3.2.4 Summary results of indicator validation

The validation of indicators performed through in-depth interviews with key informants has given the following results (see Appendix 2 for details):

- ***HAR*** and ***ANA*** are generally considered as relevant and feasible indicators.

- ***OBJ*** is valid and feasible, although one country has reservations on the validity of the OECD outcome indicators and will not provide the same data as the other countries surveyed. So it is unlikely that a common set of outcome indicators could ever be found at the EU-level.

- ***PROG*** is an indicator, on the whole, fairly valid but challenged under several respects in its content. It is deemed potentially misleading in one country because of excessive regional disparities in the matters covered. In another MS, the indicator would fail to adequately reflect a very peculiar legal situation hindering the approval of nationwide programmes. Feasibility appears very difficult when data have to be gathered at the local level as it would often be the case. However, in spite of all the reservations above, the sheer availability of programme documents at the national level appears a reasonable proxy of the overall level of policy development in all the countries considered.

- ***PROG.RES*** cannot currently be measured in any of the countries visited; which can also be considered as a proxy of the level of policy development.

- ***PART*** indicators on NGO participation in the policymaking process would sound ambiguous in many contexts (participation to which phases, formal or informal, on a permanent basis, ad hoc, etc.) and are sometimes challenged as inappropriate on substantial grounds. All in all, *PART* indicators elicit diverging views and would cause some feasibility problems.

- ***RES*** on research projects (rather than programmes) would be highly relevant, according to many, especially if formulated its simpler terms; that said, the indicator is not immediately feasible or easily available. Other more elaborated versions of the same indicators measuring resources or impact in the literature are not deemed as really worth the effort.

- ***AWA*** indicators elicit diverging views on their level of importance. Population level of awareness and degree of satisfaction with current provisions are deemed extremely relevant and regularly monitored in two countries out of four. This information is currently not available in the other two MS. There is consensus that data on information campaigns could lend themselves to ambiguous interpretations, if expressed by means of quantitative indicators only and not accompanied by adequate qualitative information; at any rate, they appear as hardly feasible.

- ***FUND*** indicators' feasibility is impinged on by the fact that expenditure data are generally difficult to collect, and at any rate this exercise would not even be as significant as to deserve the effort of setting up and funding a dedicated study. In addition, the level of interest in the data depends on the way the health system is insured against the risk of claims for damages and on the features of the national tort law.

- ***ORG*** indicators are not adequately formulated, according to some respondents. Consequently, there are concerns about their possible integration in any organisational model. However, if ever implemented, they would adequately describe the level of policy fragmentation to be found in the different countries. They are generally deemed highly feasible.

- ***NET*** is generally deemed not really relevant and, at any rate, too dependent on the national contexts. If better specified and limited to particular issues, it could however capture the implementation (or lack thereof) of the provisions on the intersectoral co-ordination mechanism envisaged for HAI.

- ***DEL*** indicators on delivery mechanisms are either considered too ambiguous at this stage - and subject to potential misunderstanding – or, at any rate, irrelevant in the local context. They would also face major feasibility problems.

- ***TRAI*** indicators are deemed fairly relevant, especially in their more general forms, although fraught with major feasibility and data accessibility problems.

- ***EVAL*** indicators are generally deemed as highly relevant (provided that they are simple, carefully worded and better qualified). They also appear as highly feasible.

- ***EXC*** and ***REP*** are not really easily quantifiable and, at any rate, they are poorly significant.

3.3 Cancer Screening

3.3.1 Background - the EU policy

The EU fundamental principles and policy objectives in the field of early detection of cancer have been consolidated in the ***Council Recommendation (2003/878)***.[46] The Recommendation builds

[46] Council Recommendation of 2 December 2003 on Cancer Screening, *Official Journal of the European Union* (2003/87 8/EC), 16.12.2003 EN, I. 327/34. The fundamental principles of screening as a prevention tool laid down in the Recommendation are modelled on two main previous sources: (i) the Council of Europe, Recommendation (94/11)

upon the previous *Recommendations on CS in the EU* prepared by the Advisory Committee on Cancer Prevention,[47] as well as on the experience of the Europe against Cancer programme. The overall purpose of the Recommendation is to encourage MS to take common action to implement national cancer screening programmes with a population-based approach and with appropriate quality assurance at all levels. More specifically, seven recommendations have been formulated, further articulated into a total of 24 specific tasks (see Table 3.6 below).

Table 3.6 - Recommended Action and Tasks

Recommendations		Specific Tasks
1	Implementation of cancer screening programmes	• offer evidence-based cancer screening through a systematic population-based approach with quality assurance at all appropriate levels • implement screening programmes in accordance with European guidelines on best practices where they exist • ensure that the people participating in a screening programme are fully informed about the benefits and risks • ensure that adequate follow-up based on appropriate guidelines is provided to those with a positive screening test • make available human and financial resources in order to assure appropriate organisation and quality control • assess and take decisions on the implementation of CS nationally or regionally • set up a systematic call/recall system and quality assurance at all appropriate levels • ensure that due regard is paid to data protection legislation
2	Registration and management of screening data	• make available centralised data systems needed to run organised screening programmes • ensure that all persons targeted by the screening programme are invited, by means of a call/recall system, to take part in the programme • collect, manage and evaluate data on all screening tests, assessment and final diagnoses • collect, manage and evaluate the data in full accordance with relevant legislation on personal data protection
3	Monitoring	• regularly monitor the process and outcome of organised screening • adhere to the standards defined by the European Network of Cancer Registries in establishing and maintaining the screening databases • monitor the screening programmes at adequate intervals
4	Training	• adequately train personnel at all levels to ensure that they are able to deliver high quality screening
5	Compliance	• seek a high level of compliance, based on fully informed consent • take action to ensure equal access to screening
6	Introduction of novel screening tests taking into account international research results	• implement new CS tests in routine healthcare only after they have been evaluated in randomised controlled trials • in addition, run trials on subsequent treatment procedures, clinical outcome, side effects, morbidity and quality of life • assess level of evidence concerning effects of new methods by pooling of trial results from representative settings • consider the introduction into routine HC of potentially promising new screening tests • consider the introduction into routine HC of potentially promising new modifications of established screening tests

on Screening as a Tool of Preventive Medicine, October 1994; and (ii) WHO, Wilson, J.M.G. and Jungner, G., 'Principles and Practice of Screening for Disease', *Public Health Papers*, No.34, 1968. The importance of screenings has been reaffirmed more recently in: Council of the European Union, Council Conclusions on Reducing the Burden of Cancer, 2876th Employment, Social Policy, Health and Consumer Affairs Council Meeting, Luxembourg, 10 June 2008

[47] Advisory Committee on Cancer Prevention, Recommendations on Cancer Screening in the European Union, prepared after the Conference on Screening and Early Detection of Cancer, Vienna, 18-19 November 1999

	Recommendations	Specific Tasks
7	Implementation report and follow-up	• report to the Commission on the implementation of this Recommendation within three years of its adoption and subsequently at the request of the Commission

To support the concrete implementation of the Recommendation, the EC calls on MS to take up the EU quality assurance guidelines for cancer screening, where they exist. The *EU Guidelines* published so far include three documents, focusing respectively on breast cancer (4th edition, 2006), cervical cancer (2nd edition, 2007) and colorectal cancer (2011). The Guidelines are intended to provide principles and evidenced-based recommendations on the quality assurance standards that should be met when implementing screening programmes, focusing particularly on the quality of procedures and follow-up actions, data collection methods and analysis, monitoring, and in some cases training of personnel. They also deal with novel tests and methods not already included in the standard practices recommended. Rather than prescribing the adoption of specific practices, adding up to those defined in the Recommendation, the Guidelines provide an inventory of best practices that can be used across a wide spectrum of different cultural and economic settings. In this sense, for the purpose of this Study it appears more appropriate to refer to the 'uptake' of the Guidelines in the MS, rather than to 'implementation', and define M&E indicators accordingly.

3.3.2 Uptake of EU Policy in MS

In 2008, the EC published the first report on the state of implementation of Recommendation 878 in MS.[48] The report was prepared by IARC on the basis of national reports submitted by MS (hereinafter 'IARC Report'). The report is currently the major source of information on the progress achieved in the implementation of the EU policy, since there exist no mechanisms at EU level for the continuous monitoring of CS activities in MS. A new evaluation is planned for the second half of 2012, whose results are expected to be published by IARC in 2013.

Key Facts. With respect to quantitative performance, the IARC report concluded that the results achieved were encouraging although considerable efforts were still required to overcome existing barriers and achieve the established targets. In 2007, about 55 million CS tests overall were performed (including breast, cervical or colorectal screening). A substantial number of these examinations (approximately 23 million) was delivered through population-based screening programmes. Although the amount of screenings performed in 2007 was considered significant in absolute terms, it has been remarked that it accounted for less than 50% of the minimum annual screenings expected if all EU citizens in the relevant age group had been involved in CS programmes (i.e. some 125 million examinations per year). Furthermore, the MS data showed that only 41% of the screenings were performed within the framework of population-based programmes.

Similarly, the degree of implementation of the EU policy with respect to qualitative aspects received a mixed assessment. On the one hand, the report signalled that eight in ten MS had complied with no less than two-thirds of the recommended items. Yet, a suboptimal degree of implementation was reported by the majority of MS surveyed in the field of (i) monitoring, (ii) provision of adequate scientific evidence prior the introduction of novel CS tests, and (iii) allocation of sufficient human and financial resources to ensure appropriate organisation of programmes and quality control. Finally, the IARC report noted the existence of significant disparities across MS in the implementation of CS programmes. While there appears to be substantial agreement across MS

[48] European Commission Health and Consumers Directorate-General and 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. A summary version of the report was also adopted by the EC, i.e. COM(2008) 882 final on the "Implementation of the Council Recommendation of 2 December 2003 on Cancer Screening (2003/878/EC)", Brussels, 22 December 2008.

on the health policy priority of establishing CS programmes of appropriate quality, as of 2007 only a minority of MS had completed or had ongoing nationwide population-based programmes (they had, respectively, seven breast screening programmes, three cervical programmes, and five colorectal programmes).

The evidence from fieldwork, showed some progress in the implementation of the CS policy, e.g. Sweden has introduced a population-based colorectal CS programme, Poland has switched to a population-based approach on CS, and where available the statistics on invitations and attendance rate seem improving (e.g. France). Still, the roll-out in many instances is not complete, and there persists inequalities across regions and social groups. At a more qualitative level, some progress can be appreciated in the studied countries with respect to the institutional and strategic framework and the organisational arrangements. This includes for instance:

- the establishment of a solid legal and strategic framework for fight against cancer having prevention and CS among its main pillar, such as the French Cancer Plan 2009-13, which lays down a series of measure and concrete actions related to screenings and defines responsibilities and indicators;
- the refinement of institutional arrangements for better delivery of programmes, as in the case of Sweden's establishment of Regional Cancer Centres;
- the co-operation with *ad hoc* scientific bodies responsible for defining implementation guidelines and releasing technical recommendations on CS programmes as in the case of the Italian three working groups on breast, colorectal, and cervical CS;
- the scaling up of monitoring and data collection system, such as in Poland with the Information System of Prevention Monitoring.

The influence played by EU policy. As noted in the IARC report, given the less widespread implementation of population-based cancer screening programmes in 2003, it is unlikely that such an increase would have been achieved in the absence of the Council Recommendation. In some cases (e.g. Slovenia) the influence of EU guidelines in refining CS programme implementation modality was openly acknowledged. In other cases, the cause-effect link is less evident, since some actions were set in motion prior to adoption of the Recommendation. However, according to the report, the discussion leading up to the adoption of the Recommendation and the parallel pan-European exchange between policy makers and experts are likely to have facilitated the realisation of numerous concrete initiatives in MS. These findings seem confirmed by the results of fieldwork, although with some caveats. Overall, the Recommendation 878 is believed having had an important, but not crucial role in propelling the MS policy on cancer screening and the setting up of related programmes. The outlook on the influence of CS Guidelines is also mixed:

- in Italy, the Recommendation is perceived having helped building consensus on the crucial 2004-2006 Screening Plan Law. As such, it is widely quoted and recognised in all relevant policy documents of the period and even today in conferences and fora on the subject. Much in the same vein, the CS guidelines can be considered the reference documents for the production of the Italian Recommendations, and some regions (e.g. Veneto) have explicitly incorporated them in their regional guideline documents for accrediting screening schemes;
- in France, there is no explicit reference to the EU Recommendation 878 and/or the Guidelines in policy documents. Despite being widely appreciated, the Recommendation is not considered as a 'source of inspiration', since national policy is antecedent. However, its utility for MS with little experience in CS is recognised. The utility of Guidelines is comparatively more appreciated, as they are considered a useful technical complement of France's own guidelines;
- in Sweden, EU policy is viewed as a useful contribution to the national policy-making process in terms of adding arguments to certain strategies or modalities, but reportedly other countries' experiences and models (e.g. Finland and the UK) have also been taken into account. Only the

national guidelines on breast CS seem having been somewhat guided by EU guidelines, although not explicitly acknowledged in the document. In the other cases the EU influence appears more marginal;

- in Poland, EU CS policy is not explicitly mentioned in policy documents and the initial inclusion of CS in the agenda is rather traced back to a previous World Bank project. However, the importance of EU action in making the CS agenda progress is widely recognised. More specifically EU action is perceived to have been particularly influential in promoting CS programmes implementation and the development of indicators of cancer incidence and screening efficiency. The Guidelines, although recognised as a useful tool and a quality source of inspiration, appear to have had limited practical impact in the country. They have not been translated nor widely disseminated; as a result, they are known only to a closed niche of experts and not necessarily to policy/decision makers.

More specifically, the fieldwork in MS allowed to gather some basic evidence on the extent of EU influence (and issues thereof) associated to different kinds of support provided to MS. The key findings are summarised in Table 3.7 below.

Table 3.7 – EU support to the policy area

Nature of EU support	*Key findings in selected MS*
Political 'pressure' contributing to the prioritisation of CS issues	With the exception of Poland, where the EU policy is believed having had a tangible influence in bringing forward the 'CS agenda', in the other MS CS were an established policy priority well before the adoption of Recommendation 878. More generally there broad consensus on the added value of disseminating CS strategies and approaches in EU countries, but their practical usefulness seems correlated with the state of play of the different MS in this field. The EU policy is seen as more useful for MS that do not have a national policy, since it may help to structure it. Instead, it is comparatively less useful for MS with a prior experience in this field and with a well-established policy already in place, which sometimes – as in the case of France – includes provisions going farther than the EU's.
Support to the dissemination of strategies and approaches that were already a priority in your country	This is considered a major added-value of EU action in this field. For instance, in Italy the 2003 Recommendation provided valuable support for the approval of key policy instruments and to build consensus among the regions that would not probably have obtained otherwise. In the case of France, one of the perceived primary inputs provided by EU policy is the setting of targets and objectives.
Advisory/technical support through instruments such as the Guidelines and / or the Joint Action (AAC Partnership)	Both policy guidance at the level of recommendations and technical guidance at the level of EU guidelines are welcome and useful but not sufficient. Feedbacks from France and Italy point out solicit more guidance the fields of organisation and governance of programmes. In the case of Poland much emphasis is placed on the need for mechanisms to promote and disseminate the Guidelines, while Swedish counterparts would favour more efforts in the establishment of dedicated technical partnerships.
Support to convergence of strategic approaches adopted by MS / 'gap' reduction among MS	Current experience is limited to data harmonisation and exchange of technical protocols; further convergence is hampered by the fact that health systems are radically different and that European strategic documents do not address how the guidance may be successfully assimilated under different governance systems. Additionally, at present there is no structured and up-to-date source of information on what other countries are doing in the field of CS (e.g. to reduce inequalities). In summary, a certain degree of convergence due to EU policy is acknowledged, but there is still much to do in this sense.

Implementation issues. The IARC Report elaborated on possible reasons for the suboptimal uptake of the EU policy in certain MS and with respect to certain aspects. The results of the Study partly confirmed the persistence of some of the issues flagged by the IARC Report conclusions, and

allowed to identify some new ones. In summary, the main factors hampering policy uptake and implementation that have been detected belong to the following categories:

- ***Human and financial resources*** - the implementation of quality and comprehensive CS programmes requires a prolonged effort in terms of human and financial resources invested. This is one of the most common constraints to the realisation of large-scale programmes, reported by eight out of ten MS covered by the IARC Report. The evidence from fieldwork confirmed that this is still the case in Poland, while in France – since the Cancer Plan 2009-2013 is a presidential priority – the financial allocations are deemed adequate. The Italian experience with the cancer screening financing laws and the modest results achieved seem to indicate that financial constraints in absolute terms are much less of a limiting factor than generally envisaged. On the other hand, in the case of Italy there seem to be cost-effectiveness issues, i.e. so long as CS programmes are only sparsely implemented, consequently failing to achieve economies of scale, cost savings will remain far from evident. Finally, in Italy specific bottlenecks in human resources due to the scarcity of certain specialised skills (radiologists, etc.) and of the capacity to interact with migrants are reported.
- ***Competition from opportunistic screening*** in certain regions (e.g. Italy) and for certain type of screening (e.g. France) and related economic interests is an obvious obstacle to organised screening programmes. The simultaneous rolling out of organised CS programmes and opportunistic screenings is perceived as a major issue in various respects: (i) opportunistic screenings may, again, affect the overall efficiency of CS expenditure (too frequent opportunistic screenings represent an extra burden for the health system); (ii) sub-optimal efficacy of screenings (since opportunistic screenings do not often respect the recommended time intervals); (iii) sub-optimal quality of screenings (which is more difficult to control in the case of opportunistic screenings).
- ***Cost-effectiveness assessment*** - linked with the above, in some cases another obstacle appears to be the scarcity of cost-effectiveness assessments of national CS programmes, which would provide useful evidence to (i) improve the efficiency of initiatives, and (ii) convince concerned actors, and particularly policy-makers, that cancer screening is a highly cost-effective investment that would allow substantial savings in the future, if properly implemented. The issue is magnified in countries where opportunistic screenings run in parallel, since the frequent lack of reliable data on opportunistic screenings may end up distorting any statistical finding on the impact of organised screenings.
- ***Political and cultural issues*** – further obstacles to policy implementation relate to specific cultural and political issues in some countries. These range from the exclusion of CS programme from the priorities of the health policy agenda due to political considerations (or – as previously discussed - due to policymakers unaware of potential benefits) to the difficulty to maintain the required effort in the long term. Similarly, 'cultural' issues were reported among the causes of suboptimal attendance to organised screenings, such as (i) insufficient awareness of target groups; (ii) cultural resistance toward the clinical practices implied, and (iii) target group preference for opportunistic screenings, due to the erroneous perception that since organised screening is offered for free the quality might not be as high.
- ***Technical and organisational issues*** – the recommended modality and quality standard for the implementation of CS programmes and in particular the wide coverage and delivery mechanism requires significant technical and organisational capacity. Reportedly, one of the most significant impediments that HC institutions had to overcome was the scarcity of appropriate professional, technical and scientific support for planning the programme, for training and supervision, as well as for monitoring and evaluation. In this respect, MS authorities (e.g. France and Italy) would support the inclusion in the EU guidelines of sections on 'high-level' programme governance issues. The discussions that followed the publication of the IARC report often highlighted the need for an increased exchange of information and collaboration between MS (e.g. Sweden) and for establishing a European centre of expertise providing technical and

expert support to MS and contributing to the continuous monitoring and evaluation of progress in the implementation of the EU policy.[49]

- ***Legal issues*** – in some Member States, the personal data management legislation poses a legal challenge to the establishment of the recommended registries. Reportedly, the problem is actual in Sweden, while in the case of France it seems to be going to be resolved soon (the law establishes CS management structures to receive authorisation from the *commission nationale informatique et liberté).* Legal constraints in data management are not only a monitoring obstacle *per se* but may also restrict the chance of cross-checking and comparing cancer screening registries and mortality databases, thus hindering CS programme efficacy assessment. However, compared to other implementation problem this issue is generally considered as less crucial. Another potential juridical-related issue has emerged in Italy, where 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.
- ***Data availability*** – the difficulty in collecting comprehensive data are not only related to legal obstacles but are often more generally related to lack / weaknesses of dedicated structures and mechanisms. The problem is openly reported in France, where regional agencies have not yet fully taken up the competencies attributed by the recent HPST Law (2008) in this field, and Cancer registries exist only in less than half of the departments. A similar problem is apparent in Italy, while in Poland significant improvements have been registered over the past few years.
- ***Timeframe*** – it has been estimated that the successful preparation and completion of nationwide population-based SC programmes require considerable time, i.e. ten years or more, depending on many factors such as the professional and organisational capacity and the infrastructure available. In this sense, the IARC report affirmed that the full impact of the Recommendation could not be fully appreciated after five years only since its adoption. Evidently, this is not an obstacle that can be removed through policy measures but is a factor that should be taken into account when designing monitoring and evaluation schemes for the EU CS policy.

3.3.3 Monitoring and indicators

Monitoring at EU level. The IARC Report was based on a series of indicators measuring both qualitatively and quantitatively the degree of implementation of the EU policy in MS, i.e. whether certain actions and specific tasks of the Recommendation had been carried out, the implementation methods adopted and possible reasons for non-implementation. In summary these indicators can be grouped in four main families:

- ***CS policy uptake –*** essentially referring to the embedding of specific programmes (breast, cervical, colorectal) in the national cancer control strategy. This indicator was also identified by the Health Strategy mid-term evaluation[50];
- ***CS programme performance –*** including a series of quantitative indicators measuring the coverage and the progress of CS programmes. Coverage and progress are reported, for instance, in terms of target population, number of persons personally invited to attend CS programmes, percentage of invited persons actually participating in the CS programmes, amount of screening tests offered (by delivery mechanism), among others;
- ***CS cost –*** focusing on the public and private aggregate costs for performing screening tests within population-based programmes, opportunistic screening programmes, and 'on-demand' screening. This indicator is intended to issue cost-efficiency considerations on the various delivery mechanisms;

[49] Pan-European Conference, 'The Burden of Cancer – How Can it be Reduced?', Brdo, Slovenia, February 2008
[50] PHEIAC Consortium, Mid-term Evaluation of the EU Health Strategy 2008-2013, August 2011

- ***Compliance with EU principles and quality standards*** – measuring the degree of adherence of national CS policies to specific aspects of the Recommendation. They are formulated in qualitative terms and measured through 'binary' variables. Examples include (i) whether a centralised data system was made available to run the CS programme; (ii) whether the process and outcomes of CS programmes are regularly monitored; (iii) whether CS tests routinely used have been evaluated through randomised controlled trials, etc.

The key aspects of EU CS policy uptake appear adequately monitored by the IARC Report. The main shortcoming of this monitoring mechanism consists of the infrequency of reviews. The new edition is planned for 2013, and there is no mechanism to keep track of evolutions in MS on a more regular basis. Secondly, the last Report focussed essentially on Recommendation 878, devoting little attention to CS guidelines uptake. In this sense, it is of limited utility when it comes to assessing to what extent these documents have supported MS in designing and implementing CS programmes.

Monitoring and evaluation at the national level. The results of fieldwork showed that further to EU level monitoring some MS have set up their own indicators and monitoring systems to supervise the implementation of national policy/programmes and related performance. The following paragraphs provide a summary review of the extant situation in the four MS covered by the Study with a view to illustrate the mechanisms in place (and related difficulties) and in particular the type of indicators used (more detailed information are provided the case study reports in Volume II). Although based on a limited number of cases, this may be helpful in understanding analogies/differences in the nature and quality of the information collected at national level, and how this information can be gathered and processed at EU level at any point in time, in the framework of the general EU policy evaluation mechanism put forward in this Study.

- ***Italy.*** The ONS (*National Observatory on Screening*) has been publishing yearly reports (some also bilingual in Italian and English) on the status of implementation of the Italian screening programmes since 2002[51]. 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 CS 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 based on indicators identified by the ministerial Working Groups on CS, including:
  (i) *Structural indicators* – they include organisational and logistical parameters, and reflect the quality of the practical steps involved in conducting the screening;
  (ii) *Performance indicators of the clinical-diagnostic process* – they are applied in the diagnostic process which is the core of the screening process; and
  (iii) *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).[52]

  The CCM (*National centre for disease prevention and control*) has also taken the first steps towards designing a more comprehensive evaluation of CS programme results. So far, it has taken action by funding (i) a pilot study on the epidemiological impact of breast cancer

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

[52] 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

screening programmes,[53] 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[54], possibly also because some of its implementation features are not in line with the standards prevailing in the rest of the country.

- ***France.*** The overall monitoring of the *Cancer Plan 2009-2013* is entrusted to a steering committee and coordinated by INCa (*National Cancer Institute*), which has also developed an IT application to support the gathering of monitoring data. The monitoring system involves three aspects:
  (i) *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.
  (ii) *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.
  (iii) *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 detailed 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 Plan 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[55], and a second is expected following the end of the initiative in 2013. With respect to specific CS programmes the regulation attributes to the local management structures 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 3.8 below. The evaluation function is also supported by HAS, which conducts *ad hoc* strategic assessments of programme including

[53] http://www.ccm-network.it/documenti_Ccm/convegni/SANIT/materiali2008/24.6/3-Valutazione_impatto_Paci.pdf
[54] http://www.osservatorionazionalescreening.it/content/le-raccomandazioni
[55] http://www.hcsp.fr/explore.cgi/avisrapportsdomaine?ae=avisrapportsdomaine&clefdomaine=6&clefr=259&ar=r&menu=09

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.[56]

Table 3.8 – 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 • 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

- ***Sweden.*** 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.[57] 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 country 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. In 2010, upon request by the government (Ministry of Education), the Swedish Research Council (*Vetenskapsrådet*)[58] was assigned the task of evaluating investments in strategic research areas, including cancer (even if

[56] 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

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

[58] *Vetenskapsrådet* is 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

CS is not specifically mentioned in the evaluation assignment, it is one of the research areas for which the Council provides funding).

- ***Poland.*** The monitoring and evaluation of cancer screening activities is undertaken by the *Health Policy Department* of the Ministry of Health as part of the National Programme on Cancer Prevention. The monitoring information is collected from the *National Coordination Centr*e on a monthly basis. 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. The evaluation of CS programmes is performed on an annual basis and is part of the annual reports on implementation of the National Programme on Cancer Prevention that the Department submit to the Parliament. 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* is set up on the basis of individual records of those participating in the screening rounds and covers the whole country. 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.

  In Poland there is also a *National Cancer Register*, which keeps track of diagnosed cancer cases, and contains salient data on patients and treatments but is not linked with the CS database. The Register 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.

3.3.4 Summary results of indicator validation

The validation of indicators performed through in-depth interviews with key informants has given the following results (see Appendix 3 for details):

- ***HAR*** indicators are generally considered as highly feasible and valid, although to some different degrees depending on the specific quality of the data available.

- ***ANA*** indicators are generally viewed as fairly valid with some caveats, mainly on the appropriateness of bibliographic indicators. Feasibility does not represent a significant issue.

- ***OBJ*** indicators are fairly valid, although with possible major feasibility problems, linked to the unclear legal status of cancer registries in several countries.

- ***PROG*** indicators are easily available and considered fairly valid, although they would require some qualification for their interpretation. Some consider that indicators based on programmes on paper are always second best as compared to actual deeds (DEL indicators).

- ***LEG*** indicators elicit slightly diverging views on validity, even in countries where legal problems with the establishment of registries are considered a major barrier. The indicators, however, are generally considered as fairly valid and feasible.

- ***AWA*** indicators are questioned on grounds that data on campaigns are considered hardly feasible and/or poorly significant. There are fairly diverging attitudes as to the importance of data on awareness among the population and different patterns of availability of such data that - if considered relevant - would probably require a *Eurobarometer* to ensure consistence across Europe.

- ***FUND*** data are generally not available as such and would require a dedicated study. Some consider it not really relevant for progress in implementation purposes, but in case, only to broadly demonstrate programme cost-effectiveness to policymakers.

- ***DEL*** data are either available or soon to be available, so generally these indicators are considered relevant.

- ***CAP*** indicators raise relevance issues, given that entering into the specifics of implementation should be left to MS discretion and ought not to be part of a EU strategy monitoring system.

- ***PRO*** indicators share similar relevance concerns as *CAP*; in fact, some question the relevance of investigating procedural aspects for a strategic monitoring system and find the indicator poorly informative.

- ***TRAI*** relevance is considered questionable in certain countries. Degrees of perceived feasibility exist across MS, but all in all implementation is uneasy.

- ***EVAL*** indicators are generally considered as highly relevant and feasible, although with some qualifications on what should count as "evaluation" and the availability of an impact component for which the considerations reported on *OBJ* above apply.

- ***REP*** indicators are considered easily feasible, although its relevance partly escapes stakeholders' understanding.

4. SUMMARY OF MAIN FINDINGS AND CONCLUSIONS

4.1 Monitoring the Health Strategy Based on Historical Criteria: Results from the Case Studies

As summarised in Table 4.1 below, results from the case studies show that most categories of indicators have appeared as both valid and feasible. Major reservations exist on the feasibility of budgetary and financial indicators, as well as on the validity and possibility to measure participative policymaking in the countries surveyed. Data on training also appear generally difficult to retrieve.

Table 4.1 – Summary Feedback from Case Studies on Validity and Feasibility of Indicators

Indicator	Patient Safety		HIAP		Cancer Screening	
	Validity	*Feasibility*	*Validity*	*Feasibility*	*Validity*	*Feasibility*
ANA	+	++	+	++	0	+
OBJ	0	+			+	0
PROG	+	0			+	+
LEG					+	+
PRI			+	++		
PART	0	-	-	-		
RES	+	-	-	--		
AWA	+	0			+	--
FUND	-	--			0	--
ORG	++	++	++	++		
NET	0	+				
PRO			-	0	0	0
DEL	--	--			+	+
CAP					0	+
TRAI	+	-			-	-
HAR	++	++			++	++
EVAL	++	+	++	+	++	++
EXC	-	+				
REP	-	-			0	0

Legend: (++) highly valid / feasible; (+) fairly valid/feasible, (-) hardly valid/feasible; (--) definitely not valid/feasible. (0) stands for diverging inconclusive judgments.

Finally, there are obviously notable differences in data availability across Member States. Possibly the most striking of them are the variations in Member States' familiarity with measuring citizens' awareness of policy issues and with survey roll-outs for policymaking purposes. Conversely, scarce use of information and communication campaigns is common to all MS covered by the study. Table 4.2 below summarises the result of the external validation exercise. Three main groups of indicators can be identified: (i) those that can be retained as primary indicators because generally considered as relevant and feasible; (ii) those that can be retained as secondary indicators, because also generally considered on average relevant and feasible although with some more reservations or limitations; and finally (iii) those that did not pass the external validation because of major reservations on their relevance and feasibility and are therefore not retained, but are nevertheless worth reconsidering in the future if EU policies are redefined and needs for monitoring agreed accordingly.

Primary indicators include those about the attainment of objectives (OBJ), organisational issues (ORG), the delivery of policy actions (DEL), the provision of harmonised data (HAR) and the establishment of monitoring and evaluation systems (EVAL) categories, as well as instances of indicators about approximation of policy concepts (ANA), programming (PROG) and commitment

to policy principles (PRI) and in particular ANA1, PROG1, PRI1 and PRI3 respectively. Indicators about regulatory action (LEG) have been retained for special cases of policies aimed at health determinants. Secondary indicators include the entire category about exchange of policy experiences (EXC) and all the remaining ANA, PRI, and PROG indicators, the EU-related funding indicators (and namely PHP.FUND and STR.FUND), the indicator on compliance to reporting requirements on policy implementation (REP1) and special cases of application of indicators about networks (NET), procedures (PRO), and enforcement of regulations (POL). Finally, indicators not retained for the time being include those on participatory processes (PART), research activities (RES), awareness and communication (AWA), training (TRAI) and funding of policies (FUND), REP.2 and the vast majority of possible uses of LEG, PRO and POL indicators.

Table 4.2 - Summary table of primary and secondary indicators and of indicators to be reconsidered in the future

Retained as primary indicators	Retained as secondary indicators	Not retained for the time being but to be reconsidered in the future
ANA1	ANA2/ANA3	(LEG)
OBJ	PROG2/PROG3/PROG.RES	PART
PROG1	PRI.2	RES
(LEG1/LEG2/LEG.3/LEG.VOL)	PHP.FUND/ STR.FUND	AWA
PRI.1/PRI.3	(NET)	FUND
ORG	(PRO)	(PRO)
DEL	(POL)	(POL)
HAR	EXC	REP.2
EVAL	REP.1	TRAI

Legend: indicators in brackets () are retained in the related category for special cases only, but have been dropped for more general purposes.

4.2 Consolidating the Internal and External Validation Processes into a Shortlist of Indicators

For the purposes of monitoring policy uptake of the policies encompassed in the EU Health Strategy, two sets of indicators have been identified as primary and secondary indicators. The first represents indicators of choice, while the latter can provide complementary information or replace primary indicators, if needed. A shortlist of possible indicators for the EU Health Strategy and related underlying policies can obtained from the matrix of possible indicators reported in Table 2.1, by applying an algorithm for indicator selection criteria. Specifically:

<u>Primary indicators</u>

- OBJ indicators are retained as primary indicators when there is agreement on the relevant way of measuring when outcome or impact have been achieved. Otherwise they are dropped;
- ORG indicators have always been retained;
- DEL indicators have been considered as primary indicators, whenever possible;
- HAR indicators have always been considered as primary indicators;
- EVAL indicators have always been considered as primary indicators;

<u>Mixed Primary/Secondary Indicators</u>

- ANA.1 indicator is retained as a primary indicator when underlying actions were expressly mentioned in the relevant EU policy documents. Cases of proposed ANA.2 and ANA.3 can be qualified as secondary indicators;
- PROG1 indicator is retained as a primary indicator. All other PROG can be considered as secondary ones;
- PRI indicators are retained as primary indicators, as far as PRI.1 and PRI.3 are concerned. PRI.2 has been considered as a secondary indicator

Indicators retained for special cases only

- LEG indicators have been retained as primary indicators for regulated markets only, and dropped in all other cases;
- FUND indicators have not been retained with the exception of PHP.FUND and STRU:FUND that have been considered as secondary indicators;
- NET indicators have been retained as secondary indicators for surveillance systems only and other special cases;
- PRO indicators have been retained as secondary indicators in special cases only;
- POL indicators when relevant for LEG purposes above have been considered as secondary indicators;
- CAP indicators have been merged with the NET indicators above;

Secondary indicators

- EXC indicators have been considered as secondary indicators; and
- REP.1 has been considered as a secondary indicator, while RES.2 has been dropped

Indicators not retained

- PART indicators have not been retained for lack of consensus on relevance;
- RES indicators have not been retained mainly because of feasibility problems;
- AWA indicators have not been retained also because of feasibility problems;
- TRAI indicators have not been retained because of lack of real consensus on relevance and feasibility issues.

This set of rules has then been applied to the matrix in Table 2.1, which is the result of the expert's internal validation assessment. It is understood that the expert's assessment may be not fully shared by the relevant Commission services; with that in mind, the matrix was so developed as to make it possible to adapt or modify it at will to better reflect specific information needs or areas deemed of interest, as well as eventually extend it to new emerging areas one day (e.g. youth, infancy, women's health). The result of the application of the algorithm above to the internal validation process is summarised in Table 4.3. Table 4.3, and it was then cross-checked with the indicators that had already been proposed in the relevant policy documents. The result of the cross-check is a tentative concise set of a maximum of six indicators per policy area in order to include both primary and secondary indicators for exemplification purposes and done with an eye to reaching the greatest possible degree of homogeneity between the indicators used, as reported in Annex F. Further simplifications are indeed possible and more stringent prioritisation criteria can be used, for instance by ruling out secondary indicators. It is worth remembering that the feasibility of OBJ indicators depends on reaching consensus on how to measure relevant outcomes, which is policy-specific. Moreover, prioritisation may depend on feasibility and resource issues as the policy uptake indicators fall into one of these three categories: a) cardinal indicators: i.e. number of MS complying with a given condition (having adopted, developed or implemented) which has a relatively simple factual evidence; b) strictly European indicators, i.e. information already available at the EU level (e.g. number of downloads of EU cancer screening guidelines) and c) inner MS indicators (e.g. number of registries of rare diseases established at the MS level).

One of the major limitations of the shortlist below is its limited sensitivity to appreciate changes over time. One criterion to assess the success of this list may look at whether eventually, if ever, this subset of indicators will be adopted in all EU MS. This basically consists of a comparison between the situation before a certain date and at a subsequent point in time; such was the approach broadly followed by the IARC Implementation Report on Cancer Screening and follows a temporal line of reasoning. If convergence is achieved after the release of the EU policy document, this somehow shows the influence the document directly or indirectly has had on the uptake process or,

at any rate, to what extent uptake has been achieved. This system of indicators does not enter into more detail about attribution problems and counterfactual considerations on convergence, because the focus is on whether policies have been taken up and not on the underlying reasons why this did or did not happen. Some flexibility is requested when assessing the timeframe of uptake: in fact, when judging on the uptake of the strategy, one should consider that documents start to be discussed long before their release and become known in their broad articulation long before their official approval (e.g. because of public consultations already outlining their possible main contents). For this reason, indicators that seem to pre-date the strategy go instead hand in hand with strategy development, whose influence starts time before actual adoption. Moreover, programmes' validity may outlive their end date.

Table 4.3 - List of indicators retained from the Policy Matrix in Table 2.1

	ANA	OBJ	PROG	LEG	PRI	PART	RES	AWA	FUND	ORG	NET	PRO	POL	DEL	CAP	TRAI	HAR	EVAL	EXC	REP
Shared Health Values	*ANA2* *ANA3*	OBJ			PRI.1			n.r	*STR: FUND*								HAR.2		*EXC.2*	
Health is the Greatest Wealth		OBJ					n.r		n.r									EVAL.1	*EXC.1*	
Health in All Policies	ANA1 *ANA2* *ANA3*				PRI.1 PRI.3	n.r	n.r			ORG.1 ORG.3		n.r.						EVAL.1		
Global Health		OBJ			*PRI2*				n.r	ORG.2		n.r						EVAL.1	*EXC.1*	
Health of Older People			PROG.1	n.r		n.r.	n.r	n.r	*PHP. FUND*							n.r	HAR.1	EVAL.1	*EXC.1*	
Tobacco		OBJ	PROG.1	LEG.1				n.r		ORG.2			*POL.1*				HAR.2	EVAL.1 EVAL.2	*EXC.1*	*REP.1*
Nutrition		OBJ		LEG. VOL	PRI.1	n.r	n.r	n.r		ORG.2		n.r		DEL			HAR.1	EVAL.3	*EXC.2*	*REP.1*
Alcohol		OBJ	PROG.1	LEG.1		n.r	n.r	n.r		ORG.1			*POL.1*			n.r		EVAL.1		*REP.1*
Mental Health		OBJ	PROG.1		PRI.1	n.r		n.r	*STR: FUND*					DEL		n.r	HAR.1	EVAL.1 EVAL.3	*EXC.1*	
Illicit Drugs	ANA.1		PROG.1					n.r						DEL			HAR.3	EVAL.3	*EXC.2*	*REP.1*
Cancer	*ANA2* *ANA3*	OBJ	PROG.2	n.r				n.r	*STR: FUND*		NET.1	n.r		DEL		n.r	HAR.3		*EXC.1*	*REP.1*
Rare Diseases		OBJ	PROG.2			n.r.	n.r		n.r		NET.1	n.r				n.r	HAR.3	EVAL.1	*EXC.1*	*REP.1*
Organ Don & Transplant.	ANA.1	OBJ	PROG.2 PROG.3					n.r			NET.1	n.r		DEL		n.r.	HAR.3	EVAL.3		*REP.1*
Injuries			PROG.1							ORG.1		n.r				n.r	HAR.2	EVAL.2		
HIV/Aids			PROG.2			n.r	n.r	n.r	*STR: FUND*					DEL			HAR.1	EVAL.3	*EXC.1*	*REP.1*
Vaccination	ANA.1		PROG.2				n.r	n.r						DEL				EVAL2		*REP.1*
Preparedness Planning		OBJ	PROG.1							ORG.1 ORG.2	n.r	PRO.1			n.r.				*EXC.2*	
CBRN	ANA.1		PROG.1							ORG.2	NET.1	PRO.1		DEL	n.r				*EXC.1*	*REP.1*
Antimicrobial Resistance		OBJ	PROG.2		PRI.1			n.r	n.r.	ORG.1		PRO.1	n.r.				HAR.1	EVAL.3		*REP.1*
Patient Safety	ANA.1		PROG.1			n.r	n.r	n.r	n.r	ORG.1	n.r			DEL		n.r	HAR.1	EVAL.3	*EXC.1*	*REP.1*
Telemedicine			PROG.1	n.r															*EXC.2*	

Legend: n.r. = not retained. Secondary indicators are reported in *italics*

4.3 Limitations of the Current Exercise

As shown in the previous sections, the identification of a coherent framework of process indicators to monitor the uptake of the EU Health Policies suffers from some inherent limitations, and in particular:

- the benchmark for reference is represented by a rather heterogeneous set of some 40 documents, with different content matters often inspired to different approaches to policymaking and relying on fairly diverse policymaking tools;
- there are very few horizontal strategic principles that can consistently be applied across all the various policy areas (HiAP, health is the greatest wealth, health inequalities, etc.) and could serve as a basis for a kind of meta-monitoring framework that could be something different from the simple addition of the main indicators applicable to the given single policies;
- also as a consequence of this, the pilot validation exercise shows that there are still major categories of indicators on which diverging value judgments persist among stakeholders;
- the proposed system can measure convergence towards certain common aims, but is of limited help in solving the problem of attributing developments to the EU influence (the so-called problem of attribution) and measure the specific contribution of EU inputs to the policymaking process ('EU added value').

This inevitably reflects the sectoral way these policies have been formed over time and the emphasis given to health outcome and impact aspects over the search of common horizontal policymaking process components. The available horizontal principles incorporated in the EU Health Strategy mainly refer to strategic aspects of the underlying health policies (e.g. emphasis on shared equity principles and the economic and global dimensions), but with the limited exception of HIAP, have hardly ever entered into health governance matters. The HIAP principle itself has rarely found application in the various sectors embraced by the EU Health Strategy.

4.4 Possible Future Developments

An alternative theoretical foundation to the policymaking cycle for the categorisation of indicators could be represented by elaborating on the stewardship concept proposed by the WHO and adopted by all the MS with the 2008 Charter of Tallinn. So far the concept has been outlined in its basic principles, but has still to be fully declined in terms of possible operational measurement[59] and benchmarks for reference. If the role of the Ministries of Health at the MS level can be represented as that of stewards steering their health systems by balancing competing influences and demands, maintaining the strategic direction of policy development and implementation; detecting and correcting undesirable trends and distortions; articulating the case for health in national development; regulating the behaviour of a wide range of actors - and establishing effective accountability mechanisms, the role of the EU could be seen as that of a steward of stewards – particularly in certain areas - and analysed and measured accordingly[60].

In the current literature on stewardship[61] six main sub-functions have been identified, and namely:

a) to formulate a strategic policy framework;
b) to ensure a fit between policy objectives and organisational structure and culture;

[59] The essential public health functions methodology developed by the WHO is to measure the performance of health systems and is based on pooling together subjective expert assessments.

[60] A similar approach is being attempted in Italy in the field of cancer screening programmes. See C M. Novinskey, Federici, A., *Stewardship and cancer screening programmes in Italy*, Italian Journal of Public Health # 2, 2011

[61] See on the subject P Travis, D Egger, P Davies, A Mechbal *Towards better stewardship: concepts and critical issues*, WHO, Geneva, 2002 http://www.who.int/healthinfo/paper48.pdf

c) to ensure tools for implementation; powers, incentives and sanctions;
d) to build consensus and partnership;
e) to generate intelligence; and
f) to ensure accountability.

For each of these sub-functions agreed benchmarks for reference could be identified at the European level by means of "framework recommendations", which also would help better define the specific components of EU added value in the various specific policy areas.

The *formulation of a strategic policy framework* would require agreement at the EU level on the minimum role the Ministries of the various MS should play in the articulation of a vision for their health programmes, the definition of short and long-term objectives, the definition of the roles played by the various stakeholders, and the criteria for prioritisation of related health expenditure, as well as for monitoring the performance of sub-centrally run health services. This would address the objection raised during the case studies that to some extent "strategies and programmes" remain a poorly determinate concept, and in certain cases it could be unclear to determine whether policy documents at the MS or RE level comply with the definition. Once the Commission had provided guidance on the minimum requirements these document should meet it would be easier to measure and quantify compliance by grouping together and adapting accordingly indicators belonging to the ANA, PROG, and EVAL categories.

Ensuring a fit between policy objectives and the organisational structure and culture appears the specific area of the policymaking process left to MS discretion because of subsidiarity considerations and the soft-law nature of EU actions. Performance can be typically measured by recourse to indicators on the degree of attainment of predefined objectives (DEL and OBJ in our proposed scheme). It is worth considering whether basic organisational requirements including the existing of procedures to communicate EU policy orientations to the various stakeholders should be clearly spelled out in a reference framework document applicable across the board. These aspects could be eventually captured by means of aptly adapted ORG indicators.

Ensuring the existence of formal tools for implementation, powers, incentives, and sanctions (including also reliance on exerting influence and other soft tools) would entail the measurement of aspects only marginally dealt with in the existing EU policy documents, such as 1) the degree of overlapping between the responsibilities of the various stakeholders concerned, and 2) the existence of systems of incentives and sanctions for the attainment of the specified objectives (first of all financial, but including also other incentives such as the provision of training or technical assistance, and operational audits). Compliance with operational guidelines (an ANA criterion) – when existing – would obviously represent an important judgment criteria. But once properly formulated, the measurement of these aspects could be carried out by means of a reformulation of the indicators proposed in the ORG, ANA and TRAI categories. This could eventually extend to FUND indicators if an agreement is reached on how financial incentives should be defined.

Build coalition and partnerships can represent a major element of stewardship in decentralised health systems and partners may variously include, among others, professional associations, patient and consumer groups, other ministries, private NGOs, medical schools and universities, as well as private companies. There are some EU health policies that at the moment (notably nutrition and obesity) that heavily rely on this sub-function. In an extreme stylised form, one could even characterise a substantial part of HIAP as an attempt to build intergovernmental coalitions and partnerships for the achievement of common health goals. The measurement of this sub-function can focus on the degree of formality of the underlying agreements, their duration (permanent, temporary; etc.), their finalisation (e.g. communication and information campaigns) and eventually

the type of counterpart involved. It is unclear whether and to what extent common European principles in these areas can be agreed, but if they could, their measurement could then be carried out also by means of an expansion of the AWA and PART categories on which at present very limited consensus can be found among stakeholders.

The *generation of intelligence* appears to be a key element of stewardship and can be split into several components. One is clearly country-specific, related to the contextual factors of a given MS, poorly formalised, difficult to analyse and often confidential and undocumented. This can be poorly standardised in any European reference framework. On the contrary, information on programme effectiveness can be standardised, for instance, according to common European guidelines on the contents and the ideal timeframe of programme evaluations. The generation of intelligence can be also represented by MS' capacity to ensure the production and dissemination of comparable epidemiological data and by the existence of research programmes to fill the information gaps. Once included in a common reference framework, all these elements could be monitored by an apt combination of the HAR, EVAL and RES categories of indicators proposed for the current monitoring system.

The scope of *ensuring accountability* can vary significantly from a limited better definition of MS information sharing responsibilities *vis-à-vis* the other MS, to the more fully fledged versions proposed at the national level and inclusive of requirements for independent watchdogs, compliance with publishing rules and standards, as well as standards for the level of access to political representatives for the citizens concerned. Accountability may also include minimum requirements about the communication and dissemination of the policy results achieved, as well as information on the level of awareness reached among the population. Depending on the scope eventually given to accountability requirements at the European level, related measurement could take place through a combination of REP and EXC indicators, as well as include elements of AWA and PART ones.

If the stewardship paradigm were followed as the reference analytical framework, one would have found that the sources of European Added Value are mainly sought in terms of powers, incentives and sanctions, and in particular in the capacity of EU policy documents of exerting a soft policy influence in the domestic policymaking process, mainly by means of political prestige considerations. Financial incentives or sanctions by means of access to PHP or structural funds have hardly ever been implemented. A case can be built that to different degrees elements of European added value can be found in requests to generate intelligence by means of comparable data and ensure a minimum of accountability by sharing best practice and results of policies. Apart from general prestige considerations, there have been relatively few instances where influence could be measured by means of compliance with given operational guidelines. Much in the same vein also the quest of European added value by means of a better fit between policy objectives and organisational structure has materialised in a very few number of cases (typically related to economies of scale, like rare diseases, or economies of network, like surveillance systems). Finally there is at least one patent case of a policy (nutrition and obesity) whose European added value has been built on building coalitions and partnerships at the European level and replicating the mechanism at the various MS levels.

Needless to say, if the various components of the EU Health Policies were better formalised in terms of defining the specific elements of European added value, the problem of attribution could be more easily tackled and the indicators targeted to measure the European specific contribution to policy convergence. However, to do that, a number of European reference framework documents should be released on the specific contents of the various sub-functions of stewardship, when declined at the European level, so that common benchmarks for subsequent measurement could be available across different policy areas.

4.5 Conclusions

The exercise has demonstrated that the hereby proposed common framework of indicators to monitor uptake of EU health policies in Member States for DG SANCO's internal strategic monitoring purposes is feasible and sufficiently robust to be scalable in the future, so to cover also other health policy areas, requiring only minor adjustments. The system is flexible enough to lend itself to be fine-tuned according to the specific information needs of the different Commission Services.

Evidence from the case studies shows that the framework can represent an effective tool to measure the progress achieved in the different areas and highlight obstacles, as well as instances of best practice. As such, it can also be used as a tool for internal Commission reflection in steering the allocation of policymaking resources towards the most effective policy interventions, or towards means whereby European investment can best be absorbed and impact the most.

Additional steps towards an eventual implementation of the indicator system above would require further validation from the concerned Commission Services together with the fine-tuning of the most relevant indicators for their specific information purposes and, where possible, further testing in other countries and policy areas.

In particular, the case studies carried out within the framework of this exercise have confirmed the relevance of indicators on (i) the adoption or transposition of policy definitions or methodologies (ANA), (ii) data harmonisation (HAR), (iii) the existence of dedicated programmes or strategies in a given policy area (PROG), (iv) the allocation of organisational responsibility (ORG), and (v) the availability of evaluation reports (EVAL). All in all, these indicators on their own represent a good proxy of the level of commitment to any given policy. Examples include, among others:

- number of MS or other relevant entities formally adopting a given methodology/problem definition - wholly or in part (ANA.1);
- number of MS that have established a strategy / programme / action plan covering the whole population (PROG.1);
- number of MS that have identified a body responsible for policy coordination / a focal point (ORG.1);
- number of MS for which a centre of expertise entrusted with disseminating best practice in a given policy area can be officially identified (ORG.3);
- number of MS providing homogeneous data to the relevant EU Health Indicator database (HAR.1);
- the number of MS that have put in place special registries when requested / number of registries established (HAR.3);
- number of MS/RE that have carried out evaluations / cost effectiveness assessments of their policies (EVAL.1); and
- number of MS/RE that have put in place a system of indicators to monitor policy implementation (EVAL.3).

Other categories of indicators can be retained as secondary indicators for complementary information purposes. They are not generally considered as valid and feasible and are subject to a number of limitations, but can nevertheless address special purposes and information needs. These include, among others:

- bibliographic indicators such as number of MS with evidence of a significant debate in the scientific literature about a methodology / policy problem (ANA.2);
- indicators on EU funding such as total structural fund financing committed to implement a given health policy (STR.FUND);

- indicators on the number of MS reporting commitment to a given policy principle to international organisations (PRI.2);
- indicators on the number of MS that have submitted their policy experiences to the relevant European Coordination Mechanisms / Working Group or dedicated database / portal (EXC);
- indicators on the number of MS that have complied with their reporting requirements when relevant (REP.1).

Awareness raising and communication (AWA), policy participation (PART), research (RES), and most policy funding (FUND) indicators have not been retained partly because of disagreements among stakeholders on their relevance in the specific country context, partly because of severe feasibility problems. At any rate, they remain worth considering in the future, should the current limitations be overcome and an agreement found on their relevance in the light of well-defined benchmarks for reference in terms of compliance with relevant EU guidelines.

To come to terms with heterogeneity and the limited availability of minimum common "process denominators" across the various policy areas, the framework of indicators had to be based on a rather general theoretical foundation such as the policymaking cycle theory. In the future, any further streamlining and consolidation of the proposed framework of indicators into a more coherent set with smaller room for disagreement, would basically depend on two conditions, that 1) the benchmark for reference to measure progress in the uptake of the EU health strategy could be more clearly focused in a shorter set of predefined shared principles valid across the various policy areas; e.g. on enhancing the value for money of the resources spent (at present the issue is dealt with as a horizontal principle in the 2007 strategy document but hardly incorporated in concrete terms in the sectoral policy documents) or on reaching a common agreement on what elements should be evaluated of the various policies and how; and consequently that 2) greater emphasis should be given to a better defined European added value dimension. Evidence from the case studies show that this would involve:

1. concentrating on a smaller number of long-term priorities. At present there is a feeling that the EU action is diluted into too many priorities, proposed over a too short period of time and therefore difficult to follow, which ultimately causes the loss of any sense of real prioritisation and of the momentum built with the success of previous initiatives;
2. gradually moving away from sectoral policy documents towards framework recommendations that can be applied across policy areas, e.g. by defining common formats for evaluating policies and share related results;
3. identifying areas of clear European added value where action should be focused (economies of scale were the clear example for rare diseases, but other sources of European added value can be identified) and providing guidance on common governance/stewardship principles including organisational aspects;
4. building consensus on ways to generate common policy intelligence at the European level so that the debate on harmonising data can be expanded to needs for applied research and on how to take into consideration the broader socio-economic contextual factors;
5. defining common principles to ensure accountability (e.g. by improving reporting requirements and agreeing publishing or data dissemination rules or common quality assurance principles);
6. better defining common policy evaluation frameworks and related methodological guidance to facilitate exchange of experiences as part of a broader effort in reaching consensus on intelligence needs; and
7. addressing areas of disagreement or limited implementation by establishing partnerships or defining financial incentives or sanctions (some interviewees suggested that a share of the PHP could be made conditional on progress achieved).

To this aim, findings from this exercise highlight that the availability of evaluation reports and, more generally, a higher level of development of the evaluation practice in health policy in any country are preconditions for any further steps towards assessing the health but also the economic costs of non-implementing the EU Strategy. Preliminary information starts becoming available in this respect in certain MS and it is reasonable to anticipate that this trend is likely to continue in the future.

Finally, further progress in tackling the problem of attribution and better assessing the role played by the EU would require a better definition of the main components of European added value. At present, with a few notable exceptions, European added value is mainly identified with exerting soft policy influence on Member States by means of recommendations and other consensus building mechanisms, which is hardly measurable in quantitative terms but with recourse to subjective expert opinions. If the role of the Commission were seen as that of "steward of stewards" within the framework of the stewardship principle agreed by the Member States with the charter of Tallinn[62] and common lines were identified on the best way to (i) maintain the strategic direction of policy development and implementation; (ii) detect and correct undesirable trends; (iii) articulate the case for health in development; (iv) interact with a wide range of stakeholders; (v) define effective accountability mechanisms and (vi) steer the role of regional and local authorities were provided, it would be possible to come to a more precise measurement of the specific contribution of the EU actions to policy convergence.

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[62] Tallinn Charter adopted at the 2008 WHO European Ministerial Conference on Health Systems: "Health Systems, Health and Wealth. See the WHO Europe conference document EUR/RC58/Conf.Doc./4 Stewardship/Governance of health systems in the WHO European Region; and the working document EUR/RC58/9 Stewardship/Governance of health systems in the WHO European Region

APPENDICES

APPENDIX 1

Analysis of proposed indicators for Health in All Policies (HIAP) in the Countries visited

ANA.1 - Formal Adoption of EU HIAP definition and HIA methodology (incl. RE* level)	With the exception of ANA.2 in IT (highly valid) these indicators are considered as fairly valid. The validity of ANA.1 is somehow limited by the fact that reference to or formal adoption of the HIAP concept is not considered as striking evidence of policy uptake (IT, SE), and that this indicator presupposes that the concept has been at least generally formalised in the countries considered, while this is not always the case (e.g. FR). ANA.1 is overall considered highly (FR, PL) or fairly (IT, SE) feasible. There is no clear consensus on ANA.2; its validity is variously assessed, going from high (IT) to fair (FR, PL) to dubious (SE). The main validity issue is constituted by the risk that small countries are underrepresented, because their experts would be part of larger international teams and therefore traceable with more difficulty, which would also impact on feasibility ANA.2 is fairly feasible where data is collected though not immediately available (IT, FR, PL); hardly feasible where data collection would require an ad hoc research, which would likely be complex and time consuming (SE). All other assessment of feasibility are either positive or highly positive
ANA.2 - Evidence of a Significant Debate in the Scientific Literature about HIAP	
PRI.1 - Existence of Health Policy Documents Including a Commitment to HIAP Principle (incl. RE level)	PRI.1 is considered definitely valid in FR (where the concept is referred to in regional strategic plans) and SE (where the 2010 PH policy calls for local HIAP commitment); some reservations exist in IT and PL. In particular, in IT it is unclear what working papers making specific reference to HIAP qualify as policy documents as well. Feasibility ranks fair (FR, PL, SE) to high (IT). PRI.2 is considered of dubious validity in most MS (IT, FR, SE); fairly valid in PL. Validity is questioned on grounds that reporting may not be a sound indication of actual commitment to the policy (IT, SE); validity also falls short where HIAP is not included in the national health strategy (FR). Feasibility is overall fair (FR, SE) or high (IT, PL), particularly where the relevant data is already available (IT, PL). There is consensus that PRI.3 is fairly valid. Validity is no higher because HIAP as commonly referred to in strategy documents does not always coincide with the terms set out by the EU (IT), or HIAP is not formally codified (FR). Also, HIAP may be inherently included in strategies and action plans, but no explicit mention is made of it (SE). Views on this indicator's feasibility, range from high where data can easily be obtained from already existing repositories (IT, PL), to fair when data is either not currently collected (SE) or fragmented (FR, SE).
PRI.2 - Reporting to International Organisations of Commitment to HIAP Principle (for instance in the WHO Healthy Cities programme)	
PRI.3 - Strategies/Programmes/Action Plans Specifically focusing on HIAP (incl. RE level)	
PART.1 - Existence of Advocacy NGOs Active in the HIAP Field	PART.1 and PART.2 appear overall of dubious validity; validity may increase, as noted in SE, if indicators' formulation may change to encompass interest groups in general and not just NGOs. Validity limits are further compounded by the absence of a full-fledged codification of HIAP (FR). Standing the current formulation of the two indicators, feasibility is appears dubious.
PART.2 - Involving of Advocacy NGOs in the Policymaking Process (incl. RE level)	
RES.2 - Resources Made Available by MS to Research Programmes in HIAP Field in Either Absolute or Relative Terms	RES.2's validity is dubious either in cases where there isn't a country-wide HIAP strategy (FR, PL), or because research funds are not or cannot be defined along HIAP topics (IT, SE). Using this indicator would require dedicated and material efforts to acquire the relevant data (SE, IT); the absence of a common understanding of HIAP botches feasibility by construction (FR, PL).
ORG.1 - Identification of a Body Responsible for HIAP Coordination / a Focal Point	It is agreed that ORG.1 would be definitely valid (IT, FR, SE, PL), even more so where such a body already exists (FR, SE). Where this body is already in place, feasibility is, logically, high. An ORG.3 relevant body exists in only one of the four countries considered (SE), where the indicator is, accordingly, definitely valid and feasible. Elsewhere, this function has been tapped by other bodies, although without a specific mandate to do so (IT, FR). It appears that in IT, FR and PL, ORG.3 functions could be performed not by a separate centre of expertise, but either by existing institutions, if they agreed to increase their mandate (IT) and/or to coordinate with other bodies (PL).
ORG.3 Existence of a Centre of Expertise Entrusted with Disseminating Best Practices on HIAP (including HIA methodology)	
PRO.1 - Introduction of HIA in Routine policy-making process (incl. RE level)	There is no consensus on PRO.1's validity. In IT, it is argued that attempting to promote HIAP by top-down introducing standard procedures is counterintuitive, so PRO.1 would be of dubious validity. Otherwise it is suggested that the indicator should be defined more precisely (FR). Another problem detected in FR, is that the
PRO.2 - Number of Relevant	

Institutions Complying with the above Procedures (incl. RE level)	sole focus of existing procedures is on environmental impact. PL assessment of PRO.1's validity is dubitative; no such procedures have been introduced but in principle the indicator would be valid. No particular objections were flagged in SE, where multiple intersectoral coordination mechanisms are in place. Feasibility correlates with the degree of adoption of these procedures, and therefore goes from fair (IT, FR, SE) to nil (PL) Opinions as to PRO.2's validity in IT, FR and PL mirror those expressed for PRO.1, highlighting the fact that PRO.1 is a PRO.2-enabler. SE notes that PRO.2 is an "advanced" indicator, so its use may be delayed to a second stage of policy uptake assessment. Feasibility spans from fair (e.g. in FR where procedures are recorded but data is somewhat fragmented) to nil (e.g. in PL where no data is currently available). Feasibility is dubious where the HIAP concept has not been fully clarified yet (IT) or where data collection is judged as demanding (SE).
EVAL.1 - Implementation of Evaluations / Cost Effectiveness Assessments of their Policies (incl. RE level)	In FR and PL EVAL.1 is considered highly valid, with FR having already introduced some form of routine impact assessment. Not so valid in countries that lack an evaluation tradition (IT); in SE, performing the cost-effectiveness of HIAP is considered to strike a blow on the HIAP concept itself. So as long as proper methodologies are devised, the indicator remains only fairly valid – and for the same reason only fairly feasible. Not feasible in PL, failing the basic preconditions for evaluating HIAP. In FR the results of the assessments are parceled across regions, yet they could still be acquired at a reasonable effort, so EVAL.1 is fairly feasible. Equally so in IT where, even if no full-fledged evaluation is conducted, the MoH commissions routine studies. In addition, the forthcoming evaluation of the National Prevention Plan may include HIA methods. Identical assessments as EVAL.1 are made of EVAL.2 in all countries. The same opinions are echoed by countries for EVAL.2, which is deemed hardly feasible in SE, in connection with the fragmentation of local-level data. Suggestions are made as to the possible reformulation of the indicator by SE (the indicator should tackle measures undertaken, and not the policy *per se*). FR is a strenuous advocate of the value added of evaluating policy, while IT is exposed to possible manipulation of evaluation results. Depending on whether evaluation or equivalent data are already available, EVAL.2 is considered fairly (IT, FR) or hardly/not (SE, PL) feasible. EVAL.3 is considered highly valid in IT and PL, less so in FR and SE. Accordingly, for FR a better indicator would be more accurately formulated (specify what is to be monitored); for SE, the indicator should monitor measures taken, and not HIAP uptake *per se*).Feasibility issues range from data fragmentation (FR, SE) to the lack of a consistent policy monitoring culture (IT).
EVAL.2 - Streamlining / modification of Policy as a Result of an Evaluation Exercise / Cost Effectiveness Assessment (incl. RE level)	
EVAL.3 - Setting up of a System of Indicators to Monitor HIAP uptake / Implementation (incl. RE level)	

APPENDIX 2

Analysis of proposed indicators for Patient Safety in the Countries visited

Indicator	Comments
HAR.4 - Alignment of Data Classification Systems to Standardised Given Procedures	A highly relevant indicator across the board (IT, FR, SE, PL). The indicator is highly feasible, and in some cases already in use. In cases where the indicator is not yet in use, data is already collected by a designated body, so making it operational would not be too demanding.
ANA.1 - Adoption of a Methodology/Problem Definition in line with international standard	A fairly valid indicator, in the sense that it's overall considered logically sound but not crucial for internal policymaking purposes; also, to be best suited for policy making, the indicator needs adapting (as shown in SE). Highly feasible everywhere, except in IT, where deploying the indicator would require some limited effort.
OUT.1 - Specific Outcome Indicator for the Stated Objective	Overall fairly valid indicators, although not necessarily the OECD-originated ones. SE and IT, for instance, collect indicators outside of, though comparable, to the OECD set. Overall fairly feasible, with considerable cross-country variation. In PL not considered feasible given that no relevant data are collected. At the other end of the spectrum, the indicator is highly feasible where such data are collected and made readily available (SE).
PROG.1 - Establishment of a PS Strategy/Programme/Action Plan covering the Whole Population	On the whole, fairly valid families of indicators, turning of dubious validity or not valid at all in cases where a PS strategy is in its early stages, and where sub-national authorities are assigned limited responsibility in setting the PS agenda (e.g. PL) or where to set a national PS strategy would be unconstitutional (e.g. IT). Indicators are also generally feasible; in some cases, feasibility is impinged on due to the fragmentation of data collection and storage at sub-national levels (e.g. IT and FR). Not feasible, failing a national PS strategy (e.g. PL).
PROG.2 - Number of RE with Strategies/Programmes/Action Plans Implemented at the Sub-national Level (% of population covered)	
PROG.3 - Number of RE with a Strategy/Programme/Action Plan still in its Planning Phase, or Implemented on a Local Pilot Basis only	
PROG.RES - Preparation of SpecificProgrammes, such as (but not only) Research Projects, on PS-related Subject	
PART.2 - Involvement of Advocacy NGOs in the Policymaking Process (incl. RE level)	Indicators considered of dubious, at most fair, validity. In particular, the terms of PART.2 and PART.3 are considered too vague and liable to bias/diverging interpretations. Doubts exist also on these indicators' relevance for policy making purposes. Failing the basic arrangements and provisions to allow for NGO participation and integrate it in policy making, these indicators are only moderately feasible.
PART.3 - Provision of Support to Advocacy NGOs active in the Given Policy Field (incl. RE level)	
RES.1 - Existence of Research Projects in the PS Field	Fairly to highly valid indicators. RES.1 could be more valid if it was formulated somewhat differently (instead of focusing exclusively on research programmes, it should encompass at other types of PS initiatives/activities. For comparative purposes, RES.2 would shed light on how poorly research budget lines score as compared to the rest of the public health expenditure. Some doubts exist (SE) as to how eloquent RES.2 and RES.3 may be and to what extent their results can be effectively compared across countries. Feasibility however is highly questionable (especially for RES.2 and RES.3), given that the information needed is not readily available in all cases, either because it is not uniformly collected or stored (fragmentation within decentralised systems exerts considerable influence in this respect, e.g. FR). Part of the information is simply not available (e.g. RES.1 in FR). In other words, considerable data collection efforts would be needed.
RES.2 - Resources Made Available by MS to Research Programmes in the PS Field in Either Absolute or Relative Terms	
RES.3 - Number of Studies/ Publications Produced by Research Programmes in PS Policy Field	
RES.4 - Number of Citations of the Studies Financed under the Programme Above in the Scientific Literature	
AWA.1 - Number of Information/Awareness Raising Campaigns and Dissemination initiatives for practitioners on PS	AWA.1 is considered of dubious validity in those countries where (IT, FR) conceptual difficulties are detected, as it bundles up together highly differing initiatives (in size, scope and target). Overall, it is held that the indicator should be defined more precisely. Data collection

Indicator	Comments
policies and issues in a Given Year	fragmentation partly corrupts the feasibility of all AWA family indicators in all the four countries considered. Although in many cases the data could indeed be retrieved from designated operators and/or bodies, to gather and assemble it would be time-consuming and require a great deal of effort, or else it could be reconstructed based on secondary sources, but at a considerable cost.
AWA.2 - Level of Awareness about PS issues among the Population	
AWA.3 - Trend in the Level of Awareness about PS issues among the Population	
AWA.4 - Estimate of Population Reached by Information Initiatives in Absolute Terms or Relative to the Potential Target	
FUND.1 - Total Budgeted Funds to Specifically Implement PS Policy in Absolute or Relative Terms	FUND. indicators are of dubious validity at most. In the case of FUND.1 this is due in part to the heterogeneity of the inputs considered (e.g. the variety of in-kind human resources in IT) or to the lack of dedicated PS budget lines (FR); it is also questionable whether it is appropriate to correlate the chances of a policy being implemented with the size of its dedicated budget lines (SE). Feasibility is considered limited for all FUND. families, in particular considering that relevant data is either not available, unreliable. In case data could be available in principle, it is noted that it would only be obtainable with difficulty (PL).
FUND.2 - Total Public Expenditure to Specifically Implement PS Policy in Absolute or Relative Terms	
FUND.3 - Total dedicated infection control staff (absolute terms or per 1000 beds)	
ORG.1 - Identification of a Body Responsible for Policy Coordination / a Focal Point	ORG. indicators are fairly to highly valid in all countries surveyed, although with some qualifications. ORG.1 is well-suited for data collection, as evidenced by the fact that such designated bodies or focal points. It is suggested that the ORG.3 should be somewhat reformulated, by better specifying the features of the centres of expertise in question to make them more easily identifiable (SE). ORG. indicators are from fairly to highly feasible. Issues arise in cases of fragmentation of data collection and storage, particularly at sub-national level. This is particularly the case of ORG.1, for which there sometimes isn't a platform or alternate mechanism to accurately reflect this information, when PS is not the sole responsibility of one entity or type of entity. E.g. in SE, with local self-government, it is inappropriate to talk about a body 'responsible' for policy coordination, but rather a body that 'provides support'. Similarly, ORG.3 feasibility is lesser where there is more than one, and not easily identifiable centres of expertise on PS.
ORG.2 - Routine Interaction with European Institutions on PS by Means of a Well-identified Institution	
ORG.3 - Existence of a Centre of Expertise Entrusted with Disseminating Best Practices in PS Area	
NET.1 - Creation of a Network of Institutions to Implement the PS Policy	Not a very valid indicator. It is considered to be open to misunderstanding owing to the fact that intersectoral coordination takes somewhat deviant forms in some countries (intersectoral coordination in IT does not fully comply with EU standards) is not unambiguously defined in all countries (IT). Doubts exist on whether this indicator is truly useful to tackle policy implementation. There is no consensus on this indicator's feasibility, reflecting the presence of cross-country variations as to whether and how data is collected on intersectoral mechanisms.
DEL.2 - Number of RE Complying with the Several Possible Relevant Features of Policy Implementation Modalities Stated in the EU Documents	DEL. Indicators face significant validity problems. They are at most considered of dubious validity, except in the case of IT, where the indicators are held as fairly valid. DEL.2's validity is questioned on account of the fact that either the EU guidelines are not explicitly complied with (e.g. FR) or else, the implementing authorities are to follow national guidelines, not necessarily the EU ones (SE). In PL sub-national organisations are entrusted with minimal PS responsibilities. Concerning DEL.3, validity is objected (i) because the indicator is considered too vague and (ii) because the number of initiatives undertaken is not necessarily indicative of the degree of policy implementation. Both indicators are considered fairly difficult, when not impossible to measure. Significant efforts would be required for data collection, so they are, at best, fairly feasible.
DEL.3 - Number of Significant Initiatives (i.e. above a certain threshold value) Undertaken to Specifically Deliver Policy	
TRAI.1 - Implementation of Training Courses on PS-related	There is no clear consensus on the validity of these indicators. In SE, TRAI.1, TRAI.2 and TRAI.3 are considered only marginally valid; as

Indicator	Comments
Subject for Healthcare Personnel (incl. RE level)	the opinion goes that it is not necessary to create *ad hoc* courses to train health professionals in PS. PS can be integrated in traditional and other pre-existing courses as a transversal subject. In SE, feasibility is questionable on account of fragmented or unavailable data collected. In FR, a disconnect exists between validity and feasibility perceptions. TRAI.1, TRAI.2 and TRAI.3are considered definitely valid (possibly poised to be included in set of national indicators) but hardly feasible (due to current data fragmentation). In PL, TRAI.1, TRAI.2 and TRAI.3 are considered valid and in principle data could be collected at no major effort. Such indicators are considered fairly feasible in IT, where relevant data is stored and retrievable online, although their validity is deemed questionable. TRAI.4 is overall valid (from fairly valid in IT to definitely valid in FR and PL), while its feasibility varies according to the level of complexity of national curricula.
TRAI.2 - Total Number of Trained Healthcare Workers on PS-related Subject	
TRAI.3 - Resources Made Available for Training in PS-related subject in Absolute or Relative Terms	
TRAI.4 - Introduction of PS in Relevant Curricula (incl. RE level)	
EVAL.1 - PS policy evaluation (i.e. regular review of practices and standards)	In PL, EVAL.1, EVAL.2 and EVAL.3 are definitely valid. EVAL.1 and EVAL.3 are considered definitely valid and highly feasible in FR and SE. EVAL.1 and EVAL.2 in IT are not available, mainly because of uncertainties on what would qualify as ex post evaluation and because policy streamlining would best be measured qualitatively rather than quantitatively. EVAL.3 is highly, as in all other MS considered and feasible – thanks to the LEA indicators system in place and complementary reports. EVAL.2 is considered very pertinent in FR (less so in SE), where the performance of the 2005-2008 nosocomial programme were explicitly taken into account for the formulation of the new PS Action Plan; feasibility dwindles from FR (where expected data collection efforts are small) to SE (flagging possible standardisation, and related measurement problems).
EVAL.2 - Change of PS Policy as a result of the above evaluation	
EVAL.3 - Establishment of a System of Indicators to Monitor Policy Implementation	
EXC.1 - Contribution by the MS of its Policy Experiences to the *PS and Quality of Care Working Group*	Clear consensus exists on this indicator's dubious validity. When not considered outright unimportant (SE, PL), the indicator is questioned on grounds that the relevant European platforms are relatively underdeveloped, and that matters other than policy making mechanisms should and generally do make the object of international exchange. Overall fairly feasible in all four MS given that data is either already collected (IT, FR) or allegedly easy to acquire (SE, PL).
REP.1 - Full or Partial Compliance with the Reporting Requirements on the Progress Reached in the Implementation of the EU Policy	IT does not routinely send progress reports to the EU but has complied with implementation report reporting requirements; FR is found to have understated some relevant PS facts when surveyed for the 2012 PS implementation report. This indicator lends itself to being misunderstood as one tries to correlate compliance with reporting requirements on implementation and implementation itself. Collecting this information is considered somewhat to very burdensome in all four countries considered. In particular, data collection in FR would require an onerous review of materials at various levels.

APPENDIX 3

Analysis of proposed indicators for Cancer Screening in the Countries visited

Indicators	Comments
ANA.1 - Formal Adoption of the EU CS Guidelines (incl. RE* level)	The related indicators are generally viewed as fairly valid, with some caveats, i.e. an appropriate definition of 'formal adoption' (ANA.1), the inability of ANA.3 to take hard copy distribution into account, the risk of overemphasising academic impact (ANA.2), regional disparities and language issues. Feasibility does not represent a significant issue in any of the countries surveyed since it requires the review of a limited number of act (ANA.1), the exploitation of standard scientific publication databases (ANA.2), or semi-automated web-counts (ANA.3). However, in some countries (SE and PL), the measuring of ANA.2 seem not very straightforward.
ANA.2 - Evidence of a Significant Debate in the Scientific Literature of the MS about CS methodology and specifically the EU Guidelines	
ANA.3 - Effective Outreach Level of the EU Guidelines in the MS (downloads, webpages visited) in Absolute or Relative Terms (% of the target population)	
OUT.1 - Specific Outcome Indicator for the Stated Objective	The output and impact indicators stated in the EU policy are generally consistent with the indicators used in the country surveyed, thus de facto confirming their validity. The feasibility of OUT.1 does not pose particular problem since the relevant information is (or is planned to be) collected. On the other hand various weaknesses in Cancer registries make measurement hardly feasible in some countries (e.g. FR) under present circumstances.
IMP.1 - Specific Impact Indicator for the Stated Objective	
PROG.1 - Establishment of a CS Strategy / Programme / Action Plan covering the Whole Population	Very relevant families of indicators (especially PROG.1) used also in the IARC Report, and accepted in all covered MS. PROG.2 and PROG.3, although not incorrect, seem not particularly informative in countries with a centralised CS model (e.g. FR and PL). Indicators are also generally feasible since they mostly require quick interactions with responsible authorities in the MS and/or the review of a limited amount of documents. Measurement may turn out somewhat burdensome in countries with regionalised system and no central 'repository' of regional plans/ programmes (e.g. IT).
PROG.2 - Number of RE with CS Strategies/ Programmes/ Action Plans Implemented at the Sub-national Level (% of population covered)	
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	
LEG.1 - Adoption of appropriate data protection legislation	The indicators refer essentially to registries (both CS registries and cancer registries). The indicator is broadly relevant since it measures the efforts in removing legal obstacles to the effective use of registries. With the exception of Italy, where data protection is still an issue for cancer registries, all other MS have adopted, or are in the process to adopt regulation addressing privacy issues in the establishment and operation of registries. The information is easily available through registries themselves (including websites) and/or through the relevant national authorities.
LEG.2 - Appropriate data protection legislation Discussed but Not Yet Adopted	
LEG.3 - Appropriate data protection legislation Still under Preparation and in its Drafting Stage	
AWA1. Information/Awareness Raising Campaigns on CS in a Given Year (period)	In IT AWA indicators are of dubious validity and hardly or not feasible. Specifically, the level of population awareness of the issue is not considered a good indication of policy implementation (thence the scarce validity). Additionally, given that this type of data is not gathered by any repository, feasibility is low in connection of the prospected efforts that would be associated with data collection (in particular where extensive surveys are required). Similarly, in SE these indicators are considered of scarce or no validity at all, and not feasible. In PL, all AWA indicators are considered valid, to some extent. AWA.1 is fairly
AWA.2 Level of Awareness about CS issues among the target Population	
AWA.3 Trend in the Level of Awareness about CS issues among the target Population	

Indicators	Comments
AWA.4 Estimate of Population Reached by Information Initiatives on EU guidelines in Absolute Terms or Relative to the Potential Target	feasible, given that data could be accessed by institutions already collecting relevant data. The remainder instead is not considered feasible. In FR, the picture is more mixed, with AWA.1 and AWA.4 considered of dubious validity, and AWA.2 and AWA.3 definitely valid. In particular, AWA.1 and AWA.4 beg the question whether quantitative data on promotional activities can really give a sense of policy implementation (e.g. no. of leaflets). They are not feasible because the EU Guidelines are not disseminated under any dedicated awareness raising initiative, and the incidence and nature of other initiatives is too wide and fragmented to keep track of them in absolute and relative terms. Conversely, AWA.2 and AWA.3 are more feasible, considering that surveys by InVS, INCa etc. are rolled out regularly and results are made public.
FUND.1 Total Budgeted Funds to assure appropriate organisation and quality control of CS programmes	In IT and SE, FUND indicators are considered of dubious validity and not feasible (with the exception of FUND.3, hardly feasible). Funds and staff allocated to CS programmes would not reflect performance. In terms or feasibility, relevant data are intermittent, if available at all. In FR, FUND indicators are considered fairly valid and hardly feasible. Feasibility issues concern the difficulty in gathering the data: those existing are incomplete or less than transparent. In PL, FUND indicators are considered of dubious or fair validity, with some data already being collected for FUND.2 (fairly feasible), while the other two are not feasible.
FUND.2 Total Public Expenditure to assure appropriate organisation and quality control of CS programmes	
FUND3 Total dedicated staff to implement and assure quality of CS programmes	
PRO.1 - Introduction of a Given Procedure in CS Routine Operations (incl. RE level)	The indicator PRO.1 is in principle relevant, but it evidently needs to be specified (i.e. which procedure for which operation). Some of these procedures are indicated in the Recommendation, e.g. the procedure for assessing new tests and techniques before their introduction. In these cases, the indicator is unanimously deemed valid, although not necessarily measured by MS. In other areas, the validity of the indicator should be assessed on a case by case basis. PRO.2 is deemed theoretically relevant although poorly informative in certain contexts. For instance, in FR CS procedures are typically mandatory and not voluntary; therefore, infringements are subject to legal sanctions. Both indicators appear fairly feasible. In particular PRO.1 would essentially require a review of CS programmes founding documents. More efforts seem needed for the practical measuring of PRO.2 since it would entail direct liaison with the MS relevant authorities. All in all these efforts seem however manageable, since it would apply only to a limited set of MS, i.e. those having a regionalised system and voluntary-based procedures.
PRO.2 - Number of Relevant Institutions Complying with Procedure (incl. RE level)	
DEL.1 - Population Reached by CS Programmes in the country, in Absolute or Relative Terms (out of the target population)	DEL.1 and DEL.2 are part of the indicators used in the IARC report to monitor the implementation of Recommendation 878 in MS. As such, there is consensus across MS on the validity of these indicators, although with respect to DEL.2 at national level monitoring efforts rather focus on the national features of programmes than on EU ones. DEL.3 is not always deemed relevant, especially under centralised models, while it is in regionalised model. Feasibility does not generally pose problems since the information is often already collected (especially for DEL.1), or in any case would require only a limited effort of review of national programme documents.
DEL.2 - Compliance with the Relevant Features of CS Implementation Modalities Stated in the EU Documents (incl. RE level)	
DEL.3 - Number of Initiatives Undertaken, i.e. CS programmes set up	
CAP.1 - Compliance with Given Equipment Technical Standards and Operational Procedures	There is no clear consensus on the validity of this indicator across the MS covered. In IT and FR validity is evident since related information is collected and published. In SE and PL this indicator has been considered by some as too detailed; i.e. for some there is no need to control the specifics or technicalities if the process is in place. Feasibility is questioned only in SE on the same basis, while in other countries the information seems relatively easily available.

Indicators	Comments
TRAI.1 - Implementation of Training Courses on CS for Healthcare Personnel (incl. RE level)	Both validity and feasibility of this indicator vary significantly across countries. In PL this indicator is currently used. In FR the CS programmes foresees also training for referring doctors and other health professionals. In IT 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. In SE, it would be considered as poorly informative. Similarly, in IT and SE it appears hardly feasible to collect the information needed to measure it, while in PL it is reportedly done, and in FR it would not require an excessive effort.
HAR.2 - Compliance with Data Comparability Criteria based on Expert Assessment	All HAR indicators appears valid in the four countries covered, with some reservations on the quality of data available which in some cases may undermine the reliability of the indicator (e.g. in the case of HAR4 in Italy – due to limited coverage of registries, or HAR2 in France due to uneven quality of data transmitted at the national level. The relevant national institutions may ensure an easy access to the information necessary to measure these indicators (i.e. ONS in IT, InVS in FR, RCC in SE and SIMP in PL). Membership of the *European Network of Cancer Registries* is sufficient to measure HAR4
HAR.3 - Establishment of Special Registries (centralised data systems for the management and assessment of CS data)	
HAR.4 - Alignment of Data Classification Systems to Standards defined by the *European Network of Cancer Registries*	
EVAL.1 – Evaluation of data from tests, assessments and diagnosis	Evaluation and monitoring is often part of national CS policies and programmes. In IT, the ONS regularly publishes interim evaluations or quality performance assessments of programmes. In FR, InVS produced annual evaluation reports based on epidemiological data. In PL, this indicator is currently measured, on the basis of the SIMP database and the National Cancer Register data. Impact evaluations are instead much less developed and more in need. Both EVAL.1 and EVAL.3 appear relatively easy to measure, since it may require a review of programme documents and a desk research of publication of relevant authorities (but language barriers may represent an issue). EVAL.2 seems somewhat more problematic in terms of both validity and feasibility. For instance, in IT, it emerged that no change of policy can result from the above evaluations, but only changes in technical implementation modalities. In FR, the indicator is deemed valid if related for instance to possible decisions on establishing CS programmes after the evaluation of pilot tests. Feasibility seems even more complex, since the link between evaluations and policies is seldom explicit and often subjective.
EVAL.2 - Change of CS Policy as a result of the above evaluation	
EVAL.3 - Regularly Monitor CS Implementation and Outcome	
REP.1 - Compliance with the EC reporting requirement	There is disagreement on REP.1, considered definitely valid only by IT. In SE it is deemed of dubious validity, and fairly valid in FR and PL. Highly feasible in IT and FR, where reporting requirements are complied with, whereas this information is scarcely or not available in SE and PL. Views vary also on REP.2. This is considered of dubious validity in IT and SE, fairly valid in FR and PL. Feasibility is scarce as the level of reporting varies considerably over time, following no foreseeable pattern. So for instance, it is unknown whether the reports of the Italian National Screening Observatory are regularly sent to the EC, while in FR there is no established mechanism for the dissemination of the information outside of the country. In SE, the information is apparently not collected.
REP.2 Availability of Reports or parts thereof on the Progress Reached in Implementing CS Containing Information Not Shared with the EU	

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