Cost/benefit analysis of a sustainable EU Health Information System

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Acronyms and Abbreviations

AMR	Anti-Microbial Resistance
BAU	Business-as-Usual
CBA	Cost-Benefit Analysis
DG EMPL	Directorate General for Employment, Social Affairs and Inclusion
DG SANTE	Directorate General for Health & Food Safety
EARS-Net	European Antimicrobial Resistance Surveillance Network
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHI	European Core Health Indicator
ECHIM	ECHI Monitoring (Joint Action)
EFTA	European Free Trade Association
EGHI	Expert Group on Health Information
EHII	European Health Information Initiative
EHIS	European Health Interview Survey
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
ENRC	European Network of Cancer Registries
ERIC	European Research Infrastructure Consortium
EU	European Union
EU-SILC	European Union Statistics on Income and Living Conditions
HAI-Net	Healthcare-Associated Infections Surveillance Network
HSPA	Health System Performance Assessment
JAF	Joint Assessment Framework
JRC	Joint Research Centre
IARC	International Agency for Research on Cancer
MRSA	Methicillin Resistant Staphylococcus Aureus
MS	Member State(s)
NGO	Non-Government Organisation
OECD	Organisation for Economic Co-operation and Development
PPS	Point Prevalence Survey
ToR	Terms of Reference
WHO	World Health Organisation

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1.1 EXECUTIVE SUMMARY (EN)

Introduction.

The purpose of this Study is to review the costs and the benefits for Member States (MS) counterparts and beneficiaries of the EU health information system and to compare the current set-up with a possible system built on a sustainable ground. The dimensions of the analysis regard in particular: (1) indicator development and implementation; (2) data analysis and reporting to the competent entity.

The EU health information system is not defined as such in the EU policy. For the purpose of this Study it encompasses the various health information initiatives and the related indicators developed and implemented at EU-level with the support of EU-funding.

The Study complements other ongoing activities of the Commission on health information systems and takes into account the evolving international context. The initial scope of the Study was refined in accordance with the evolving policy needs of the Commission. In particular, the emphasis of the Study shifted from comparing specific policy options to a more explorative assessment of the current situation and its merits and constraints against a theoretical scenario where fully harmonised and policy-relevant indicators are implemented comprehensively across MS. This speculative scenario served as a benchmark to assess in qualitative terms the current gap, the efforts needed to bridge it, and the need for further investments.

Overview of Methodology.

The methodological design of the Study is supported by (1) an underlying 'theory-of-change' (TOC) describing how robust harmonised indicators may contribute to cross-cutting, systemic benefits through their proper use in policy processes at MS-level; and (2) a previous analysis of the stakeholders potentially involved in data collection, reporting and use, particularly in the five MS selected for in-depth analysis.

The findings of the evaluation are based on the triangulation of various sources of evidence, including direct consultations of key informants, desk review of documentary sources, and data mining on relevant databases. More specifically:

1) First and foremost, ***six case-studies***, on internationally-harmonised indicators representing different policy areas and implementation modalities, namely:
   - cancer incidence and prevalence,
   - healthy life years
   - total and hazardous alcohol consumption
   - healthcare-associated infections (MRSA incidence),
   - waiting time for elective surgery,
   - share of surgical procedures performed as day cases.
2) ***Consultation of stakeholders***, including (1) in-depth semi-structured interviews with 65 key informants from five selected Member States (France, Italy, the Netherlands, Finland and Poland), and selected EU and international organisations and stakeholders; (2) a targeted qualitative survey addressing selected public health experts, policy-makers, statistical offices, and major other stakeholders in all EU MS, EFTA countries and EU candidate countries – as well as a parallel survey of EGHI members.
3) ***Desk research*** covering both case-study indicators and health information systems at large, including EU policy and initiatives, international organisations

reports and strategies, statistical databases, scientific literature and miscellaneous grey literature.

4) ***Mapping*** of existing EU and other international organisations' health databases, as well as ad hoc indicators developed in the framework of major EU-funded initiatives.

Summary of Key Findings

The current state of the health information system. The current EU Health Information System comprises several health and health system-related indicators developed over time under different frameworks. In addition to the indicators regularly collected by Eurostat and other EU agencies (ECDC, EMCDDA) in the framework of existing policies and regulations, numerous EU-funded projects and *ad hoc* initiatives have defined and implemented multi-country health indicators on a temporary basis. The ECHI initiative was the first and most structured attempt to set up an integrated information system and EU-wide data platform on health. However, the evidence from previous evaluations - confirmed in the current Study – indicates it is scarcely used as a reference source for cross-country comparative assessments. The ongoing BRIDGE-Health project, which pulls together the most relevant EU-funded initiatives in this area, is expected to produce a rationalisation and consolidation of the existing framework and to possibly contribute to the transition toward a more integrated EU health information system.

From the perspective of national data providers, the fragmentation of sources is multiplied by the various existing health databases and projects run e.g. by OECD, WHO-EURO and other international partners. This contributes to a proliferation of indicators that is sometimes felt as causing an unnecessary duplication of efforts. The situation has, however been improving, and there is evidence that today the level of coordination is greater than in the past. A concrete example is the case-study indicator on the share of day cases operations, whose data are collected in a harmonised way through the OECD, Eurostat and WHO's joint questionnaire on non-monetary health care statistics.

Various Member States also maintain domestic non-harmonised indicators covering the same areas of internationally-harmonised indicators as part of their national health information systems. Domestic indicators usually respond to the specific information needs of the country and to the diverse characteristics of health systems, but sometimes also reflect reservations as to the relevance, reliability and utility of certain harmonised indicators in their current definitions. This is the case, for instance, of the current indicators on hazardous alcohol consumption, which some Member States (MS) collect separately. All in all health information maintains a strong national dimension. National-level databases and analytical work remain by far the preferred source of access to health information among stakeholders.

The implementation status of EU health indicators and related burden. The findings of the case-studies indicate the level of MS adoption of harmonised indicators and the compliance with data requests are generally satisfactory and on an increasing trend. This is evident for indicators backed by data collection regulations (EHIS) or specific policies (e.g. the Council Recommendation 2009 on healthcare-associated infections) but holds true also for indicators supported by gentlemen's agreement like OECD's indicator on waiting times for elective surgeries, whose number of reporting countries has been steadily increasing over time. There remain gaps in the territorial coverage and/or the level of detail for some indicators, but the issue seems more severe for *ad hoc* indicators collected under specific and time-bound projects. The 'fatigue' caused by the proliferation of such initiatives and budgetary issues is increasingly constraining MS capacity to take part in pilot initiatives.

On the other hand, despite a steady increase in coverage, there are persisting weaknesses and implementation disparities affecting the perceived and actual robustness and comparability of certain harmonised indicators. This concerns, for instance, survey-based indicators (EHIS and EU-SILC), due to a widespread scepticism towards self-assessed health and cultural bias factors. Furthermore, it emerged comparability is affected by various other factors including disparities in the implementation and processing methods (e.g. MRSA incidence), diverging national classifications and definitions (e.g. share of day cases), different collection and quality control capacity (e.g. cancer incidence), specific policy-induced alterations of data (e.g. waiting times) etc. Reliability and comparability issues emerged with virtually all the indicators analysed in-depth. However, these issues do not necessarily associate with a perceived lack of potential for future use, once the indicator will be fully and consistently implemented.

The costs of producing health information at the country level is still a poorly investigated area, and only gross estimates could be calculated using a mix of data producers' appraisals, analysis of the chain of underlying activities, and extrapolations from similar tasks. The structure and the level of costs vary significantly, especially in relation to the source and methods selected. Registry-based indicators are particularly burdensome due to overhead costs and when active search is required. Population surveys are also on the expensive side but sample sizes and the implementation method chosen (e.g. CATI, self-administered etc.) can make a significant difference. Indicators based on administrative data that are collected routinely for other purposes (e.g. hospital discharge registries, health fund reimbursement tables etc.) are among the cheapest raw data sources.

The costs of following data treatment and reporting – if carried out at MS level – present smaller variations. It generally consists of the activities needed to gather raw data from source points (caregivers, local/regional authorities etc.) or survey datasets, to validate them through appropriate quality control, and reporting them to the competent international databases. Sometimes MS have to face additional burden that is not strictly implied by the implementation mechanism of the indicator. This primarily derives from the parallel implementation of domestic non-harmonised indicators in the same policy areas and/or, to a much lesser extent, by non-coordinated requests for data from multiple entities.

The use and benefits of EU health indicators. Implementing an indicator (i.e. collecting and reporting data) is generally not sufficient to ensure the expected benefits do materialise. This requires in the first place that better information translates into MS-level strategies and policies that better tackle country's health priorities and improve health systems performance, reducing also the geographical imbalances and inequalities across segments of the population. The policy process (in broad sense) is the key driver for contributing to the ultimate goals of improving population health and the sustainability of health systems. Health information is essential to contribute to specific stages of the policy cycle, i.e. from problem analysis to the evaluation of policy impact, but can also contribute to it indirectly, e.g. via a comparison of policies and performances between countries, or through more general support to research and innovation, citizens' awareness, and other specialised monitoring and knowledge purposes.

The degree of uptake and use of harmonised indicators in Member States may depend on a number of factors, which concern the indicator itself and the national context, and eventually determines the extent to which their perceived value outweighs or not the implementation costs. The Study showed that on average EU health indicators are underused in policy-related process, due *inter alia* to:

- 'mismatches' between the information produced and the actual national needs and priorities (including possible inconsistencies with the specificities of national systems);
- insufficient awareness among decision-makers and associated limited commitment for use of indicators in the policy process;
- perceived redundancy with other domestic or international indicators;
- 'usability' aspects, such as accompanying analytical work and guidance on how to interpret the information, and timeliness of data.

Some of the case-study indicators analysed are used in the policy process, but more for background analysis and general monitoring of trends rather than for establishing specific policy targets and commitments. Cancer incidence, for instance, is sometimes used as a benchmark for long-term strategies but strictly speaking the evaluation of policies is more often done through outcomes (survival rates) and/or prevention (screening) indicators. The link with target-setting is more straightforward for health system indicators in relation with specific measures adopted (e.g. waiting time guarantees). The results showed also persisting limitations in the use of harmonised indicators for the quantification of disease burden and the measurement of health system performance. There are initiatives ongoing at the international level, as well as a growing body of scientific literature, but only in few countries this type of analyses has just been mainstreamed in the policy process.

As regards the other drivers of indicators value, there is convincing evidence that certain harmonised indicators have a 'knowledge value' that justifies their implementation, irrespectively of their direct impact on policies. The healthcare-associated infections (HAI) indicator collected by ECDC is a case in point in various contexts. Analogously, cancer incidence and prevalence indicators are largely and usefully used to describe and analyse broader epidemiological trends. Other indicators, like waiting times, have a potential for general public interest although the OECD version seems still underused in this respect. Conversely, the widespread issues affecting the true comparability of data across countries severely hinder their use for benchmarking purposes (i.e. comparing policies and performance). While direct comparisons between countries are therefore hardly feasible or significant, more valuable opportunities are offered by trend comparisons. This approach maintains that irrespectively of national specificities, the stable and consistent measurement of the same indicator over time may allow meaningful comparison of trends across countries.

Scenario analysis and comparison. The potential benefits that result from the harmonisation of indicators are manifold, and include inter alia facilitating comparison across different contexts, offering robust benchmarks for assessing the performance of policies and health systems, pooling data useful for research and knowledge, etc. The evidence collected indicates that in the absence of any major intervention on the current EU Health Information System the ongoing process towards a greater cross-country harmonisation of health indicators may slow down, but only for indicators that are perceived redundant or poorly relevant for country needs. In other cases, rather a spontaneous increase in coverage and quality of the information is expected. Budgetary constraints may impose containment of expenditure, but this may affect primarily *ad hoc* indicators rather than harmonised ones. If proper maintenance is not ensured, the utility and relevance of the EU indicators and platforms like the ECHI Data Tool would likely decline, and stakeholders would increasingly refer to other national or international sources for their information needs. Imbalances between the implementation costs and the actual benefits for some of the EU harmonised indicators may worsen.

In order to achieve a full harmonisation and satisfactory implementation of EU indicators in a sustainable manner, significant investments would be needed. In particular, most indicators seem to need interventions to increase their robustness and true comparability in view of their use for benchmarking and policy purposes. In

various instances these seem to be pre-conditions for the potential benefits to materialise. At the same time, there is no guarantee that the investments required for a full and sustainable implementation of indicators would pay-off, since there are various degrees of uncertainties between the availability of robust information, its consistent use for better interventions and the actual materialisation of the desired effects. In the first place, it is essential that the selected indicators respond to concrete and pressing policy needs and are designed to this end, which was not always the case in the past. Before investing in this area, it is also important to consider that – as case-study indicators showed – costs would mainly increase in the short-run, while benefits may materialise in the medium/long-run. Moreover, the burden would not distribute equally, but would be borne by certain Member States more heavily than others.

Conclusions and Recommendations

Enhancing the consolidation and coordination trends. The future development of the EU health information system appears linked to various ongoing processes whose outcome is difficult to forecast, e.g. the ongoing BRIDGE-Health project, the proposed European Research Infrastructure Consortia (ERIC) on a health information system, the new DG SANTE initiative on State of Health in the EU, the JAF-Health etc. This is coupled with major initiatives with similar objectives being promoted by international organisations (e.g. the WHO/EURO European Health Information Initiative). Any possible intervention in the field of the EU health information system has to duly take stock of the complexity of this scenario and its rapid evolving, and should aim at contributing to integrating the existing sources and governance mechanisms rather than setting up new ones, which might result in an additional source of burden for MS.

Enhancing policy-related use of harmonised indicators. The potential benefits of having EU harmonised indicators in place are constraint by various factors limiting their use in the policy process and for related purposes. Some of these issues may be addressed by specific actions and without recourse to major policy initiatives. In summary, enhancing policy-related use of indicators would require: (i) mechanisms to reduce the time-lag in the publication of indicators; (ii) more flexible and rapid processes to update the indicators collected in view of emerging policy-relevant challenges, (iii) more policy-oriented "knowledge-based" products complementing the provision of indicators with analysis, (iv) adequate visibility and communication actions, as well as mechanisms for restitution of the information to raw data producers.

A second key area of improvement concern the emphasis on what should be achieved by comparability and where efforts should be aimed at. As seen, despite harmonised specifications, there remain significant implementation disparities or country-specific biases, which may prevent their meaningful use for cross-country benchmarking. The direct and punctual comparison of country data points is poorly informative *per se* and potentially contentious. Much more promising instead is the use of harmonised indicators for same-country assessments of trends and for the comparison of these trends across countries.

Adopting incremental measures to mitigate the burden of indicators. The comparative analysis of the development scenarios has shown that the achievement of truly comparable and fully implemented health indicators might sometimes require substantial investments whose rationale and justification is not apparent, given the abovementioned risks and constraints on the benefit side, and taking into account the financial pressure that some national health information systems are enduring. It is also important to consider that the possible benefits from investments would eventually materialise after a relatively long period of time and their magnitude would

depend on a number of external factors that cannot be controlled, as well as that the costs would affect some players much more than others.

Conversely, there is room to increase value-for-money of the current information system by pursuing burden-mitigating and cost-saving approaches through the provision of enhanced governance mechanisms. In particular as regards: (i) the consolidation and more stringent filtering of *ad hoc* initiatives on health information based on actual needs; (ii) the opportunity offered by 'big data' (primarily administrative information) for collecting health indicators in a more cost-effective way than surveys and other resource intensive methods; (iii) the opportunity offered by (semi-)automated systems for data gathering and reporting, by creating the necessary link with parallel developments in the area of e-health.

1.2 RÉSUMÉ (FR)

Introduction.

Le but de cette étude est d'examiner les coûts et les avantages pour les homologues des États membres (EM) bénéficiaires du système d'information sur la santé de l'UE, et de comparer l'état actuel avec un éventuel système édifié sur un terrain durable. Les dimensions de l'analyse portent notamment sur: (1) l'élaboration et la mise en œuvre d'indicateurs; (2) l'analyse des données et les rapports à l'entité compétente. Le système d'informations de santé de l'UE n'est pas défini comme tel dans la politique de l'UE et, aux fins de la présente étude, il englobe les diverses initiatives d'informations sur la santé et les indicateurs connexes élaborés et mis en œuvre au niveau de l'UE et / ou avec le soutien du financement européen.

L'étude parachève d'autres activités en cours de la Commission sur les systèmes d'information de santé et prend en compte le contexte international en évolution. La portée initiale de l'étude a été affinée en fonction des besoins en évolution de la politique de la Commission. En particulier, l'accent de l'étude est passé de la comparaison des options spécifiques de politiques à une évaluation plus explorative de la situation actuelle et de ses mérites et contraintes par rapport à un scénario théorique où des indicateurs pleinement harmonisées et politiques sont mise en œuvre globalement dans les Etats membres. Ce scénario spéculatif a servi de référence pour évaluer en termes qualitatifs l'écart actuel, les efforts nécessaires pour combler celui-ci, et pour estimer l'éventualité de nouveaux investissements.

Aperçu de la méthodologie.

La conception méthodologique de l'étude est soutenu par (1) une « théorie du changement » sous-jacente décrivant comment des indicateurs harmonisés et solides peuvent contribuer à des avantages systémiques transversaux, grâce à leur bonne utilisation dans les processus politiques au niveau des Etats membres; et (2) une analyse préalable des acteurs potentiellement impliqués dans la collecte , les rapports et l'utilisation des données, en particulier dans les cinq États membres sélectionnés pour une analyse en profondeur. Les résultats de l'évaluation sont basées sur la triangulation de diverses sources de données, y compris des consultations directes des informateurs clés, des examen de sources documentaires, et des explorations de données sur des bases de données pertinentes. Plus précisement:

5) D' abord et avant tout, ***six études de cas,*** sur les indicateurs harmonisés au niveau international, représentant les différents domaines des politiques et les modalités de mise en œuvre, à savoir:
   - l'incidence et la prévalence du cancer,

- les années de vie en bonne santé
- la consommation totale et dangereuse d'alcool
- les infections nosocomiales (incidence du SDRM),
- le temps d'attente pour une chirurgie élective,
- la part des interventions chirurgicales effectuées en cas de jour.

6) ***Consultation des parties prenantes***, y compris(1) des entretiens semi-directifs approfondis avec 65 informateurs clés de cinq Etats membres sélectionnés (France, Italie, Pays-Bas, Finlande et Pologne) et une sélection d'organisations et de parties prenantes européennes et internationale ; (2) une enquête qualitative ciblée pour répondre à la sélection d'experts de la santé publique, de décideurs, de bureaux de statistiques et d'autres parties prenantes importantes dans tous les Etats membres de l'UE, les pays de l'AELE et les pays candidats à l'UE - ainsi qu'une enquête parallèle de membres du Groupe d'experts de la santé.
7) ***Recherche documentaire*** couvrant des indicateurs, des études de cas et des systèmes d'informations sur la santé en général, y compris les politiques et initiatives de l'UE, des rapports et stratégies d'organisations internationales, des bases de données statistiques, de la littérature scientifique et diverses littératures grises.
8) ***Cartographie*** des bases de données de santé existantes de l'UE et d'organisations internationales, ainsi que des indicateurs ad hoc mis au point dans le cadre des grandes initiatives financées par l'UE.

Sommaire des résultats clés

Etat actuel du système d'information sur la santé. Le système actuel d'information sanitaire de l'UE comprend plusieurs indicateurs de santé liés à des systèmes de santé développés au fil du temps dans différents cadres. En plus des indicateurs régulièrement collectés par Eurostat et d' autres agences de l' UE (ECDC, OEDT) dans le cadre des politiques et règlements en vigueur, de nombreux projets financés par l' UE et des initiatives *ad hoc* ont défini et mis en œuvre des indicateurs de santé dans plusieurs pays sur une base temporaire. L'initiative de l'Indicateur de santé de la Communauté européenne a été la première et la plus structurée des tentatives de mettre en place un système d'informations intégré et une plate-forme de données sur la santé à l'échelle européenne. Cependant, les données des évaluations antérieures - confirmées dans l'étude en cours - indiquent qu'elle est à peine utilisée comme source de référence pour des évaluations comparatives entre pays. Le projet BRIDGE-Health en cours, qui rassemble les plus pertinentes des initiatives financées par l'UE dans ce domaine, devrait conduire à une rationalisation et une consolidation du cadre existant et contribuer éventuellement à la transition vers un système d'informations plus intégré sur la santé de l'UE.

Du point de vue des fournisseurs de données nationales, la fragmentation des sources est multipliée par les différentes bases de données de santé existantes et les projets de santé menés par exemple par l'OCDE, l'EURO/OMS et d'autres partenaires internationaux. Cela contribue à une prolifération d'indicateurs parfois ressentie comme provoquant une duplication inutile des efforts. La situation a cependant été améliorée, et il est prouvé aujourd'hui que le niveau de coordination est plus grand que dans le passé. Un exemple concret est l'indicateur d'étude de cas sur la part des opérations de cas de jour, dont les données sont collectées de manière harmonisée par les questionnaires communs sur les statistiques de soins de santé non monétaires de l'OCDE, l'Eurostat et l'OMS.

Divers États membres conservent également des indicateurs nationaux non harmonisés couvrant les mêmes domaines d'indicateurs internationalement harmonisés dans le cadre de leurs systèmes nationaux d'information de santé. Les indicateurs nationaux répondent généralement aux besoins d'information spécifiques

du pays et aux diverses caractéristiques des systèmes de santé, mais parfois reflètent également des réserves quant à la pertinence, la fiabilité et l'utilité de certains indicateurs harmonisés dans leurs définitions actuelles. Tel est le cas, par exemple, des indicateurs actuels sur la consommation dangereuse d'alcool, que certains États membres relèvent séparément. Dans l'ensemble, les informations de santé maintiennent une forte dimension nationale. Les bases de données et les travaux d'analyse au niveau national restent de loin la source privilégiée d'accès à l'information sur la santé parmi les parties prenantes.

L'état de la mise en œuvre des indicateurs de santé de l'UE et charges connexe. Les résultats des études de cas indiquent que le niveau auquel les Etats membres ont adopté des indicateurs harmonisés et le respect des demandes de données sont généralement satisfaisants et ont une tendance à la hausse. Cela est évident pour les indicateurs appuyés par des règlements de collecte de données (Enquête de santé européenne par interview) ou des politiques spécifiques (par exemple, la recommandation 2009 du Conseil sur les infections nosocomiales), mais c'est également vrai pour les indicateurs pris en charge par des accords tacites comme l'indicateur de l'OCDE sur les temps d'attente pour les chirurgies électives, dont le nombre de déclarations par pays n'a cessé d'augmenter au fil du temps. Il reste des lacunes dans la couverture territoriale et / ou le niveau de détails pour certains indicateurs, mais la question semble plus sévère pour les indicateurs *ad hoc* recueillis dans le cadre de projets spécifiques et limités dans le temps. La « fatigue » causée par la prolifération de ces initiatives et les questions budgétaires limite de plus en plus la capacité des Etats membres de prendre part à des initiatives pilotes.

D'autre part, en dépit d'une augmentation régulière de la couverture, des faiblesses et des disparités de mise en œuvre persistent, affectant la robustesse et la comparabilité perçues et réelles de certains indicateurs harmonisés. Cela concerne, par exemple, les indicateurs fondés sur des enquêtes (Enquête de santé européenne par interview et SRCV/UE), en raison d'un scepticisme généralisé sur la santé auto-évaluée et les facteurs de préjugés culturels. De plus, la comparabilité est affectée par divers autres facteurs, notamment les disparités dans les méthodes de mise en œuvre et de traitement (par exemple, l'incidence du SDRM), les classifications et définitions nationales divergentes (par exemple, la part des cas de jour), les différentes capacités de collecte et de contrôle de la qualité (par exemple, l'incidence du cancer), les modifications de données induites par les politiques spécifiques (par exemple les temps d'attente), etc. Des questions de fiabilité et de comparabilité ont émergé avec la quasi-totalité des indicateurs analysés en profondeur. Cependant, ces questions ne s'associent pas nécessairement à un manque apparent de potentiel pour une utilisation ultérieure, une fois que l'indicateur sera pleinement mis en œuvre de façon cohérente.

Les coûts de production de l'information de santé au niveau des pays est encore une zone peu étudiée, et seules des estimations brutes pourraient être calculées en utilisant un mélange d'évaluations des producteurs de données, d'une analyse de la chaîne des activités sous-jacentes, et d'extrapolations de tâches similaires. La structure et le niveau des coûts varient considérablement, en particulier par rapport à la source et aux méthodes sélectionnées. Les indicateurs basés sur les registres sont particulièrement lourds en raison de frais généraux et lorsque une recherche active est nécessaire. Les enquêtes de population sont également chères, mais la taille des échantillons et la méthode de mise en œuvre choisie (par exemple CATI, auto-administrée, etc.) peut faire une différence significative. Les indicateurs fondés sur les données administratives qui sont collectées régulièrement à d'autres fins (par exemple les registres de sortie des hôpitaux, les tableaux de remboursement des fonds de santé, etc.) sont parmi les sources de données brutes les moins chères.

Les coûts du suivi du traitement des données et des rapports – s'il est effectué au niveau des Etats membres - présentent des variations plus petites. Il se compose

généralement des activités nécessaires pour recueillir des données brutes des points de source (les fournisseurs de soins, les autorités locales / régionales, etc.) ou des ensembles de données d'enquêtes, afin de les valider grâce à un contrôle de qualité approprié, et de les rapporter aux bases de données internationales compétentes. Parfois, les Etats membres doivent faire face à des charges supplémentaires que le mécanisme de mise en oeuvre de l'indicateur n'implique pas strictement. Cela découle principalement de la mise en œuvre parallèle des indicateurs nationaux non harmonisés dans les mêmes domaines d'action et / ou, dans une bien moindre mesure, par des demandes non coordonnées de données provenant de plusieurs entités.

L'utilisation et les avantages des indicateurs de santé de l'UE. La mise en œuvre d'un indicateur (c'est à dire, la collecte et la communication des données) n'est généralement pas suffisante pour s'assurer que les bénéfices attendus se matérialisent. Cela nécessite en premier lieu que de meilleures informations se traduisent par des stratégies et des politiques au niveau des Etats membres qui abordent mieux les priorités de santé de pays et qui améliorent la performance des systèmes de santé, en réduisant les déséquilibres géographiques et les inégalités entre les différents segments de la population. Le processus des politiques (au sens large) est le facteur clé pour contribuer aux objectifs ultimes d'amélioration de la santé de la population et la durabilité des systèmes de santé. Les informations sur la santé sont essentielles pour contribuer à des étapes spécifiques du cycle politique, que ce soit de l'analyse des problèmes à l'évaluation de l'impact des politiques, mais elles peuvent également contribuer indirectement, par exemple via une comparaison des politiques et des performances entre les pays, ou par un soutien plus général à la recherche et à l'innovation, à la sensibilisation des citoyens, et à d'autres surveillances spécialisées et des fins de connaissances.

Le degré d'absorption et d'utilisation d'indicateurs harmonisés dans les États membres peuvent dépendre d'un certain nombre de facteurs, qui concernent l'indicateur lui-même et le contexte national, et qui éventuellement détermine la mesure dans laquelle leur valeur perçue l'emporte, ou non, sur les coûts de mise en œuvre. L'étude a montré que les indicateurs moyens de santé de l'UE sont sous-utilisés dans le processus lié aux politiques, en raison *notamment de:*

- «asymétries» entre l'information produite et les besoins et priorités nationales réels (y compris les éventuelles incohérences avec les spécificités des systèmes nationaux);
- une sensibilisation insuffisante des décideurs et un engagement associé limité sur l'utilisation d'indicateurs dans le processus politique;
- la redondance perçue avec d'autres indicateurs nationaux ou internationaux;
- des aspects d' «utilisation», comme par exemple l'accompagnement des travaux d'analyse et les conseils sur la façon d'interpréter les informations et l'actualité des données.

Certains des indicateurs d'études de cas analysés sont utilisés dans le processus politique, mais plus pour l'analyse de fond et la surveillance générale des tendances que pour établir des objectifs et des engagements politiques spécifiques. L'incidence du cancer, par exemple, est parfois utilisée comme une référence pour les stratégies à long terme, mais à proprement parler l'évaluation des politiques est le plus souvent faite via des indicateurs de résultats (taux de survie) et / ou de prévention (dépistage). Le lien avec la définition des objectifs est plus simple pour des indicateurs de systèmes de santé en relation avec des mesures spécifiques adoptées (par exemple, des garanties de temps d'attente). Les résultats ont montré également la persistance des limitations dans l'utilisation d'indicateurs harmonisés pour quantifier la charge de maladies et la mesure de la performance du système de santé. Il y a des initiatives en cours au niveau international, ainsi qu'un nombre croissant de littératures scientifiques, mais ce

type d'analyse vient d'être intégré dans le processus politique de seulement quelques pays.

En ce qui concerne les autres pilotes de valeur des indicateurs, il existe des preuves convaincantes que certains indicateurs harmonisés ont une «valeur de connaissance» qui justifie leur mise en œuvre, indépendamment de leur impact direct sur les politiques. L'indicateur des infections nosocomiales (HAI) recueilli par l'ECDC est un cas d'espèce dans divers contextes. De manière analogue, les indicateurs d'incidence et de prévalence du cancer sont largement et utilement utilisés pour décrire et analyser les tendances épidémiologiques plus larges. D'autres indicateurs, comme les temps d'attente, ont un potentiel d'intérêt général, bien que la version de l'OCDE semble encore sous-utilisé à cet égard. A l'inverse, les problèmes courants qui affectent la véritable comparabilité des données entre les pays entravent gravement leur utilisation à des fins d'analyse comparative (à savoir la comparaison des politiques et des performances). Bien que les comparaisons directes entre les pays soient donc difficilement réalisables ou importantes, des comparaisons de tendances offrent plus d'occasions précieuses. Cette approche soutient que, indépendamment des spécificités nationales, la mesure stable et cohérente du même indicateur au fil du temps peut permettre une comparaison significative des tendances parmi les pays.

L'analyse et la comparaison de scénarios. Les avantages potentiels de l'harmonisation des indicateurs sont multiples, et offraient, entre autres, de faciliter la comparaison entre des contextes différents, d'offrir des repères solides pour évaluer la performance des politiques et des systèmes de santé, de mettre en commun des données utiles pour la recherche et la connaissance, etc. Les données recueillies indiquent que, en l'absence de toute intervention majeure sur le système d'informations de santé actuel de l'UE, le processus en cours vers une harmonisation des indicateurs de santé parmi les pays peut ralentir, mais seulement pour les indicateurs qui sont perçus comme redondants ou non pertinents pour les besoins du pays. Dans d'autres cas, on prévoit plutôt une augmentation spontanée de la couverture et de la qualité de l'information. Les contraintes budgétaires peuvent imposer des confinements de dépenses, mais cela peut affecter principalement les indicateurs *ad hoc* plutôt que ceux qui sont harmonisés. Si une bonne maintenance n'est pas assurée, l'utilité et la pertinence des indicateurs et des plates-formes de l'UE, comme l'outil de données des Indicateurs de santé de la Communauté européenne, diminueraient probablement, et les parties prenantes se référeraient de plus en plus à d'autres sources nationales ou internationales pour leurs besoins d'informations. Les déséquilibres entre les coûts de mise en œuvre et les avantages réels pour certains des indicateurs harmonisés de l'UE pourraient empirer.

Afin de parvenir à une harmonisation complète et à une mise en œuvre satisfaisante des indicateurs de l'UE d'une manière durable, des investissements importants seraient nécessaires. En particulier, la plupart des indicateurs semblent avoir besoin d'interventions pour augmenter leur robustesse et leur véritable comparabilité en vue de leur utilisation à des analyses comparatives et à des fins politiques. Dans divers cas, ceux-ci semblent être des conditions préalables pour que des avantages potentiels se matérialisent. Dans le même temps, il n'y a aucune garantie que les investissements nécessaires pour une mise en œuvre complète et durable des indicateurs auraient des résultats satisfaisants, car il existe différents degrés d'incertitudes entre la disponibilité d'une information robuste, son utilisation cohérente pour de meilleures interventions et la matérialisation réelle des effets souhaités. En premier lieu, il est essentiel que les indicateurs sélectionnés répondent aux besoins concrets et pressants des politiques et soient conçus à cette fin, ce qui n'a pas toujours été le cas dans le passé. Avant d'investir dans ce domaine, il est également important de considérer que - comme les indicateurs d'études de cas l'ont montré - les coûts augmenteraient principalement dans le court terme, alors que les avantages ne peuvent se matérialiser uniquement dans le moyen / long terme. En outre, la charge

ne serait pas répartie équitablement, mais serait prise en charge par certains États membres plus lourdement que par d'autres.

Conclusions et Recommandations

Améliorer les tendances de consolidation et de coordination. Le développement futur du système d'informations de santé de l'UE apparaît lié à divers processus en cours dont l'issue est difficile à prévoir, par exemple, le projet BRIDGE-Health en cours, les consortiums d'infrastructures de recherches européennes (ERIC) sur un système d'information de santé, la nouvelle initiative de la DG SANTE sur l'état de santé dans l'UE, le JAF-santé, etc. Ceci est associé à la promotion d'importantes initiatives ayant des objectifs similaires par des organisations internationales (par exemple l'Initiative européenne d'informations sur la santé OMS / EURO). Toute intervention possible dans le domaine du système d'informations de santé de l'UE doit dûment tenir compte de la complexité de ce scénario et de son évolution rapide, et devrait viser à contribuer à l'intégration des sources existantes et des mécanismes de gouvernance plutôt que d'en créer de nouveaux, qui pourraient entraîner une source supplémentaire de charge pour les Etats membres.

Améliorer les utilisations d'indicateurs harmonisés liés aux politiques. Les avantages potentiels de disposer d'indicateurs harmonisés de l'UE sont restreints par divers facteurs qui limitent leur utilisation dans le processus politique et à des fins connexes. Certaines de ces problèmes peuvent être résolus par des actions spécifiques et sans avoir recours à des initiatives politiques majeures. En résumé, pour améliorer l'utilisation d'indicateur lié aux politiques, il faudrait: (I) des mécanismes pour réduire le décalage dans la publication d'indicateurs; (Ii) des processus plus souples et plus rapides pour mettre à jour les indicateurs collectés en vue des nouveaux défis politiques pertinents, (iii) des produits "basés sur la connaissance", plus axés sur les politiques, complétant la fourniture d'indicateurs avec des analyses, (iv) une visibilité et des actions de communication adéquates, ainsi que des mécanismes de restitution de l'information aux producteurs de données brutes.

Un deuxième domaine clé de l'amélioration concerne l'accent à mettre sur les résultats par comparabilité et le but que les efforts doivent viser. Comme on le voit, en dépit de spécifications harmonisées, il reste d'importantes disparités de mise en œuvre ou des préjugés propres à chaque pays, qui peuvent empêcher leur utilisation significative pour une analyse comparative entre les pays. La comparaison directe et ponctuelle des points de données des pays est peu informative *en tant* que *tel*le et potentiellement litigieuse. Beaucoup plus prometteuse est l'utilisation d'indicateurs harmonisés pour l'évaluation d'un même pays afin d'évaluer les tendances et de les comparer dans les différents pays.

L'adoption de mesures progressives visant à atténuer le fardeau des indicateurs. L'analyse comparative des scénarios de développement a montré que la réalisation des indicateurs de santé vraiment comparables et entièrement mis en œuvre peut parfois nécessiter des investissements importants dont la raison d'être et la justification ne sont pas évidentes, compte tenu des risques et des contraintes mentionnées ci-dessus au niveau des avantages, et en tenant compte de la pression financière sur certains systèmes nationaux d'information sur la santé. Il est également important de considérer que les possibles avantages des investissements finiraient par se matérialiser après une période de temps relativement longue et que leur ampleur dépendrait d'un certain nombre de facteurs externes qui ne peuvent être contrôlés. De plus les coûts affecteraient certains participants beaucoup plus que d'autres.

A l'inverse, il est possible d'augmenter le rapport qualité-prix du système d'informations actuel en poursuivant des approches pour atténuer le fardeau et pour réduire les couts en fournissant des mécanismes de gouvernance améliorés. En

particulier en ce qui concerne: (i) la consolidation et le filtrage plus rigoureux des initiatives *ad hoc* sur les informations en matière de santé en fonction des besoins réels; (Ii) en conformité avec les travaux récents financés par l'UE, l'occasion offerte par les «données volumineuses» de collecter des indicateurs de santé d'une manière plus rentable que les enquêtes et autres méthodes intensives de ressources; (Iii) l'opportunité offerte par les systèmes (semi)automatisés de collecter des données et de les rapporter, en créant le lien nécessaire avec des développements parallèles dans le domaine de l'e-santé.

2. INTRODUCTION

Nature of the Report. This Draft Final Report (the "Report") has been prepared in the framework of the assignment titled "*Cost/benefit analysis of a sustainable EU Health Information System"* (the "Assignment" or the "Study"). The Report is submitted to the European Commission – Directorate General for Health and Food Safety (DG SANTE) by a grouping led by Economisti Associati s.r.l. including Coffey International Development Ltd. trading as "The Evaluation Partnership", Libero Istituto Universitario Carlo Cattaneo – CREMS, IBF International Consulting and CEMKA-EVAL (hereinafter collectively referred to as "the Consortium" or "the Consultant").

Purpose and scope of the Assignment. The Assignment complements other ongoing activities of the Commission on health information systems and, in particular, it aims at assessing and comparing the costs, the administrative burden and the benefits of the current system based on *ad hoc* indicators with a system based on relevant, harmonised and sustainable indicators implemented across EU Member States. Originally, the findings of the Study were expected to inform the Impact Assessment of a new DG SANTE policy initiative in this area, but the Commission eventually changed policy needs, hence the ultimate purpose of the Assignment has been reviewed, as described in detail in Section 3.

The EU health information system is not defined as such in the EU policy. For the purpose of this Study it encompasses the various health information initiatives and the related indicators developed and implemented at EU-level with the support of EU-funding. In particular the Study has been conducted on six case-study indicators and in a sample of five EU Member States, but with a view to drawing more general EU-level lessons and indications.

The evolving context of health information in Europe was duly considered in the realisation of the Study. This includes ongoing EU-funded initiatives and projects (e.g. BRIDGE Health), as well as the in-the-making 'State of Health in the EU' initiative, and the Joint Assessment Framework (JAF) process. Outside of the EU framework, the WHO and OECD health information initiatives have been taken into account.

Structure of the Report. The Report is divided in two volumes: ***Volume 1 – Main Text, and Volume 2 – Annexes***. Volume 1 is divided into 7 Sections, following the standard structure for evaluation reports provided in the *Better Regulation ToolBox.*[1]

- ***Section 3*** illustrates the background of the EU Health Information System and how the initial orientations had evolved. It also describes the operational context and the various initiatives ongoing or planned at EU-level and by other international organisations;
- ***Section 4*** summarises the underlying evaluation questions of this study, as restructured in the course of the Assignment;
- ***Section 5*** describes the underlying 'theory of change' as well as the methodologies and tools used for data collection and analysis in the various phases of the Assignment;
- ***Section 6*** deals with the 'state-of-play' of the EU Health Information System, the stakeholders overall perception, and provides the results of the mapping of datasets and *ad hoc* indicators initiatives;

[1] SWD(2015) 111, http://ec.europa.eu/smart-regulation/guidelines/docs/br_toolbox_en.pdf

- ***Section 7*** provides a detailed and evidence-based assessment of the various issues at stake. It is divided into four parts dealing respectively with: the implementation of EU indicators in Member States (7.1), the use made of EU indicators and related benefits (7.2), the implementation costs and burden (7.3), the comparison of possible scenarios for the way forward (7.4);
- ***Section 8*** summarises the key findings and provides a set of conclusions and recommendations for the way forward.

Volume 2 contains six Annexes, namely:

- Annex A – List of stakeholders consulted.
- Annex B – The case-study indicators reports.
- Annex C – Survey of stakeholders' datasets.
- Annex D – The consultation documents.
- Annex E – Mapping of EU indicators
- Annex F - Bibliography.

3. BACKGROUND TO THE INITIATIVE

3.1 Background

The background of this Assignment lies in the intention to scale up and systematise the health information available at EU level - both on specific issues and in a cross-country perspective - so as it can better inform policy-making and steer appropriate investments in the health system. The bulk of the existing EU health information system comes from a series of indicators developed by the ***ECHI / ECHIM*** projects and joint actions. The initiatives lasted from 1998 until 2012,[2] and during their lifetime developed and proposed a list of 88 health-related indicators, drawn from a number of different international and project-based sources (first and foremost Eurostat, OECD and WHO). The ECHI did not necessarily coincide with the indicators envisaged in the various Commission's sectoral policies, and did not exhaust the EU-funded efforts to build health information to be used for cross-country comparisons.

The ECHI indicators were meant to be disseminated through the Commission's ECHI Tool. The database was to integrate the information already available in the international databases, such as the WHO *Health for All*, the OECD *Health Data* and the Eurostat databases, and to complement it with ECHIM-originated information directly drawn from national sources. Thus, all national-level data / indicators not already included in the other international datasets could be made available. The ECHI Tool evolved into the ***ECHI Data Tool*** (currently online)[3], which compiles available data on the ECHI indicators and other centrally-collected health indicators, and includes a dashboard with data presentation options.

In 2011, the EU Council first called on the European Commission to consider ways to improve availability of comparative data and information on unhealthy lifestyle behaviours, social health determinants and non-communicable chronic diseases.[4] These had to be obtained from sustainable health monitoring systems already in place or to be eventually established at the EU-level. Then, in 2013 the EU Council more specifically invited the Commission and the Member States to cooperate with a view to establishing a ***sustainable and integrated EU health information system***, built on the outcome of ECHI /ECHIM Joint Actions and the work of other similar groups and projects.[5]

In 2011, the European Parliament had asked the Commission to look at the possibilities of extending the remit[6] of the ***European Centre for Disease Prevention and Control*** (ECDC) to encompass also non-communicable diseases and using it as a centre for data collection and development. Moreover, some Member States had also called for the establishment of a new European Agency to this aim, or alternatively for the extension of the mandate of the current ones to cover health information. However, the recent independent evaluation of ECDC showed there was little consensus on extending the ECDC mandate to non-communicable diseases and

[2] The European Community Health Indicators (ECHI) initiative started more than a decade ago with the 1997-2002 EU Health Monitoring Programme, which included several projects about developing health indicators aimed at overcoming the difficulty to get a harmonised picture of Europeans health conditions at that time. In 2007, the implementation of the ECHI system became one of the explicit objectives of the EU Health Strategy and the ECHI initiative was supported by the creation of a dedicated ECHIM project (where "M" stands for monitoring). In 2008 ECHIM was financed as a joint action.

[3] http://ec.europa.eu/health/indicators/indicators_en

[4] Council of the European Union conclusions of 1-2 December 2011 on closing health gaps within the EU through concerted action to promote healthy lifestyle behaviours.
http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/126524.pdf

[5] Council of the European Union conclusions of 10 December 2013 on the 'Reflection process on modern, responsive and sustainable health systems'.
http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/lsa/140004.pdf

[6] This option is envisaged in the ECDC founding regulation

significant obstacles to consider.[7] In more general terms, the evaluation of the use and impact of ECHI highlighted a general agreement on the need to move away from a project-based approach and pursue ECHI embedding into a permanent, institutional mechanism at EU level.[8] The evaluation also found that the ECHI shortlist should be given a clearer legal status, as this has represented a barrier to its uptake in a number of countries.

As a follow up of the 2013 Council Recommendation, the Commission ***Expert Group on Health Information (EGHI)*** – which involves Member States and other key stakeholders - also called for the setting up of an EU health information system which would use the European Core Health Indicators (ECHI) as a basis for improving the availability of health information across the EU. The EGHI Members prepared a scoping paper for the establishment of a ***European Research Infrastructure Consortium*** (ERIC)[9] on Health Information – an approach explicitly mentioned also in the 2013 Council Conclusions. The purpose was to offer a basis for discussion, since several Member States were still of the opinion that the extension of the ECDC mandate would constitute a better option. A relevant previous experience existed, i.e. the SHARE-ERIC (the Survey of Health, Ageing and Retirement in Europe) - a multidisciplinary and cross-national panel database of micro data on health, socio-economic status and social and family networks.[10] The EGHI scoping paper considered transferring the indicators developed under several relevant EU projects to the prospected EU health information system. The proposed ERIC was supposed to support not only the Commission, but also international actors like OECD and WHO, thus fostering the harmonization of indicators across the different organisations and remove duplications.

In 2015 the ***BRIDGE Health project*** was launched, with the aim *inter alia* to prepare the transition towards a sustainable and integrated EU health information system supporting evidence-based health policy and research for the EU and Member States[11] To this end, BRIDGE Health builds on the outcomes of a series of previous EU projects that focused on various domains, such as health system monitoring, indicator development, data collection systems and methods, registries etc. with a view to enhancing synergies, transferability of information, and continuity. The project will provide blueprints and/or concepts of building blocks for a future EU health information structure, evaluating among others the above ERIC option. The Project includes a working package specifically dedicated to the maintenance of ECHI indicators with the following key tasks and objectives:

- Revitalize and strengthen the network of national capacities for assessing, reviewing, developing and using ECHI-indicators;
- Map the data availability for the ECHI Shortlist in EU-Member States;
- Perform technical and content-related evaluations of the current ECHI-indicator approach including, where necessary, revisions and further development of the current ECHI Shortlist;
- Design and fill a European health indicator repository;
- Contribute to capacity building.[12]

[7] Economisti Associati, The second independent evaluation of the ECDC in accordance with its Founding Regulation (European Parliament and Council Regulation (EC) no 851/2004), October 2014, http://ecdc.europa.eu/en/aboutus/Key%20Documents/ECDC-external-evaluation-2014.pdf
[8] Economisti Associati, Evaluation of the use and impact of the European Community Health Indicators ECHI by Member States, August 2013, http://ec.europa.eu/health/indicators/docs/echi_report_v20131031.pdf
[9] http://ec.europa.eu/health/strategy/docs/hi_eric_scopingpaper_en.pdf
[10] SHARE-ERIC covers approximately 110,000 individuals (more than 220,000 interviews) from 20 European countries. http://www.share-project.org/contact-organisation/share-eric.html
[11] BRIDGE Health stands for **BR**idging **I**nformation and **D**ata **G**eneration for **E**vidence-based **H**ealth policy and research. http://www.bridge-health.eu/
[12] Source: http://www.bridge-health.eu/content/european-core-health-indicators-monitoring

3.2 The Proposed Policy Initiative and the Evolving Framework

The initial proposed policy initiative. Against the above-described framework, DG SANTE included in its Roadmap a possible policy initiative consisting of the adoption of a Decision on the establishment of a sustainable EU Health Information System. In the first half of 2016, the Commission policy needs were re-oriented and the focus of the study was adjusted accordingly.

In its initial intentions, the initiative involved the creation of a sustainable governance system for the definition of EU health indicators that would put MS at the centre of the process, by means of a dedicated Comitology process responsible for selecting and formally adopting a set of selected indicators maintained by a separate structure (e.g. the abovementioned ERIC), and collected by Eurostat and/or other international organisation under enhanced cooperation agreements. The objectives of the initiatives included (i) improving the collection of the indicators needed for policy-making and key investment decisions; (ii) ensuring a better implementation of data collection; (iii) reduce the burden for reporting health data; and (iv) scaling up (via the JRC) the implementation of registries on cancer and rare diseases in the EU. A broad convergence of and synergy with parallel initiatives was also envisaged and in particular:

- the *Health System Performance Assessment* (HSPA) process (methodologies and tools),
- the *Joint Assessment Framework on Health* (JAF Health) initiative of the Social Protection Committee,
- the *European Semester* process, as far as the evaluation of health systems challenges are concerned,
- the implementation of the *Eurostat Regulation on Public Health Statistics*,
- the EU Strategic Framework on *Health and Safety at Work 2014-2020*,
- the implementation of the Directive on *Patient's Right in Cross-border Healthcare*,
- the development of a *Digital Single Market* for the health sector.

'State of Health in the EU'. In June 2016, the Commission announced the State of Health in the EU initiative for 2016-17. This is a joint undertaking of the European Commission, the OECD and the European Observatory on Health Systems and Policies, in collaboration with Member States. The stated aim is "to boost analytical capacity and support Member States with their evidence-based policy making".[13] The exercise is structured over a two-year cycle including four deliverables:[14]

- "The bi-annual Health at a Glance: Europe report, prepared by the Organisation for Economic Co-operation and Development (OECD), with the latest edition published in November 2016;
- A package of individual country health profiles for each Member State, prepared by the OECD and the European Observatory on Health Systems and Policies in cooperation with the Commission, first available in November 2017;
- A Commission paper to accompany the country health profiles. The flagship report will build on the findings from the two deliverables above, linking them to the broader EU agenda, emphasising cross-cutting policy implications, the potential for mutual learning and highlighting EU added value;
- The fourth action, offered as soon as the second and third are released (starting November 2017), comprises voluntary exchanges that Member States can request to discuss best practices and other findings from the State of Health in the EU."

[13] Commissioner for Health and Food Safety Vytenis Andriukaitis presentation at the EPSCO Health Council in Luxembourg, June 2016.
[14] Source: http://ec.europa.eu/health/state/summary_en

Cross-country benchmarking is an essential aspect of the 'State of Health in the EU' initiative and the underlying package of country health profiles. This requires that the indicators used in this exercise are comparable. In other words, the country health profiles entail *de facto* the harmonisation of a set of underlying health indicators, although by means of a voluntary rather than a legal obligation. Country level indicators will be drawn from the *Health at a Glance* Report, which in turn may relate to a number of data sources, including health statistics databases (Eurostat, WHO, OECD), and may build on the existing indicator repositories like the ECHI shortlist and the JAF Health initiative, or the *Health Systems in Transition* (HiT) series of the European Observatory on Health Systems and Policies.[15] In this respect, the scope and variety of 'State of Health in the EU' indicators seem larger than what originally envisaged for the EU Health Information System, which was mostly intended for the stabilisation and sustainability of (a set of) ECHI indicators.

The evolving framework of the Assignment. The present Assignment was commissioned in the context of the above policy initiative process, with a view to collecting and elaborating factual evidence on the respective costs and benefits of leaving things as they are now (no policy change) or undertaking different possible policy approaches. In fact, despite policymakers and experts (EGHI) alike concurred on the shortcomings of the current *ad hoc* system, the extent of the current inefficiencies and of 'missed opportunities' had never been investigated systematically. In this sense, the policy process required more evidence in order to come to an informed decision on whether or not to proceed with the envisaged policy initiative.

Following a change in the policy needs of the Commission, in the second meeting held in mid-April 2016, it was eventually agreed with the Client to maintain the focus of the Study on the costs and the benefits of having harmonised indicators in place, but without reference to a specific policy initiative. It was decided that the Study should rather review the current implementation status, highlight possible inefficiencies and look into the demand of beneficiaries for soft actions (if any) aimed at redressing current issues and improving the costs/ benefits balance. Finally, the need was highlighted to include the 'State of Heath' initiative in the picture, to avoid further fragmentation and inconsistencies, and to ensure maximum coherence and synergy across all processes falling under the general heading of the EU Health Information System.

[15] HiT summaries are not based on a formally established list of indicators but constitute the basis for the development of various qualitative indicators possibly useful for country health profiles.

4. EVALUATION QUESTIONS

Purpose of the Assignment. According to the initial Specifications, the purpose of the Assignment is "to evaluate the costs and the benefits of different health information systems" and in particular a system built on *ad hoc* indicators versus a system built on a sustainable ground. The Specifications further clarified that the comparison concerns two main dimensions: (1) indicator development (covering all activities needed to operationalise an indicator, including definition, specifications etc.); (2) reporting data for the calculation of the indicator (to different organisation separately or in a harmonised way).

This formulation reflected the initially envisaged policy initiative described above, and the need to conduct an Impact Assessment on it. As the policy initiative was suspended, one of the two comparator of the exercise ceased and the emphasis of the Study shifted from comparing two clear policy options (through quantitative techniques) to a broader assessment of the current situation and its merits and constraints against a theoretical situation where fully harmonised and relevant indicators are implemented comprehensively and consistently across MS. In the design of the Study this speculative scenario served as a benchmark to estimate the current gap, the efforts needed to bridge it, and to comment on how the possible benefits may or may not justify further investments.

The research / evaluation questions. The ToR did not contain explicitly a list of evaluation questions, but they can be inferred triangulating the above objectives, the set of operational tasks foreseen, and the clarifications provided by DG SANTE at the time of re-orientation of the Assignment. The evaluation (or research) questions of the Assignment can be formulated as follows:

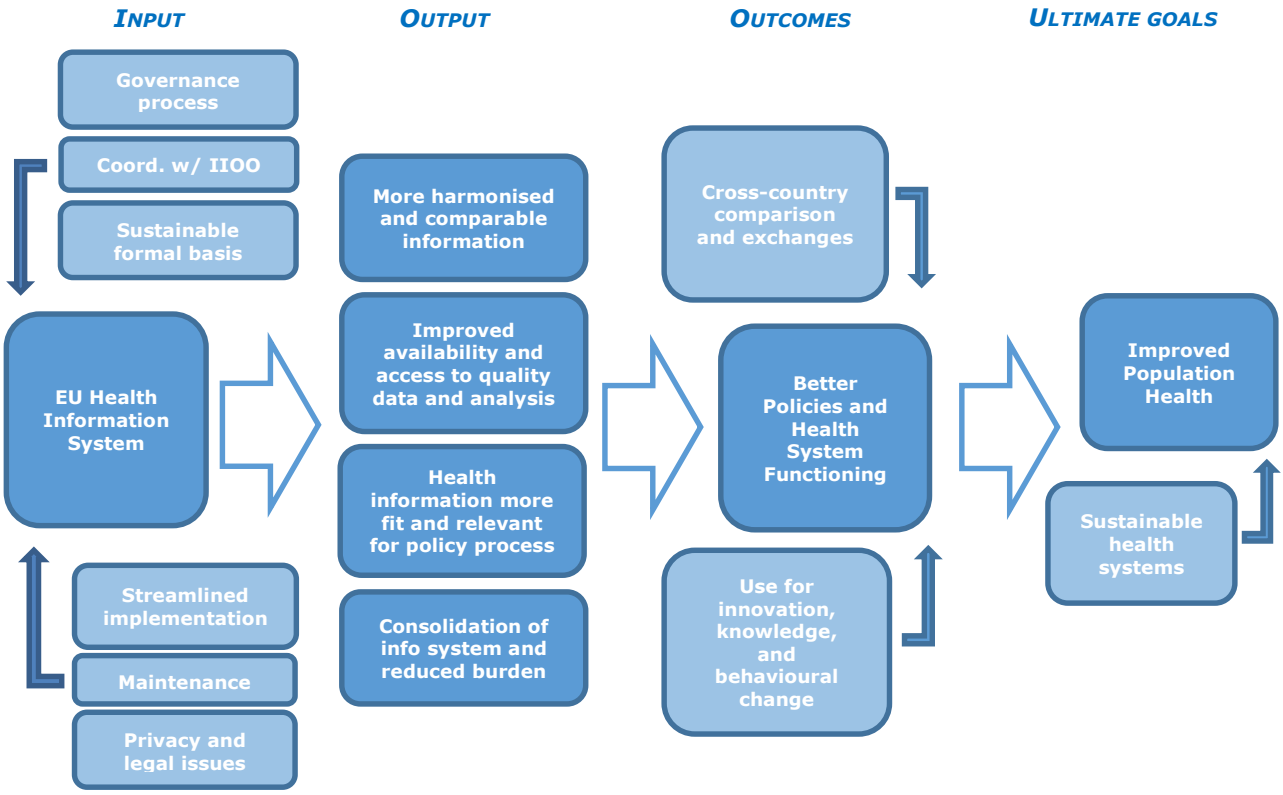
1. What is the level of adoption of EU indicators in Member States? To what extent they have become part of the national health information system? Are there parallel concurrent indicators in place (nationally or internationally-defined)?
2. What is the implementation status of indicators in Member States? To what extent are data coverage and details satisfactory? Are data robust and reliable? Is maintenance and update ensured? What is the true degree of harmonisation of the indicator reported by different countries?
3. To what extent are harmonised indicators implemented in MS actually taken up and used by stakeholders and beneficiaries? What is the perceived utility and added-value? How are indicators used in the policy process, cross-country benchmarking, or other knowledge purpose? What are the expected benefits and the possible influencing factors?
4. What are the costs and burden borne by competent authorities and the different players involved in collecting raw data, processing and elaborating them and reporting/transmitting them to the relevant EU or international databases? What is the 'avoidable' burden associated to duplication of efforts and other constraints? What is the perceived balance between aggregated implementation costs of indicators and the actual and potential benefits form their use?
5. What would be the likely evolution with the implementation and use of EU indicators if no further action is taken at EU level? Conversely, what is the level of efforts needed to achieve an optimal and sustainable implementation and use of indicators? How do these effort possibly compare with the level of benefits that can be expected?
6. Based on that which recommendations for the way forward can be formulated, having in mind that a fully-fledged policy initiative is not envisaged?

5. METHOD/PROCESS FOLLOWED

5.1 The Underlying Theory of Change

Overview. The methodological design of the Study is supported by an underlying 'theory-of-change' (TOC) describing how the EU Health Information System may contribute to generate health gains for the population and to improve health systems on the whole. The TOC (illustrated in Figure 5.1.1 below) describes the 'results chain', from the inputs to the direct outputs of the Health Information System, and the expected contribution to broader outcomes, which are the drivers for the materialisation of ultimate goals. The TOC is a theoretical model whose aim is to isolate and highlight specific elements and causal (or contribution) links to be analysed in greater depth. The model is also intended to provide a reference framework enabling the comparison between the current situation and alternative scenarios for the way forward. Being a synthetic and abstract model it does not list exhaustively all the possible factors at play but only those deemed fundamental. A first version of the TOC was included in the Consultant's Proposal. The current one is a modified version that takes into account the revised focus of the Assignment.

Figure 5.1.1 - Overall Theory of Change



In this model, the ***Input*** coincides with the EU Health Information System, not intended as a structure or facility in the strict sense (as clarified by DG SANTE in the inception phase), but rather in functional terms, i.e. the aggregate of EU-level policies and strategies, governance and maintenance mechanisms, funded-initiatives etc., that underlies the production of health- and health system-related indicators and the corresponding analyses and dissemination activities.

The theoretical model does not distinguish between the current 'ad hoc' system and a sustainable system, since the difference between the two consists in how they deal

with a few main factors and the underlying arrangements. As concerns 'internal' factors, the most relevant appear to be: (i) the overall burden of implementing indicators and possible streamlining measures; (ii) the maintenance and update of the indicator; (iii) the efforts to remove legal obstacles that may hinder or increase the costs of implementation. As concerns 'external' factors related to the operating environment, the most relevant appear to be: (i) governance mechanisms to mainstream the MS policy-makers' demand and needs into the system, for a greater participation, ownership and alignment; (ii) mechanisms for the effective coordination with the other international organisations; and (i) a policy framework providing a formal and sustainable status to selected indicators as well as the mechanisms and procedures pertaining the EU Health Information System.

The direct ***output*** of such system can be manifold but for the purpose of the analysis four main interrelated items have been considered: Firstly, the sheer availability of health data of sufficient quantity (e.g. coverage, details etc.) and quality (robustness, reliability etc.), as well as appropriate tools for access to datasets, dashboards, and supporting analytical work. Secondly, the production of information that is fit and relevant for the policy process (at MS and EU level), i.e. informed by policy needs, usable for policy evaluation, etc. Thirdly, the production of indicators that are truly comparable and not only formally harmonised, i.e. that takes into account country's specificities and cultural bias, and are not subject to other 'hidden' causes of disparity. Finally, the reduction of unnecessary burden due to fragmentation of initiatives and other inefficiencies. The current 'ad hoc' or a potential sustainable system may evidently deliver this output with a different degree of success.

The above output may fully or partly translate into broader ***outcomes,*** which are also the ***intended benefits*** of having comparable health indicators in place in the EU. The level of outcome primarily depends on the actual use of harmonised indicators and the related health information, but not entirely. The materialisation of the expected benefits requires also other external conditions and factors that vary across countries and policy areas. In this sense, there is no causal relation between the output (health information produced) and the outcomes (e.g. improved health policies) but a more undetermined contribution.

- First and foremost, robust health indicators may ***enable MS-level strategies and policies*** that better tackle country's health priorities and improve health systems performance, reducing also the geographical imbalances and inequalities across segments of the population. In fact, their presence might eventually translate into: (i) efficiency gains / cost savings, (ii) improved health outcomes / reduced health risks, (iii) better programming of health systems.
- In addition to that, in order to have a European added value from data comparison, institutional mechanisms must be in place so that these information needs are translated into indicators common to all MS and are subsequently communicated to relevant stakeholders or the public at large. The added-value of the EU Health Information System (and similar supra-national systems), lies to a great extent in the opportunity it offers to ***benchmark policies and performances between countries***, and induce through it policy changes and reform.
- The link with the policy process may also be indirect, and contribute to make policy change happen by providing stakeholders with ***robust evidence and more comprehensive knowledge***. In this sense, harmonised and comparable indicators may (i) support research and innovation; (ii) inform the activities of public health experts, health professionals, caregivers etc.; and certain indicators may also (iii) respond to an information demand of the general public (public accountability) and/or be helpful in nudging citizens' behaviour.

If and how indicators-enabled policies and strategies may lead to attaining ***ultimate goals*** for national health systems and the population at large further can only be assumed on a theoretical basis, since the impact of possible reforms should be seen in the light of broader societal trends that vary case-by-case. This dimension is reported in the TOC mostly to underline the existence of a further layer of complexity, which makes any attempt to quantify the benefits of health information system at this level extremely speculative.

The merits of comparable indicators and possible alternatives. As part of the theoretical model used in this Study to assess the rationale for strengthening the EU Health Information System, it is useful to compare the apparent merits of cross-country comparison through harmonised indicators with existing alternatives, i.e. using exclusively national (non-harmonised) indicators for policy-making purposes. It is important to underline that this represents a highly hypothetical counterfactual scenario, since EU harmonised indicators are a fact, and there is no country in the EU where they are neglected. As discussed further below, there can be situations where formally harmonised indicators are actually not fully comparable, but no country relies entirely on indicators that are different from those formalised at supranational level.

- ***Benefits from comparable indicators*.** Comparable indicators are for a MS a way of assessing the performance of their health systems and of benchmarking it against other countries. These measurements are aimed to:
  (i) identify good and bad service delivery practice, or good and bad practitioners;
  (ii) design health system reforms;
  (iii) protect patients
  (iv) increasing the efficiency of public resources; or
  (v) make the case for investing in health care.

  These expected benefits are made possible by changes in information technology and associated advances in measurement methodology and presuppose that most health systems have similar goals and face similar challenges, such as demographic change, limited resources and rising costs.

  International comparisons are therefore assumed to provide vast potential for cross-country learning. In particular, through comparative assessments of health system performance, policy-makers are provided with a benchmark that allows them to identify *in which areas* they are performing above or below expectations. Even more importantly, comparison of harmonised indicators – when accompanied by adequate analysis - provides them with tools to understand what *the drivers* of performance are as well as guidance on where to look for *potential solutions* to problematic aspects.

  According to public health research, the major benefit of international comparisons is their potential to provide a snapshot assessment of different experiences and to constitute a 'quasi-experimental laboratory'.[16] In fact, international comparisons offer the possibility of:
  (i) exploring ***new and different policy options***;
  (ii) ***mutual learning*** and even policy transfer of best practices implemented elsewhere; and

[16] The seminal contributions in this respect can be considered Nolte, E., Wait, S. and McKee, M. Investing in health: Benchmarking health systems, London, 2006 and Nolte, E. et al. Learning from other countries: an on-call facility for health care policy, Journal of Health Services Research and Policy, 13 pag 58–64., 2008; Nolte, E. and McKee, M. (2008). Measuring the health of nations: updating an earlier analysis, Health Affairs (Millwood) , 27(1): 58–71; Nolte, E. (2010), International benchmarking of healthcare quality. A review of literature. RAND Europe.

(iii) ***reconsidering and reviewing national policy*** in the light of concrete evidence.

International benchmarks can help formulate national policy programmes and priorities. For instance, the National Scorecard on U.S. Health System Performance assessed how well the United States health system performed in relation to comparable benchmarks from a set of six other industrialized countries. Similar initiatives are routinely carried out in Canada and Australia. This may regard also specific policy areas, as in the positive cases reported in Box 5.1 below.

Box 5.1 – Examples of international benchmarking as a policy-making driver

Cancer policy in the UK. Cancer has long been a major issue in British health policy, not only because of the large burden of the illness but also from the policy debate raised by benchmarking with other Countries. Actually comparative evidence on cancer survival indicators provided within the framework of the EUROCARE project proved instrumental in the development and implementation of a comprehensive national cancer programme and the waiting times to receive cancer treatments entered the political debate. Benchmarking with other neighbouring Countries on cancer survival rates that highlighted a relatively bad performance triggered the Department of Health to carry out a retrospective baseline audit of waiting times for patients diagnosed with cancer in the UK, which confirmed the size of the problem. The EUROCARE study findings published in the European Journal of Cancer showed that in the period 2009-2015 survival rates to cancer improved in most of EU countries, but not in the UK. The cancer survival indicator was at 79.1% in England, 78.5% in Scotland, and 78.2% in Wales, whereas the EU average was 81.8%. In the case of bowel cancer, the UK was about 5-6 percentage point below EU average; for prostate cancer Austria and Finland scored survival rates 10 percentage point higher than the UK. The analysis demonstrated that the major differences reflected poor rates of early diagnosis in the UK, with one in five cancers not spotted until a patient arrives at Accident & Emergency departments. As a result of the publication of the comparative study, the Health Secretary announced that from 2020 patients with suspected cancer will be given a definitive diagnosis or the all-clear within a month, in a bid to tackle late diagnosis.

Infant mortality in the Netherlands. In a similar vein international benchmarking on infant mortality data made available by the EURO-PERISTAT project triggered a policy debate in the Netherlands, because of the country's poor performance (the second worst in the EU). The role played by the strong preference for homebirths was considered controversial by analysts, however reforms to reduce the infant mortality rate were introduced and perinatal infant mortality rate has subsequently decreased.

- ***Benefits from national alternatives to comparable indicators*.** There are differences between benchmarking international health indicators and using national frameworks of reference for health indicators. First of all, international frameworks inevitably require a consensus, which is often a compromise, on the major goals and key components of the health system aspects worth measuring. These measurements can be very broad in scope as they are targeted at influencing general systemic reform. National measurement frameworks, on the other hand, more narrowly focus on national health system governance and administration, which may range from pervasive hands-on management to more detached supervision and steering by incentives.

  International comparison schemes have been developed with the aim of helping national systems to improve through mutual learning, but despite an increased availability of such schemes there is only limited evidence of change. A first possible explanation is that often international comparisons focussed pragmatically on areas where the information is abundant and easy to collect, which are not necessarily the priority areas for policy reform. Secondly, the significance of comparisons may be jeopardised by a lack of sufficient understanding of differences and specificities of national set-ups and *modus operandi*, and the risk

of misinterpretations is high. These problems do not affect national indicators and measurement frameworks, which maytherefore be preferred. To sum up, the factors and conditions that may prompt the recourse to national health indicators are as follows:

(i) The dynamic of certain indicators may embrace factors that are beyond the control of national health authorities and policy-makers, or poorly lend themselves to be directly tackled via specific interventions. National indicators may lie more within the actual outreach of competent authorities.
(ii) Health indicators used for benchmarking do not necessarily consider the link between resource allocation and performance and may, for instance, call for investment in areas that are not one countrys' priorities.
(iii) International indicators are often built on guiding normative principles about the desirable targets and performance, which are not necessarily shared by decision-makers and other stakeholders in the different countries and/or may conflict with the interests of other groups.
(iv) Differences in terminology, coding and broader cultural factors may limit direct comparison of certain data, especially survey-based indicators.
(v) The interpretation of indicators is far from straightforward, given the complex and multidimensional nature of underlying health problems, and should be fine-tuned to specific MS circumstances as in the example reported in Box 5.2 below.
(vi) Finally, and possibly even most importantly, health outcomes respond to health policies with a time-lag that is typically long (e.g. in the case of cancer incidence). Cross-country benchmarking is generally not able to capture this dynamic, depriving comparison of much of its value. One-country assessment of historical series is more suitable in this respect.

Box 5.2 – Examples of difficult interpretation of comparative indicators.

The health Consumer Powerhouse has long released its Euro Health Consumer Index that benchmarks the performance of the different European States from a patient's perspectives. The last Euro Health Consumer Index[17] notes that the most dramatic reduction of MRSA rates has taken place in the UK, with a percentage of resistant infections dropped from ca. 40 % in 2006 to ca. 15 % in 2014.[18] This result seems due to intense and effective efforts in hospital hygiene, and not to a reduction of antibiotics prescriptions. On the contrary, the OECD "Health at a Glance" data on the volume of antibiotics prescribed showed that the per capita consumption in the UK has been increasing faster than in the rest of EU, from 14 to about 21 defined day dosage per 1,000 individuals between 2000 and 2014.[19] In the case of UK, the MRSA incidence indicator can therefore be eloquent on the improvement of healthcare practices, but may be misleading if used to assess anti-microbial resistance policies on the whole. Only a careful analysis may provide the correct interpretation.

With respect to antimicrobial resistance policies, the issue of antibiotics prescriptions has become a public health priority over the past two years. At the end of 2015, Public Health England published a guidance on antibiotic consumption[20], and general practitioners have been given economic incentives to decrease prescriptions. This objective has been taken up by NHS and, reportedly, the total number of antibiotics prescribed went down by over 2.6 million in one

[17] Health Consumer Powerhouse, "Euro Health Consumer Index 2016", Report, January 2017. http://www.healthpowerhouse.com/files/EHCI_2016/EHCI_2016_report.pdf, pag. 43
[18] The sources used by the Consumer Powerhouse are ECDC's EARS-Net surveillance reports. In particular, see: (1) ECDC, "Antimicrobial resistance surveillance in Europe 2009. Annual Report of the European Antimicrobial Resistance Surveillance Network (EARS-Net). Stockholm: ECDC; 2010; and (2) ECDC, "Antimicrobial resistance surveillance in Europe 2014. Annual Report of the European Antimicrobial Resistance Surveillance Network (EARS-Net). Stockholm: ECDC; 2015. EARS-net data show a marked decline in MRSA incidence, however, as discussed in other Sections of this Report, this indicator has to be taken with caution since incidence tends to be higher in MS with better or more rigorous detection capacity (such as the UK).
[19] Source: OECD, "Health at a Glance", various editions of the report, from 2005 to 2016.
[20] https://www.gov.uk/government/publications/health-matters-antimicrobial-resistance/health-matters-antimicrobial-resistance

year alone.[21] Also in this case, the process seems completely unrelated with the MRSA incidence trends in the country.

[21] https://improvement.nhs.uk/news-alerts/helping-gps-cut-antibiotic-prescriptions/

5.2 Data Gathering Methodology

5.2.1 Overview

The findings of the Assignment are based on the triangulation of several sources of evidence, including direct consultations of key informants, desk review of documentary sources, and research on relevant databases. The main design and implementation features of the methods and tools for data collection and analysis used in the Evaluation are described further below. For better clarity, the various methods and tools used are referred to in the Report as follows:

i) ***Case-Studies***, i.e. in-depth analysis of six internationally-harmonised indicators selected in agreement with DG SANTE, and representing different policy areas and implementation modalities. Case-studies involved field-work in five Member States, interviews with key informants and gathering of documentary sources.

ii) ***Consultation of stakeholders***, i.e. a web-based questionnaire survey addressing public health experts, policy-makers, statistical offices, and major other stakeholders in all EU MS, EFTA countries and EU candidate countries – as well as a parallel survey of EGHI members. Additionally, a few in-depth interviews with major DG SANTE partners and with selected EU-level industry, professional, patients and other stakeholder organisations.

iii) ***Desk research*** covering both case-study indicators and health information system at large. Including EU policy and initiatives, international organisations reports and strategies, scientific literature and miscellaneous grey literature.

iv) ***Mapping*** of existing EU and other international organisations health databases, as well as ad hoc indicators developed in the framework of major EU-funded initiatives.

To set the stage for the various planned activities, the Consultant carried out during the inception phase a ***stakeholder analysis***. This horizontal task involved an initial mapping of the key national players potentially involved in data collection, reporting and use, in the five MS selected for the fieldwork, as well as preparation of a long-list of potential respondents for the survey of the stakeholders.

5.2.2 Case-study indicators

In accordance with the Specifications, the Assignment involved an in-depth analysis of six case-study indicators. The provisional list of case-study indicators provided in the Specifications has been modified during the Inception Phase in agreement with the Commission, to ensure the maximum coherence with the 'State of Health in the EU' process, and the revised scope of the Assignment. The objective of the revision was to have an overview of different typologies of indicators with peculiar cost implications and therefore a list inclusive not only of representative ECHI Indicators drawn from the EHIS survey, but also comprising indicators at different development stages used under the JAF, ECDC pilot indicators and indicators jointly gathered with the OECD and the WHO.

The proposed sample, is provided in Table 5.2.1 below. A more detailed description of the indicators is provided in Section 6.3. The criteria underlying the choice of case-study indicators can be summarised as follows:

- All case-study indicators have been chosen from the list of 'core' or 'supplementary' indicators tentatively identified for 'State of Health in the EU' (based on the version available at the time of the Study design). This not only allowed avoiding duplication or further fragmentation but was also a confirmation

of their perceived utility for policy-making (given the policy-orientation of the initiative). Three different categories of indicators identified in the 'State of Health in the EU' are represented in the sample, in particular (i) Health Status; (ii) Determinants of Health; and (iii) Assessment of Health System, further broken down by effectiveness, accessibility and resilience.[22]

- The sample should include primarily but not only ECHI indicators (e.g. MRSA Incidence is not in the ECHI shortlist), and have different ECHI status. In the sample selected, there are ECHI indicators fully implemented and measured (e.g. healthy-life years, total alcohol consumption); ECHI indicators implemented but with data not available or incomplete (cancer incidence, share of day cases, hazardous alcohol consumption); ECHI indicators identified but not fully developed (waiting times for elective surgeries).
- To represent the variety of EU and non-EU sources, it seemed also important to include indicators based on data collected by different institutions or facilities. In this sense, the sample includes two EUROSTAT indicators based on different data sources (Healthy-life years, and the EHIS-based hazardous alcohol consumption), one indicator from ECDC, one indicator from OECD, and two indicators from the international system (IARC data on cancer and WHO-GISAH data on total alcohol concumption). The 'share of day cases' indicator represents an interesting instance of joint collection (EUROSTAT / WHO / OECD).
- Methodological considerations also played a major role in the selection. The proposed indicators present different features as regards: (i) the level of stability; (ii) the degree of harmonisation; (iii) the different data source (clinical reporting systems, population based survey, administrative sources, epidemiological registries etc.); (ii) the actual collection of corresponding data. The intention was to take into account the variety of possible impacts and the different types of costs and benefits for the different stakeholders that may arise from different types of indicators.
- As much as possible emphasis was placed on thematic aspects that rank high on the EU agenda, i.e. have been the subject of major recent initiatives, or will be in the near future.

[22] It was proposed not to cover other indicators of the organisation of the health system due to their mostly descriptive character, and to include two health status indicators, so as to balance a selection that otherwise can be excessively skewed on health system performance.

Table 5.2.1 – Proposed List of Case-Study Indicators

#	Indicator	State of Health - Category	ECHI chapter and status	Type of data	Data source
1	**Cancer incidence and prevalence**	Health Status	[20] – Health Status Implementation Section (not available on ECHI Data Tool)	Incidence mostly based on *cancer registries*. In some MS complemented by survey data. Prevalence, extrapolated from incidence data through *modelling*.	IARC GLOBOCAN and CI5 databases[23]
2	**Healthy life years**	Health Status	[40] – Health Status Implementation Section (available EU 28)	Second-level indicator, combining: Interview survey data on self-perceived health (GALI), and Life expectancy (demographic mortality data)	EUROSTAT
3	**Total and hazardous alcohol consumption**	Determinant of health	[46, 47] – Determinants of Health *Total consumption* – Implementation Section (available EU28) Hazardous consumption – Implementation Section (not available on ECHI Data Tool)	Total consumption: mixed data including surveys, industry data, FAO database. Hazardous consumption: European Health Interview Survey (EHIS) from EUROSTAT.	WHO-GISAH (Total) EUROSTAT (Hazardous)
4	**Healthcare associated infections (MRSA Incidence)**	Health System Assessment - Effectiveness	Non-ECHI	Overall Healthcare Associated Infections: Point Prevalence Survey (carried out at hospital level) MRSA Incidence: statistics from The European Surveillance System (TESSy) based on case reporting from laboratories and healthcare providers in the EARS-Net	ECDC
5	**Waiting time for elective surgery**	Health System Assessment - Accessibility	[81] – Health interventions Development section	Administrative records (healthcare providers discharge registries). Interview-based alternatives are also being proposed.	OECD
6	**Share of surgical procedures performed as day cases**	Health System Assessment - Resilience	[73] – Health intervention Implementation section (not available on ECHI Data Tool, only overall number of surgery is provided)	Administrative records, collected in a harmonised manner, through the Joint Questionnaire	OECD-WHO-EUROSTAT

[23] http://globocan.iarc.fr/Default.aspx

The ***Interview programme*** for the case-studies covered five 'sample' Member States selected during the inception phase, namely: Finland, Poland, Italy, France and the Netherlands. The main focus of the interviews was to discuss the status and implementation of the six case-study indicators selected for the Study, as well as to discuss the possible impact of two scenarios: (1) a change toward a more sustainable EU Health Information System and (2) no change of the *status quo*. In the first stage, the Consultant developed specific 'Research Frameworks' for each of the six case-study indicators considered (see Annex B). The use of common Research Frameworks – although tailored on the specific indicators – ensured a consistent analytical approach across the sampled MS. A generic checklist was also developed to guide the discussion with transnational organisations with more global interests on cross-country health indicators.

Direct contacts with potentially interested informants were developed in parallel with the preparation of the Research Frameworks. The selection of counterparts was largely informed by the stakeholder analysis conducted in the inception phase, complemented by the indications of the corresponding EGHI members who helped the Consultant in all the five MS selected identify the key informants and stakeholders best-positioned to respond to the research questions.

As detailed in the Table below, some 65 relevant informants were interviewed overall (see Annex A for the full list), in line with the initial targets. It is important to highlight that these figures refer to individual interview settings and not physical persons. In fact, in many instances interviews involved several staff from the same office or service. In-depth interviews in the Member States involved the most relevant national authorities and experts responsible for: (i) the development / maintenance of indicators; (ii) the analysis, statistical treatment and reporting of the indicator; (iii) the possible policy use of the indicator. Depending on country specific health system organisation, interviews involved staff of the Ministry of Health, the public health institution, national statistical offices, thematic agencies and bodies (e.g. cancer registries, alcohol control agencies), expertise and research centres etc.

Table 5.2.2 – Overview of the in-depth interviews carried out

	Finland	France	Italy	Netherlands	Poland	Multi-Country / EU Level	Total
Number of interviews	9	11	11	8	14	12	**65**

5.2.3 Consultation of stakeholders

On-line surveys. The second major source of evidence used in the Assignment to integrate and extrapolate the evidence from the case-studies was a qualitative survey of national stakeholders.[24] The survey addressed different types of stakeholders, including policy-makers, public health institutes, other competent authorities, statistical institutes, centres of expertise, and stakeholder organisations. The list of potentially concerned stakeholders was set up pulling together: (i) active search of the relevant counterparts' contact details through institutional websites, memberships of networks and expert groups and the like; (ii) specific indications collected from the stakeholders interviewed during the fieldwork; and (iii) lists of statistical and public health counterparts and focal points provided by DG SANTE. A list of more than 550 potential respondents have been set up (the full list was provided with the Interim Report).

[24] The survey of stakeholders could not be (and was not intended being) statistically representative in strict sense, due to the peculiar composition and limited expected size of the potential target group and the uncertainties as to the size of the total population sufficiently informed about the subject matter.

Given these specificities and based on previous similar experiences since the beginning of the exercise a response rate of about 10%, and a conservative target of no less than 50 responses from 20 different countries was estimated. With ***overall 77 valid responses from 26 countries*** (actual response rate: 13.6%) the target was met. The full list of respondents is provided in Annex A. An overview of the key features of the survey sample is provided in Box 5.3 below.

In parallel with the national stakeholder survey a similar questionnaire-based consultation was conducted among national EGHI members. Nearly one in three EGHI members contacted followed up on the invitation (overall ***ten questionnaires*** received).

Box 5.3 – Overview of the survey respondents

- The large majority of respondents (87%) declared to use health indicators more than once in a month or year in their professional activity. Respondents reported heterogeneous reasons for their interest and use of health indicators. 57% of them declared design/monitoring of policies and initiatives as the main reason, followed by scientific/academic research (49% of respondents), information to target groups/general public, and healthcare management. Residual reasons for use were epidemiological work and patient advocacy. In most of cases (61%) respondents reported being interested in health indicators for more than one previously reported reason.
- Regarding the thematic areas of interest, almost 60% of respondents reported being interested in all three macro-categories of indicators presented (population health status, determinants of health and health system performance).
- Focusing on population health status choices, respondents declared to be mainly interested in chronic diseases (60%) and healthy life expectancy (53%). On the contrary, for determinants of health thematic areas, responses were more or less equally split among all three options proposed: alcohol consumption, smoking habits and other risk factors. Concerning health system performance specific areas, more than half of respondents expressed their main interest for health policy and reform and healthcare financing and expenditure.

The stakeholder survey was implemented by means of an ***online questionnaire*** consisting of 15 main questions each broken down in various sub-questions, amounting to overall 70 consultation items. The themes covered include (i) the use made of health indicators and preferred sources; (ii) implementation status and perceived trends; (iii) use and utility of EU harmonised indicators and obstacles thereof; (iv) measures to reduce the burden and increase the benefits of indicators. Questions were mostly closed-ended, and respondents were asked to provide their ratings (degree of satisfaction, agreement etc.) on a 1-5 scale. The dataset of results is provided as Annex D.

The online survey tool was developed under the MySQL-based *LimeSurvey* application. The Team tested the script prior to roll-out to ensure that all routing instructions and questions wording were correct and clear. Particular attention was paid to ensuring the application worked properly on all platforms and devices (including tablets and smartphone).

The survey ran between 2 November and 12 December 2016. Personal invitations to participate - supported by an appropriate introduction letter – were e-mailed to the selected sample of potential respondents. The invitation contained a brief description of the objective of the survey, a weblink to the questionnaire's hosting page, and the confidentiality and protection of personal data provisions. During the implementation period, the Consultant offered a 'help-desk' email service to participants, addressing questions and providing clarifications to respondents. A 'gentle reminder' was sent one week before the expiration of survey deadline to those who had not responded yet.

The questionnaire for the EGHI members slightly differed from the questionnaires for external stakeholders. It included a few more questions (17 main questions, amounting to 84 consultation items) and more open-ended. The questions for EGHI members reflected their better knowledge of the current EU health information system and of the ongoing processes. Results were also analysed separately, taking into account the specific role of the EGHI group in the current system. The dataset of results is also provided in Annex D.

Complementary in-depth interviews. As reported in Table 5.2.2 above, some 12 additional in-depth interviews were conducted with 'supra-national' and horizontal partners. These involved either experts for specific indicators (individual or representing EU-wide projects), or stakeholders organisations representing the broad interests of certain target groups (e.g. medical device and pharmaceutical industries, patients, public health NGOs etc.). To have a complete overview of the broader context, some of the key partners of DG SANTE on health information were also approached. Interviews were conducted with DG EMPL (as regards JAF), JRC (for ENRC), and WHO/EURO (for EHII). The European Observatory on Health Systems declined the invitation, and by the time of writing Eurostat and OECD had not followed up.

5.2.4 Desk research

In parallel with the interview programme, the Consultant implemented an in-depth review of the documentary sources available. Not including the EU level policies, projects and other initiatives - whose census was already performed and included in the Inception Report – more than 300 sources (including databases) were reviewed in this phase (see Annex F). The deskwork concentrated on two main areas:

(1) Indicator-related sources, including definitions and metadata, reports and analysis, review of competing indicators, scientific literature, papers etc. as well as specific databases (Eurostat, OECD, WHO, MS-based, project-based etc.)
(2) MS-level sources, including the legal and policy frameworks, studies and reports form national agencies, institutes and universities, 'benchmarking' studies etc.

Various documentary sources were identified with the support of national or international stakeholders (including EGHI members) during interviews. At the same time the analysis of the literature revealed a relative scarcity (and in some cases virtual absence) of the following types of sources:

- National-level policy documents using the health indicators under analysis to set specific policy targets to be measured objectively, as well as other reports on the impact of introducing certain indicators in the national system.
- National-level reports on the costs of collecting health data.
- Scientific literature quantifying the benefits of improved health indicators on policy-making (qualitative analyses are more frequently available is instead).
- Scientific literature quantifying the broader impact of health indicators on public health objectives.

5.2.5 Mapping of EU indicators

One of the main research areas of the Assignment concerns the level of fragmentation in the current EU Health Information System. This is the consequence of various factors including: (i) a variety of *ad hoc* indicators established in the framework of temporary initiatives (with possibly no sustainable follow-up); (ii) formally harmonised EU indicators not implemented in all MS, or implemented in a non-harmonised way;

(iii) 'concurrent' indicators developed by other international organisations or programmes not harmonised with the corresponding EU ones.

There is general consensus on the existence of such fragmentation, but its magnitude is largely unknown. In the initial stage of the Assignment, a mapping of the (main) databases and sources of indicators available in Europe (both EU and non-EU based) was conducted. In addition to the indicators collected by Eurostat and other EU agencies under regulatory or voluntary agreement (the EU 'harmonised' indicators), the mapping covered a sample of 12 EU-funded initiatives, mostly gathered under the current BRIDGE Health project. The mapping analysed also the catalogues of health information initiatives based on data and indicators collected by third parties, namely ECHI and the JAF-Health. To allow comparison and identification of coordinated / overlapping work areas, the main databases of OECD and WHO/EURO were also considered. The results of this mapping are discussed in Section 6 below. The raw databases used for the analysis are reported in Annex D.

It is worth mentioning, that a systematic review and mapping of all indicators in place in Europe is currently being carried out by the Dutch RIVM in the framework of the WHO/EURO EHII initiative.[25] The results of this mapping will be reportedly available in the first quarter of 2017.

[25]http://www.euro.who.int/en/countries/netherlands/news2/news/2012/11/rivm-and-whoeurope-to-collaborate-on-health-information-provision
http://www.rivm.nl/en/Topics/W/European_Health_Information_Initiative/Work_in_Progress

5.3 Approach to the Analysis

5.3.1 The judgment criteria

The research conducted on case-study indicators focussed in the first place on collecting concrete evidence of their implementation and uptake by national and – where relevant supranational – stakeholders. The heterogeneity of the indicators selected and the qualitative nature of the research required to maintain certain flexibility in the research framework (see Annex E). A set of common judgment criteria corresponding to the evaluation questions was used, in order to ensure coherence in the analysis. However, the significance of these criteria for the various case-study indicators somehow varies. In connection with the above evaluation questions, the judgement criteria include:

- The formal ***adoption*** of the indicator in the country, possibly under specific policies or programmes.
- The degree of ***coverage*** of data collection activities, and the level of detail and granularity provided.
- The ***reliability and robustness*** of the data reported, in relation with their design and the quality process they undergo.
- The appropriateness of ***maintenance and update*** activities.
- The extent of true ***harmonisation and comparability*** across countries of the results.
- The perceived ***relevance for policy-making*** and country's specific characteristics and needs.
- The perceived ***added-value*** in relation to non-harmonised domestic indicators and other concurrent ones.

In the architecture of the case-study analysis these criteria constitute the building blocks for the estimation of costs[26] and possible benefits of indicators, and they were used (or a section of them) for both the baseline analysis of the current situation and of the likely future scenario.

5.3.2 The estimation of costs and benefits

Costs and burden. The estimation of the implementation costs of the indicator required in the first place to reconstruct the salient steps of the process going from the collection of raw data at data points to the reporting of processed information or datasets to Eurostat, ECDC, OECD or the other competent entities. Such process may vary significantly across countries and often national stakeholders were not in the position to know how the entire data flow works and/or to estimate the related costs and burden particularly on healthcare providers. To somehow level differences, the analysis focussed on the salient steps of the process (necessary in all MS) and comparable metrics were used, e.g. unit cost per case (instead of country-level aggregates), time burden to implement a certain action (in normally efficient conditions) etc. The exercise evidently required a certain degree of approximation and in some extreme cases, guess-estimates based on comparisons with similar exercises were also used (e.g. for surveys). Obviously, the cost of labour and price levels play a major role in determining the actual costs of indicators, and also for this reason more neutral metrics like time-burden were sometimes preferred. Extrapolation of cost data to EU level implies a series of very strong assumptions and was done only in a few cases where procedures turned out to be sufficiently similar in the different contexts (e.g. cancer registries).

[26] Costs depend on processes, but these may vary to fulfil to different extent the judgement criteria above.

In general the costs and burden factors considered in the analysis included:

- ***Data collection costs***, from the data point to the aggregated country dataset.
- ***Analysis and reporting costs,*** from data cleaning and validation to the processing and treatment required by the indicator specifications, to the reporting/transmission to the competent database.
- ***Additional burden*** typically due to concurrent indicators, non-harmonised reporting to different entities, legal constraints and the like.

Use and benefits. The potential benefits of indicators depend in the first place on their uptake and concrete use by policy-makers and stakeholders. Overall, the dimensions reviewed in this Study include:

- the perceived overall ***utility and added-value*** of harmonised indicators;
- their use for ***policy process*** (in broad sense);
- ***other possible uses*** not directly for policy-making (epidemiology, research, accountability etc.);
- and specific use for ***cross-country comparison*** and benchmarking.

This approach is informed by the underlying 'theory of change' described in section 5.1, in that benefits (outcomes) may materialise only as a consequence of policy actions enabled by the use of indicators. This enabling can take place in a variety of means: indicators may simply contribute to raise awareness on policy issues, support the identification of policy problems, or inform the design or the monitoring of policy initiatives or represent targets to be achieved. In this respect, the analysis was carried out using a distinct qualitative approach, aimed at drawing evidence from the case-studies on how indicators are concretely used at present, the perceived obstacles, and the perspective on their future use and utility.

5.3.3 The comparison of Scenarios

In the conclusive stage, the above costs and benefit dimensions have been investigated in comparative terms, i.e. considering two main scenarios: (i) the no change scenario; and (ii) a scenario where a hypothetical sustainable system ensures a satisfactory implementation of fully-harmonised indicators. There are evidently various degrees of abstraction in the analysis, which reflects the various limitations and constraints in quantifying costs and benefits of indicators that have been evidenced in the Study, as well as absence of a clear reference framework for the change scenario after the EU policy initiative has been suspended. The analysis is therefore essentially based on a qualitative, multi-criteria assessment, supported by the case-study evidence that was collected in the sample MS and extrapolated so as to draw indications on broader EU-wide trends. Since each indicator has its specificities, the analysis of scenarios has been presented separately, but based on a common analytical framework structured as follows:

- The '***No Change' Scenario*** is a projection over a mid-term period (conventionally 4-5 years) of the current trends observed with the implementation of the indicator and its use. In this sense, it is a dynamic scenario that takes into account the expected evolution in the absence of any EU level action (outside of the ordinary maintenance and reporting activities).
- The ***Sustainable System Scenario*** is a hypothetical benchmark that consists of assuming a satisfactory and sustainable implementation and a full harmonisation of the indicator. Needless to say, the actions required to achieve this vary across indicators. In some cases, there is a need to expand coverage; others required improved quality control; others required eliminating duplications etc. For this scenario full compliance is assumed (working hypothesis), although in reality resistances and distortions in implementation may persist. The objective is to

compare the estimated burden of achieving full compliance with the estimated effects this may have on the use of the indicator, hence its benefits.

- With respect to ***costs and burden***, two main aspects are considered: the likely trends with implementation (data coverage, harmonisation and quality etc.) and with analysis and reporting activities.
- With respect to ***use and benefits***, two main aspects are considered: the likely impact on the use for policy purposes and for other purposes (e.g. epidemiology, research, accountability etc.). The third main 'driver', i.e. the use for comparison and benchmarking, is subsumed in these two dimensions, actually representing the most important criterion for their assessment.
- Finally, an analysis of the ***estimated net effects of change*** is presented. This summarises the net gains or losses that can be anticipated from pursuing the sustainable system scenario. In addition to a general assessment, it includes specific considerations on: (i) medium-term evolution (costs tend to be in the short run, while benefits in the long run; (ii) extent of distributional effects (not all countries are affected in the same way); and (iii) sensitivity or the level of uncertainty of estimates due to major factors that are hard to forecast.

The analytical framework used to compare the two scenarios for each of the case-study indicator analysed is provided in Figure 5.3.1 below. More details on its use and the criteria used for rating impacts are provided in Section 7.5.1.

Figure 5.3.1 – Template for the comparison of alternative scenarios for the EU Health Information System.

	No Change Scenario		**Sustainable System Scenario**	
Implementation costs/burden	***[rating]***	***[key motivation]***	***[rating]***	***[key motivation]***
Analysis and reporting costs/burden	***[rating]***	***[key motivation]***	***[rating]***	***[key motivation]***
Use and benefits for policy process	***[rating]***	***[key motivation]***	***[rating]***	***[key motivation]***
Use and benefits for other knowledge purposes	***[rating]***	***[key motivation]***	***[rating]***	***[key motivation]***
Estimated net effects of change	**Overall:** ***[rating + key motivation]*** **Medium-term evolution**: ***[rating + key motivation]***. **Distributional effects**: ***[rating + key motivation]*** **Sensitivity (level of uncertainty)**: ***[rating + key motivation]***			

5.3.4 Methodological limitations and assumptions

Constraints to the generalisation of findings. The case-study approach envisaged in the Study specifications had the merit of allowing an in-depth assessment of the mechanisms underlying the implementation of EU indicators in MS, i.e. data sources, players involved, activities required, perceived burden and use. As confirmed by various stakeholders, these aspects have been poorly investigated so far at EU but also at MS levels. On the other hand the qualitative nature of the evidence that the case-study approach allows inevitably implies serious limitations for their generalisation. This is even more evident since two parallel generalisation processes are at stake, i.e. across countries, and across all existing indicators. While the selection of sample MS and case-studies indicators was done so as to ensure sufficient heterogeneity and representativeness, all generalisations of results should be taken with some caution.

Limited 'validated' figures available. For the major part, the Study investigated areas where very limited pre-constituted information exists. This was magnified by the switch from a Study oriented toward a precise policy initiative, to a more explorative and knowledge-building exercise. The literature reviewed included only few very focussed or 'pioneer' studies dealing with the costs of health indicators (but a bit more for health information structural aspects). In many cases, national stakeholders were not in the position to provide validated figures on the expenditure on indicators or the time burden required to perform certain indicator-related activities, and sometimes these had to be reconstructed based on similar activities or inferred from back-of-the-envelope calculations, or rough estimates of the orders of magnitude at stake. Still, in many cases the estimates collected in different countries converge, confirming the overall magnitude was correct. The Consultant remains responsible for all the approximations and simplifications made necessary to have rough cost estimates at the individual country level, as these could not be validated by any official means.

Multiple uncertainty layers behind benefits. The estimation of benefits was even more complex than that of costs. Virtually no literature exists on the quantification of the benefits that may derive from having harmonised indicators in place. Most of the sources available – including international organisations' studies and report – rather focus on qualitative aspects i.e. how indicators can help design and implement initiatives that may lead (under certain conditions) to some general benefits. The in-depth consultation of MS key experts confirm the difficulty of attributing a tangible benefit to an indicator, be it the reduction of disease burden, system cost-savings and the like. Sometimes, the very attempt to quantify the value of information was perceived as a vain exercise. Therefore, the analysis concentrated on the factors beyond the use / non-use of indicators and the drivers through which they may contribute to policy change.

General attribution constraints. In connection with the above, the attribution of certain costs and benefits is seldom straightforward. In many cases, indicators are by-products of data sources and activities that would take place anyway and whose costs cannot be (entirely) attributed to the harmonised indicators process. The same applies to use and benefits: indicators can be in some cases a pre-condition for benchmarking activities, the development of evidence-based policies etc., but many other factors are at play – which are sometimes more fundamental than the availability of the indicator (e.g. the existence of a policy problem).

A largely theoretical 'change' scenario. Putting on hold further policy initiatives in this areas (beside – of course - the ongoing processes), *de facto* left the scenario analysis component of the Study without a clearly defined comparator. While the 'no change' dynamic scenario could be developed based on the current trends, for the 'change' scenario a highly hypothetical configuration had to be assumed. As described, the aim was mostly to assess the gap between the actual situation and an ideal situation where indicators are satisfactorily and sustainably implemented and fully harmonised according to respondents' perceived needs. Views on what is meant by 'optimal implementation' and the action required are inevitably subjective, and the perceived utility of the indicator may significantly influence stakeholders' assessment of the efforts needed to achieve it.

An evolving context. The way forward for the EU Health Information System cannot be disjointed from the other main processes ongoing at EU level, and the initiatives being implemented by other international organisations. However, limited insights were available during the implementation of the Study on the state of progress and the strategic framework of some major processes, such as the 'State of Health in the EU', the possible ERIC on health information, the BRIDGE Health project, and other external initiatives. In this sense, there is the risk that changes in the overall context may require a further revision of the course of action suggested here.

6. IMPLEMENTATION STATE OF PLAY

6.1 An Overview of the Issues at Stake

In recent years, the health information landscape in Europe has been characterised by a substantial complexity of initiatives loosely related to a comprehensive and coordinated strategy. In addition to well-established indicators anchored in the EU policy, a number *ad hoc* indicators have been developed on a pilot or temporary basis within the framework of various public health-funded and research projects, which were not always followed up by a concrete adoption, as it is still the case for about forty ECHI indicators. This proliferation of initiatives has led to a situation where a number of indicators have been or are being developed but not actually gathered in any sustainable way, or only partly gathered in certain Member States only, which ultimately hinders their comparability and their possible use for EU benchmarking and evaluation purposes.

Moreover, a number of health indicators have been developed and collected, but not necessarily adopted by policy or agreed for use for that purpose. The availability of the indicators proposed within the framework of some mainstream policies of recognised EU added value is also not always clear[27]. This seems to be due to a mix of obstacles such as cost constraints, feasibility issues, low strategic priority, or lack of methodological consensus. The sheer complexity of the system also plays a major role. In particular, it is worth noting that some EU countries with small populations frequently find it challenging to comply with the data-reporting requirements agreed at the international/EU level, because of insufficient human and technical capacity and resources.

To illustrate this degree of complexity, the Consultant has conducted in the inception phase a review of the possible EU-level sources of health information which resulted in a list of more than 200 projects and other initiatives[28], complemented by nearly one hundred policy documents ('soft' and 'hard' policies). In parallel, a mapping of the specific health indicators both 'harmonised' (part of the *Eurostat* data catalogues or other EU agencies formalised indicators) and *ad hoc* (developed in the framework of temporary projects) has been conducted, resulting in more than 1,000 items[29] complemented by nearly another 500 indicators included in the main OECD and WHO databases (Annex C).

This has created a paradoxical situation where health indicators are perceived as both abundant and missing, depending on their intended use and the stakeholders concerned. As figure 6.1.1 below demonstrates while survey respondents are generally satisfied with the availability of international health indicators, the level of satisfaction among those specifically concerned with policy aspects is somehow lower. In fact, at a more granular level of analysis, EGHI respondents have highlighted major specific shortcomings in indicators on health inequality and healthcare efficiency, while

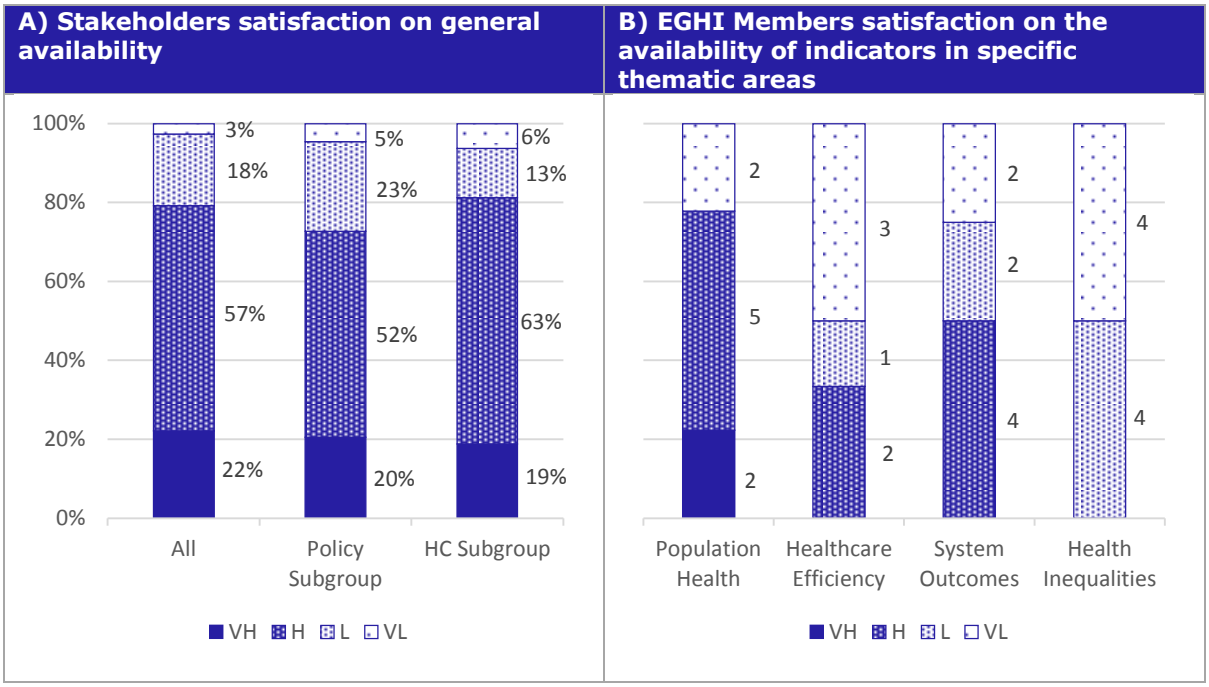
[27] For instance, the Council Recommendation on a European Action in the field of Rare Diseases, proposed to use health expectancy indicators: PYLL (Potential Years of Life Lost), DALY (Disability-Adjusted Life Years), HLY (Healthy Life Years), but this would require registers of deaths due to rare diseases and a proper ICD sub-classification of such deaths reportedly not (fully) in place.

[28] These include PHP projects, research projects, joint actions, and partnerships approved prevalently (but not exclusively) in the past 10 years, which involved the definition/collection of health data and indicators in specific policy areas (including on health systems and health determinants).

[29] This includes in excess of 200 indicators in the Eurostat databases (including the 'social' catalogue) and more than 800 mapped items (including very detailed metrics) collected under the major initiatives that have been brought forward under the BRIDGE Health project, to which some 150 ESPAD indicators could be further added.

more traditional indicators on the population health are considered much better developed.

Figure 6.1.1 – Consultation results on the satisfaction with the availability of internationally-harmonised indicators



Legend: VH: Very High; H: High; L: Low; VL: Very Low
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

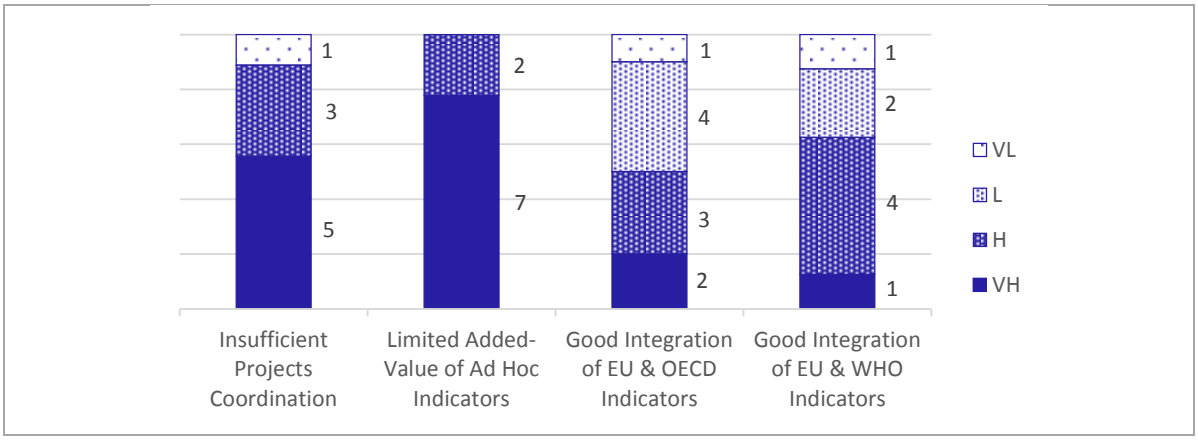
The fragmentation mechanisms have self-reinforcing negative effects. As the ECHI evaluation demonstrated[30], sometimes this proliferation of conflicting requests creates a 'vicious circle' where the indicator is perceived as unstable / not sustainable over time and is, therefore not adopted to prevent the downsides of its possible discontinuation – which may *de facto* enhance the likelihood of its discontinuation for lack of policy relevance.[31] This issue is analysed in greater depth in the next Section.

Fragmentation issues in the indicator development phase are compounded by some duplication issues in reporting and data processing. In fact, in parallel to health information produced under EU policy or financing, major sources of cross-country health information are represented by the WHO and OECD databases and analyses. Despite the conspicuous collaboration, these have produced over time a proliferation of indicators in the same policy area, at times truly complementary, but at times perceived by stakeholders as overlapping, due to heterogeneous definitions, calculation methods, and/or collection modality. The situation has reportedly improved and the level of coordination today is much greater than in the past (e.g. the use of *Joint Questionnaires*), but there can be still cases of concurrent definitions and of multiple reporting.[32]

[30] Public Health Evaluation and Impact Assessment Consortium (PHEIAC), 'Evaluation of the use and impact of the European Community Health Indicators ECHI by Member States', 2013.
[31] This was the case, for instance, with EHIS indicators in some Countries, when the 'sunset clause' on their possible discontinuation was made known.
[32] As late as 2015 the JAF-Health had to seek WHO advice to identify which of the numberless indicators on child vaccination produced at various levels by various bodies could be considered the most relevant to synthetically monitor developments EU-wide.

As figure 6.1.2 below demonstrates, EGHI respondents certainly perceive the issue of limited integration and coordination of the EU indicators with those produced by WHO and OECD as much less important than sheer proliferation of *ad-hoc* indicators or limited overall coordination of initiatives in the indicator design phase. Proper exploitation of synergies and making reporting more efficient is a crucial demand but there are practical issues, especially where reporting is not voluntary but follows an agreed obligation (i.e. not all WHO indicators are implemented on a voluntary basis[33]). The main reasons behind having different indicators for the same policy range from sheer major differences on definition issues to subtler overlapping issues (e.g. period of reference), to measurement methodologies (typically self-reported data vs diagnosis/clinical registries), misalignments in the definition of age categories (e.g. adult defined as 15+ vs 18+) and different reference populations in the databases. A recent WHO study[34] commissioned by DG SANTE on indicators for non-communicable diseases shows that around one-third of the indicators for non-communicable diseases included in ECHI and the WHO Global Monitoring Framework for non-communicable diseases do overlap, which allows synergies in data collection, while in the remaining two thirds – although addressing the same policy areas - major differences remain as to their definition.

Figure 6.1.2 – EGHI consultation results on integration/fragmentation of health indicators sources



Legend: VH: Very High; H: High; L: Low; VL: Very Low
Note: 'Don't know' answers are not reported.

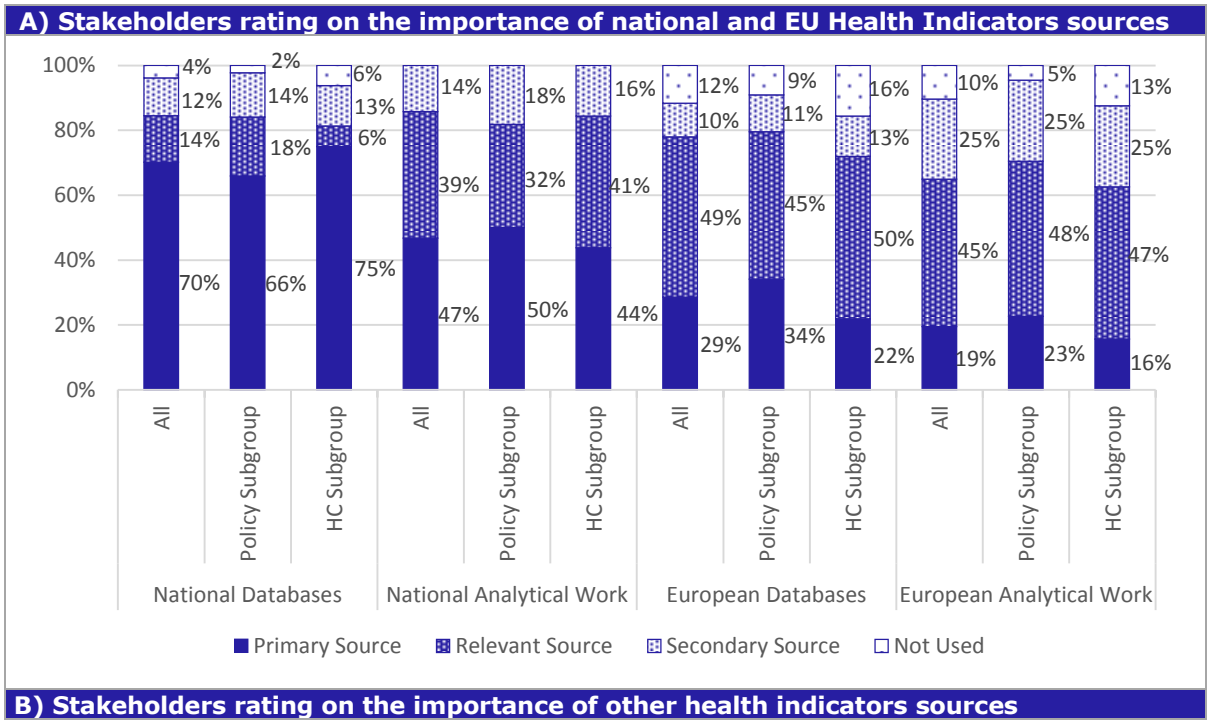
Finally there are countries that traditionally have maintained a high level of investment in developing their own indicators for domestic, immediate policymaking purposes, irrespective of comparability considerations and needs, and have taken the lead in developing their own reporting standards. For instance, in the UK the need to tackle the leading causes of early death was recognized in the Government White Paper, *Saving Lives: Our Healthier Nation*, and avoiding preventable deaths became a Government priority since then. In response to the White Paper, an extensive public consultation was conducted in 2006 that elicited stakeholders' views on the definition of "avoidable" or "premature" mortality, in the light of advances in medical treatment and societal changes. This is because definitions of what is regarded as "avoidable", "preventable" and "premature" imply value judgements that may differ between societies and are bound to change over time. So, some Member States may prefer developing their own indicators because they are more in line with their policy priorities and cultural environment. This is a problem that was reported, for instance,

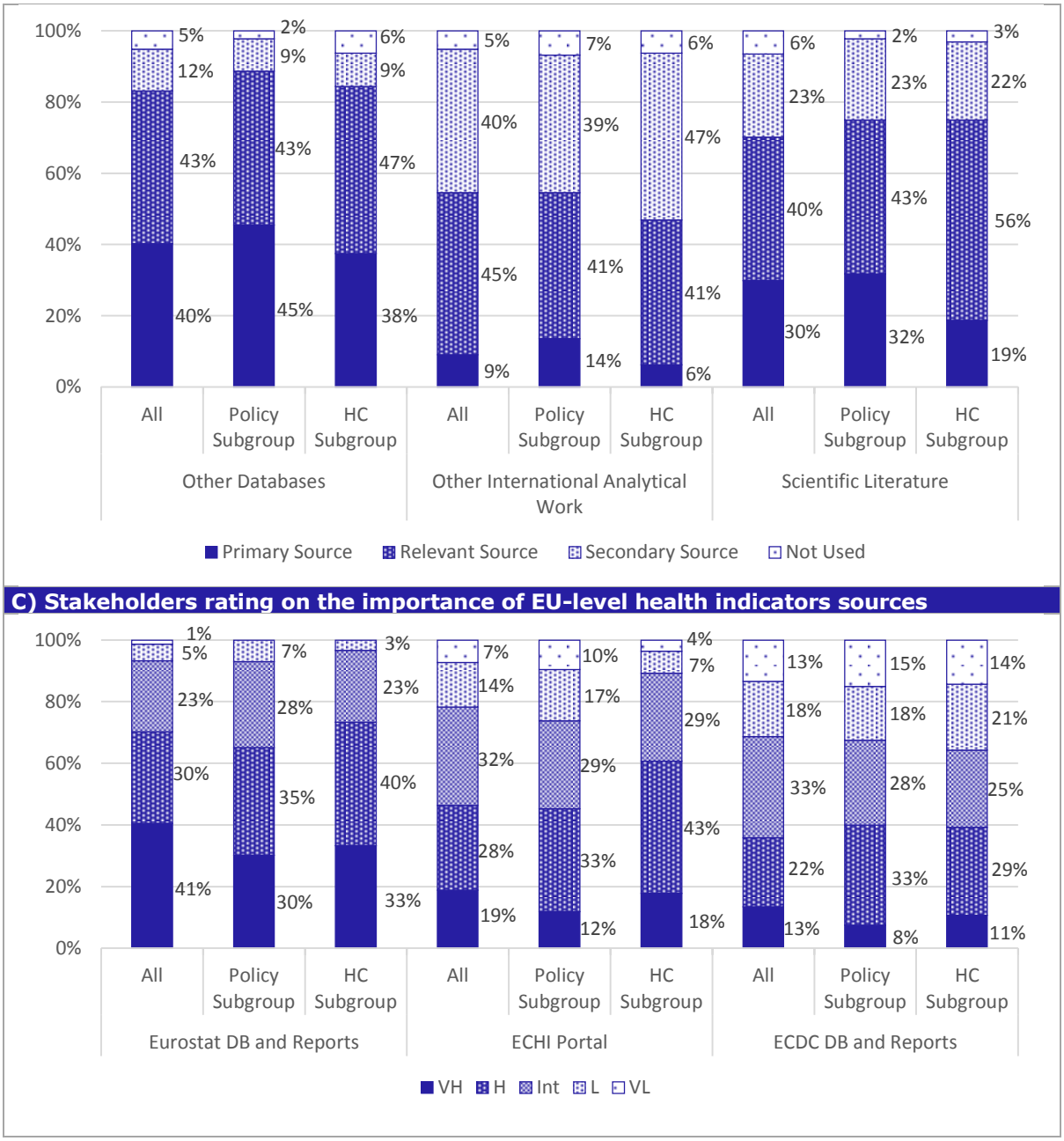
[33] For instance, the World Health Assembly in May 2013 developed a list of 25 indicators to track global progress in Countries' commitment to the prevention and control of the major non-communicable diseases and their key risk factors developed on the basis of a global assessment of their burden and projections for the future
[34] http://ec.europa.eu/health/indicators/docs/incd_en.pdf

with some ECHI-EHIS-based indicators that had been developed without engaging all MS stakeholders.

At any rate, survey respondents widely confirmed that national databases and analytical sources remain the preferred means of access to health indicators, followed by the databases of the international organisations and articles in the scientific literature (see figure 6.1.3 below). This finding is far from surprising if one considers the consolidated tradition these sources have as data providers and the long familiarity data users have built with them. It is worth noting that when it comes to indicators drawn from analytical work, EU sources are preferred to international reports as primary sources of information. Generally speaking professional users interested in policymaking do have a slight preference for reading indicators within the framework of analytical work as compared to other data users. Respondents have also confirmed *Eurostat* as the most important source of EU health indicators, while the ECHI database remains comparatively lesser known among those with a professional interest in policymaking.

Figure 6.1.3 – Relative importance of the sources used to access health indicators





Legend: Very High; H: High; Int: Intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

6.2 Overall Mapping of the EU Health Information System

6.2.1 The state of the EU indicators

Overview. The EU system of health indicators includes two main groups. One is composed of relatively well harmonised sources with a clear legal basis such as the Eurostat statistics, the mandatory ECDC indicators on communicable diseases and the EMCDDA so called five key epidemiological indicators[35] whose EU-wide implementation was endorsed by a Council Recommendation in 2001. The other group comprises of a wealth of EU-funded project-based and other initiatives (including ECHI itself) whose long term sustainability and legal status remain more uncertain. At times the distinction between the two is more blurred than it might appear, as some Eurostat indicators are also maintained and supervised by external EC-funded projects and the ECDC itself funds some of its indicators on a project basis, as these remain outside the formal EU surveillance system (one of these for instance is the indicator on MRSA that at any rate is implemented following a Council Recommendation). Aside from these EU-funded sources, other indicators have reached a status of *de facto* associated sources to EU initiatives. The most relevant example is probably represented by the ESPAD indicators on alcohol and drug consumption in schools, among 15-16 years old teenagers, that have been stably incorporated into the EMCDDA work.

Eurostat. The basis for health data collections within Eurostat the Regulation (EC) No 1338/2008 on Community statistics on public health and health and safety at work.[36] Various Commission Regulations were adopted over time to implement or complement the framework regulation, including for instance:

- Commission Regulation (EU) 2015/359 on statistics on healthcare expenditure and financing;
- Regulation (EU) No 1260/2013 on European demographic statistics, and the following Commission Implementation Regulation (EU) No 205/2014;
- Commission Regulation (EU) No 141/2013 as regards statistics based on the European Health Interview Survey (EHIS), and Commission Regulation (EU) No 68/2014 on EHIS statistics by reason of the accession of Croatia to the European Union;
- Commission Regulation No 349/2011 on statistics on accidents at work;
- Commission Regulation (EU) No 328/2011 on statistics on causes of death.

The core of the Eurostat health dataset traditionally consisted of indicators on causes of death collected since 1994 from national death registries. This was expanded with Commission Regulation 328/2011 into a set of different aggregated indicators including death rates from chronic diseases and suicides, and including the calculation of related life expectancy data. These statistics, combined with other Eurostat survey data on self-reported health status and unmet needs for health care services, has given rise to the 'healthy life year' indicator, which is one of the best known Eurostat health indicators. Another area of Eurostat's significant involvement is the collection of statistics on healthcare resources (staff and facilities) and health care activities (consultations and discharges) from MS. Since a few years, data in this area are collected by means of a joint questionnaire with WHO and OECD. The European Health Interview Survey (EHIS) collects information on various aspects of health status of population and its non-medical determinants, life styles and health behaviour,

[35] These are: 1) general population surveys, 2) high-risk drug use, 3) treatment demand indicator, 4) drug-related deaths and mortality, and 5) drug-related infectious diseases.
[36] Regulation (EC) No 1338/2008 of the European Parliament and of the Council of 16 December 2008 on Community statistics on public health and health and safety at work

including, among others, alcohol consumption and hazardous alcohol consumption. A new, expanded wave of EHIS has been recently completed.

ECHI. Eurostat indicators represent one of the main sources from which the ECHI project drew to build the list of the so-called "European Core Health Indicators". They represent a compilation of 88 indicators from various official sources and, in a few cases, project sources not all of them actually implemented, for which further harmonisation was deemed necessary. They are roughly equally divided between indicators on health status and indicators on health interventions/health services, including data from European cancer registries whose management and validation is jointly shared by the JRC and IARC-WHO. A small subset of indicators on demographic factors and health determinants (most of which developed in EHIS to be collected by Eurostat) completes the ECHI list. Since ECHI has been running as a project for several years in a row, its activities have now been incorporated within the framework of the BRIDGE Health Project. As the name itself indicates, BRIDGE Health is intended to provide cumulative bridge financing to a number of previous project-based initiatives, including ECHI itself, that have proposed indicators whose continuation had been previously validated as deemed worth on the basis of an EGHI scoping paper, ascertaining consensus among high-level MS representatives.

BRIDGE Health. Some 750 different health indicators are now being supported under the BRIDGE Health project (see annex C) and represent the continuation of nine different public health projects, as described in box 6.1 below. Some 60% of them (460) have been proposed by a single project focused on monitoring child and adolescent health in Europe, due to lack of data for this segment of the population. As was the case for ECHI, not all these indicators are *ad hoc*, many of them actually draw from existing sources. Others, conversely, derive from other EU public health initiatives[37], so that the total number of referenced *ad hoc* project sources increases to a total 17. On top of that, BRIDGE Health also provides financing to former initiatives aimed at creating a European harmonised protocol for Human Biomonitoring (HBM)[38] to assess environmental risks and to the idea of establishing cohort-based indicators of maternal and child health.

Box 6.1 - Indicators Included within the Framework of BRIDGE Health

- EUROCISS implements population-based registers for the surveillance of AMI/ACS and stroke morbidity and mortality and considering both fatal and non-fatal events occurring in and out of hospital, thus providing estimates of key indicators such as attack rate and case fatality. It has proposed some 27 indicators, ten of which from the EHMR project.
- EUROHOPE aims to evaluate the performance of European health care systems in terms of outcomes, quality, use of resources and costs as far as acute myocardial infarction, stroke, and infants with very low birth weight and very low gestational age are concerned. It includes a total of 82 indicators, of which 7 are drawn from OECD Health Care Quality Indicators variously collected in the 2003-2009 period and 14 implemented within the framework of the EUROHOPE Nordic Hospital Comparison initiative.
- ECHO also measures the performance of European health systems in a comparable and quantifiable way to evaluate health outcomes with an emphasis on hospital quality of care. It includes 33 original indicators of cardiovascular procedures, low value care indicators, potentially avoidable hospitalisation indicators, orthopaedic care indicators, patient safety indicators, and risk adjusters to equalise results of comparative analyses.

[37] These include namely: 1) CHILD, 2) HBSC, 3) CEHAPE, 4) Scientific Platform on Lifestyle Determinants of Obesity, 5) Child Safety Report Card, 6) ACCIS, 7) EHMR, 8) SHARE.

[38] Human biomonitoring is a scientific technique to assess whether and to what extent given environmental substances have entered human bodies and how exposure may be changing over time. This is done by measuring the concentration of natural and synthetic compounds in body fluids (blood, urine, and breast milk) or tissues (hair, nails, fat, and bone)

- EUROPERISTAT establishes a perinatal health information system on fetal, neonatal, child and maternal health, and related population characteristics, risk factors and healthcare services by means of 35 different indicators, a few of which have been already incorporated in ECHI and adopted by Eurostat.
- EUBIROD is to implement a sustainable European Diabetes Information System through the coordination of existing national / regional registries and the systematic use of the BIRO technology. Its 45 proposed indicators also at times overlap with health determinant indicators already proposed by ECHI.
- EHLEIS/EUROHEX is to provide a co-ordinated analysis and synthesis of life and health expectancy indicators and refine and maintain the HLY indicator implemented by Eurostat. It works with all the original series of the GALI question as collected by means of the SILC, the European Community Household and the European Social Survey (ESS) and also considers the additional data made available by the SHARE project specifically focused on the elderly.
- EHES is to complement registries and interview-based surveys by collecting information on four health status indicators on blood pressure, blood cholesterols, blood glucose, and obesity by means of health examination surveys[39] and were partly incorporated in ECHI.
- EUROSAFE ensures the maintenance of four ECHI indicators on home, leisure, sport and school injuries, road traffic injuries, workplace injuries, and suicide attempts that are not presently collected by any international organisations including Eurostat.
- *Progetto Cuore* is to develop European registry based heart disease morbidity indicators based on the standards deployed by the ISS Osservatorio Epidemiologico Cardiovascolare / Hes. It currently includes 33 indicators for the total population, the elderly and menopausal women of which some are HES while others broadly overlap with ECHI indicators on health determinants.
- Riche is an FP7 co-funded project to investigate Child and Adolescent Health in Europe, identify related gaps and priorities in child health research development of a roadmap for European Child and Adolescent Health Research. The project made use of as many as 460 different health indicators all of which from secondary sources. These include 90 indicators or so, drawn from the WHO-HFA database, another 75 borrowed from the Scientific Platform on Determinants of Childhood Obesity, 80 policy-related indicators from the Child Safety Report Card, 35 from the UNICEF database, 14 ESPAD indicators on alcohol and drug abuse, 40 indicators from the CHILD project and another dozen from miscellaneous sources including WHO.

As can be seen within the framework of BRIDGE Health around 250 *ad hoc,* mainly morbidity, indicators have been proposed - child health not included. They present various degrees of overlap with existing ones and among themselves. They particularly cover cardiovascular diseases, diabetes and related health determinants. The project should ensure their methodological development with a view to transferring their further development and maintenance to a more stable governance mechanism currently identified in a possible ERIC.

6.2.2 Major international partners

OECD. OECD maintains a database of a total 235 health indicators including some 15 context economic and demographic ones and its core area of macro data on health expenditure. OECD is one of the largest providers of health care quality indicators that account for one quarter of OECD's total offer of health indicators. OECD is well known for having had a pioneering role over time in measuring healthcare performance and maintains a very large set of indicators on both health resources (a total of 88 now often jointly gathered with WHO and Eurostat) and healthcare utilisation (27), together accounting for half of the indicators in its catalogue. Actually, it often occurs that indicators aimed at measuring health performance are eventually upheld by other

[39] EHES measurements expected to be included in every national HES include: height, weight and waist circumference; blood pressure; non-fasting blood samples for total and HDL-cholesterol; fasting blood sample for glucose.

projects/initiatives after having been pilot tested by OECD. On top of that OECD specialises in niche areas with an economic and health management dimension such as workforce migration, the pharmaceutical market and long term care resources. It is worth noting that OECD has kept a specific approach to the measurement of non-medical determinants of health by sticking to indicators of physical quantities and supply data to be used as benchmarks of reference for consumption (e.g. alcohol). This complements the approach of relying on more subjective survey-based measurements followed by the EU.

The OECD indicators are annually updated, presented, analysed and extensively commented in the *Health at a Glance* report that also includes a comparative dashboard of the most relevant ones to identify top, medium and low performers among OECD member countries. Since 2016 OECD has been requested to extend its data gathering activities of health care quality indicators to all EU MS, including those that are not OECD members. OECD also highlights constraints on data comparability particularly when it comes to comparisons between self-reported data (e.g. obesity, alcohol consumption, etc.) that are deemed underestimated when compared to more reliable objective measurements in the same area. This methodological stance is also one of the reasons why OECD preferably sticks to objective measurement of non-medical determinants of health. OECD also publishes information on the most accessed indicators in their data base. From these data it appears that OECD caters to an audience that is particularly interested in health management aspects and preferably seeks data on health expenditure, healthcare resources and health activities. Conversely, health status and risk factors come at the end of the list of the requests most frequently received from OECD database users.

WHO. WHO maintains as many as eight different databases of health inidicators, namely:

(i) the general *European Health for All database (HFA-DB),* which includes also sectoral databases such as the GISAH on alcohol;
(ii) the *Health 2020 indicators*[40] that specifically focus on monitoring the degree of achievement of the objectives of the Health 2020 Strategy whose degree progress is more analytically commented in *The European health report 2015*;
(iii) *The European database on human and technical resources for health (HlthRes-DB)* that is a database specifically comprising of some 200 detailed indicators on health resources available in the different countries in terms of personnel and medical equipment;
(iv) *The European mortality database (MDB*) that provides figures on over 800 causes of death, of which more than half are cancer-related, thereby representing by far the largest such repository of information available;
(v) *The global eHealth survey 2015* that represents the largest database about the implementation status of health policies and programmes worldwide; while
(vi) *The Health Behaviour in School-aged Children (HBSC*) groups more than 110 indicators on health-related behaviours among school-aged children including some 40 risky behaviours related to consumption of tobacco, alcohol or illicit drugs and recourse to violence;
(vii) the *Child and adolescent health* that provides some 40 indicators specific for Child and adolescent health;
(viii) the *Environment and Health Information System (ENHIS)* that provides some 60 indicators of environmental health, including second-hand smoking and a sample of 8 human biomonitoring values.

[40] Health 2020 core indicators were agreed by the WHO European Region Member States for monitoring progress towards the Health 2020 targets. Some of these indicators are based on official WHO sources and other are based on non-WHO sources, such as UNESCO and UNDP. Data from WHO sources can be accessed and queried at national level, while data from non-WHO sources are available in aggregated form, for groups of Member States.

The mainstream WHO European HFA database (see annex C) includes a set of 210 health indicators covering mortality (60 indicators), morbidity (44 indicators of which 16 are from infectious diseases surveillance systems), lifestyle and health determinants (11 indicators), environment (9 indicators), health care resources (21 indicators) as well as health care resources utilisation and costs (25 indicators). Mortality indicators broadly overlap with those provided by Eurostat, while indicators on healthcare resources specialisation and costs tend to cover the same areas as the OECD ones but do not necessarily fully coincide with them. The WHO approach to lifestyle indicators is also quantitative as the OECD one, although often expressed in slightly different terms (i.e. with reference to calories per capita etc.). The WHO has long been supportive of the burden of disease approach which is managed by the Institute for Health Metrics and Evaluation and examines the effects of disease and disability in terms of disability-adjusted life-years, or DALYs[41]. At least 15 EU MS have already conducted studies based on the burden of disease methodology (namely, the Netherlands, Spain, Belgium, Denmark, the UK, France, Germany, Italy, Poland, Portugal, Estonia, Austria, Bulgaria, Lithuania, Romania) and some of them in several areas.

Since 2006, the WHO has been implementing the "European Health Information Initiative" (EHII) with a view to streamlining the health information systems and increasing their added value. The EHII comprises of six strategies. One of these, the *Support for information strategy development* is explicitly aimed at strengthening the use of information, evidence and research for policy making also by means of a more rational use of the indicators themselves. The Health Evidence Network established within the framework of the EHII with the purpose of promoting evidence-based policymaking and increasing the use of indicators has already produced 69 Country reports to this aim. This also first focussed on operational aspects for simplifying data collection at the Member State level by means of the *Joint WHO-Eurostat-OECD Questionnaire* whose scope is being increased over time.

EHII work has then moved to more strategic rationalisation aspects. In particular a European action plan has been presented in September 2016 with the objective of simplifying reporting for the Health 2020 Strategy (described in box 6.2 below) and for the parallel health-related component of the UN Global Goals for Sustainable Development, as well as for the UN Action Plan for the Prevention of Non Communicable Diseases, but potentially scalable to all other regional policy initiatives managed by means of target indicators. For instance, one of the indicators proposed in the EU Alcohol Strategy overlaps with a Health 2020 Strategy Indicator. This has involved a mapping of existing and future health and well-being indicators used in Europe, in order to develop recommendations for a common core of 29 indicators proposed for reference to WHO Regional Office for Europe, the European Commission and OECD that is aligned with other accepted monitoring systems globally. The action plan is currently under discussion and a feedback from participating countries is expected in 2017. The EHII is also promoting the establishment of a Burden of Disease Network in the European Region devoted to building capacity and exchanging of findings regarding their burden of disease. The network currently consists of representatives from 10 Member States in the Region.

[41] The burden-of-disease approach brings together measures of mortality, morbidity and disability in order to analyse the effect of disease on populations. Whereas public health is often strongly focused on causes of death, a burden-of-disease approach is more comprehensive, acknowledging people's experience of real life.

Box 6.2 - The core indicators for the WHO Health 2020 Strategy

The Health 2020 Strategy is articulated into six strategic objectives or targets, of which one policy-related, measured by means of 19 different core health indicators plus 18 additional ones.

1. Reduce premature mortality rate in Europe
- Alcohol consumption
- Measles vaccination
- Mortality from external causes (M,F)
- Obesity (M,F)
- Overweight (M,F)
- Polio vaccination
- Premature mortality (M,F)
- Tobacco smoking (M,F)

2. Increase life expectancy in Europe
- Life expectancy (M, F)

3. Reduce inequities in Europe
- Infant mortality (M, F)
- Life expectancy (M, F)
- National health inequities policies
- Primary school enrolment (M,F)
- Unemployment

4. Enhance the well-being of the European population
- Life satisfaction
- Primary school enrolment (M,F)
- Sanitation (urban, rural)
- Social support
- Unemployment

5. Universal coverage and the right to health
- Health expenditures
- Measles vaccination
- Out-of-pocket expenditures
- Polio vaccination

6. National target or goals set by Member States
- National accountability mechanisms
- National implementation plans
- National policies aligned with Health 2020
- National target setting

6.2.3 The way forward

'State of Health in the EU'. The European Commission is moving towards promoting evidence-based policymaking by means of health indicators at the national level through the 'State of Health in the EU' inititative, which involves the preparation of country health profiles on a two-years basis. The 'State of Health in the EU' will presumably involve the release of concise and policy-relevant profiles summarising the state-of-play in each EU Member State concerning: 1) the health status in the country, 2) the determinants of health, 3) the organisation of the health system, and 4) the effectiveness, accessibility and resilience of the health system. The country health

profiles may emphasise country-specific characteristics and challenges, and potentially steer policy dialogue.

The initiative envisages the production of a biennial State of Health in the EU report, comprising the EU-focused OECD *Health at a Glance Report* followed one year later by a report of the OECD and the European Observatory on Health Systems and Policies that will serve as a basis for the individual country health profiles for each Member State. The first series of country health profiles is expected to become available in November 2017. The discussion on the indicators to be used for the initiative seems still ongoing. Evidently, it is fundamental that the indicators selected are robust, harmonised and policy fit, otherwise the exercise would obviously miss its target. It is also evident that the list of indicators that will be eventually selected for the 'State of Health in the EU' will *de facto* enjoy a special status and constitute the core of a list of sustainable EU indicators.

A proposed ERIC. As concerns the maintenance and governance of the EU health information system, in 2013 the proposal was made of borrowing from the governance of RTD projects the mechanism of a 'European Research Infrastructure Consortium (ERIC)'. This Consortium would group public health institutes and indicator providers across Europe and be tasked, among others, with[42]: the definition of work plans for indicator development for population health and health systems monitoring and the related maintenance of a network of national experts, the production of standardized and comparable health examination indicators for major chronic disease risk factors (obesity, hypertension, high cholesterol and diabetes), the establishment of a system for management of standardized data, the development of prioritisation criteria for the monitoring of impacts of environmental chemicals on health and the coordination of biomarker, monitoring and reporting on perinatal and child health issues, the establishment of a platform for population based registries for diseases, injury surveillance and for clinical and administrative data on healthcare including the establishment of standards and approaches for clinical and administrative health data collection and sharing between countries, and in line with the 'State of Health in the EU' approach, support in the identification, assessment, validation and implementation of a common set of methods to be routinely applied for the evaluation of health care systems (healthcare performance, evaluation of health care policies, impact of interventions, etc.). Transfer of activities to an ERIC, after BRIDGE Health financing is completed, is, however not yet secured due to various financial and technical constraints that are being addressed by the promoters of the initiative.

JAF-Health. Since 2013, the Joint Assessment Framework on health (JAF-Health) has been running as proposed by the Social Protection Committee (SPC) with a view to strengthening the evidence base in its activities related to health policy and to creating a link first and foremost with the identification of challenges within the Europe 2020 Governance structure and the European Semester but also in relation to in-depth thematic reviews and any other relevant tasks in the context of the Open Method of Co-ordination (OMC). The various European semesters have put an emphasis on the effectiveness of the health systems to contribute to preserving and restoring good health of the EU's population and their fiscal sustainability. Monitoring of healthcare performance in general and long term care systems performance have therefore become a priority[43] together with that of related policy developments. JAF-Health is to support monitoring and assessment of structural reforms under the Employment Guidelines through a quantitative indicator-based assessment methodology. The findings from this assessment represent the basis for identifying and verifying progress towards the common objectives of the OMC health strand, and for supporting the work on development of Staff Working Documents (SWD) and Country Specific

[42] See EGHI, 'A potential ERIC on Health Information', Scoping Paper for considerations of EU Member States and EEA/EFTA countries in the Expert Group on Health Information, 17 December 2013. http://ec.europa.eu/health/strategy/docs/hi_eric_scopingpaper_en.pdf

[43] http://ec.europa.eu/europe2020/pdf/2016/ags2016_draft_joint_employment_report_en.pdf

Recommendations (CSR). Reservations have been made about the suitability of the JAF Health proposal for deriving conclusions or recommendations in the course of the European Semester process, due to the limitations in data availability.

So far JAF has been articulated into a list of some 60 health indicators variously grouping indicators of health outcomes, health system access, healthcare quality, and health systems resources mainly from Eurostat and OECD sources. The first Country Recommendations produced highlighted several limitations in recourse to JAF Health data only. Moreover, the problem of incomplete data coverage in the area of health hindered the use of a weighted EU-28 average as a reference point for illustrating the indicator results, the way it is conceptualised in the core JAF. Furthermore it was recognised that timeliness of data collection poses problems as sometimes the updates are available only every 5-6 years as was the case of EHIS. It was therefore proposed to improve continuity of JAF Health indicators based on EHIS by their inclusion in the EU-SILC health module with a view to collecting lifestyle indicators every 3 years instead of 5-6 years. It was also concluded that policy recommendations could not be based on JAF Health indicators alone, but that they should be based on an in-depth review of time trends based on nationally available data that arguably would face less time lags in data availability.

6.3 State of Implementation of Selected EU Indicators in Member States

This section describes the current state of implementation of the six case-study indicators selected, with special focus on the five sample Member States identified. Since case-studies are the major source of first-hand information in this Study, it is important to briefly outline the salient aspects of the indicator definition, the methodology recommended and the data sources. This section highlights the main disparities that exist with these aspects across MS, and provides an overall mapping of the main alternative indicators that exist at international or national level in the same policy area.

6.3.1 Cancer incidence and prevalence

Cancer morbidity is a major cancer-monitoring indicator that lends itself to multiple uses including measuring the burden of disease and the room available for prevention policies. The ECHI indicator on cancer incidence defined as: "*The number of patients with newly diagnosed cancer during a given calendar year divided by person-years at risk, expressed per 100.000 population.*"[44] No ECHI data have been published as EU-harmonized data, as the indicator is still considered under development. This also depends on the uneven availability of cancer registries across the EU[45] and possible disagreements on which cancers to monitor since incidence and prevalence vary from Country to Country.

Incidence is calculated for all cancers combined without non-melanoma skin cancer and for nine specific cancers[46]. The OECD Health at a Glance report publishes data on breast cancer, prostate cancer, lung cancer and colorectal cancer incidence. These parameters have been selected because these types of cancer together account for half of the estimated overall burden of cancer in OECD countries. All these synthetic indicators use the IARC GLOBOCAN, ECO and CI5 plus databases, which gather data from Member States through the WHO Health for All survey and directly store registry data. The preferred data sources are cancer registries (population based or established at the regional/local level). Cancer registries, however, are unevenly distributed across the EU and other estimation methods are used where they are not available. Because of different algorithms, IARC results may differ from those calculated at the national level or by the European Network of Cancer Registries (ENCR)[47]. GLOBOCAN and ECO also calculate ***prevalence*** of cancer by means of mathematical models based on incidence. The standard methodology used by GLOBOCAN/ECO may produce different results from those developed by national bodies with the same raw data. It appears that GLOBOCAN and ECO use different population sizes for their estimates.

Alternative indicators to the ECHI/GLOBOCAN ones are sometimes produced at the national level for domestic reporting. This mainly depends on the availability of more recent and updated raw data. There is also substantial heterogeneity in how registers lag behind in processing cancer data, and delays of several years can be common in certain regions. To maintain long series often dating back several decades, there can be differences in the type of cancers included in the national version of the indicator, and in the algorithm used to extrapolate prevalence data from incidence or in the

[44] ECHI project factsheet indicator #20
[45] e.g. Greece has no data sources from registries whatsoever and therefore incidence data are estimated by extrapolating mortality data from registry ratios in neighboring countries
[46] Namely: 1) trachea, bronchus or lung, 2) breast, 3) colorectal, 4) prostate, 5) stomach, 6) melanoma, 7) cervical, 8) leukaemias/lymphomas and, 9) all childhood cancers
[47] The European Network of Cancer Registries is an umbrella organization of cancer registries currently hosted by the JRC

population used as a basis for estimates. Italy for instance routinely publishes data on incidence and prevalence of seven cancers and its internal prevalence data differ from the GLOBOCAN ones. Some countries complement data on prevalence with survey-related sources. ECHI and WHO are the only two sources of data on cancer incidence and prevalence from Cancer Registries or extrapolation from mortality sources and the two indicators should actually coincide weren't it for reporting patterns to the underlying databases, and different algorithms for extrapolation. An additional specific indicator on cancer incidence in children has been proposed under BRIDGE Health based on the findings from the CHILD project.

6.3.2 Alcohol consumption (total and hazardous)

The analysis covered two indicators, i.e. total and hazardous alcohol consumption, which are generally considered complementary. The background for these indicators is characterised by a plethora of parallel domestically-established indicators. In fact, the majority of the countries reviewed in this Study have substantially maintained the alcohol monitoring system that was in place before the establishment of EU or internationally-harmonised indicators.

At the population level, correlations between ***per capita alcohol consumption*** and mortality rates over time are used to demonstrate the link between consumption and its health consequences. In fact, one important goal of alcohol epidemiology is to link alcohol consumption with alcohol–related problems. The indicator on total alcohol consumption is defined as: "*The total (recorded + unrecorded) amount of alcohol consumed per adult (individuals aged 15+) over a calendar year, in litres of pure alcohol or Total Adult Per Capita (Total APC).*"[48] Recorded alcohol consumption refers to official statistics from various sources (production, import, export, and sales or taxation data, typically excises, or eventually dedicated surveys), while the unrecorded alcohol consumption refers to alcohol that is not taxed and is outside the usual system of governmental control and it is estimated through various means.[49] The indicator is calculated by WHO-GISAH by summing the recorded consumption of three-year average with the unrecorded estimates.

There are several reasons behind the existing disparities in the approach to measure total alcohol consumption, and namely:

- availability of data from specific sources. For instance, in some MS certain drinks are not subject to excise duties, therefore tax receipts cannot be used as a data source for consumption;
- the need to have detailed breakdowns at the regional or even local level when consumption patterns are very diversified within the country (e.g. in connection to tourism activities);
- the different ways to estimate unrecorded consumption in relation to country's specificities (e.g. self-distillation, undeclared wine, smuggling, cross-border shopping), as well as the uncertain reliability of survey due to different levels of social stigma associated to it.

Hazardous alcohol consumption is a survey-based indicator (not yet available at the time of writing) which will result from the second wave of the EHIS survey carried out in the 2013-2015 period. The EHIS II now includes six questions on alcohol consumption, four of which were not included in the first pilot EHIS questionnaire that

[48] ECHI indicator factsheet

[49] There is a ranking of possible sources. The first priority as a source of data is given to government statistics including those based on surveys; second are country-specific alcohol industry statistics in the public domain (IWSR-International Wine and Spirit Research, OIV-International Organisation of Vine and Wine, Wine Institute, historically World Drink Trends); and third is the Food and Agriculture Organization of the United Nations' statistical database (FAOSTAT)

was run in 2006-2009 in a subset of MS. The aim of these questions is to come to an estimate of hazardous alcohol consumption. In the first EHIS this was defined as: *The percentage of men/women having over the week on average ≥2 drinks/day (women) or ≥3 drinks/day (men*). Now, as agreed within the framework of the EU alcohol strategy, this is defined as an intake of 60+ grams of pure alcohol on one occasion, monthly or more often, during the past 12 months. Previously, a similar indicator was collected by means of *Eurobarometer* and, in some MS, by national surveys, with notable limitations in sampling strength and comparability. Since 2013, EHIS has been enshrined in a regulation[50] and must be carried out at least every five years. Nothing hinders MS from carrying out more frequent surveys.

The need to maintain parallel domestic measures of hazardous alcohol consumption has been generally caused by two main reasons:

- the need to align data with definitions of hazardous alcohol consumptions that are laid down in the guidelines for clinicians and prevention services that are elaborated by national or regional public health authorities;
- the perceived possible bias induced by posing these questions in the framework of a health-related survey rather than in a more 'neutral' setting.

Alternative indicators. The OECD maintains a separate alcohol consumption database updated annually based on a collection of various national sources (mainly administrative and fiscal data), which often do not include unofficial consumption. There is an additional WHO survey aimed to investigate health behaviour in school children (HBSC) that specifically targets children aged 11, 13 and 15 and appears therefore complementary to EHIS (which covers the 15-65 age range). On top of that, ESPAD collects indicators on hazardous alcohol consumption among teenagers of 15-16 age by means of a school survey. This has been endorsed as a potential European Indicator within the framework of the BRIDGE Health project together with another dedicated indicator on hazardous consumption among the youth from the CHILD project and an additional "objective" indicator of hazardous alcohol consumption defined as the share of hospital patients with an alcohol diagnosis.

Certain Member States tried to develop new synthetic indicators combining up hazardous alcohol consumption and binge consumption behaviours. For instance, Italy has adopted in 2015 an indicator of *"consumption of alcohol at risk"* that is composed by the share of population below 18 consuming any quantity of alcohol, those exceeding a daily consumption of 2 standard units of alcohol for men, and 1 for women and the elderly, and the share of those involved in binge drinking at least once a year[51].

6.3.3 Healthy-life years (HLY)

The ECHI indicator of healthy-life years (HLY) measures the number of remaining years that a person of specific age is expected to live without any severe or moderate health problems. This information is essential for the programming of healthcare resources and, in general, improving the sustainability of health systems. The indicator is collected by Eurostat, based on self-perceived survey questions included in the annual EU-SILC survey (the so-called GALI - Global Activity Limitation Instrument). The GALI measures the extent of any limitations due to a health problem[52] that may have affected respondents, for at least six months. The HLY

[50] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0141&from=EN
[51] Istisan, Epidemiologia e Monitoraggio Alcol-correlato in Italia e nelle Regioni – Rapporto 2015 http://www.iss.it/binary/publ/cont/15_3_web.pdf
[52] The notion of 'health problem' for Eurostat's HLY reflects a subjective disability dimension (disability as such has been never standardized in objective, measurable terms).

indicator combines this self-perceived limitation due to health with mortality data (life expectancy).

There are a series of composite indicators of life expectancy variously combining mortality and morbidity aspects and aimed at providing a summary measure of population heath. While healthy life years is regularly collected in all the Member States visited with a view for its publication as a European indicator, it is not necessarily the indicator more frequently used for that purpose at the national level or the same indicator disseminated as the Healthy Life Years in the different national health information systems. As a result of that, the indicator usually coexists with other similar indicators implemented at the national level or is known nationally in a format slightly different from the one published at the EU level, possibly resulting in diverging values. There are a number of reasons why experts and stakeholders in some countries use differently-defined versions of Healthy Life Years, namely:

- national life expectancy tables are perceived as more precise and reliable than those currently calculated at EU level[53];
- preference given to slightly different formulations of the GALI question in order, for instance, to ensure comparability with domestic historical series in place;
- the need to have a regional breakdown of data or by socio-economic status;
- different availability of life expectancy data at birth.

***Alternative indicators*.** All Member States reviewed here but Finland have also collected data to calculate the WHO "disability-adjusted life year" (DALY)[54], which extends the concept of potential years of life lost due to premature death to include equivalent years of 'healthy' life lost by virtue of being in states of poor health or disability. DALY combines mortality and morbidity, using a complex econometric model, which includes weighting function, time-discounting, and approximately 400 health conditions. DALY is perceived as an indicator complementary rather than alternative to HLY in terms of approach and philosophy. It does not lend itself to be used for monitoring purposes, as effectively as HLY and being very far from basic data it is perceived as not handy as an early warning system. It is frequently used for analytical purposes to highlight drivers behind problem causes and the possible redressing actions.

6.3.4 Healthcare associated infections (MRSA incidence)

Health care-associated infections (HAI), or infections acquired in health-care settings are the most frequent adverse event in health-care delivery. The surveillance for HAI is in the remit of ECDC, who coordinates the work of the Healthcare-Associated Infections Surveillance Network (HAI-Net)[55]. The single aggregated HAI indicator is defined as: *The crude prevalence of residents with at least one HAI in long-term care facilities (LTCFs).* This indicator is collected via the Point Prevalence Surveys (PPS), which replaced the previous system based on self-reporting. Actually, the HAI-net administers two different PPS: one for acute care hospitals and one for long-term care facilities (LTCFs). The first PPS wave in acute care hospitals was conducted in 2011-2012 and involved 1149 hospitals in 30 countries. The second wave (2016-17) is ongoing, and the initial feedbacks indicate an increase in the participation.

Among the most frequent adverse events is the infection from a variant of *staphylococcus aureus* resistant to meticillin (MRSA), which is isolated in about 5% of

[53] In some MS mortality tables are based on historical trends and not on the algorithm used at EU level. The ultimate ambition of the latter method is to develop a sophisticated calculation system, but is reportedly not very precise at certain age ranges. A number of interviewees believe it should be changed.
[54] http://www.who.int/healthinfo/global_burden_disease/estimates_country/en/
[55] http://ecdc.europa.eu/en/healthtopics/healthcare-associated_infections/hai-net/Pages/HAI-Net-surveillance-network.aspx

all healthcare-associated infections (it is also denominated 'healthcare-acquired MRSA'). For this reason, although the issue is typically covered by the surveillance systems for antimicrobial resistance (AMR), MRSA incidence is often used as a proxy for HAI. MRSA is a public health priority in Europe, especially in southern countries (Italy, Greece), whereas other EU MS seemingly managed to keep the rate of MRSA under control or even diminish it, through a mix of measures.[56] The MRSA incidence indicator is defined as: "*Staphylococcus aureus. Percentage (%) of invasive isolates with resistance to meticillin (MRSA)".*[57] The indicator is developed and maintained by EARS-Net – i.e. the ECDC-coordinated EU surveillance network for antimicrobial resistance (AMR). EARS-Net involves representatives from EU28 Member States who collect routine clinical antimicrobial susceptibility data from a network of participating laboratories and directly upload data to The European Surveillance System (TESSy) at ECDC on a yearly basis.

Alternative indicators. The incidence of MRSA is broadly considered an important surveillance indicator, although in some countries, where the reported incidence is minimal (e.g. Finland[58]) it is not viewed as a good proxy for HAI. Also some Italian regions are moving towards considering *Klebsiella pneumoniae carbapenemase* (KBC)-producing bacteria[59] as a more relevant indicator for early warning purposes since MRSA is viewed as too narrow in scope (surgical units only), while there is a growing need to monitor AMR also in nursing homes (e.g. through *Klebsiella*). The EARS-Net data collection and publication (under the auspices of ECDC) is the undisputed reference source for practitioners. In parallel, some MS operate national surveillance mechanisms partly overlapping with the EARS-Net. For instance, in Poland, in addition to the EARS-net affiliated system, managed by the National Medicine Institute, there is a regulatory reporting system[60], which is mandatory for all hospitals, and consists of an annual report of all AMR cases that is transmitted to the central Chief Sanitary Inspectorate (but not to ECDC). The indicators collected through these two systems are not consistent due to different coverage, methods and reliability.

6.3.5 Waiting times for elective surgeries

The importance of monitoring waiting times for non-urgent health services is related to both the need to prevent health adverse effects to patients (stress, anxiety, pain etc.) and to prevent dissatisfaction and perception of health system inefficiency. This indicator was included in the ECHI shortlist (with specific focus on elective surgeries), but a final agreement on its definition could not be found before the end of the Joint Action, so after a period in the 'implementation section' of the ECHI list it was eventually declassed to the 'development section' of the list. The definition retained in ECHI reads: "*the average waiting time for elective (non-urgent) surgeries of PTCA (Percutaneous Transluminal Coronary Angioplasty)*[61]*, hip replacement and cataract operation, measured in number of days"*.

[56] For instance, in Germany MRSA rates seemingly decrease from 20% in 2011 to 12.8% in 2015, with the introduction *inter alia* of patient isolation in its national protocols. Source: Bundesministerium für Gesundheit, Bundesministerium für Ernährung und Landwirtschaft, Bundesministerium für Bildung und Forschung (2015), DART 2020, Bundesministerium für Gesundheit, Berlin

[57] http://ecdc.europa.eu/en/healthtopics/healthcare-associated_infections/hai-net/Pages/HAI-Net-surveillance-network.aspx

[58] THL, 'Antimicrobial Resistance in Finland. Finres 2012.', Discussion Paper 15/2014, 2014. https://www.julkari.fi/bitstream/handle/10024/116015/THL_TP15_2014_eng.pdf?sequence=1

[59] Klebsiella pneumoniae carbapenemase (KPC)-producing bacteria are a group of emerging highly drug-resistant Gram-negative bacilli causing infections associated with significant morbidity and mortality worldwide.

[60] Bill of 5th December 2008 "preventing and combating infections and infectious diseases in the population"; and regulation 23 November 2011 "List of the alarm indicators, HAI registration and alarm factors and current epidemiological situations in hospitals.

[61] Percutaneous Transluminal Coronary Angioplasty

At the international level, OECD has tested its use in the early 2000s based on a pilot survey in six countries (OECD Waiting Time Project)[62]. This pilot exercise had a limited follow up. In 2011-12, OECD mandated a second Waiting Time Project with the objectives of comparing policies across countries and collect comparative waiting times figures for specific procedures.[63] As a result, various countries started collecting and reporting the indicator to OECD, although with various methodological disparities. The indicator definition used in this Study is the OECD one: *inpatient waiting times (from specialist addition to the list) of patients treated in a given year (publicly-funded patients)*[64]*.* In addition, OECD publishes a parallel waiting time indicator, i.e.: the waiting time of patients on the list at a given census date (at a certain point in time instead of those treated in a given period).

As discussed above, the ECHI Joint Action did not manage to find an agreement on the definition of the indicator. In particular, the open issues with the ECHI definition were mainly three (i) the appropriateness of the three elective surgeries selected to measure the indicator (percutaneous transluminal coronary angioplasty, hip replacement and cataract operation); (ii) the alternative between calculating waiting time at the time of admission to the treatment or at a given periodic census of patients on a waiting list; (iii) the use of mean or median or both values. The second OECD project on waiting times addressed these issues conducting a pilot assessment of all these variants. Despite the different MS capacity to produce the data requested, the results show there is no consensus on which metric is more significant for waiting times, i.e. waiting times for patients treated, or waiting times for patient on the list, and whether waiting times should be measured since patient placing on the list or since GP/family doctor referral to specialist. An additional harmonization constraint is the different system used by MS for the classification of surgical procedures, i.e. different versions of the ICD-CM (International Classification of Diseases – Clinical Modification) code[65], and national variants. In some countries the code is attributed ex post (at discharge point), preventing *de facto* interim monitoring

Alternative indicators. The OECD data come from national administrative databases. Some alternative versions of this indicator based on interview surveys also exist. This is notably the case with the Commonwealth Fund survey, which in various editions included questions on waiting times[66]. Data were collected from 11 countries, of which 5 were EU MS, but in relatively small samples of the population. Some countries also collect the 'referral to treatment' waiting times, which measure the time elapsed from GP / family doctor referral rather than from addition to the list by the specialist. However, only few countries seem in the position to report such indicator (e.g. Denmark), so this indicator – although collected in the 2011/12 project – is not reported in the OECD database. There is general consensus among practitioners on the superior quality of administrative records (such as hospital discharge registries) as compared to interview data, like those produced by the Commonwealth Fund, which were however used in the past in some OECD reports.

Interview surveys are sometimes used to externally assess the validity of administrative data (Poland) or to replace them (France). However, it is worth noting

[62] Hurst, J. and L. Siciliani (2003), "Tackling Excessive Waiting Times for Elective Surgery: A Comparison of Policies in Twelve OECD Countries", OECD Health Working Papers, No. 6, OECD Publishing. Siciliani, L. and J. Hurst (2003), "Explaining Waiting Times Variations for Elective Surgery Across OECD Countries", OECD Health Working Papers, No. 7, OECD Publishing.

[63] Siciliani, L., M. Borowitz and V. Moran (eds.) (2013), Waiting Time Policies in the Health Sector: What Works?, OECD Health Policy Studies, OECD Publishing. http://dx.doi.org/10.1787/9789264179080-en

[64] See above

[65] http://stats.oecd.org/wbos/fileview2.aspx?IDFile=cae608c4-fa81-4f56-8d7f-a0d4d609de80

[66] A question was asked to households to ascertain the percentage of respondents who waited for elective surgery for four months or more. The survey results are particularly useful to compare countries with and without a waiting time problem, though the information is only available at an aggregate level and obtained with a relatively small sample size and may suffer from recall bias: http://www.commonwealthfund.org/interactives-and-data/international-survey-data

that the Social Protection Committee integrates waiting times (for medical examinations and 'to see a doctor' – elective surgeries not included) in the indicator on access to health care proposed for the Joint Assessment Framework (JAF) methodology (along with costs and distance).[67] The proposed indicator is interview-based (EU SILC) and regards self-reported decisions to give up a health treatment or visit due to too long waiting lists.

6.3.6 Share of day cases

A day-care discharge is the release of a patient who was formally admitted in a hospital for receiving planned medical and paramedical services, and who was discharged on the same day. The development of same-day surgery in hospitals or outside hospitals has been generally encouraged across Europe as a way to reduce costs by avoiding unnecessary hospitalisations. A Study published by OECD in 2012 (funded by the EU) aimed at assessing the performance of hospitals in Europe by comparing the share of surgical procedures performed as inpatient or day cases.[68] The study revealed significant variations across Europe in the average length of stay in hospital and the share of patients treated on a same-day basis (as day cases and outpatient cases). Eurostat collects and publishes an indicator on day cases defined as[69]: Share of surgical procedures performed as day cases on the total, where a 'day case' is described as follows: "*day care comprises medical and paramedical services (episode of care) delivered to patients who are formally admitted for diagnosis, treatment or other types of healthcare with the intention of discharging the patient on the same day. An episode of care for a patient who is admitted as a day-care patient and subsequently stays overnight is classified as an overnight stay or other in-patient case*."[70]

The data that OECD and Eurostat collect on surgical procedures are not always consistent due *inter alia* to differences in counting method and in the definition and coverage of day surgery. The results of the OECD pilot data collection confirmed that many countries are still only able to report data on day cases in hospitals and unable to report data on outpatient cases i.e. where patients are not formally admitted in hospital or in any other health care facility (typically ambulatory setting). Against this background, OECD, Eurostat and WHO-Europe have agreed to collect data on outpatient cases for two surgical procedures, namely cataract surgery and tonsillectomy, which are performed to a large extent as day surgery. No relevant 'alternative' indicators in this area have been identified.

[67] DG EMPL, Towards a Joint Assessment Framework in the Area of Health. Work in progress: 2015 update. http://ec.europa.eu/social/BlobServlet?docId=14949&langId=en

[68] https://www.oecd.org/health/Comparing-activities-and-performance-of-the-hospital-sector-in-Europe_Inpatient-and-day-cases-surgical-procedures.pdf

[69] Data are submitted to Eurostat on the basis of a gentlemen's agreement that is without a legal obligation. There is no implementing legislation in the area of non-expenditure health statistics.

[70] http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_non-expenditure_statistics_-_methodology

7. ANSWERS TO THE EVALUATION QUESTIONS

7.1 Overview

This Section deals with the core research questions of the Study, i.e. the implementation costs and benefits for national stakeholders of EU harmonised indicators, and how the balance is expected to evolve under the different scenarios considered. The analysis builds primarily on the findings from the six case-study indicators that have been researched in-depth in the five sample Member States (Finland, Poland, Italy, France and the Netherlands). These findings have been triangulated and corroborated with further EU-level interviews and analysis of documentary sources, as well as with the results of the survey consultation of national stakeholders and EGHI members. Where relevant, the survey respondents have been segmented by specific sub-groups to highlight variation in the ratings and in particular the sub-group of respondents concerned in health indicators from a policy perspective ('policy-concerned') and the sub-group of respondents concerned in health indicators from a healthcare management perspective ('HC management-concerned').

The structure of this Section includes four more chapters, as follows:

- **Implementation status.** This sub-sections deals with the state of implementation of indicators. In particular, if and how the indicator is collected and the degree of population coverage, possible issues affecting the quality and maintenance of the indicator, and the actual level of harmonisation and cross-country comparability.
- **Use and benefits.** The potential benefits of indicators depend in the first place on their uptake and concrete use by policy-makers and stakeholders. Overall, the dimensions reviewed in this sub-section include: the perceived overall utility and added-value of harmonised indicators, their use for policy process (in broad sense); other possible uses not directly related to policy-making (epidemiology, research, accountability etc.), and specific use for cross-country comparison and benchmarking.
- **Estimated implementation costs and burden.** The analysis addressed – with the inevitable uncertainties due to the various information gaps - the costs for all players related to: collecting raw data (e.g. recording on a registry, running a survey…), aggregating, validating and treating raw data and elaborating the indicator (including statistically) and reporting / disseminating the indicator. It also addressed the issue of unnecessary burden due to parallel implementation of concurrent indicators and duplications in data reporting, as well as stakeholder perceived factors to improve the cost / benefit balance of harmonised indicators.
- **Scenario Analysis.** The final section analyses and compares the expected trends of costs and benefits associated with the implementation of specific indicators, under two main scenarios: (i) the no change scenario; and (ii) a scenario where a hypothetical sustainable system ensures a satisfactory implementation of fully-harmonised indicators. The analysis is essentially based on a qualitative, multi-criteria assessment, supported by the case-study evidence that was collected in the sample MS and extrapolated so as to draw indications on broader EU-wide trends.

7.2 Implementation Status of EU Indicators

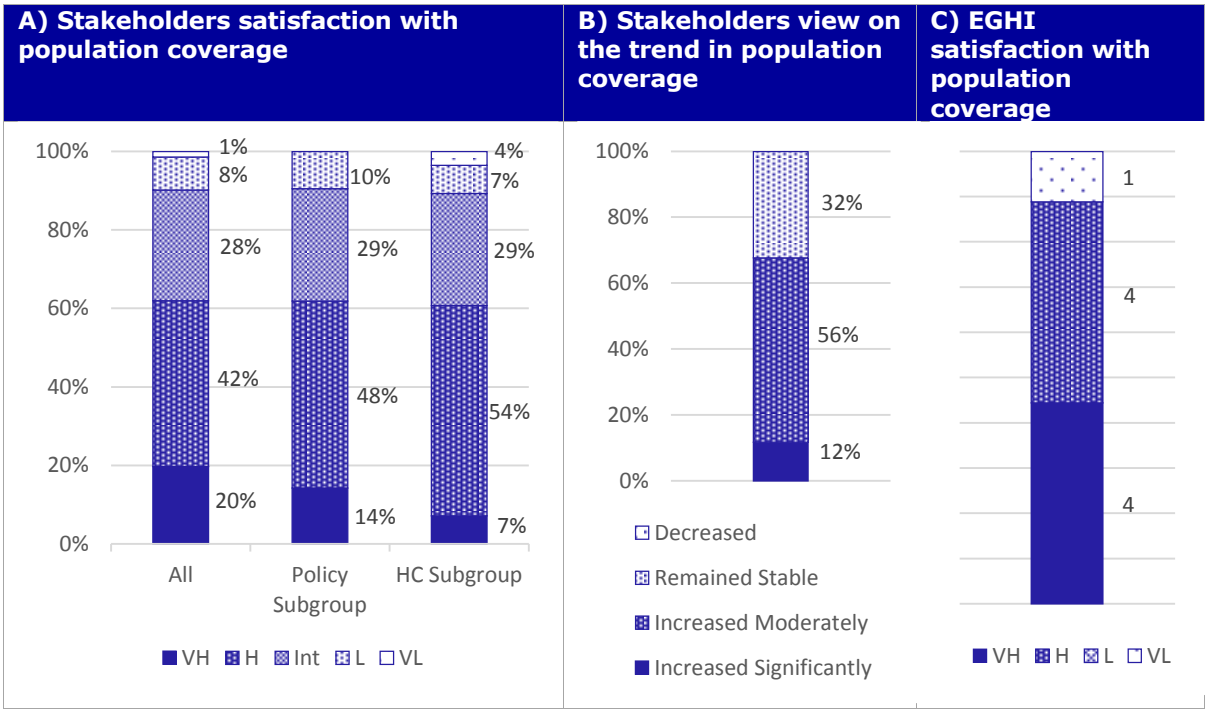
7.2.1 Data collection and coverage

The coverage of indicators. Overall, the comprehensiveness and coverage of the datasets collected for the compilation of EU indicators has been improving over time, due to various processes: in the first place, the formalisation of some previously *ad hoc* exercises as Eurostat indicators (e.g. EHIS, EU SILC), then peer pressure on data providers to improve representativeness of data (e.g. cancer registry), and finally grassroots pressures in areas of widespread concern (e.g. from patient associations, environmentalist groups). For instance, various MS have adopted over the last five years initiatives to strengthen the outreach of their cancer registries, although not always followed by consistent financial investments. Similarly, the number of isolates tested for MRSA in the sample countries has grown by 30% in five years.

In a few cases, the data collection growth was driven by specific national policies. This is the case with the adoption of waiting times 'guarantees' in Finland. As regards softer mechanisms it is relevant to report the incentives to participate in the ECDC Point Prevalence Survey on HAI in Poland (reported better performance scoring by the National Health Fund) as well as similar incentives Dutch healthcare providers used to receive if they reduced waiting times.

This trend is also confirmed by the survey results, which clearly showed that more than two-thirds of the stakeholders consulted perceive a positive trend in the overall coverage of international indicators (Figure 7.2.1). Altogether, the level of satisfaction with the current coverage is positive, with only less than 10% of critical views.

Figure 7.2.1 – Consultations results on population coverage



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

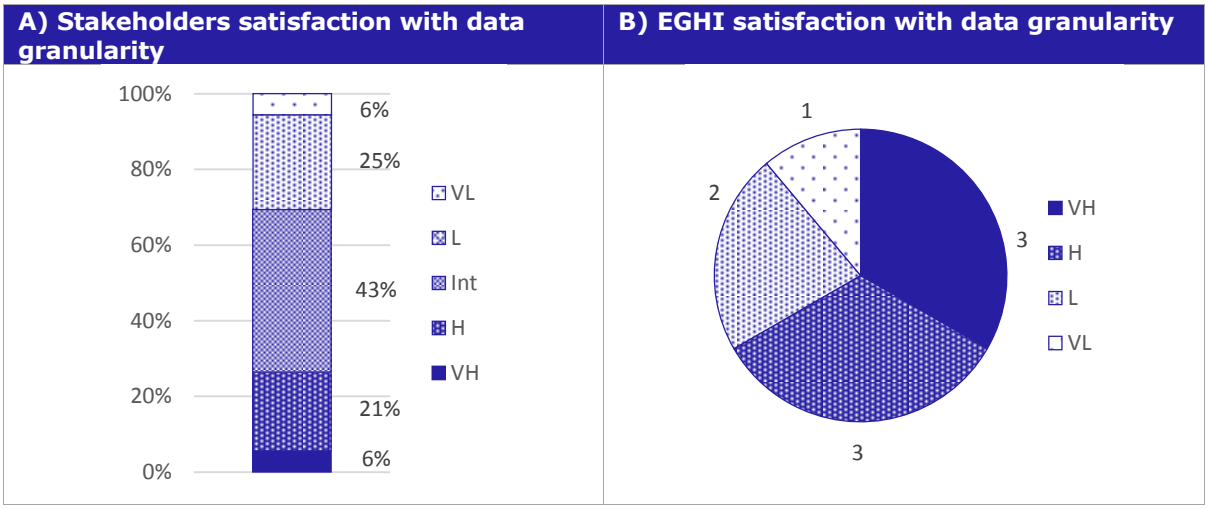
Adoption by MS. In the majority of cases, increased coverage has also been tantamount to a higher number of reporting countries. This is obviously a visible consequence of the formalisation of pilot exercises in EHIS, but can be noted to have

spontaneously occurred also in other cases without the need for a formal regulation. So the sheer process of developing an indicator increases the number of reporting countries. For instance, Poland and Italy started reporting waiting times to the OECD in 2012 and 2013 respectively. However, also the reverse trend could be observed, i.e. some countries reported difficulties to report cancer data to JRC in the detailed format required due to privacy safeguard legal provisions.

Granularity of data. The simplifications requested by synthetic international indicators go against a trend towards growing demand for increasingly detailed and analytical data. The survey results show a lower degree of satisfaction with the level of granularity of the data available, i.e. with the categories used to break down the information across social or geographical subgroups. In the health equity perspective these are referred to as 'dimensions of inequalities' (or equity stratifiers) and are often essential to correctly interpret data, understand trends and differences, and design policies. Only 27% of respondents are satisfied with the current granularity of indicators in this respect. Qualitative feedbacks have also highlighted the poor correspondence between the offer of regionally disaggregated data with a demand for information reflecting the actual administrative classifications used in the country, and the limited analytical power of the age sub-groups used for stratification.

In the case of MRSA and HAI this level of geographical detail is a highly informative aspect. While data can be comprehensive – especially in some countries – the level of breakdown available is not always adequate to needs. For instance, in some cases data do not adequately distinguish invasive infections, in other cases the information on the setting where the infection was acquired is missing (hospital, nursing home, community etc.), or data are aggregated at an intermediate level so that useful information is lost. In general, these factors reduce the significance of the information. Various MS have compensatory surveillance mechanisms in place to detect early-on anomalies of trends and may run *ad hoc* surveys to look into the origin and distribution of emerging issues.

Figure 7.2.2 – Consultation results on data granularity



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: 'Don't know' answers are not reported.

Table 7.2.1 – Summary of results from the case-studies

Indicator	Selected evidence from fieldwork
Cancer incidence and prevalence	• The geographical coverage of cancer registries has increased over the last few years. Finland and the Netherlands have a virtually complete coverage. At present, there are few countries with no registry at all (Greece and Hungary) and some with various degree of regional coverage only: Romania, France, Italy and Spain. All the others have national registries in

	place. This is due to a combination of factors. • On the demographic side, both cancer incidence and prevalence have increased in absolute terms due to the ageing of the population which makes cancer more socially visible. This has reportedly raised the level of political interest. This has been complemented by growing pressure from patient associations and other grassroots groups (environmentalists, etc.). Recently, the demand for prevalence data has also been growing in response to the increasingly perceived need to assess the costs of long term care of cancer patients on healthcare systems and related possible inefficiencies.
Healthy life years	• With the exception of the Netherlands, there was no regular survey to calculate this kind of indicators before HLY was harmonised at the EU level. By imposing to carry out the annual SILC survey Eurostat has therefore enabled national series to become available on a permanent basis from 2004 to 2014.
Healthcare associated infections (incidence of MRSA)	• The population coverage of MRSA surveillance data varies among reporting countries. Some countries report data from large national surveillance systems, while in others a much smaller subset of local laboratories and hospitals participates into the exercise, with inevitable consequences on statistical significance. Moreover, in some MS the size of the population observed is not constant over time due to variations in the number of participating laboratories and the number of isolates analysed. • HAI indicators are collected through the Point Prevalence Surveys (PPS) in long-term care facilities and acute care hospitals. In the case of PPS in long-term care facilities, the overall coverage varied remarkably and the representativeness of the samples was judged insufficient for statistical purposes. In the case of PPS in acute care hospitals, the participation rate varied from e.g. some 100% in Finland to 34% in the Netherlands, and was very low in France (3%), Italy (5%) and Poland (4%). • In some countries, participation in PPS was encouraged by means of reward mechanisms, e.g.: in Poland the National Health Fund promotes and rewards hospitals to take part in PPS giving them additional points in the scoring mechanisms that is used to estimate financial transfers. In any case, the representativeness of PPS data marked a significant improvement over the previous 'self-reporting' data collected by HAI-Net on surgical site infections and intensive care units infections. In Italy, it constitutes the only monitoring system of this kind country-wide.
Waiting times for elective surgeries	• As compared to the first OECD project (early 2000s), many countries are now reporting data on waiting times for elective surgeries. With the exception of France, all the other countries in the Study sample have now been included in the OECD database, two of them (Italy and Poland) recently. There remain some disparities in the territorial coverage, but the trend is clearly on the rise. • The indicator is statutorily collected in those countries that have adopted specific measures or targets to reduce waiting times or maintain them at an acceptable level. This is the case of e.g. Finland - where a 'waiting time guarantee' has been established - or the Netherlands, where incentives are in place to enhance care-givers productivity. However, if one considers waiting times as an indicator of access to health rather than of system efficiency, the coverage seems still insufficient. • The OECD data generally refer to procedures performed in hospitals for inpatients. This means that the indicator is silent on outpatient procedures (that represent a significant share of the total for certain operations like cataract) and out-of-pocket or insurance-based private care.
Share of day cases	• The information on surgical procedures are routinely collected and reported by health care providers for administrative purposes. It is only in insurance-based systems that hospital discharge registries are deemed to underestimate severely the total number of cases. These mechanisms typically allow to distinguish inpatient procedures from day cases, therefore

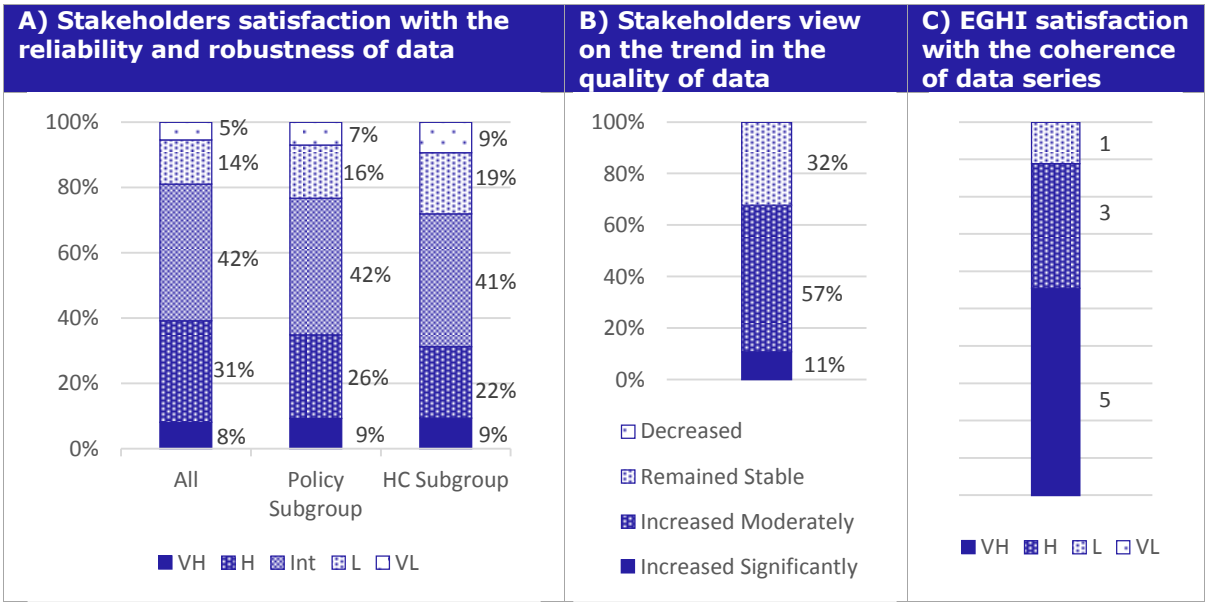
	the indicators is relatively easy to measure and there is a satisfactory coverage across MS. • Conversely, outpatient cases are not so straightforwardly available, since they are not covered by discharge registries and often paid for through mixed financing mechanisms. Procedures performed by private providers and paid out-of-pocket by patients are generally not tracked.

7.2.2 Data quality and maintenance

Overall perceived quality. A general judgement on the 'quality' of the EU indicators is outside of the scope of this Study and is probably a question that cannot be answered meaningfully, given the variety of indicators and heterogeneity of methodologies in place. However, the subjective perceptions of stakeholders on whether the indicator measurements are robust and reliable are important in order to anticipate possible obstacles and success factors behind their uptake and use at MS level. This is even more so in the case of stakeholders variously concerned with policy processes and/or healthcare management. The results reported in Figure 7.2.3 below highlight that about one-fifth of respondents is not satisfied with the overall indicator quality, and this dissatisfaction tends to increase in the 'healthcare'-related subgroup. This is possibly due to the greater maturity and harmonisation of cross-country population health information as compared to healthcare system indicators. However, a robust majority of respondents does believe there has been a substantial improvement over time.

A perceived poor reliability of the indicator now is not necessarily associated with a perceived lack of utility in the future when the indicator is assumed to be at full regime and its potential completely expressed. On the contrary, the current limitations are often considered a challenge to be surmounted by ensuring sufficient investment in time and resources. The most notable example is perhaps represented by MRSA and HAI indicators, which are for various reasons not considered (yet) as fully reliable, but at the same time regarded as highly necessary and potentially very useful in the long term. It is projected that the indicators will become increasingly stable over time and this seems generally associated with a higher perceived reliability of the indicator.

Figure 7.2.3 – Consultations results on data quality



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for

healthcare management purposes. 'Don't know' answers are not reported.

Issues of reliability and robustness of indicators. A common criticism and a perceived cause of limited dependability of the indicator is represented, for survey-based indicators, by the poor reliability of self-assessed health and the difficulties experienced in getting consistent and comparable information because of biases due to cultural factors. As will be discussed below, this represents also a major obstacle to perceived cross-country comparability. In the sample of indicators reviewed, this issue applies first and foremost to HLY (as self-reported disability would depend on context factors) and hazardous alcohol consumption (impact of social stigma).

According to some MS stakeholders HLY is of limited use unless a major methodological review is performed (which explains why it is frequently used in association with DALY). As concerns alcohol consumptions the reliability of EHIS based data is instead challenged by the diverging results of nationally-conducted surveys on the same subject.

Although survey-based, the HAI-PPS faces only marginally this problem, since it collects clinical evidence and not opinions. However, its robustness is potentially affected by the concrete methods used for the implementation, the skills of enumerators, and the seasonality. Other indicators, including those based on registries or administrative data, are also faced with methodological issues that can have a negative repercussion on their strength. For instance, the share of day cases indicator in various countries can be inluenced by 'double counting', i.e. the practice of registering separately certain multiple procedures that are carried out on the same patient as part of the same treatment.

The technical capacity of data collection entities and the quality of the procedures followed plays an evident role in the robustness of the results. International validated guidelines, standards and certifications are among the measures used to ensure the consistency across sources. However, significant disparities in the technical capacity of players, also within the same country, still affect the perceived quality of data from some cancer registries and/or microbiology laboratories.

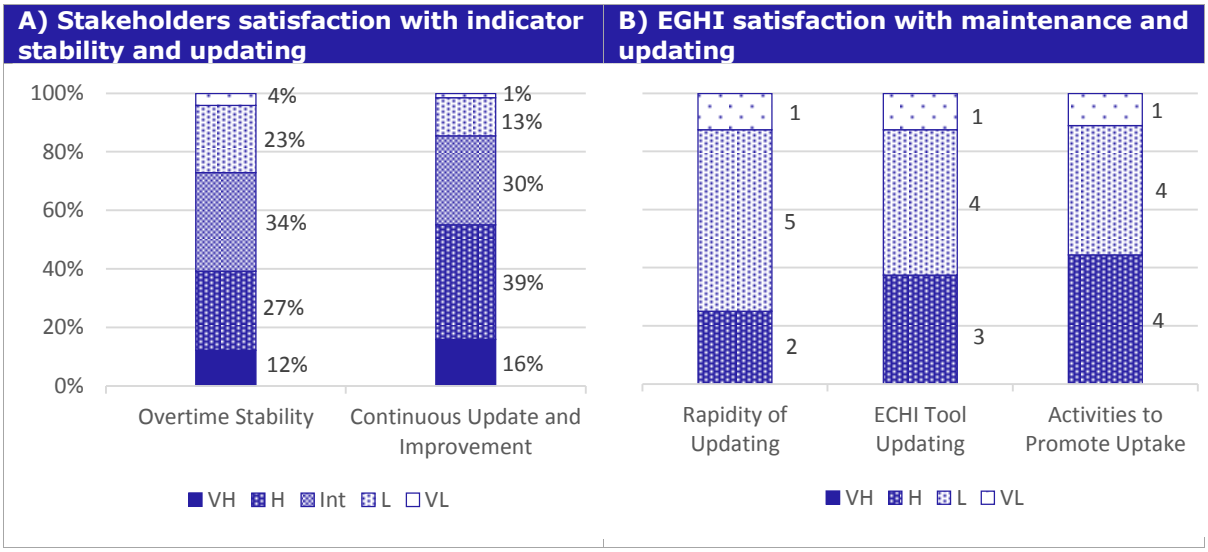
Maintenance and update. The 'maintenance' of an indicator within the health information system designates a set of activities that follow the development and standardisation of the indicator specifications and methodology. These range from technical updates aimed at correcting issues and improving harmonisation, to periodical reviews of the information provided and measures to enhance relevance and utility so as to promote its use. The same concept applies to the health information system on the whole, where identifying knowledge gaps in emerging areas and updating priorities for monitoring and analysis in a coordinated manner is a crucial task. The risk is that poor maintenance may translate in poor relevance of the information collected and ultimately into an unjustified data collection burden and/or a quality decline. At the same time, stability is fundamental to build meaningful data series and to be able to appreciate trends. For this reason, the updating of the specifications of an indicator - as well as of the overall indicator catalogue - requires a good coordination among all interested parties, including data users, to avoid unnecessary disruptions.

As shown in Figure 7.2.4, most stakeholders are satisfied with the level of maintenance of internationally harmonised indicators, although a non-negligible 45% expressed a neutral or even negative overlook. This percentage of unsatisfied respondents becomes even higher when it comes to assessing the perceived stability of the information, due to the breaks in time series caused by the frequent revisions.

The EGHI members consulted mostly confirmed the current maintenance shortcomings at the EU level. In particular, the updating process is too slow, partly due to the

complex procedures to revise data specifications and collection and – according to some stakeholders – the insufficient involvement of policy-makers' perspectives in deciding the information needs. The issue is possibly more acutely perceived in strategic areas like health system performance and health inequalities. As regards the ECHI Data Tool, issues were reported with the delay in updating new data, as well as with the lack of a clear underlying design, which contributes to make it apparently much less used than the other main international databases (moreover limited efforts seem in place to promote its use).

Figure 7.2.4 – Consultation results on maintenance and update of indicators



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: 'Don't know' answers are not reported.

Table 7.2.2 – Summary of results from the case-studies

Indicator	Selected evidence from fieldwork
Cancer incidence and prevalence	• Availability of data from cancer registries tends to be loosely correlated with the income and development level, although with notable exceptions. In some less developed areas, recently-established cancer registries often face accreditation/quality control problems. Different degree of compliance with internal and international quality control schemes is perceived as a major cause of non-comparability. • One of the main quality issues regards the mechanisms to avoid double counting. According to some experts' gross estimates cancer registries can be considered as a good reliable source of data for 50% of the EU population or so; some 30% still face some quality problems hindering full comparability; and another 20% of the population is essentially not covered.
Total and hazardous alcohol consumption	• In the majority of the Countries reviewed the EU indicator of hazardous alcohol consumption has added value to the existing ones (e.g. the French Health-Barometer Survey and the Health, and Healthcare and Insurance Survey, the Finnish Drinking Habits Survey) and therefore generally resulted in increased availability of data. But in some cases surveys carried out in different framework conditions have produced results not fully consistent with the available national series.
Healthcare associated infections (incidence of MRSA)	• Technical implementation aspects influence the significance of the MRSA incidence indicator. EARS-Net data are exclusively based on invasive isolates from blood or cerebrospinal fluid. This restriction prevents some of the inconsistencies that would arise if isolates from all anatomical sites were accepted. However, invasive isolates may not be representative of isolates of the same bacterial species from other sites of infections, i.e.

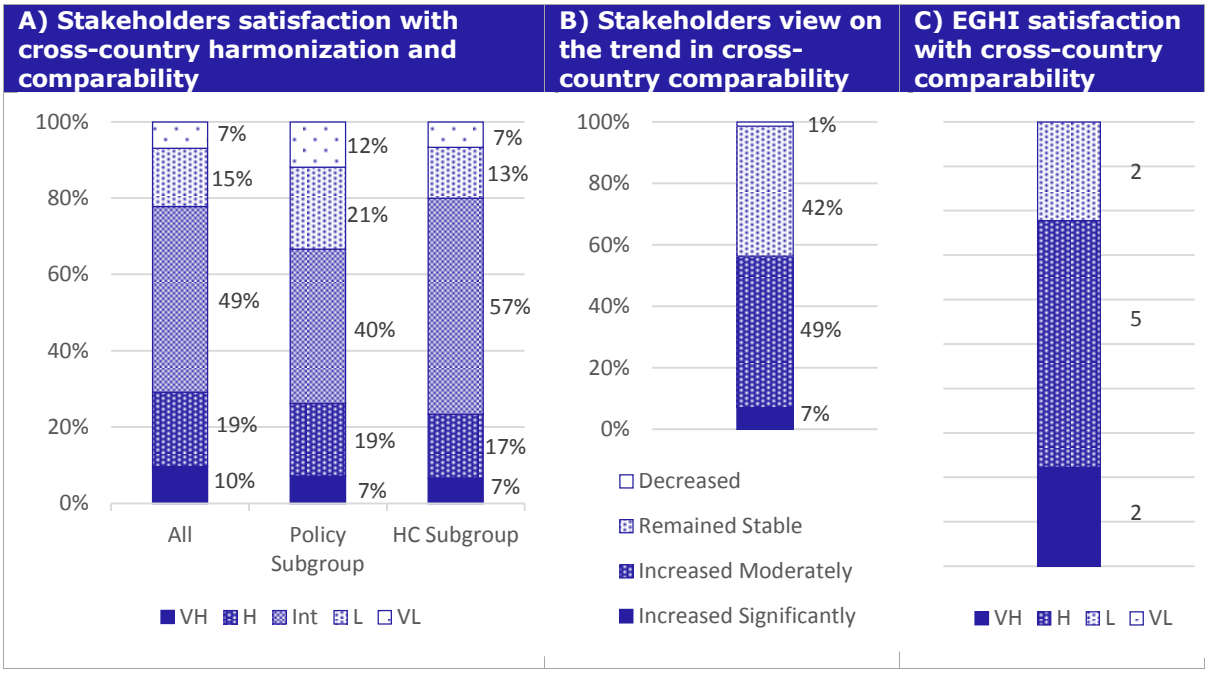
	urinary tract infections, pneumonia, wound infections, etc. Case ascertainment of patients with bloodstream infections (BSIs) is strongly linked to diagnostic practices and the frequency with which blood cultures are taken. Therefore, variations in blood culture frequency (non-differential sampling) result in an increasing uncertainty when comparing resistance percentages between health care providers. Differential sampling can occur if blood cultures are typically only performed after empiric treatment shows no adequate therapeutic response. Predictably, this will lead to a serious overestimation of the resistance percentage. • The use of guidelines for clinical breakpoints varies among countries in Europe, and in some instances even between laboratories in the same country. Some countries, including France and the Netherlands, have set up a "*National Antimicrobial Susceptibility Testing Committee*" as recommended by the EUCAST initiative, while others haven not. The ability to identify the microorganism and its associated antimicrobial susceptibility pattern may - and reportedly do - differ among laboratories.
Waiting times for elective surgeries	• While several countries reported only the main surgical procedure during a hospital stay (in France the unit of analysis is the 'hospital stay'), other countries record either all procedures performed or up to a certain number of procedures per patient, leading to double / multiple counting (this issue may apply also with e.g. cataract surgery performed in both eyes in Finland).
Share of day cases	• There are differences in the counting methods across countries. While several countries reported only the main surgical procedure during an hospital stay (in France the unit of analysis is the 'hospital stay'), other countries record either all procedures performed or up to a certain number of procedures per patient, leading to double / multiple counting (this issue applies also with e.g. cataract surgery performed in both eyes in Finland).

7.2.3 Harmonisation and comparability

Overall perceived comparability. Most of the perceived issues with robustness and reliability of indicators have a direct influence on stakeholders' views on the actual degree of harmonisation and cross-country comparability of data. In other words, even when the definition and the data collection methodology are standardised there remain uncertainties on whether the indicator does measure exactly the same parameter in all countries and supports meaningful cross-border benchmarking. The stakeholders' views in this respect are mixed, with positive views slightly prevailing over negative ones. However, among the policy-concerned subgroup of users scepticism prevails (Figure 7.2.5). This hints at the fact that the interpretation and use of results for comparing different countries' approaches can be particularly challenging and controversial (more in-depth analysis in Section 7.3.3). According to the majority of stakeholders consulted, cross-country comparability has improved in recent years, but less proportionally than the perceived trends in quality and availability of data (as seen in the previous sections), suggesting that more efforts are required before harmonised indicators can be systematically and consistently used for comparative purposes.

The EGHI members consultation revealed a more positive picture, partly explained by the awareness of the notable improvements occurred against the various methodological constraints. As discussed further below, the use of harmonised indicators for cross-country comparison requires an in-depth familiarity with the technical issues and limitations of the indicator, which among EGHI members is certainly greater than among other national stakeholders.

Figure 7.2.5 – Consultation results on harmonization and comparability of data



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

Comparability issues. The efforts to harmonise certain health indicators and standardise data collection and treatment methodologies do not always translate into an immediate comparability of results. More often than not – as the ECHI Joint Action experience showed – harmonisation is a long and multi-staged process that typically requires dealing with the specificities of a variety of national health systems (and regulatory frameworks), and when these are somehow by-passed through standardised EU-level surveys, there still remain problems with translating questions in a way that measure the same thing across different contexts and removing cultural bias from the interpretation of answers.

The indicator on the share of day cases clearly illustrates the issue. The indicator is highly standardised as it is also part of the OECD, EUROSTAT and WHO 'joint questionnaire on non-monetary health care statistics', the level of harmonisation and comparability of data has improved significantly. Being based on administrative records (discharge registries and the like) the indicator is not subject, in principle, to self-assessment or other subjective bias. Still, data on the share of day cases may have different meanings in different context because of:

- National differences in the very definition of 'day case'. For instance in the Finnish guidelines, a surgical procedure should be considered a day case if it is performed with intravenous infusion or local anaesthesia and carried out in an operating theatre. However, some procedures, which in principle can be considered as day cases, are not performed in an operating theatre, so hospitals may classify them differently.
- Differences in the definition and classification of surgical procedures. In the absence of an international classification of procedures, the OECD and Eurostat

have used the ICD-9-CM classification as a reference. Various EU countries have adopted this system but not all of them: for instance Ireland is reportedly using ICD-10-AM Australian classification system.
- Differences in the coverage of the indicator. Most countries report only the procedures performed by hospitals, but a few include also those performed as outpatient cases. The use of different denominators evidently alters the significance of the ratio.
- Difference in the number of procedures performed due to different level of demand and perceived needs. Certain countries perform up to three times more surgeries per 100,000 population than others.

A conceptually similar comparability issue affects MRSA incidence and HAI indicators. First of all, it should be noted that the likelihood of these infections is evidently higher in acute care hospitals in general, and in hospital specialized in certain surgical operations in particular, rather than in other settings. Secondly, these rates may positively correlate with one country's ability to carry out a more systematic and comprehensive surveillance, rather than with the ability to effectively tackle the issue.

In addition to the above factors affecting the consistency of the information collected in different country contexts, there are also policy and health practice specificities that have to be taken into account in analysing the rationale for disparities across countries. In other words, also assuming the indicators do measure the same thing in different contexts, the interpretation of differences should duly consider policy-driven factors such as the presence/absence of incentives e.g. to perform surgeries in outpatient settings or to reduce waiting times, as well as clinical practice (e.g. in Poland it is not allowed to perform percutaneous transluminal coronary angioplastyas a day case).

All in all, the above comparability issues lead various public health experts consulted to conclude that harmonised indicators are probably more meaningful for same-country vertical assessments over time (provided robust historical series are available) than for cross-country comparison. This is certainly the case for most of the indicators analysed in this Study.

Table 7.2.3 – Summary of results from the case-studies

Indicator	Selected evidence from fieldwork
Cancer incidence and prevalence	• There are different views as to the share of registry-based data needed to ensure the corresponding indicators are fully reliable and comparable. Some critics pointed out that data originating from registries in one country cannot be compared at all with data extrapolated from mortality tables in another country. • A second major limitation of comparability relates to the perceived difference in quality of the raw data across country (as discussed above). In this sense, there would be the need for stronger joint data audit systems.
Total and hazardous alcohol consumption	• While it is acknowledged that total alcohol consumption remains characterised by intrinsic limitations in comparability due to the different sources used, its main weakness is that it also includes non-drinkers, which can be misleading under certain conditions. • The comparability of hazardous alcohol consumption suffers from the usual limitations population surveys have when implemented in different cultural contexts, including different propensity to report abuse, framework effects and social stigma. To this aim, it has been observed that the level of harmonisation cannot be further increased unless major methodological overhauls, e.g. anonymous surveys, are carried out (at present, not always compatible with the different national laws in place on official statistical surveys).

Healthy life years	• It is generally recognised that the HLY indicator poses cross-country comparability issues. These relate to possible discrepancies in the way the global activity limitation indicator (GALI) question is asked or in the methods in the methodology used to carry out the SILC survey across MS. • Moreover, it has been highlighted that the GALI questions have the drawback of covering too many different aspects in one single question, which makes it difficult to properly interpret respondent's answers. For this reason, there is a demand for further refinement of the indicator at the European level to improve harmonization.
Healthcare associated infections (incidence of MRSA)	• There are several reasons why the indicators on MRSA and HAI are generally considered as not comparable across countries by stakeholders. In a nutshell: (1) disparities in the number of reporting laboratories and isolates examined; (2) sampling mechanisms, affecting the likelihood of finding resistant isolates in the samples tested; (3) different incentives for physicians to report the data on a voluntary basis; (4) high variability across regions and within regions themselves; (5) different technological abilities of microbiology laboratories; and (6) in the case of PPS, seasonality may affect the outcome of the survey. • These factors may easily lead to misinterpretations of the aggregated figures on the incidence of MRSA / HAI registered in different countries. Paradoxically, these rates may positively correlate with one country's ability to carry out a more systematic and comprehensive surveillance. The same consideration may apply to individual health care providers.
Waiting times for elective surgeries	• It is generally admitted that the indicator is probably more significant for same-country over time assessment than for cross-country comparison. The disparities in definitions, collection methods and coverage are significant (also within the same country).
Share of day cases	• Since OECD, EUROSTAT and WHO included day cases in their 'joint questionnaire on non-monetary health care statistics', the level of harmonisation and comparability of data improved significantly. However, the indicator on day cases does not necessarily measure the same thing in all countries. According to the evidence collected the possible issues regards: (1) differences in the very definition of a 'day case'; (2) differences in the population covered; (3) differences in the counting method and risk of 'double-counting'; (4) differences in the definition and classification of surgical procedures; (5) differences in the coverage of the indicator (a few countries include also the procedures performed as outpatient cases, so the different 'denominator' may alter the significance of the indicator); (6) variation in the number of procedures performed due to different levels of demand and perceived needs. Certain countries perform up to three times more surgeries per 100,000 population than others.

7.3 Use of EU Indicators and related Benefits

7.3.1 Overall utility and added-value of EU indicators

Perceived utility, drivers and obstacles. According to the Theory of Change underlying this Study, there is a series of drivers through which better health information can translate into tangible gains for population health and health systems sustainability. A detailed review of the relevant logical chains is provided in Section 5.1 of this Report, in a nutshell:

i. through the uptake and use of the indicators, and the information they provide, in the ***policy process*** (from design to monitoring) and/or ***healthcare system programming and management*** (in the case of certain health system indicators);
ii. through the improved ***knowledge*** that is made available to specific target groups and for specific goals, e.g. for epidemiological surveillance and prevention, research an innovation, information to health professionals, information to the public etc;
iii. in the case of internationally-harmonised indicators – through the opportunity to ***compare and benchmark*** across countries, so as to exchange best practice and foster cooperation.

As regards drivers (i) and (ii), the utility is broadly correlated with the quality and coverage of the information (as discussed in section 7.2) as well as with the relevance to actual needs and demand. Driver (iii) underlines the added-value of having EU-wide harmonised indicators instead of national ones. In as much as it fosters better and more evidence based initiatives and pools the information across the EU to generate more robust knowledge, it can be also viewed as a meta-driver ideally contributing to drivers (i) and (ii) above. The three drivers are analysed in the following sub-sections in the light of the evidence collected.

Overall, only some 15% of stakeholders believe the potential benefits of EU indicators are highly exploited at the country level, while some 40% think their use is limited or nil (Figure 7.3.1). Looking into the perceived obstacles it emerges that they result from a combination of factors. In particular:

- the possible lack of policy-makers' awareness of EU indicators, and the associated limited political commitment to their implementation (or the perceived need for it) are among the major obstacles according to stakeholders. This may translate also into shrinking budgets for their implementation, which in turn may lead to a further decline in their relevance for policy-making.
- Sometimes this is associated with more general relevance issues, i.e. the mismatch of indicators with national features and needs (including the required granularity of the information). This problem regards more frequently health system indicators and is felt more acutely by EGHI members, although for some informants there is an excessive emphasis on the disparities of national systems.
- Both the abovementioned issues call into question the usability of the information produced in the policy process. This concerns *inter alia* whether indicators are accompanied by sufficient analytical work guiding a mixed audience (including policy-makers) towards a correct interpretation of data – an aspect that the EGHI members consulted tend to see as deficient.
- Another aspect is whether the timeliness of data publishing is compatible with the policy cycle and other decision-making processes. Finally, uncertainties about the long-term stability of indicators may hinder their uptake. However, with few notable exceptions, this is seemingly not a primary issue for EU harmonised indicators.
- The added-value and utility of EU indicators may be affected by perceived

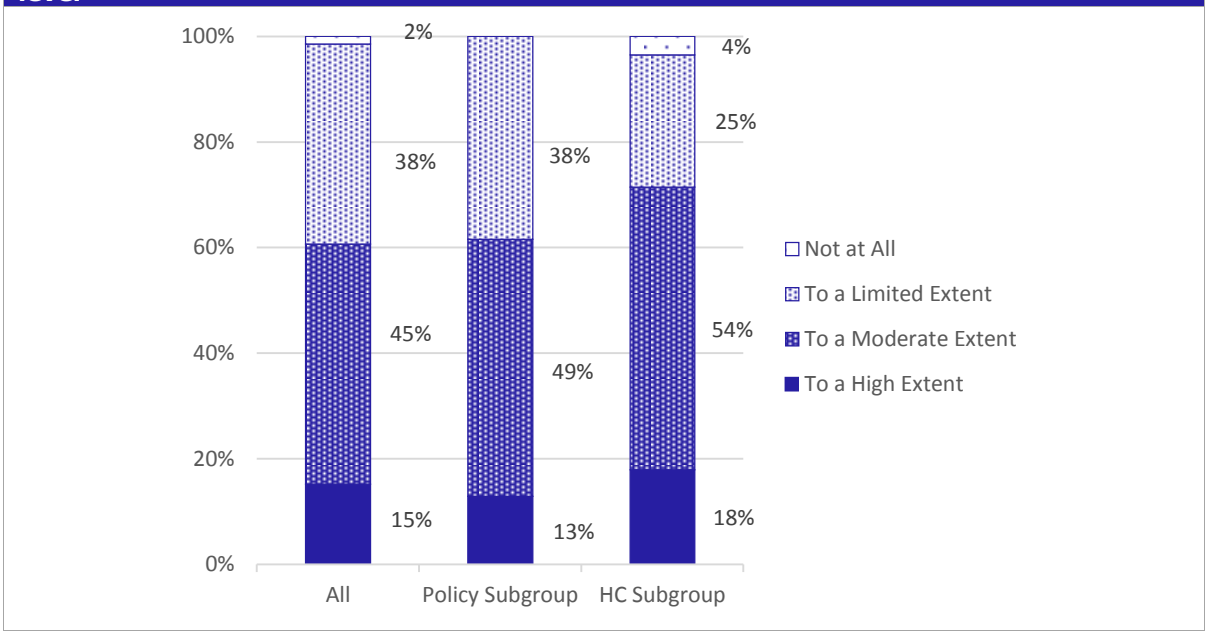
redundancy with other domestic or international indicators. The survey results suggest that these are not major obstacles to the utility of EU indicators. Problems may arise in the case of significant disparities of results, but as discussed further below the frequency of such issues is decreasing (especially between international organisations).

Added-value against other sources. As emerged from the survey, national databases and sources of analytical work still play a major role in the health information for stakeholders (see Section 6). Some 70% of all respondents consider national databases as their primary source of health indicators, while in the case of EU harmonised databases the percentage is less than 30%. This figure should be interpreted in the light of the fact that in many instances the data reported in national and EU databases are the same, thanks to the increasing harmonisation, but there are still various national indicators implemented in parallel to similar EU ones, as well as national variants of harmonised indicators, that are being used to better align the information with country needs and priorities. As will be further elaborated in the next section, this has an evident impact in terms of duplication of efforts. A concrete example from the case-study indicators is hazardous alcohol consumption. There is a general recognition of its utility, but in none of the MS reviewed for this Study the harmonised EU indicator has been used in national policies. National indicators are rather used to this end (e.g. in Italy).

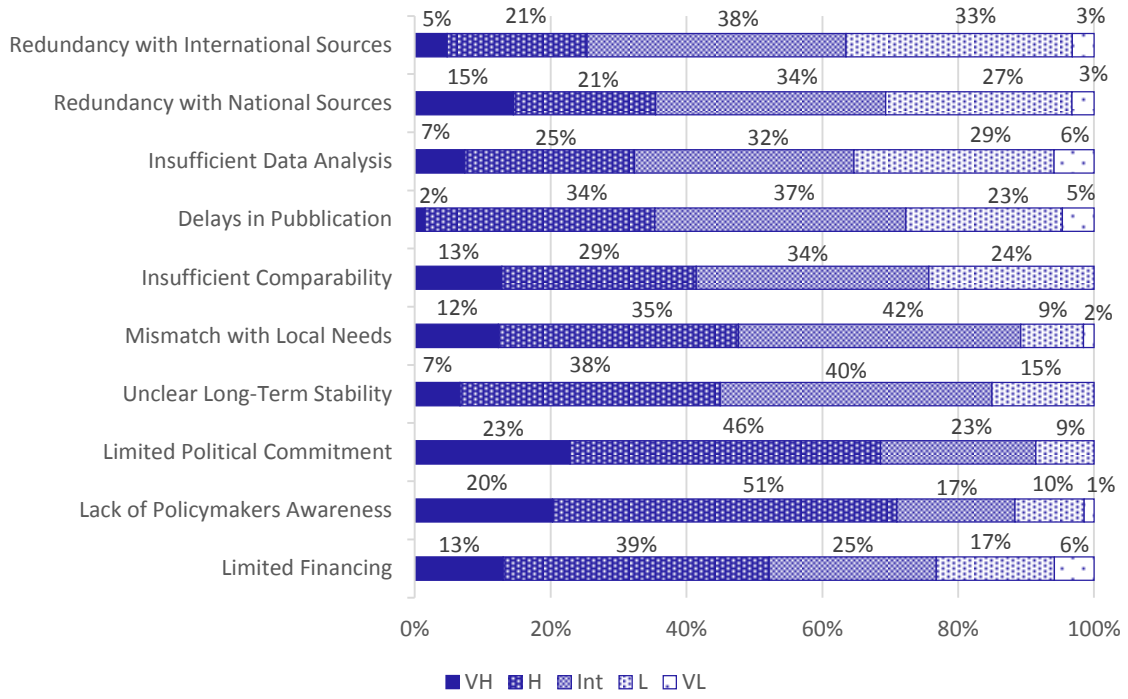
Similar considerations apply to the comparative added-value of EU and other international databases and analyses (OECD and WHO systems). Again, the EU data sources, and particularly the ECHI data tool, come second in the ranking of stakeholders' primary sources. But in this case the gap is smaller - i.e. for 40% of respondents other international organisations' databases are a primary source, against 29% for EU databases – and notably, when it comes to analytical work, EU sources are more frequently considered primary sources than other international organisations' sources.

Figure 7.3.1 – Consultation results on the perceived benefits from EU Indicators and hindering factors

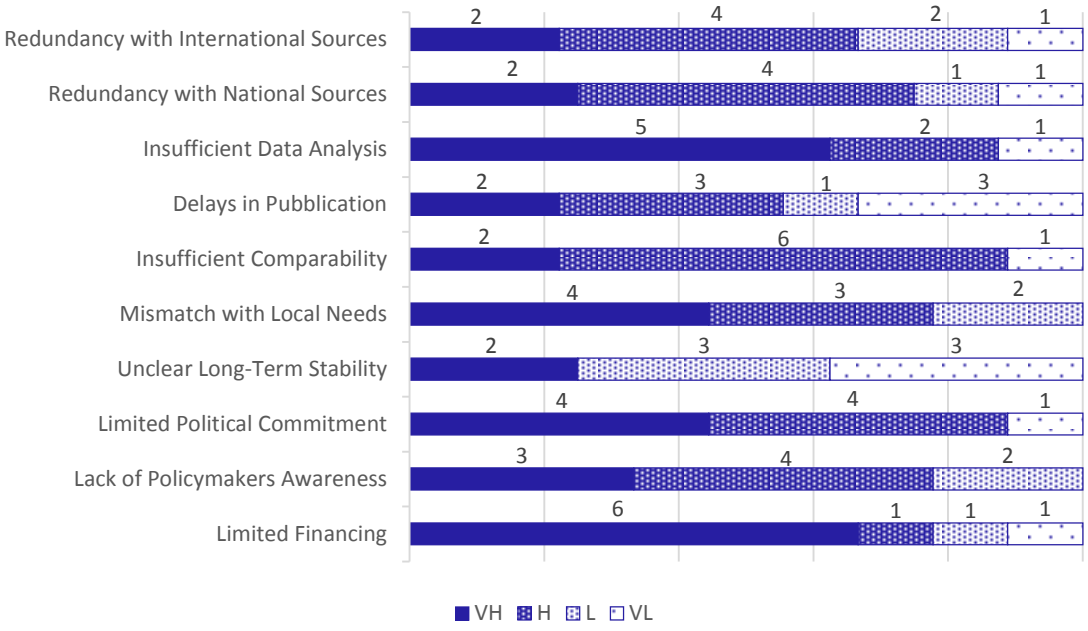
A) Stakeholders' views on the degree of exploitation of EU Indicator benefits at country level



B) Stakeholders' views on the relevance on factors affecting the utility of eu indicators



C) EGHI views on the relevance on factors affecting the utility of eu indicators



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

7.3.2 Use and benefits for health and healthcare policies

Setting and monitoring policy objectives. As described in the Theory of Change, a proper uptake and use of the health information produced by harmonised indicators may have beneficial impacts on the policy process at large. Depending on the type of indicator and the policy area the possible use consists of being able to devise more

informed and evidence-based policies and strategies, setting and monitoring policy targets, and – in the case of healthcare system indicators – supporting performance assessment and more efficient programming and spending. As discussed, these are possibly the most important direct objectives of a harmonised health information system, but the achievement of these 'ultimate goals' - improved population health and sustainability of health systems – requires a further step: the adoption and implementation of effective policies and initiatives. In other words, health information may enable and trigger better decision-making, but if and how this will produce tangible benefits depends on a number of other factors that often pertains to the national political sphere.

Overall, there is a strong consensus among stakeholders on the importance for country-level policy-making and healthcare system programming of having EU harmonised indicators in place. As shown in Figure 7.3.2, this consensus is even greater among stakeholders specifically concerned with policy process and healthcare management. Based on the perceived trend, the area of healthcare systems is also where the uptake of internationally-harmonised indicators has been fastest in the recent past.

With respect to the specific case-study indicators analysed, their use in policy processes has been mixed and can be appreciated only from a qualitative perspective. The indicators on the incidence of health issues are more easily used for background analysis and assessment of trends in the population rather than for setting specific policy targets. This is the case with indicators precisely conceived for this purpose, such as HLY, which was primarily designed in the framework of the Lisbon Strategy to forecast the effect of ageing on the active population. Certain researchers are analysing healthy life expectancy for similar strategic purposes, i.e. reviewing the health-initiatives with the major potential to contribute to its increase, and forecasting priorities for future medical expenditure.

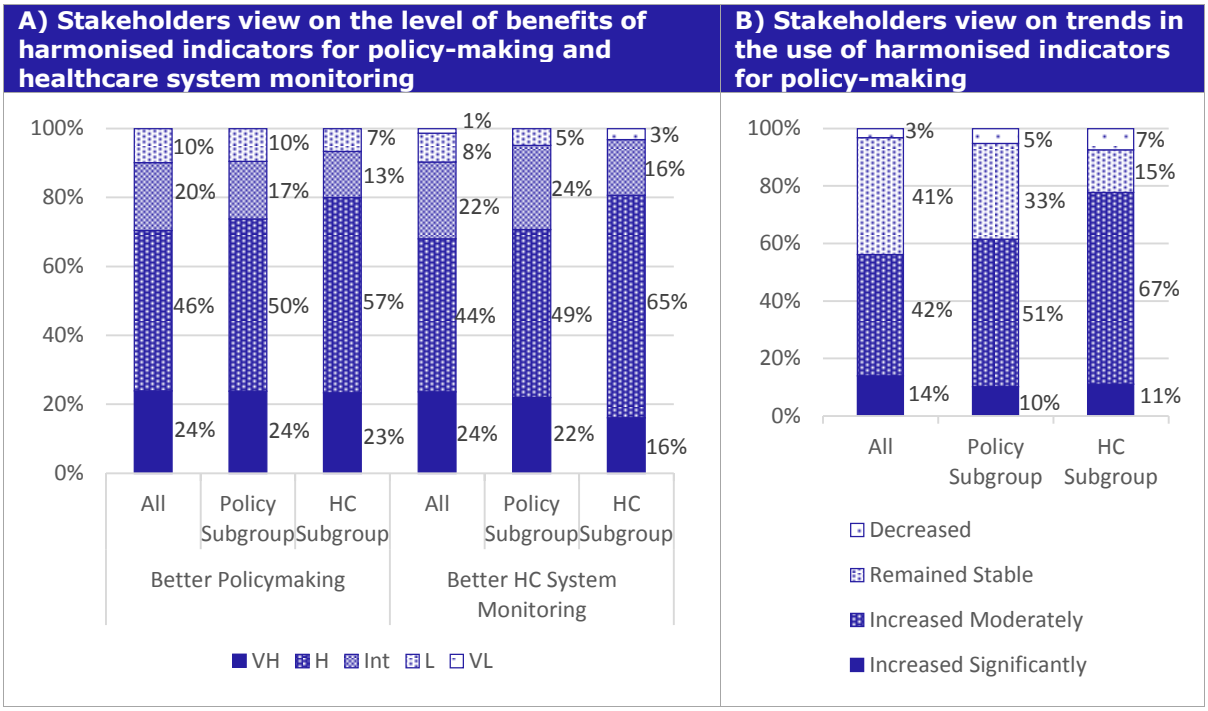
There are instances where cancer incidence is also used for setting objectives of long-term strategies (e.g. in France and Poland) but more often, other cancer-related indicators are being used for specific policy target setting, such as survival rates, decrease in mortality rates, and the benefits of cancer screening and other prevention policies. Similarly, it is rare to find the PPS-based HAI prevalence indicator used for monitoring the achievements of MS specific measures. More frequently, policy initiatives in this area make reference to input or process indicators, such as the number of beds in isolation rooms, the consumption of hand rub, the number of hospitals taking part in the PPS etc.

As regards the health system indicators analysed, the link with target-setting seems more straightforward since the very origin of the indicator somehow lies, or is closely connected to a policy process. The number of surgical day cases is a routine information in the healthcare providers' registries. But it becomes a relevant indicator when countries adopt specific policies to encourage the shift from in-patient to day-case surgeries for certain operations. For example, France adopted a target of 50% of overall surgical procedures performed as day cases by the end of 2016 (baseline 40% in 2013). Similar considerations apply to countries having adopted waiting time guarantees, like Finland, where monitoring waiting times has been embedded in legal enforcement, but also to countries like the Netherlands where mechanisms to enhance productivity (thus shortening waiting lists) have been promoted. Of course, the same mechanism works also the other way round: in France, waiting times have never been considered a policy priority therefore a corresponding harmonised indicator has never been adopted.

Finally, there are instances where the indicator is simply not considered fit for setting policy targets. For instance, total alcohol consumption is seldom viewed as a policy target in itself due to serious difficulties in tracing a clear correlation between consumption and disease. In this sense policy-makers rather opt for harm-related

indicators.

Figure 7.3.2 – Consultation results on the use of harmonised indicators in policy process and perceived benefits



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

Quantification of disease burden and health system efficiency. A robust health information system may enable better policies and healthcare management but the debate on how this may translate into ultimate benefits for national health systems and citizens, and how to measure it, is still at the initial stage. This may partly relate to the fact that MS have different approaches and traditions with respect to evidence-based public health policies and evaluation. The establishment of policy targets is not always associated with an estimation of the exact dimension and underlying factors of the issues at stake, of the realistic outcomes that can be expected from certain investments, and of other external factors that may boost or jeopardise target achievements.

In this sense, one of the first steps toward a benefit-producing indicator consists of its use for a quantification of the problem and, possibly, of the share of the problem that can be solved through appropriate policy measures. Depending on the nature of the problem, this may take the form of e.g. burden of disease assessments or potential savings made possible by health system performance assessments. Among the case-studies reviewed, cancer incidence and prevalence is evidently at the basis of various existing studies on the burden of cancer intended to support both prevention policies and to forecast healthcare expenditure. Similarly there have been attempts to estimate burden of disease in Europe attributable to alcohol and the burden of healthcare associated infections. The indicator on the share of day cases also intends to highlight the extent of the unnecessary cost of performing certain operations through hospital admission rather than in ambulatory settings.

However, with some notable exceptions, these estimates were not always taken up in policy targets and remained among policy background evidence but not for an ex ante

assessment of the expected burden savings - a measure that can be instead found in some ex post literature (e.g. the impact of certain HAI-prevention measures, or the cost savings connected to switching to ambulatory surgery). In other words, public authorities today are not in a position to quantify systematically the reduction of burden associated to policy implementation, although it is worth mentioning that this is certainly a growing research area in various MS and IIOO. There are two practical consequences of this uncertainty: (1) the difficulty in estimating how the concrete benefits compare with the level of efforts and financial investment required (and the risk of non-performance) may affect the efficient allocation of resources and prioritisation of policy initiatives; (2) the added value of the underlying information, and the 'return' from investing in the implementation of harmonised indicators is therefore difficult to appreciate.

An additional complication is the fact that policy implementation mechanisms and incentives may somehow 'distort' the impact of reforms and the ensuing burden savings and other effects. This is for instance the case with reimbursement policies on day-case surgery. In principle, switching from in-patient to day-case settings would reduce the unit cost of operations. Various literature sources estimate these savings between 25% and 68% of the total costs. On the other hand, in reality an increase in the share of day cases does not immediately translate into economic savings for the system. First of all, substantial savings are possible only if the switch to day cases is accompanied by a reduction of inpatient beds, i.e. a case-for-case replacement of inpatient surgery with day surgery. The reduction in beds needs to be significant in order to allow a parallel reduction of inpatient staff. Without such trade-off, the increase of day cases may lead to a general increase of operations with possible rise of expenditure. Secondly, various countries have adopted an incentive scheme that makes it negligible or cancel any difference in the amount reimbursed to healthcare providers per unit case. On the one hand these schemes are conceived to accelerate the transition to day case surgery, but on the other hand they inevitably level-off (at least temporarily) the potential savings in terms of overall healthcare expenditure.

Finally, it is worth considering that the rationale behind certain policy measures is not entirely driven by economic or health benefits, and the social dimension (particularly health equality) or patient satisfaction has been gaining an increased importance. This explains, for instance, why specific policies on waiting times for elective surgeries have been enacted in various MS, although their reduction would imply an increase in health expenditure and there is no evidence of significant better health outcomes for patients with shorter waiting times. In this case, it would be clearly misleading to judge the cost-opportunity of investing on such information on the grounds of possible economic benefits or health benefits (in strict sense) for patients.

Table 7.3.1 – Summary of results from the case-studies

Indicator	Selected evidence from fieldwork
Cancer incidence and prevalence	• Indicators on cancer incidence are seldom used to set policy targets by MS, but in some instances they are used for monitoring long-term strategies (e.g. Cancer Plans and the National Health and Environment Plan, in France; national health programme 2006-2015 and the National Strategy for Fight Against Cancer 2015-2024, in Poland). For typical short-term policies (3-5 years span) incidence is not perceived as an informative indicator, since policy-driven variations, e.g. linked to prevention, occur on a longer time scale (some five to fifteen years' time lag). In this sense, for policy-making and monitoring purposes other indicators are often preferred, such as cancer survival and decrease in overall mortality rates or, eventually, the specific impact of cancer screening as secondary prevention measures or other prevention policies on the incidence of related cancers (e.g. smoking prevalence, HPV vaccination etc.). • Cancer incidence and prevalence indicators are also used for studies on

	the burden of cancer for the healthcare system, which provides background evidence for policy-making and programming. Interestingly, the same indicators may support substantially different burden estimates, due to different calculation methods, which clearly illustrates one of the main challenges in assessing the potential policy benefits associated with having indicators in place.
Total and hazardous alcohol consumption	• Policy-makers usually refrain from using total alcohol consumption as a policy objective in itself and rather opt for harm-related indicators, due to serious difficulties in tracing a clear correlation between consumption and disease (except for cancer). • Total alcohol consumption has been used, with some *caveats* and notable limitations in the EU-funded seminal study estimating the burden of disease in Europe attributable to alcohol. A similar exercise was conducted recently in a Dutch study. • In the MS reviewed for this Study, no policy was found using the harmonised EU indicator of hazardous consumption but some countries use domestically-defined hazardous consumption indicators.
Healthy life years	• The Netherlands have set a policy target of increasing life expectancy without physical limitations and made the first projections on current trends. A study is currently ongoing on the health-initiatives with the major potential to contribute to that target. The policy target has been defined in terms of life expectancy without physical limitations, since this is considered a good proxy of future medical expenditure, while HLY appears more appropriate as an indicator of anticipated level of participation in the labour force, as it was originally proposed in the Lisbon Strategy. • For policy monitoring purposes, the HLY is extensively used also in a number of Polish policies and strategic documents. • In fact, there are methodological limitations in using HLY to extrapolate projections on the future economic burden of ageing. Generally speaking, it is noted that HLY poorly lends itself to disentangle the effects of cohort-related changes in mortality tables, from genuine trends in perceived good health and health-related limitations. For this reason, in various context HLY is coupled with DALY for a better analysis of the trends and the dynamics at play (e.g. in the field of chronic and infectious diseases as well as concerns the environmental drivers of disability).
Healthcare associated infections (incidence of MRSA)	• As regards the use of the MRSA incidence indicator in national policies, various MS have adopted AMR comprehensive strategies, action plans and programmes, which may include, among other things, measures to prevent and control infection from drug-resistant strains of pathogens like MRSA. However, none of the MS analysed has included in policy documents specific targets of reduction of MRSA incidence. • It is also rare to find the PPS HAI prevalence indicator used in specific country policies on HAI or, more generally, on patient safety. More frequently, national policies and programmes in this area make reference to input or process indicators, such as the number of beds in isolation rooms, the consumption of hand rub, the number of hospitals taking part in the PPS etc. • The burden of HAI has an evident patient safety component (cost of illness, fatalities), and an economic cost for health systems that include the cost of alternative antibacterial therapy and other medical care and the general cost for hospitalization of patient. However, only few countries have attempted or will attempt an estimation of this burden (e.g. The Netherlands, Finland). Typically, these exercises are conducted by public health experts without a direct reflection on the country's policies or targets or on a pilot basis. More often, big hospitals implement such analyses on their own.
Waiting times for elective	• The indicator is relevant for policy processes especially in those countries that have adopted specific measures or targets on waiting times, in

surgeries	response to an emerging issue. In particular: (1) Finland has adopted a National Health Care Guarantee in 2005, in order to reduce the significant waiting times for certain procedures. As a results, waiting times decreased sharply from 2004 to 2011; (2) in the Netherlands, since the approval of the Health Insurance Act in 2008 the patient has a right to know waiting times at the healthcare unit level for outpatient / inpatient treatments and to receive a diagnosis. This is intended to spur competition among providers and help the patient choose. Rather than an efficiency indicator, it was conceived as an indicator of quality of care; (3) In Italy, the monitoring of waiting times was one of the priorities of the "National Plan for Waiting Times Containment" and the availability of administrative data on the subject has improved accordingly. Waiting time is one of the parameters according to which the performance of the health care systems at regional level is measured. • Policies aimed at reducing waiting times may have adverse effect on health expenditure. Scholars' publications clearly showed negative association between waiting times and capacity, measured in terms of either number of beds or number of practising physicians. Analogously, a higher level of health spending appeared systematically associated with lower waiting times. Moreover, for some commentators increased spending on elective procedures may eventually divert resources from more urgent needs. There is also mixed evidence on the benefits of reduced waiting times in terms of health outcomes. It is usually argued that patients waiting too long might suffer for worsened health outcomes (i.e. health gain due to the delayed treatment might be lower than if they had surgery earlier), but this is not necessarily confirmed in the literature.
Share of day cases	• In order to promote an increase of day surgery some countries have adopted specific targets and incentives. For example, France adopted a target of 50% of overall surgical procedures performed as day case by the end of 2016 (baseline 40% in 2013). To encourage the change, the same tariff is applied to all procedures (based on the diagnosis-related group - DRG) irrespectively whether as an inpatient or a day case (in the absence of complication factors). • A report published in 2014 in France, estimated the economic benefits for the health system of an increase of ambulatory (outpatient) surgery. Assuming day surgery in ambulatory setting reaches between 54.8% or 65.6% by 2018, the expected cost savings for providers would range between € 400 and € 700 million per year. • Similarly, in Finland surgical procedures are reimbursed based on the DRG tariff, which in general does not distinguish between inpatient and day cases. Therefore, hospitals increasingly aim at reducing the length of stay and increasing the share of day cases, in order to improve cost-efficiency and productiveness. In Poland, the tariff reimbursed for surgical procedures is slightly lower for day surgery than for overnight stays. Conversely, in the Netherlands the payment policy has moved towards considering treatments and conditions as a basis for reimbursements and day cases as such have lost much of their previous significance as a policy incentive. • The general financial incentives adopted to promote day surgery had the merits of increasing the share of day cases, reducing the average length of hospitalization. The extent of savings reported in the literature ranges from 25% to 68% of hospital costs per surgery as compared to inpatient costs. In addition, the recourse to day cases (when based on best practices) may have contributed to mitigating the burden of post-acute care and the risk for patient safety. No significant difference in outcomes is instead reported.

7.3.3 Use for other knowledge purposes

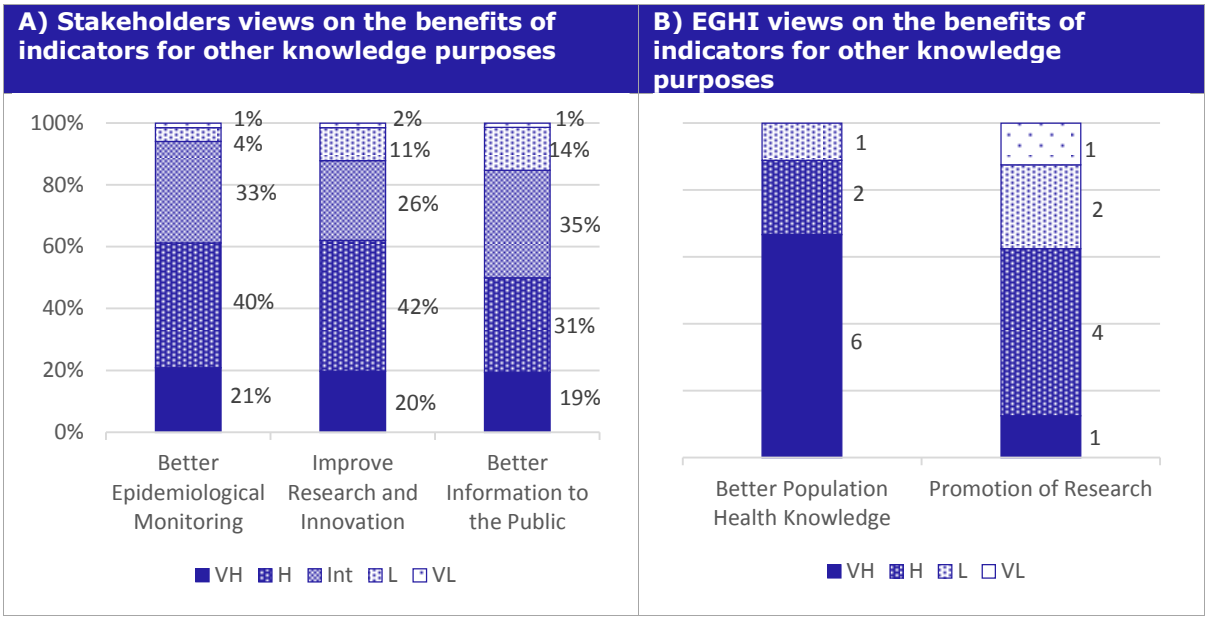
The main perspective from which health indicators have been analysed in this Study is

their contribution to improving public health policies and health system performance, since these are the main objectives underlying the Commission's efforts in this area. However, the link with the ultimate objectives may also be less straightforward, and mediated by other indirect mechanisms. In a nutshell:

- Harmonised indicators may have an informative value per se, regardless of their use for specific policies. Whether for epidemiological or other reasons, indicators can be essential to public health experts, health professionals, providers, insurances etc. for broader informative purposes. The PPS-based HAI indicator represents a case in point. At the moment, it responds primarily to an information need of health providers themselves and/or public health inspectorates for their own safety management purposes, and there is overall consensus on its utility in this respect. Analogously, cancer incidence and prevalence indicators have been mostly used so far to describe trends and supporting epidemiological analysis rather than to inform policies in the strict sense. This is particularly true with tobacco and obesity related cancers.
- Robust harmonised indicators may also support research and innovation. With few exceptions the indicators considered have been subject of scholarly research, which – as seen – it is also a common channel to produce evidence for the policy making. However, there is an added value in pooling data also from a scientific perspective (e.g. incidence of rare diseases) that should not be neglected, since it may ultimately accelerate the development of health technologies and pharmaceutical products. On the other hand, it is noted that due to poor granularity or other specification constraints the indicators analysed do not always appear fit for this purpose (see Figure 7.3.3.B below). Some stakeholders also pointed out how the harmonised indicators catalogue lacks health system outcome indicators in sufficient quantity.
- Finally, certain indicators may also respond to an information demand of the general public (public accountability) and/or are particularly fit for communication purposes (and nudge behaviours). This, by definition, includes indicators calling into question citizens' habits and behaviours (alcohol consumption, smoking prevalence, dietary habits etc.) as well as citizens' rights and access to service (e.g. waiting times). The public demand in certain area may prompt the adoption of specific initiatives but this is an effect that is not feasible to quantify.

The survey results on this topic confirm the majority of stakeholders attribute potential benefits to the use of harmonised indicators for non-policy purposes, although somehow smaller than the perceived policy-related benefits (see Section 7.3.2 above). The benefits in terms of information to the public are comparatively not as clear as for the other dimensions (Figure 7.3.3 below).

Figure 7.3.3 – Consultations results on the use for other knowledge purposes and related benefits



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

Table 7.3.2 – Summary of results from the case-studies

Indicator	Selected evidence from fieldwork
Cancer incidence and prevalence	• So far, the use of incidence and prevalence indicators has largely remained focussed on describing trends and supporting epidemiological analysis rather than to inform policies in the strict sense. This is especially true with tobacco and obesity related cancers, as the abundant scientific literature may confirm.
Total and hazardous alcohol consumption	• Certain Member States have included permanent monitoring of total alcohol consumption per capita as part of their health information system (e.g. Finland), but when this happens these indicators are usually complemented by survey data on non-drinkers and former drinkers as share of the population. • In Poland, the data on alcohol consumption are used *inter alia* by the competent agency (PARPA) to prepare a yearly report on the implementation of the *Act on Upbringing in Sobriety and Counteracting Alcoholism* presented by the Council of the Ministers to the Parliament.
Healthy life years	• The use of HLY for generic monitoring purposes is quite widespread, e.g. to measure trends in the general health of the population or for budgetary discussion on the potentially active labour force. For instance, Italy publishes the national version of the indicator among its official list of sustainable welfare indicators and as such, HLY data were included in the *Report on the Health Status of the Country 2012-2013*. • Similarly, HLY is also now routinely included in the public finance policy annual debate conducted by the Ministry of Economics and Finance in France (following the same path as the UK).
Healthcare associated infections (incidence of MRSA)	• The trends reported in ECDC reports have undergone statistical significance testing and sensitivity analysis to neutralise the effects of selection bias. Despite clear improvements, a few aspects (in addition to comparability) partly undermine the utility of the MRSA indicator for epidemiological surveillance purposes, namely: (i) data are published with excessive delays, i.e. up to two years after data collection, (ii) the level of

	granularity is not optimal. • The HAI indicator, and specifically the PPS survey are similarly affected by the above publication delays, but less severely. To cope with that, some MS starts publishing data when only 50% have been received. More importantly, countries have introduced mini-annual PPS or other *ad hoc* forms of collecting HAI data on a more frequent basis.
Waiting times for elective surgeries	• In France the indicator is not considered policy relevant. Recently, an increased attention is placed on waiting times for certain diagnostic services, but elective surgeries remain 'not an issue'. On the other hand, this is an indicator easy to understand also by non-expert audience, and is therefore often used both by national authorities and the media for reporting to the public on the functioning and performance of the health system.

7.3.4 Use for cross-country benchmarking

Overview of perceived benefits. The use of EU harmonised indicators for cross-country comparison and benchmarking is evidently connected to their actual level of harmonisation and comparability and the perceptions of key stakeholders in this regard. As discussed in Section 7.2.3, the formalisation of a harmonised indicator does not necessarily entail that the different national measurements have the same meaning out of context. In other words, even when specifications and implementation methodologies are fully coherent across countries (which is not always the case, as discussed), there often remain reservations on how disparities in rates and rankings may legitimately support policy evaluations.

The results of the survey reported in Figure 7.3.4 indicate that stakeholders – especially from the healthcare-concerned sub-group - are quite positive about the trend in indicators comparability registered in the past few years, but this should be seen in the light of the widespread scepticism about the actual degree of harmonisation, reported in Section 7.2.3. The relatively low number of positive feedbacks from EGHI members suggests that the obstacles for a direct cross-country comparison remain significant and difficult to overcome.

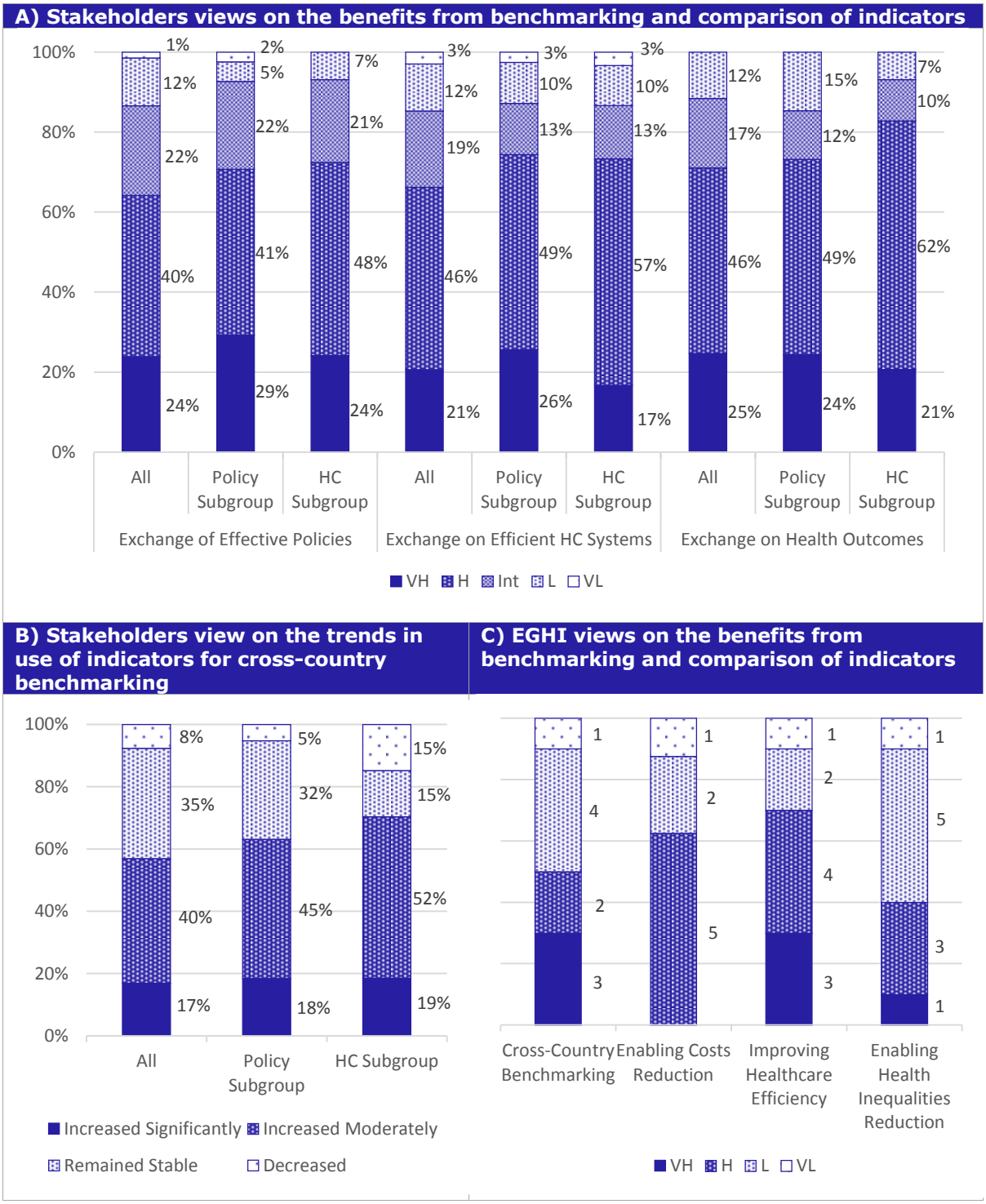
On the other hand, there is a general appreciation of the potential benefits that may derive from a proper exploitation of internationally-harmonised indicators from an individual country perspective. Comparative assessment may promote domestic debates on certain themes and eventually prompt 'fitness checks' of national policies on certain issues. Examples of positive cases include:

- The effects of data comparison on perinatal mortality in the Netherlands, following the results of the *Peristat* project. The comparative assessment reportedly revived the discussion on the quality and efficiency of prevention and care and the introduction of a country-wide system of perinatal audit.
- The EUROCARE project proved instrumental in the development and implementation of a comprehensive national cancer programme in the UK. Benchmarking with other neighbouring Countries on cancer survival rates seemingly prompted the Department of Health to carry out a retrospective baseline audit of waiting times for patients diagnosed with cancer in the UK. As a result of the publication of the comparative study, the Health Secretary announced that from 2020 patients with suspected cancer will be given a definitive diagnosis or the all-clear within a month, in a bid to tackle late diagnosis.
- The introduction of waiting times guarantees for elective surgeries in Finland a few years ago, reportedly stemmed from the unfavourable comparison in this country's performance against other Nordic countries, at that time.

- The high share of surgical procedures carried out as a day cases in some MS, contributed to influencing other countries policies on adopting incentives to this end. This was seemingly the case in Poland with cataract surgery.

More generally, mindful comparisons accompanied by robust guidance on the proper interpretation of data and an adequate framework for discussion may eventually foster the active exchange of 'best practice' on effective policies and healthcare management and promote innovation and reform.

Figure 7.3.4 – Consultation results on trends and benefits of cross-country Benchmarking



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.

Note: Policy Subgroup includes respondents primarily interested in health indicators for policy design/monitoring purposes. HC Subgroup includes respondents primarily interested in health indicators for healthcare management purposes. 'Don't know' answers are not reported.

Actual use of specific indicators. The above considerations mostly regard the potential and pioneer use of harmonised indicators for cross-country benchmarking, but in reality this potential is seldom exploited at present, as the case-study findings suggest. The main barriers to more extended recourse to benchmarking include:

- The perceived non-comparability of data due to e.g. the substantial disparities of national health systems (e.g. waiting times), the subjective elements embedded in the indicators (alcohol consumptions and HLY), and the detection and reporting capacity (MRSA).
- The suboptimal relevance of the indicator for policy comparison, as is for instance the case with cancer incidence: other outcome indicators like cancer survival rates are much more interesting to this end. Similar consideration applies to HAI and HLY, since these indicators poorly lend themselves to direct use for policy-making, but are rather useful for more general monitoring.
- Policy-makers' awareness and the availability of analyses fit for use in the policy process are cross-cutting obstacles that seemingly affect a variety of indicators. The evidence from fieldwork indicates that in a few contexts the data and indicators that the public health institutions and statistical offices process and transmit to the relevant international database are not necessarily and systematically debated and exchanged with decision-makers for domestic policy-making purposes.

Removing or mitigating these barriers may certainly contribute to a greater recourse to benchmarking for improving national policies and, more generally, to reap the benefits from the current investment in health information. In this respect, however, it is unlikely that fully transparent and measureable evidence can be ever collected. Policy-makers and stakeholders in general, concur that harmonised indicators – regardless of technical or methodological issues – cannot straightforwardly translate into a comparative judgment on national systems performance, since this would require to consider all country specificities. On the other hand, robust cross-country data may offer MS the opportunity to identify 'weak' areas or provide evidence on the potential effectiveness of certain policies before they are introduced. A well-known example in this respect is the work of the Association of European Cancer Leagues on tobacco control policies, which include the elaboration of a Tobacco Control Scale in Europe that provides a detailed rating on a series of national policies, based on their estimated effectiveness.[71]

While direct comparisons between countries appear hardly feasible or significant under the current condition, the opportunities offered by trend comparisons are more valuable, such as comparing one-country time series with another. This approach maintains that irrespectively of national specificities, the stable and consistent measurement of the same indicator over time may allow comparing trends across countries. The validity of this approach was repeatedly confirmed with respect to survey-based indicators as well as where the specificities of the underlying health systems prevent any meaningful possibility of direct comparison (e.g. waiting times).

Table 7.3.3 – Summary of results from the case-studies

Indicator	Selected evidence from fieldwork
Cancer incidence and	• Cross-country benchmarking takes place mainly in the field of cancer survival, where it has been used to assess clinical practices and

[71] See: Joossens L., Raw M., "The Tobacco Control Scale 2013 in Europe", a report of the Association of European Cancer Leagues, 2014.

prevalence	guidelines. This was *inter alia* the main rationale behind the idea of establishing a European Cancer Observatory as a side product of the *Eurocourse* project. • It is more difficult to find examples of comparative assessments of incidence data used to benchmark policies for cancer incidence reduction. This seems connected to difficulties in assessing in a standardised manner the degree of implementation of domestic interventions and policies intended to reduce cancer incidence. Smoking cessation policies are in this respect at a more advanced stage than policies and interventions aimed at healthy nutrition and physical activity. The available time series are at present too short to appreciate possible policy effects.
Total and hazardous alcohol consumption	• Benchmarking on alcohol consumption usually occurs outside of the formal policymaking processes and is not directly informed by the EU harmonised indicators. For instance, comparative data are included in the Italian Annual Relation to Parliament on the Implementation of the Law on Alcohol, but these are based on mixed sources, including *Euromonitor*. The purpose is more to highlight the specific features of domestic consumption against international patterns (e.g. daily consumption of alcohol at mealtime) than to evaluate policies or inform policy revisions.
Healthy life years	• There are important reservations among key national stakeholders about HLY cross-country benchmarking and its utility for policy-making. The experience showed that results are extremely sensitive to survey delivery modalities (computer-administered telephone interviews - CATI, face to face, etc.) and other context factors (SILC rather than household surveys) and this affects the significance of the differences observed between MS. • More granularity and details would be necessary, e.g. differentiating HLY among socio-economic groups, but this would inevitably increase the implementation costs of the indicator.
Healthcare associated infections (incidence of MRSA)	• There are inherent limitations in the use of current MRSA incidence indicator for cross-country comparison, and the issue is explicitly acknowledged in the last ECDC annual report. The methodologies used (sampling, breakpoints), the diagnostic capacity, and the coverage are so diverse across countries as well as within the same country that aggregated national-level measures may eventually not represent the actual situation of the country. In this sense, there are instances where the data collected and reported by ECDC through its sample of laboratories do not match with other country data reported by hospitals based on clinical records. • For most stakeholders this indicator is currently more significant to monitor trends in one country rather than for cross-country comparison, but also in this case the variation in the reporting laboratories and other discontinuities in the data series require that results are taken with caution. • In the case of HAI – as measured through PPS – the use for cross-country comparison is partly hindered by the relatively recent establishment of this exercise, as well as by the harmonisation issues previously discussed, i.e. the self-selection bias (participating hospitals are not necessarily a representative sample of all hospitals in the country), and disparities in implementation capacities and the methods to run the survey.
Waiting times for elective surgeries	• The first element of cross-country disparity lays in the uneven perception of the issue. Waiting times are the results of complex, country-specific interactions between the demand and the supply of health care, and their significance varies substantially across countries. Accordingly, waiting times may be perceived as a key issue in one country – or regions - and not in another, depending on multiple country-specific variables. It is generally admitted that the indicator is probably more useful for same-country over time assessments than for cross-country comparison. • Reportedly, some cross-country use of the indicator is done on *ad hoc*

	basis between comparable national systems, e.g. between the Netherlands and Germany, among Nordic countries etc.
Share of day cases	• The use of the indicator for cross-country benchmarking is affected by a series of harmonisation and comparability issues. These issues concern the way the indicator is implemented, but more importantly the effects that country-specific policies and incentives as well as medical practices (which may also differ across caregivers) may have on the very significance of the indicator. The data show very marked differences between MS for certain procedures (hip and knee replacement), but to what extent these can be considered an indicator of efficiency or technology adoption requires a case-by-case assessment. In fact, there can be differences in perception and acceptability of risks behind the share of day cases for certain procedures (e.g. in Poland it is not allowed to perform a percutaneous transluminal coronary angioplasty as a day surgery; similarly there can be constraints about tonsillectomy in children).

7.4 Implementation Costs and Burden

7.4.1 Overview

The costs of producing health information and running the relevant systems are still a poorly investigated area. There have been only a few attempts to estimate the aggregated cost of health information systems or specific parts of it, especially in the developing and emerging countries, mostly in the context of background studies supporting major health system reforms.[72] Besides that, the expenditure data available in the EU countries mostly concern specific actions, like the cost of a survey or a service. None of the MS selected for the fieldwork reportedly assess the overall cost of its health information system in an aggregated manner. This obviously implies the impossibility of estimating with any degree of certainty the monetary aggregated cost of the EU health information system as a whole, both in terms of the sum of national systems and in terms of the extra burden it may impose on national stakeholders.

To cope with the paucity of information, this Study has collected the available evidence on the implementation costs of the selected case-studies indicators based on the rough estimates of directly concerned stakeholders in the Member States, distinguishing between the raw data collection costs, the analysis and reporting costs, and the 'avoidable' burden due to duplication of efforts and the like. The exercise proved complex for a number of reasons that are summarised below. Quantifications should be therefore taken with caution.

With respect to data collection, the major controversial aspects regard: (i) how to consider the costs of raw data that are collected primarily for administrative purposes, i.e. for which the indicator is a by-product. In principle, the share of costs of generating these data that can be attributed to indicator-making is marginal or nil; (ii) how to deal with indicators based on data collected through multi-purpose surveys, which include various other questions on a number of different themes; (iii) how to include in the estimates immaterial, irregular and non-specific activities (such as familiarisation with data request, training etc.). In principle, the data processing and reporting is a more clear-cut activity, but also in this case it might be not feasible to attribute these costs across specific indicators and in particular to distinguish between activities pertaining to the calculation of EU harmonised indicators and other health information activities performed by the same staff.

More generally, in as much as some EU harmonised indicators have replaced or modified national ones, it can be argued that the implementation of EU indicators should account for only a fraction of the actual costs, but evidently this cannot be exactly defined. This issue is relevant also for the assessment of possible change scenarios, since the estimation of the additional costs imposed should always be seen in the light of the present ones.

In the computation of costs, it is also important to consider the 'unnecessary burden' due to duplication of efforts. In particular, this may regard the parallel implementation of EU harmonised indicators and national ones in the same policy areas, and the non-coordinated requests for indicators from multiple organisations.

[72] See for instance: Sally K. Stansfield, Julia Walsh, Ndola Prata, and Timothy Evans, "Chapter 54 - Information to Improve Decision Making for Health" in "Disease Control Priorities in Developing Countries", 2006, The International Bank for Reconstruction and Development/The World Bank Group. The authors estimate a per capita annual costs of a comprehensive HIS ranging between US$0.53 (developing countries) to US$2.99 (industrialised counties).

7.4.2 The costs of EU indicators: evidence from case-studies

Cancer incidence and prevalence. The specifications of the ECHI indicator on cancer incidence identified IARC GLOBOCAN as the preferable source. This is based, where available, on the cancer registries established at country or sub-national (regional/local) level, which are therefore used in this Study as the reference for estimating the costs of the indicator. Cancer registries, however, are unevenly distributed across the EU and where they are not present other estimation methods are used, depending on the information available in the country concerned. Cancer prevalence data are calculated by GLOBOCAN and ECO by means of mathematical models on the basis of incidence data. In this sense, there are no additional data collection costs for MS to calculate this indicator.

Cancer registration can be considered as an extremely labour intensive activity and personnel costs are typically reported to account at least for some 80% of total costs, as also confirmed in the available literature[73]. These refer to the amount of variables recorded in the database and the effort required by retrieving information from primary data sources.[74] There is a wide range of cost estimates per registered case across the EU. In the sample MS they range from approximately € 10 to € 100 per registered case. This is in line with literature studies, which report a range as wide as from € 6 to € 213 per registered case.[75] Unit costs tend to increase for registries with complete coverage, since the last 5% of cases usually requires substantial investigative work to be identified. The underlying factors affecting unit costs across MS include: (1) the availability of digitalised vs. manual records; (2) the number of variables recorded (and complexity); (3) average labour costs; (4) economies of scale - since the analytical work is not proportional to the number of cases processed, it may account to up of 40% of costs for smaller registries activities (i.e. explaining some 25%-33% of the unit costs variation); (5) institutional arrangements may significantly affect running costs (premises made available for free etc.).

Reimbursement to hospitals for their notification efforts is not generally considered a cost component. This is either because data are part of the routine administrative and reporting work (Italy) or because contractual arrangements are established where data are provided in exchange to access to registries themselves (the Netherlands). In Germany there were seemingly discussions on whether to reimburse healthcare providers from € 5 to € 50 per case to compensate for the administrative burden and the secretariat work. The time burden for health professionals to compile the registry form for a new case was estimated by some stakeholders about 15-20 minutes.

Substantial variation of the impact of EU regulations on personal data protection on costs is also reported. Countries with heavy implementation requirements in terms of data encryption and segregation can easily have extra 30% operational costs because of local requirements to comply with these regulations (e.g. Germany as compared to the Netherlands).[76]

The cost of complying with IARC quality standards vary with the development stage of the registry and its capacity. They can be up to 10% of total costs in the establishment / accreditation phase, and no more than 2-3% of costs at full regime. However, where the amount of errors in total records is substantial, this can easily

[73] Zanetti, R., Sacchetto, L., Calvia, M., Bordoni, A., Hakulinen, T., Znaor, A., H. Møllere, S. Sieslingf; H. Comberg; A. Katalinich; Rosso, S. (2013). Economic evaluation of cancer registration in Europe. Eurocourse WP3 Working Group. Journal of registry management, 41(1), 31-37.

[74] Most registries are actually involved in active data search and have to reconstruct a patient's health path based on secondary sources available in the different administrative systems. It takes skilled staff to properly classify cancers by nature and clinical course according to IARC standards. Reportedly, some staff have attended a minimum of 40 hour training course to learn data inputting.

[75] Zanetti, R., et al., 2013.

[76] In extreme cases, this can reach the legal impossibility of transmitting registry records abroad in another jurisdiction, as it is apparently the case in Finland.

reach some 7-8% of total costs. Compliance with quality standards also *de facto* coincides with the costs of transmitting data to IARC/ENRC in their call for data.

The work needed to calculate the indicator also varies. The collected estimates indicate it may amount typically to some 15% - 25% of the unit cost per registered case. Once incidence data are available, prevalence data can require an additional one month of a statistician's work. In Countries with decentralised regional / local registries, the aggregation of data in a national database and related extrapolations can require at least an additional full-time job (including for quality check).

The costs of reporting/disseminating the indicator domestically *de facto* often coincide with the costs of maintaining a website for communication purposes and can be considered marginal, hardly exceeding 2-5% of total budget of the registry. Analysing and producing reports and publications is often separately funded and at times research grants represent an important source of revenue for the registry.

Table 7.4.1 – Estimated costs and burden of the indicator

Cancer incidence and prevalence	Brief description of cost items	Costs estimates (human / financial resources)
Data collection	• Establishment/overall maintenance of cancer registries. Typically higher for small registries. • Raw data collection (record compilation) – typically not a specific cost item for registries. • Quality check of raw data, database cleaning etc. and inputting (depends on the number of variables)	**Estimated cost per case at cancer registry:** b/w € 10-100 **Time burden for calculating incidence:** b/w 10%-50% of analytical work of the registry **Reporting**: ca. 2-5% of total costs (including national level dissemination)
Data treatment and reporting	• Statistical processing for the calculation of incidence (depends of the number of variables). Processing includes new cases and old cases carried forward. • In MS with a network of local registries additional resources (up to a dedicated staff) are needed to aggregate data at central level. • Harmonised prevalence is calculated at GLOBOCAN level, so it is not a specific cost item for registries. • Transmitting data to IARC/ENRC.	
Other cost/burden factors	• The activities of registries typically go beyond maintaining records and calculating incidence, and may include collecting and processing data on screenings and other prevention activities, survival rates, domestic estimates of prevalence etc. It includes also the connected reporting activities. A significant share of their budget is therefore absorbed by activities not specifically related to the collection of the harmonised indicator. • For various countries the data privacy regulation may represent a significant obstacle and potentially a burden for reporting data at EU level.	

Total and hazardous alcohol consumption. The two indicators covered in the analysis (total and hazardous alcohol consumption) are calculated on the basis of different data sources and methodologies. Therefore they also differ with respect to the specific costs and burden they generate for national counterparts.

- ***Total alcohol consumption*** (as defined under ECHI) is calculated by WHO-GISAH by summing the recorded consumption of three-year average with the estimates of the unrecorded one. The recorded alcohol consumption is typically based on official statistics from various sources (production, import, export, and sales or taxation data, typically excises), while the unrecorded alcohol consumption refers to alcohol that is not taxed, is outside the usual system of governmental control and is estimated through various means. Although the indicator is mostly designed to assess the correlation with alcohol-related diseases, in some instances the indicator is estimated the other way round, i.e. inferring consumption from the incidence of related diseases.[77]

  The costs of gathering statistics from trade, excise and other administrative sources cannot be evidently attributed to the costs of the indicator, so in this case raw data collection is negligible and all costs relate to analysis and reporting. The time burden of calculating total alcohol consumption based on administrative data was estimated in the range of one to three staff/month of a statistician. The variation can be due to the level of disaggregation of the underlying raw data, the degree of geographical breakdown available, and the need to introduce correcting factors (e.g. discounting tourists' consumption when it is required).

  The additional effort required by ensuring methodological compliance with international standards and double reporting to both the WHO and the OECD databases is considered minimal and can be estimated in less than one person-month in the worst of cases. All in all the cost of production of these indicators should come at a maximum in the region of some €5,000-10,000 roughly equal to some €100-300,000 EU-wide. Publication and dissemination of the indicator domestically *de facto* amounts to its publication often as a pdf report on the internet, and possibly, participation into dissemination events, such as the yearly *Alcohol Prevention Day* in Italy. But these costs cannot be directly attributed to the implementation of the indicator.

- ***Hazardous alcohol consumption*.** This is a survey-based indicator, actually part of the EHIS survey. The second wave of EHIS was much more standardised than the first one, but there are still cross-country differences in the implementation methods (CATI, self-administered mail questionnaires etc.) affecting significantly its overall costs. For the statistical offices responsible for its implementation it is also difficult to disaggregate the EHIS costs from more general household surveys that include EHIS modules, as well as the human resources spent on EHIS from the overall activities of a statistical department.

  Assuming that costs are allocated proportionally to the number of alcohol questions included in the EHIS (about 5%), the estimates collected range from as little as some € 10,000 (for a self-administered survey) to some € 50,000-85,000 for a survey embedded in statistically-significant household surveys or carried out with similar methodology[78]. This would be tantamount to an EU-wide cost in the range of €150,000 to €1.5 mln. This seems in line also with the cost assessment carried out in the recent Impact Assessment accompanying the Regulation on statistics collected through individual-level samples.[79] According to the Impact Assessment, EUHIS overall data collection costs may amount to some € 14 mln, which means a pro-quota (5%) for alcohol section of about € 0.7 mln.

  The work needed to specifically process and review survey data with a view to their transmission – inclusive of an analysis – also varies but is generally reported

[77] This approach has evidently implications on the significance of the information and is one of the issues concerning the harmonization of this indicator that have been discussed above.
[78] The order of magnitude of the costs of statistically significant household surveys for the country considered is approximately 1.o to 2.5 million euro.
[79] SWD(2016) 283 Final. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016SC0283

to remain in the region of some three senior expert/months. When carried out by means of direct face-to-face interviews some 50% of costs can be attributed to interviews themselves (of which 70% for fieldwork and 30% training) and another 50% to survey design and data processing. These include also the costs of reporting the results to Eurostat. Since data publication is not completed, other dissemination costs at this stage are irrelevant. Again, the Impact Assessment[80] data are compatible with the estimates elaborated in the present Study: data treatment and dissemination costs for the alcohol section of EUHIS (pro-quota) would amount to about € 0.2 mln EU-wide, which is broadly equivalent to an estimated 3 month/senior staff per MS.

Table 7.4.2 – Estimated costs and burden of the indicator

Total alcohol consumption	**Brief description of cost items**	**Costs estimates (human / financial resources)**
Data collection	• Sourcing data from existing statistical databases (trade, excise etc.) – virtually no attributable costs. • Raw data collection (record compilation) – typically not a specific cost item for registries.	**Time burden for calculating total consumption:** b/w 1/3 month/staff of a statistician **Estimated overall cost (per Country):** €5,000-10,000
Data treatment and reporting	• Quality check and validation of recorded consumption, estimation of unrecorded consumption. • Statistical processing for the calculation of total consumption and transmission to WHO and OECD.	
Other cost/burden factors	• In some countries the reporting system is not fully harmonised, and there is parallel analysis and reporting from different entities to different entities (WHO, OECD, RARHA Joint Action).	
Hazardous alcohol consumption	**Brief description of cost items**	**Costs estimates (human / financial resources)**
Data collection	• Implementation of the EHIS survey (some 5% of the questionnaire regards alcohol consumption). Costs may depend on the modality of administration.	**Estimated cost per country:** b/w €10,000-85,000 (the alcohol module of EHIS, estimated *pro-quota*) **Time burden for processing and reporting data:** ca. 3 month/staff (senior statistician)
Data treatment and reporting	• Quality check of raw data, database cleaning etc. and inputting (depends on the number of variables) • Basic statistical processing (the calculation of indicator is done by Eurostat) and transmission.	
Other cost/burden factors	• Some MS continue collecting similar information covered by EHIS, through national survey, since they can count on long and consistent time-series (e.g. the Finnish Regional Health and Wellbeing). This translates into an extra burden, which however cannot be easily overcome by merging the two exercises since questions are different. Discontinuing national surveys would translate into a significant information loss.	

Healthy-life years. HLY is a composite indicator that combines mortality data (life expectancy) with health status data (self-perceived health). In this sense it is a combination of ordinary demographic data and of survey data - since self-perceived

[80] *Ibid.*

health is estimated on the basis of the so-called GALI (Global Activity Limitation Instrument) module of the *Eurostat* EU-SILC survey. Since it derives from other data sources, it is generally considered an indicator whose direct implementation costs are very limited.

GALI represents a very small part of the SILC survey. Its costs can therefore be considered as nearly negligible and generally well below €10,000 annually. When implemented within the framework of larger household surveys the proportion of costs related to GALI can reach as high as €20,000 or so on a yearly basis.[81] This is due to the fact that SILC is implemented by means of CATI interviews on a smaller sample of individuals (from 7,000 to 12,000). Since the longitudinal component of the SILC is a 4 year panel, and thus individuals get older as does the panel, in some countries an additional sample of about 100 young persons is added yearly to compensate the ageing of the youngest selected respondents (16+) and keep the panel representative of the whole adult population. The costs of these adjustments are difficult for national counterparts to estimate.

The HLY indicator is calculated by Eurostat so no data processing or analytical work is required for MS in addition to SILC-related data validation and reporting. All in all the work devoted to the indicator maintenance and supervision is unlikely to exceed a maximum of three month/staff time, which includes also following up developments at the European level. Depending on the different costs of labour, this may correspond to some € 10-15,000 yearly.

Cases of 'parallel' elaboration of the indicator, done at the national level, have been reported. This may result in an additional burden (about few months of statistical work), which is not required under the existing arrangements, but is possibly triggered by some reservations expressed by stakeholders on the comparability of the indicator. It can be assumed that improved harmonisation would make such parallel exercises unnecessary.

Table 7.4.3 – Estimated Costs and Burden of the Indicator

HLY	Brief description of cost items	Costs estimates (human / financial resources)
Data collection	• Implementation of the EU SILC survey (GALI only a marginal fraction of it). • Sourcing mortality data from demographic statistics. • Virtually no directly attributable costs	**Estimated cost per country:** b/w € 10,000 - 20,000 (GALI module) **Time burden for processing and reporting data:** ca. 3 month/staff (senior statistician)
Data treatment and reporting	• Statistical processing of EU SILC data (only marginally attributable to HLY purposes). • The calculation of the HLY indicator is done by Eurostat at no cost for MS.	
Other cost/burden factors	• Reportedly, there are cases of parallel calculation of the indicator.	

Healthcare associated infections (MRSA Incidence). In this Study two indicators have been actually considered. The prevalence of HAI in hospitals have been estimated for a few years by ECDC by means of a Point Prevalence Survey (PPS) involving healthcare facilities participating on a voluntary basis. The second related indicator is the incidence of MRSA, which is isolated in about 5% of all healthcare-associated infections (it is also denominated 'healthcare acquired MRSA'). The indicator is based

[81] The data collection costs for SILC have been estimated in the Impact Assessment (SWD(2016) 283 Final) at € 0.68 mln per MS on average. In this sense, the GALI pro-quota cost is assumed at about 2.5% of the total SILC cost.

on the routine clinical antimicrobial susceptibility data collection carried out in Member States and communicated by the EARS-Net partners to ECDC, for publication in *The European Surveillance System* (TESSy).

- ***HAI indicators (based on PPS)*.** The costs of this indicator coincide with the costs of running and aggregating data from the PPS. Being a voluntary exercise, the coverage of PPS as well as the data collected varies across MS[82], with evident effects on its costs. For this reason, rather than the costs per country it seems more relevant to estimate the costs per hospital and/or per patient (data are collected at patient level and then aggregated at hospital level). The time burden required to fill in the survey per 100 patients is grossly estimated between 12 and 24 hour/staff. In the case of big hospitals, different teams implement the survey in parallel with possible extra costs of coordination.

  Since many hospitals still use paper-based records, the processing of the information can be laborious. Some countries report about six weeks to gather data from hospitals and complete the uploading of data on the ECDC platform. Others estimate some 500 working hours per survey. Others reported up to some 3-4 FTE/year per PPS. In this case, the number of participating hospitals is a key factor (e.g. 59 in Finland and 33 in the Netherlands, for the 2011/12 edition). From a funding perspective, this seems the most problematic step, since various stakeholders report underfunding or the need to perform the work on a non-paid basis.

- ***MRSA Incidence***. There are two main cost factors in the indicator production, i.e. the cost of laboratory testing on antimicrobial susceptibility of isolates, and the cost of aggregating the data from participating laboratories in the network, and uploading them on the ECDC TESSy platform. MRSA screen tests reportedly have a commercial price of approximately €30-35. However, these procedures are performed as part of the diagnostic process therefore their costs cannot be attributed to implementation of the indicator in the strict sense.

  The costs of participating laboratories to transmit the data to the EARS-net national data manager could not be estimated precisely, but is assumed limited and around one week staff equivalent per year. Actually, there can be other indirect costs connected to being included in the network mostly related to quality-assurance and controls, but these cannot be attributed specifically to the MRSA indicator, since laboratories report on several other data. Similarly, it is difficult to estimate the extent of the work done at central level to process the data received from laboratories and upload them into the TESSy system, disaggregating MRSA data from the rest. At this level the time burden depends primarily on the recording method, and specifically whether the ECDC 'Isolate Form' is filled out electronically or manually. The data collection for EARS-Net is supported by WHONET (Microbiology Laboratory Database Software), which provides standardised procedures to perform data entry and to export data in EARS-Net exchange format, and which can be used locally by participating laboratories and centrally by country data managers. In some countries, the notification is largely automated and therefore central-level work is minimal. In other contexts, some respondents reported an effort of up to 100 man/hours per year.

[82] Some sections of the questionnaire are not compulsory and hospitals may decide whether to collect them or not.

Table 7.4.4 – Estimated Costs and Burden of the Indicator

HAI (based on PPS)	Brief description of cost items	Costs estimates (human / financial resources)
Data collection	• Implementation of the PPS in participating hospitals (depends on the implementation of facultative question modules). First aggregation of data at hospital level.	**Time burden for data collection:** b/w 12–24 man / hour per 100 patients **Time burden for processing and reporting data:** b/w 3.5 to 48 month/staff (per survey)
Data treatment and reporting	• Aggregation of data from hospital, quality check and validation (depends on the availability of automated reporting tools). • In some countries, intermediate surveillance entities at regional level participate to the process (with escalating time-burden). • Statistical processing of data and reporting to ECDC (voluntary non-paid time is not calculated).	
Other cost/burden factors	• N/A	
MRSA Incidence	**Brief description of cost items**	**Costs estimates (human / financial resources)**
Data collection	• Raw data are collected by participatory laboratories. Time burden difficult to extrapolate for one specific pathogen. • MRSA screen tests are performed by routine and cannot be attributed to the indicator. • The number of participating laboratories and of isolates tested change every year, hence the related data collection costs.	**Time burden for data collection:** assumed a max of one staff/week per laboratory per year (including maintenance). **Time burden for processing and reporting data:** b/w 20-100 man/hours per year per country.
Data treatment and reporting	• Aggregation of data from laboratories is done at central level. The burden depends essentially whether an automated or manual recording system is in place. • Further statistical processing of data is done at ECDC level and is not attributable to the indicator.	
Other cost/burden factors	• Laboratories undergo constant quality control and requests to improve standards and technologies. These processes evidently impose a burden that is reflected in better quality indicators.	

Waiting times for elective surgeries. The Waiting Times indicator is published by OECD on the basis of national aggregated figures that are drawn from the registry data of the healthcare providers. The cross-country disparities in the healthcare management are reflected in the fact that two indicators are actually collected by OECD: the waiting times of patients treated in a given year and the waiting times of patients on the list at a given census date. Most of the countries visited report only data on patients treated in a given year, so the analysis has concentrated on this version. Other differences in the recorded metrics exist (e.g. median vs. average value etc.) but with no tangible effects on the costs and burden of the indicator. The data collected cover seven elective surgical operations.

The evidence collected in the sample MS shows that the burden of collecting and reporting this indicator is low. First of all, data on waiting times for inpatient treatments are by-products of the ordinary health care management process and can

therefore be estimated and reported by hospitals on the basis of their discharge registries with a minimal calculation effort. The estimated workload at the hospital level has been estimated around one staff/day per month. Additional burden may occur when hospital data are aggregated at regional level before being transmitted to the central level. But also in this case the level of effort required seems almost negligible. In principle, the indicator could be effortlessly calculated also by countries that do not currently do it, provided that an efficient hospital information system is in place. It is worth highlighting that any extension of the indicator coverage to outpatient care and/or private care would instead entail a major burden, especially in contexts where the information should be collected through a number of non-harmonised sources.

Statistical treatment and reporting costs are also modest. Health care providers often transmit to competent bodies data that are already aggregated and therefore require minimum processing. Therefore, the competent statistical body only has to further aggregate the information received from hospitals to calculate the synthetic indicators. The downside of this process – as reported in some countries – is that data analysts have little insight into the quality and the reliability of the raw data. The only international organization gathering information on waiting times is the OECD, so there is no extra burden for MS associated to international reporting. The estimates collected from MS ranges from a minimum of one week to a maximum of one staff/month per year to elaborate and report the information to OECD.

Table 7.4.5 – Estimated costs and burden of the indicator

Waiting times for elective surgeries	Brief description of cost items	Costs estimates (human / financial resources)
Data collection	• Gathering of data on waiting times of patients from providers' registries (typically discharge registries). The cost of keeping the registry is obviously not computed (not 100% coverage, not in all MS). • Automated information systems can make a significant difference. • Aggregation of data at regional level (where relevant).	**Time burden for collecting raw data:** b/w 10 and 15 man/days per hospital per year (assuming no automated calculation system and including maintenance). **Time burden for processing and reporting:** b/w 1 and 4 weeks per country.
Data treatment and reporting	• Statistical processing of the information received from HC providers. Data validation may be hindered by lack of access to the raw data. • Aggregation and transmission to the OECD.	
Other cost/burden factors	• N/A	

Share of day cases. Eurostat collects and publishes data on selected surgical operations broken down by in-patient, day case or (where available) outpatient modality. There is no implementing legislation in the area of non-expenditure health statistics and these data are submitted to Eurostat on the basis of a 'gentlemen's agreement', which implies a certain level of methodological disparity across countries. Until recently, the data on surgical procedures were collected separately by OECD, Eurostat and WHO-Europe using different definitions and specifications, which caused a duplication of burden for national level counterparts. In 2013, the three

organisations included these metrics in their 'joint questionnaire on non-monetary health care statistics', which *de facto* eliminated overlapping and duplications.[83]

The implementation cost of producing and reporting this indicator is generally very limited, since the indicator is built on data that are collected by care providers and the payment system (health funds, insurances etc.) is part of their ordinary administrative process. In this sense, there are no additional data collection costs for care providers that can be directly attributed to the indicator. At the hospital level, data on surgical procedures are registered in the information system by competent staff, through a procedure that may require on average some five minutes. Some hospitals have a dedicated department dealing with the management of data and their transmission to the payment system. In some countries (e.g. Poland, Italy) data are aggregated at an intermediate level (regional health authorities) before being transmitted to the competent payment/administrative authority. From there, they are eventually transmitted to the competent statistical offices in various formats and depending on the underlying information system in place.

The statistical elaboration and reporting of the indicator is performed by public health institutes or other central statistical agencies. The specific burden of these tasks is difficult to disaggregate from other statistical processing performed by the same entities. Gross estimates collected during fieldwork vary according to the level of efforts deployed to make data consistent with the European definition (including possible corrections for double-counting and age-standardisation of data). Besides these validation activities – whose burden varies significantly across countries - the calculation of the indicator is relatively straightforward since it consists on the ratio between day case surgeries and the total surgeries performed. The plausible time burden can range from one staff/week to one staff/month for a standard efficient system.

Table 7.4.6 – Estimated costs and burden of the indicator

Share of day cases	Brief description of cost items	Costs estimates (human / financial resources)
Data collection	• Gathering of data on surgical procedures from providers' administrative records. The cost of keeping records is obviously not computed. • Aggregation of data at regional level (where relevant), or at 'health fund' level.	**Time burden for collecting raw data:** ca 5 minutes per procedure (but not attributable to the indicator).
Data treatment and reporting	• Statistical processing of the information received from HC providers. Data validation may be hindered by lack of access to the raw data. • Aggregation and transmission under the Joint Questionnaire.	**Time burden for processing and reporting:** b/w 1 and 4 weeks per country.
Other cost/burden factors	• Before the adoption of the Joint Questionnaire by Eurostat, OECD, and WHO there was an additional burden for MS to report figures separately.	

[83] A common shortlist of 17 surgical procedures plus 5 subgroups has been adopted by the three organisations. In addition to the total number of procedures, a split between inpatient cases and day cases is requested for each type of surgical procedure. For the first two procedures on the list (cataract surgery and tonsillectomy), the number of outpatient cases in hospital and outside hospital is also requested, where possible, in order to provide more complete coverage of same-day surgery. Following the SHA (*System of Health Accounts)* definitions, day cases are defined as admitted patients, while outpatient cases are defined as non-admitted patients.
https://www.oecd.org/statistics/data-collection/Health%20Data%20-%20Guidelines%202.pdf

7.4.3 The balance of costs and benefits of harmonised indicators

As emerged in the previous section, the potential benefits that internationally harmonised indicators may offer to national stakeholders seldom translate at present into concrete and measurable gains. Evidently, generalisations should be taken with caution given the specific features of each indicator and the diverse implementing conditions and policy processes at national level. However, it is possible to identify certain factors and trends beyond the sub-optimal balance between the implementation burden of indicators and their perceived benefits, so as to draw insights on what improvements are more urgent within the overall EU health information system.

Some specific issues have been already presented in the above analysis of case-study indicators. In this section these are triangulated with the feedback from stakeholders and EGHI members' consultations. In particular, the surveys have investigated the approaches that may result into a reduction of the current implementation burden, and those possibly ensuring a greater materialisation of tangible benefits.

Burden reduction. There are various areas of possible interventions for reducing the current burden of implementing harmonised indicators in Member States (see Figure 7.4.1):

- ***Consolidation and coordination*** at international level emerged as one of the major tools to reduce burden at national level. The rationale for having harmonised indicators includes the opportunity of achieving economies of scale, but these are potentially jeopardised by the current fragmentation of *ad hoc* initiatives, as described in Section 6. Over the past years a wealth of projects, networks and other initiatives have been supported by the EU and by other organisations, which involved the production of health information of various kinds and often on a pilot and temporary basis. According to EGHI members this is one of the top resource constraints at the moment, and the data collection 'fatigue' has reportedly led to greater difficulties in involving national stakeholders in new exercises. The BRIDGE-Health project was *inter alia* conceived to respond to the need for consolidating and coordinating EU level efforts in this area. It should be noted that the consolidation should not translate into a sheer reduction in the number of harmonised indicators collected, but rather into a better selection of the indicators needed.

  There is also a widespread demand for a continuous improvement of the coordination among the main international organisations and agencies collecting and publishing multi-country indicators, regarding both the harmonisation of indicator specifications and data collection methodology and practices. It is important to highlight that stakeholders perceive a positive trend in this respect but not always as fast as desired.

- In some policy areas there are ***parallel indicators elaborated at country level,*** which result in a duplication of efforts for national competent counterparts. The analysis of case-study indicators showed various instances of such duplications, typically triggered by the perceived poor relevance of the harmonised definition for the specific domestic needs and/or the reluctance to discontinue national time-series coherently collected for several years. According to national stakeholders, in the majority of cases EU harmonised indicators are implemented in co-existence with national ones, and only rarely have replaced/absorbed them. The main differences in data collection methods and definitions but sometimes also the way the indicator is calculated may vary. The existence of a parallel national indicator normally implies that the harmonised one is collected and reported only in compliance with the commitments undertaken, but it is the nationally-defined

indicator that is actually used in the policy process. In other words, in such instances the harmonised indicators may be perceived as a pure burden (similar views were collected for instance with the hazardous alcohol consumption data). Indicators better aligned with country needs as well as mechanisms – where feasible – to convert national indicators into harmonised ones are consequently seen as major areas for burden reduction.

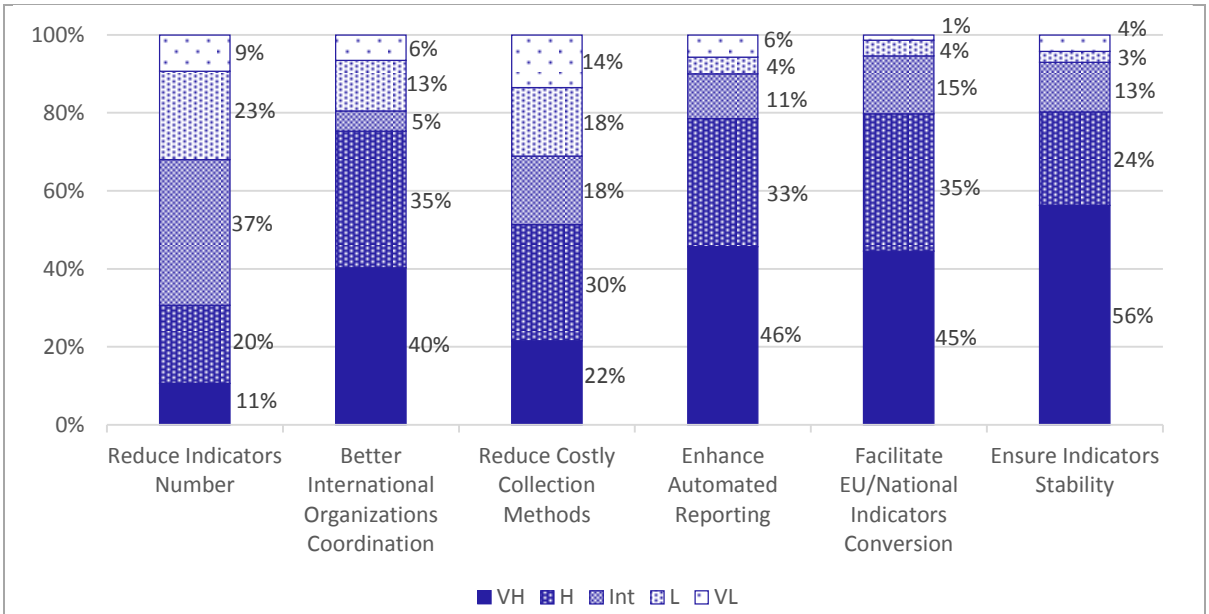
- There are various other ***implementation aspects*** affecting the burden of harmonised indicators, which regard its maintenance, data collection methods, and reporting methods. Being case-specific, generalisations are not always feasible, but overall these may regard three aspects. Firstly, the costs of collecting data through different methodologies may vary significantly. As it emerged from case-study indicators, a survey-based indicator is several times more expensive than an indicator based on administrative data and semi-automated sources. Also within surveys, there can be significant differences between e.g. a CATI and a self-administered questionnaire. According to some EGHI members, the benefits of survey-based indicators to a lesser extent outweigh their costs than do the benefits of indicators that are implemented on the basis of health registries and administrative sources. Needless to say, the option of switching to less-costly data collection methodologies is not always available, but according to some stakeholders there is room to explore creative ways to better exploit raw data already available.[84]

  Secondly, a reduction of the reporting costs can be made possible by implementing an automated reporting system. Similarly, mechanisms are being developed by ECDC for various TESSy data reporting. The legal issues (microdata sharing) and the technical issues (IT standardisation etc.) associated with such mechanisms are non-negligible, so this option appears unrealistic for the near future, although there is already published literature on this approach.[85]

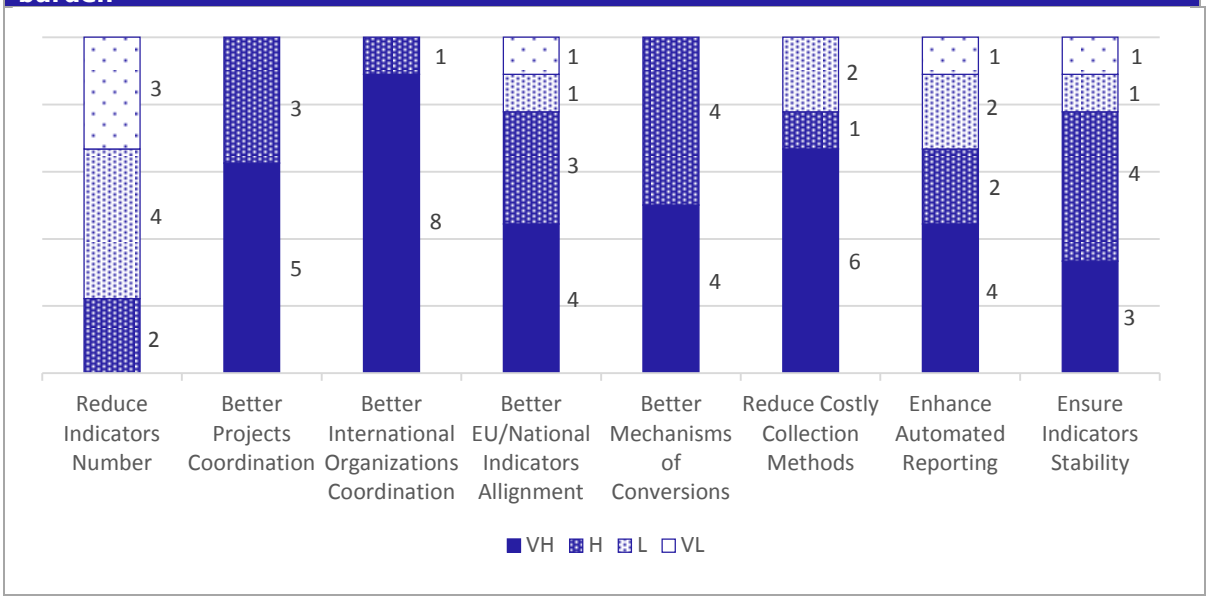
Figure 7.4.1 – Consultation results on ways to reduce the burden of implementing harmonised indicators

A) Stakeholders' perceived importance of possible ways to mitigate indicators burden

[84] For instance, in Italy there have been pilot attempts in the past to move towards estimating cancer incidence and prevalence based on administrative data and precisely data on patient exemptions from the fees of medical examinations, but the results appeared in conflict with the other sources and poorly reliable.
[85] Carinci, F., 'Essential levels of health information in Europe: An action plan for a coherent and sustainable infrastructure', *Health Policy*, No 119, 2015, pp. 530-538.



B) EGHI Member's perceived importance of possible ways to mitigate indicators burden



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: 'Don't know' answers are not reported.

Enhancing benefits. In parallel to reducing burden, initiatives can be taken to enhance the use and the ensuing benefits from harmonised indicators. These largely confirm the obstacles discussed in Section 7.3 and in addition provide a broad outlook on the perceived priorities and most promising areas of improvement. In particular:

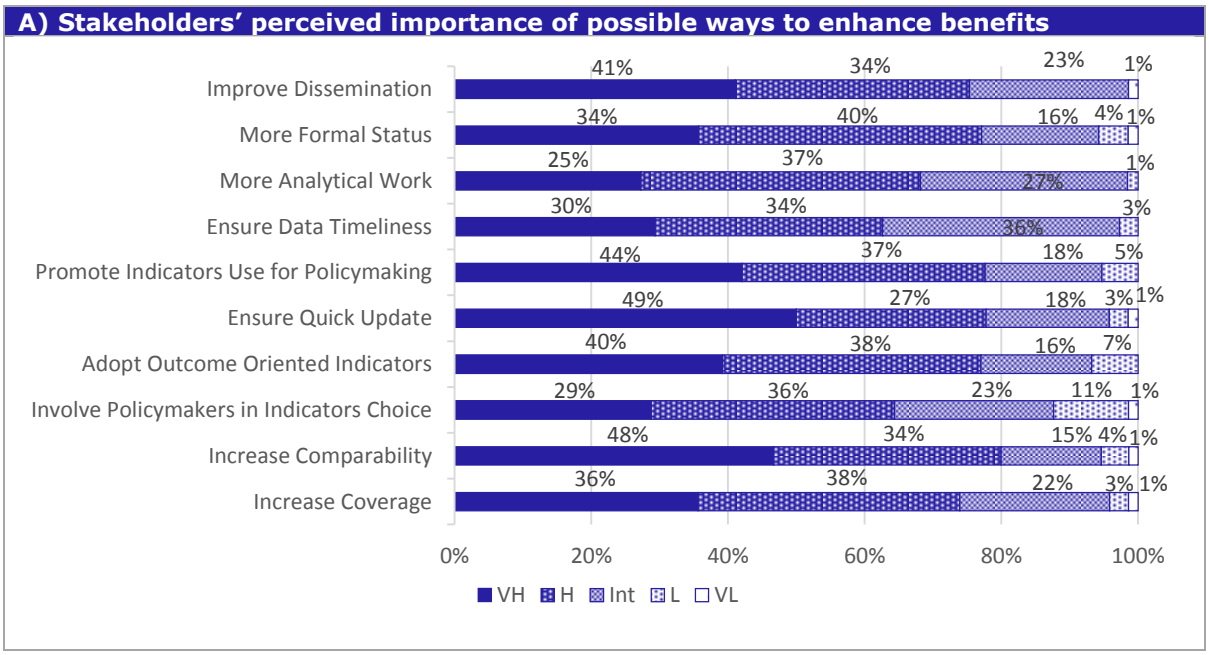
- As regards the current ***level of implementation***, increasing comparability is unsurprisingly considered the most effective way to produce concrete benefits. There is wide consensus among stakeholders – especially policy-concerned ones – and EGHI members on the priority of achieving a more robust level of cross-country harmonisation. There is also a need to extend coverage of existing indicators.

- ***Relevance and utility*** of indicators is a major area of concern when it comes to the cost/benefit balance. The survey results confirm that in various instances the current harmonised indicators poorly match with policy and monitoring needs of national stakeholders and/or are poorly used for that purposes. The vast majority

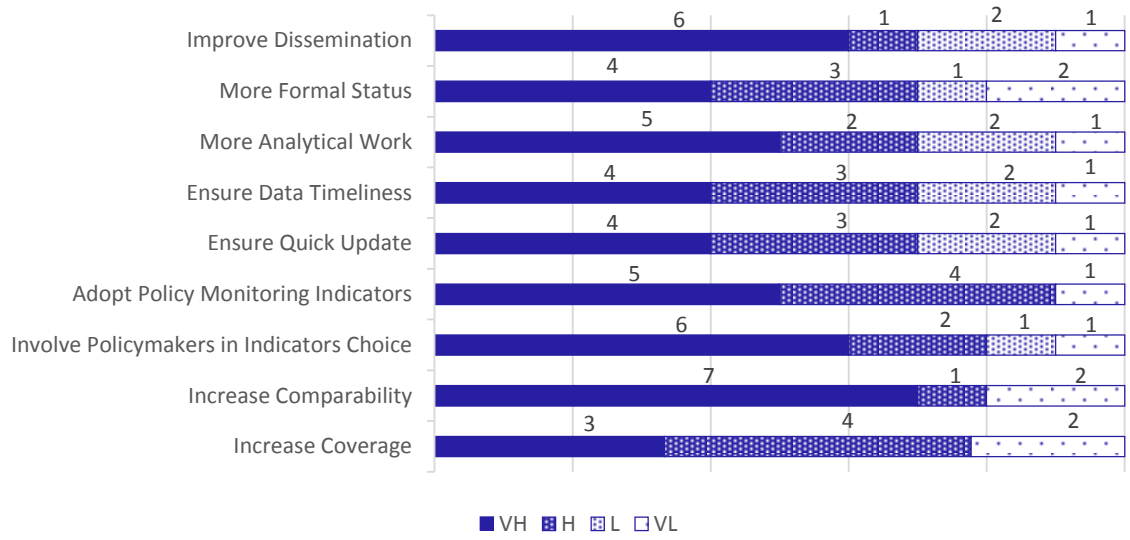
of stakeholders - especially among the policy-concerned – believe that a more quick update and adaptation of indicators to changing needs would make a big difference in terms of utility. Certain emerging trends require a prompt monitoring but the current mechanisms to develop and formalise indicators at EU level cannot simply cope with the agility requested. The result is that the system is able to produce the indicators needed too late for policy needs. Involving policy-makers in the process of identifying the priority indicators is already done at various levels and is not seen as a key area for improvement. Better awareness-raising and promotion of the existing indicators (and analyses) among policy-makers might instead have a significant return in terms of use.

- Various measures to improve the ***usability of indicators*** may possibly contribute to their actual use and benefits, but as compared to the other aspects they seem less decisive. A possible exception is dissemination, which in line with the above awareness of policy-makers mentioned above, many stakeholders and EGHI members consider necessary to improve the cost/benefit balance of the current indicators. Giving harmonised indicators a more formal status seems instead slightly less crucial for their utility, although it is still favoured by a vast majority of survey participants.

Figure 7.4.2 – Consultation results on ways to enhance the benefits of harmonised indicators



B) EGHI Member's perceived importance of possible ways to enhance benefits



Legend: VH: Very High; H: High; Int: intermediate; L: Low; VL: Very Low.
Note: 'Don't know' answers are not reported.

7.5 Scenario Analysis and Comparison

7.5.1 Overview

This final Section analyses and compares the expected trends of costs and benefits associated with the implementation of specific indicators under two main scenarios: (i) the no change scenario; and (ii) a scenario where a hypothetical sustainable system ensures a satisfactory implementation of fully-harmonised indicators. There are evidently various degrees of abstraction in the analysis, which reflects the various limitations and constraints in quantifying costs and benefits of indicators that have been evidenced in the Study, as well as the absence of a clear reference framework for the change scenario after the EU policy initiative has been suspended. The analysis is therefore essentially based on a qualitative, multi-criteria assessment, supported by the case-study evidence that was collected in the sample MS and extrapolated so as to draw indications on broader EU-wide trends. Since each indicator has its specificities, the analysis of scenarios is presented separately, but based on a common analytical framework structured as follows:

- The '***no change' scenario*** is a projection over a mid-term period (conventionally 4-5 years) of the current trends observed with the implementation of the indicator and its use. In this sense, it is a dynamic scenario that takes into account the expected evolution in the absence of any EU level action (outside of the ordinary maintenance and reporting activities).

- The ***sustainable system*** scenario is a hypothetical benchmark that consists of assuming a satisfactory and sustainable implementation and a full harmonisation of the indicator. Needless to say, the actions required to achieve this vary across indicators. In some cases, there is a need to expand coverage. Others would require improved quality control and others would require eliminating duplications etc. For this scenario full compliance is assumed (working hypothesis) although in reality resistances and distortions in implementation may persist. The objective is to compare the estimated burden of achieving full compliance with the estimated effects this may have on the use of the indicator, hence its benefits.

- With respect to ***costs and burden***, two main aspects are considered: the likely trends with implementation (data coverage, harmonisation and quality etc.) and with analysis and reporting activities.

- With respect to ***use and benefits***, two main aspects are considered: the likely impact on the use for policy purposes and for other purposes (e.g. epidemiology, research, accountability etc.). The third main 'driver', i.e. the use for comparison and benchmarking, is subsumed in these two dimensions, actually representing the most important criterion for their assessment.

- Each aspect is ***rated on a scale*** from -2 to +2 that summarise the expected magnitude and direction (negative rating stands for decrease, while positive stands for increase) of the expected variation from the present situation. Table 7.5.1 below describes the criteria underlying the rating scale. For the 'no change' scenario ratings indicate how things will evolve without further EU action (endogenous change). For the sustainable system scenario, ratings express the expected variation 'over and above' the endogenous change expected. Importantly, ratings cannot be 'summed up' since they relate to different dimensions of analysis that typically have different scales of magnitude. For instance, a requirement resulting in doubling the amount of statisitician work is significant in terms of variation (+100%) but can be limited in absolute terms (i.e. from one to two staff/week), and certainly cannot compare with the overall burden

for one MS to report an indicator previously not collected, although in this case the EU-level variation is theoretically small (one country over 28 MS). Ratings are accompanied by qualitative comments summarising the underlying rationale.

- The ***estimated net effects of change*** summarise the net gains or losses that can be anticipated from pursuing the sustainable system scenario. In addition to a general assessment, it includes specific considerations on: (i) medium-term evolution (costs tend to occur in the short run, while benefits in the long run; (ii) extent of distributional effects (not all countries are affected in the same way); and (iii) sensitivity or the level of uncertainty of estimates due to major factors that are hard to forecast.

Table 7.5.1 – Rating scale judgment criteria

Rating	Criteria	
	Implementaion, analysis and reporting costs/ burden of the indicator	**Use and benefits of the indicator for policy process or other pruposes**
-2	Expected significant decrease of costs/burden as compared to the current situation	Expected significant decrease of use and ensuing benefits as compared to the current situation
-1	Expected moderate decrease of costs/burden as compared to the current situation	Expected moderate decrease of use and ensuing benefits as compared to the current situation
0	Negligible or neutral effects on costs/burden as compared to the current situation	Negligible or neutral effects on use and ensuing benefits as compared to the current situation
+1	Expected moderate increase of costs/burden as compared to the current situation	Expected moderate increase of use and ensuing benefits as compared to the current situation
+2	Expected significant increase of costs/burden as compared to the current situation	Expected significant increase of use and ensuing benefits as compared to the current situation
Note: *in the event of multiple effects going in opposite directions, the rating provided represent an aggregation of all the effects expected taking in to account their magnitude.*		

7.5.2 Cancer incidence and prevalence

'No Change' Scenario. There remain positive expectations as to the growing geographical coverage of registry-based data, though possibly at a slower pace than in the last decade. This is likely to increase implementation costs, although the net impact on total unit costs cannot be foreseen for sure, because of the concurring impact of several other cost drivers. These include, on the one hand, increased costs due to: 1) enhanced emphasis on external quality certification; 2) increased importance of legal issues (e.g. data privacy); 3) demand for more detailed and granular data; 4) pressure to have data published as quickly as possible. On the other hand, there is already pressure to reduce operating expenses using passive searches and to invest in the automation of information systems with a view to reducing staff costs, especially where labour costs are high. Requests to have more frequently updated data are likely to have a major impact on registries. According to practitioners clearing backlogs due to more intensive need for passive searches and keeping the pace with more productive operational settings can easily increase operational costs by 60% on a yearly basis. There are no estimates available on the share of the population for which backlog in recording is substantial, and not simply apparent and due to delayed data collection.

In publicly funded health systems, there appears to be a growing demand of prevalence data to estimate the total economic burden on the healthcare systems and

reduce economic inefficiencies in the provision of care, both at the programming and evaluation stages. This implies that prevalence data are linked in the registries with detailed data on the treatments received. Insurance-based systems have less of this need as data on patients' clinical paths are already available to insurance companies themselves and there is little need for them to ask for registry data.

There is also a growing demand for complementing prevalence data with patients' subjective quality of life assessments by means of targeted surveys, although this can create problems with personal data protection regulations. Much in the same vein, there appears a market demand for highly disaggregated data from the pharmaceutical industry and for the assessment of the effectiveness of drugs as required in the new pharmacovigilance regulations[86].

Left on its own, the system is expected to naturally evolve towards growing levels of regional disparities with regions characterized by layers of highly specialized registries increasingly involved in more sophisticated provision of very disaggregated data, and a layer of ordinary ones just tasked with ensuring adequate geographical coverage of basic statistics for public health purposes.

Sustainable System Scenario. The main areas of improvement required with these indicators relate to increasing geographical coverage and enhancing the quality and robustness of data collected by less-strong registries. Both would have significant cost consequences, although the first much more than the latter. A request to come to complete geographical coverage of registry data may come down to about €1.00 per inhabitant (varying with purchasing power and labour costs in a country and the need for active search). This is roughly equivalent to less than 1% of total cancer care costs, but EU-wide it may amount to some half billion Euro annually. Of these, some EUR 100 mln would represent an additional expenditure. A share of these costs is directly related to the collection of basic incidence data.

The costs of harmonization strictly speaking are likely much lower and possibly in the region of a total EUR 10-30 mln for an ideal coverage EU-wide, as they fundamentally overlap with quality controls for compliance with IARC/ENRC case classification procedures and the need to amend/change data entries. They also benefit from economies of scale and therefore would tend to decrease with the actual degree of population coverage. Therefore, those already incurred could be at present very conservatively assessed in the range of 7-21 mln €, although some of these would have to be borne at any rate for quality control purposes even in the absence of jointly agreed protocols, so they cannot be considered as truly additional. Data duplication does not appear as a major stumbling block for providers at the national level as compared to uncertainties in the relationship between IARC and JRC as regards ownership of the information included in the databases and related rights of use. Some would like to see some strengthening or more clarity in the legal basis in the relationships between JRC and IARC which is far from being as straightforward as that between ECDC and WHO on surveillance data on communicable diseases. Most of the costs related to the sustainable system scenario would not be equally distributed across countries and would be significant in particular where registries are less developed and/or recently established. Regulation would be needed to provide registries with a clearer financial framework that could offset financial mechanisms but this appears outside the boundary of the Treaties.

[86] These trends take place in an environment of substantial uncertainty still characterized by a very heterogeneous legal framework with different sets of rules enforced on the sale of data (ranging from sheer prohibition to reimbursement of additional costs only) or sheer lack of rules altogether. This has increasingly raised issues about how to benefit from this demand while ensuring independence in data provision that are currently in the agenda of many cancer registries across Europe. Indicators based on registries are always liable to be displaced by major breakthrough in intelligent IT systems processing administrative data and therefore be replaced by administrative sources only. There are no elements to assess the likelihood of such a disruptive innovation in the near future. Some believe it unlikely simply because it has not materialized yet in spite of expectations along these lines in the past.

It can be reasonably estimated that in the long run incidence data will be increasingly used to assess the effectiveness of prevention interventions other than cancer screening, although this is likely to happen especially in countries with more advanced systems that would not have to bear the costs of further harmonization. This could lead to a growing demand of data for cross-country comparisons, once the problem of harmonising correlating variables is solved (at present there are still uncertainties on how to express obesity, smoking and drinking habits in a harmonised way) and sufficiently long time series have become available. To become of use for policy monitoring, harmonised data on cancer incidence require both a consolidated time series of some five to fifteen years and investment in data gathering and better standardized correlating variables on obesity, smoking and drinking habits to measure related prevention policies. Once these are available, the benefits can eventually materialise.

	No Change Scenario		Sustainable System	
Implementation costs/burden	**+1**	Spontaneous growth of geographical coverage	**+2**	Would require much stronger effort in geographical coverage
Analysis and reporting costs/burden	**0**	No relevant change expected	**+1**	Additional cost to ensure quicker publication of data
Use and benefits for policy process	**+1**	Increasing demand for health system effectiveness assessment outside prevention	**+2**	Demand to assess the effectiveness of prevention policies other than cancer screening
Use and benefits for other knowledge purposes	**+1**	Demand from patient associations and pharmaceutical industry	**+1**	Demand from patient associations and pharmaceutical industry
Estimated net effects of change	**Overall:** Moderately positive. The sustainable scenario would compound to an existing trend towards greater geographical coverage and therefore relieve only additional constraints to data comparability and analysis across Europe. It could however only limitedly affect some of stronger obstacles faced by registries. **Medium-term evolution**: Moderately positive. Investment in increased comparability requires at least a ten year lapse period before being able to deliver valuable results for research. **Distributional effects**: Very high. The sustainable scenario would particularly affect MS with less developed cancer registries without countering the tendency towards a two layered system made of increasingly specialized and routine registries. **Sensitivity (level of uncertainty)**: Very high. The analysis above is much exposed to substantial changes into the cost structure of the indicator due to digitalization, other cost drivers and eventually the appearance of 'big data' technologies.			

7.5.3 Total alcohol consumption and hazardous alcohol consumption

'No Change' Scenario. Since there are several instances of parallel national indicators on alcohol consumption and alcohol-related harm, it is likely that for budgetary constraints some of these will be cut or merged. Being more expensive, cutting on surveys may enhance savings. Actually, certain MS have already experienced delays in EHIS implementation due to budgetary restrictions and have had plans to merge EHIS with other national exercises. The demand for regional or local scale data will not change, since alcohol-related policies often have a strong

regional / local dimension. Therefore, granularity requirements and the need to ensure comparability over time with existing datasets will be responded to. This creates a possible scenario where EHIS is simplified and streamlined to its core dimensions, while non-harmonised and locally-based data gathering increases.

On the other hand, a shift can be expected in the long run from mostly locally-driven interventions to broad national policies aimed at curbing consumption, by means of various forms of taxation (from excises, to differentiated taxation for low alcohol content, etc.), as well as towards introducing restrictions in the legal possibility of buying alcohol (from increase in the legal age to reduced availability of sale points). This could eventually switch interest from purely output-driven indicators towards more outcome-oriented and fine-tuned data on hazardous alcohol consumption in general. It can also be anticipated that there will be a growing demand for data on hazardous alcohol consumption in order to better calculate the trade-offs between the economic benefits from decreased consumption in terms of lower burden on the health system, and the costs from decreased fiscal revenues due to loss of excises on sales.

The use of the EHIS indicators for policymaking purposes is not expected to increase unless a broad consensus on a common definition of hazardous alcohol consumption is reached. Therefore, the added value of EHIS indicators, besides generic cross-country comparability (subject to the usual limitations of survey-based data) is not going to improve. The only exception is due to the fact that the indicator, in its current format, does allow to create correlations between excessive alcohol consumption and health inequalities and the general demand for data on health inequalities is projected as growing. But also in this case the evidence is controversial, and there are studies concluding that alcoholism is not so significantly correlated with socio-economic and income-related variables, as compared to other main areas of public health prevention.[87]

Sustainable System Scenario. Demand for improved comparability of the indicator focuses on more harmonized implementation modalities, and above all, more frequent data gathering. A simple rescheduling of the exercise from every five years to every three years would create a 40% increase in underlying costs. A part of these costs could be eventually compensated by an overall rationalization of the European surveys, although this would require a revision of the questionnaire and new pilot testing exercises. Based on past experiences these one-off costs can reach as high as 5% of subsequent survey implementation costs. The double reporting to WHO and OECD is not reported as a major cause of costs and therefore limited savings are possible from further merge or rationalisation of reporting systems to international organizations. It is noted that total alcohol consumption in its present definition still relies on MS voluntary commitments to make data available and could benefit from a stronger legal basis, although this is not going to have major repercussions on the cost structure, as the indicator remains defined as based on available sources. Stronger harmonisation would require a survey-based approach, which is already feasible under EHIS under no additional cost burden, but with all the limitations and possible inconsistencies/underestimates survey-based data pose in their comparisons with actual physical quantities. Since total alcohol consumption is of little use for setting policy targets unless accompanied by more granular data on non-drinkers, and is de facto replaced by hazardous alcohol consumption, benefits to users of data from harmonisation would also be minimal.

Apart from the use for health inequalities mentioned above, opportunities to increase added value for final policy users would presuppose an agreement of the different Member States in harmonising their definitions of consumption at risk in their policies. To this aim it is noted that Member States still significantly differ in their definition of

[87] See for instance: the Sardinia Health Prevention Programme in Italy.

consumption at risk for policy purposes[88], and there is little consensus on possible convergence towards a harmonised EU policy approach in this respect to define concrete interventions accordingly.

	No Change Scenario		Sustainable System	
Implementation costs/burden	**-1**	Pressure to reduce costs by merging exercises and reduce surveys likely	**+1**	Enhanced comparability would require more frequent survey implementation
Analysis and reporting costs/burden	**0**	No relevant change expected	**-1**	Some minor savings possible by discontinuing double reporting
Use and benefits for policy process	**0**	No relevant change expected	**0**	Unlikely to change substantially if no common definition of hazardous consumption for policy purposes is reached
Use and benefits for other knowledge purposes	**+1**	Increased demand to study health inequalities although of possible limited policy significance	**+2**	Better comparable data to study health inequalities and alcohol consumption at the EU level
Estimated net effects of change	**Overall:** Neutral. The sustainable scenario would go against a growing tendency to rationalise the number of alcohol-related indicators that could eventually result in the absorption of the ECHI one. Benefits for the policy process unlikely to materialise unless a common definition is given to hazardous alcohol consumption. **Medium-term evolution**: Modestly positive. Current frequency of EHIS widely reported to be insufficient for policy purposes and to materialize in workable series in a period of time short enough to be of use for policymaking. Requests to shorten the interval of the survey would improve its value over time. **Distributional effects**: Low. The sustainable scenario likely to favour the informational basis of those interested in alcohol-related health inequalities. This is however not expected to materialize in major policy initiatives as these are not considered a consumption driver. **Sensitivity (level of uncertainty)**: Medium. The analysis above is exposed to cost drivers in opposite directions and the sensitivity of the analysis is bound to compensate for each other factor to some extent.			

7.5.4 Healthy-life years

'No Change' Scenario. The fieldwork evidence indicates a growing demand for 'customised' versions of the HLY indicator, more aligned with the country-level information needs. Taken together these may anticipate an increase of costs under various dimensions. These translate into requests not only for more data at the regional/local level, but also for more precise life expectancy tables from national data and for an increased detail and larger samples for those aged 85 years or over. For some stakeholders, the current SILC sampling is too small to provide a detailed understanding of trends, particularly among the elderly and the very elderly. This risks putting the SILC version of the indicator at the margin without further investment. All this is bound to represent a more substantial burden for data gathering as the GALI question is duplicated in other surveys.

[88] See E.Scafato, L. Galluzzo, S. Ghirini, C. Gandin, *Where do EU Countries set the limit for low risk drinking*, Results from the RaRHA Survey June 2016. http://www.rarha.eu/Resources/Guidelines/Pages/details.aspx?itemId=2&lista=Guidelines&bkUrl=Resources/Guidelines/

The analytical and reporting burden seems bound to grow, because as HLY enters the budgetary debate, pressure to have updated data also increases. The national statistical offices have to face requests for updates while the harmonised EU indicator is published with a 2 to 3 year time lag. This is also compounded by the fact that as the demand for assessing health inequalities increases, it is also expected that HLY will have to provide a regional dimension and this will require larger samples[89]. All in all this could easily more than double related collection costs.

The expected use of the HLY in their national versions can be anticipated as growing over time, although it will also face increasing concurrent use of the DALY indicator which at that level of detail will tend to overlap with the prospective use of these national HLYs. The WHO has reportedly been strengthening its own European Burden of Disease Network with a view to broadening the sample of cases monitored and to complementing results with analysis of the reasons behind recorded trends. This is also expected on the one hand to increase matching requests of broadening the information basis of HLY and on the other hand of creating more coordination between the methodological approaches to the two indicators to improve analysis of results.

Sustainable System Scenario. The HLY indicator has suffered from a certain lack of stability due to sensitivity to survey implementation modalities. Use for policymaking purposes has been hindered by the late appearance of the European HLY as compared to its national versions and by concurrent use of DALY. Most importantly HLY would have suffered from limited availability of analysis explaining the reasons behind its trends. It can be anticipated that the sustainable system scenario will follow the same trends towards larger samples. In particular, there is a perceived need to strengthen the design of the indicator by broadening its sample and by addressing its current weaknesses: an insufficient coverage of prevailing conditions among the very elderly including those living in nursing homes or with dementias. This is very likely to increase the costs of the underlying survey. This will be partly compensated by the streamlining and rationalisation of the statistical programme already envisaged (and whose adaptation costs can account for 5% of the related survey costs).

As mentioned above, this can be compounded by the need to further harmonise the survey implementation modalities. This is similar in nature to the work done in 2008 by Eurostat with the help of some national researchers to standardize the wording of the GALI questions. This was described as a heavy and burdensome process requiring several meetings but eventually led Eurostat to come in 2011 to a situation where around 25 countries used similar translations (or fairly similar ones). These coordination costs could easily amount to a few hundred thousand Euro EU-wide, as this is likely to trigger the need to carry out pilot tests to compare results under different implementation scenarios/regional or age-related dimensions of data. This amount is, however, relatively insignificant compared with the likely increase in the implementation burden.

To increase benefits to users once data are more harmonised, there remains a need to further strengthening the analysis of results. HLY are now processed by Eurostat and the BRIDGE Health successor of the EHLEIS joint action[90] and an agreement has been reached to publish the same datasets. However, existing analyses are mainly of a

[89] For instance, while both Italy and the Netherlands already can cope with this demand for regional breakdown of data, the fact that the SILC survey is not representative at the regional level is already acutely perceived in France. The only European survey representative in France at a regional level is the INSEE's employment survey *(Enquête Emploi)* and discussions are now under way to include the GALI question also in this survey. This would both increase the statistical significance of the sample and provide new opportunities to study relations between employment status and health/disability. In parallel INSEE is also exploring the possibility of including the GALI questions in other large national surveys or even as a part of the common set of variables included in all its surveys.

[90] For an overview of EU-funded health expectancy project see EUROHEX webpage: http://www.eurohex.eu/index.php?option=ehleisproject

descriptive nature and more should be made available to understand the underlying driving factors by distinguishing between purely cohort-based effects and real disability issues, including better coordination with the parallel work done within the framework of the European Burden of Disease Network on DALY. Since available series are already quite long, the benefits of analytical work should materialise relatively quickly. No other major users of the HLY indicator are reported, except for policymakers interested in financial projections.

	No Change Scenario		Sustainable System	
Implementation costs/burden	**0**	Limited further investment expected due to competition with national versions	**+2**	Would require harmonization of survey implementation modalities and larger size to cover regional inequalities.
Analysis and reporting costs/burden	**0**	No relevant change expected	**+1**	Need to offer better analysis of causes behind trends
Use and benefits for policy process	**+1**	Demand for indicators on health inequalities bound to increase	**+2**	Demand for more sophisticated and analytical data bound to increase
Use and benefits for other knowledge purposes	**0**	No relevant change expected	**0**	No relevant change expected
Estimated net effects of change	**Overall:** Neutral. The sustainable system scenario would add potential benefits from more analytical work in exchange for increased implementation and harmonisation costs. The likelihood that this translates in benefits depends on quality of analytical work and removal of statistical noise from data. **Medium-term evolution**: Fairly Positive. Available series already long enough to allow quick materialization of benefits to intended users. **Distributional effects**: Very low. The sustainable scenario is not expected to trigger any major distributional effects. **Sensitivity (level of uncertainty)**: High. Most of the benefits will materialize also in function of the parallel concurrent use of DALY and synergies between the two will require dedicated indicator maintenance work.			

7.5.5 Healthcare-associated infections (MRSA incidence)

'No Change' Scenario. As regards the MRSA Incidence indicator, a slightly positive trend in the EU level coverage of the EARS-Net surveillance has been registered during the past few years. ECDC reported that the overall number of isolates undergoing antimicrobial susceptibility testing has increased by some 10% in four years.[91] The growth was uneven and in some MS a decrease of coverage was also registered. This mixed trend is expected to continue, with new laboratories joining the network as well as a switch from 'quantity' to 'quality' as anticipated in some of the reviewed countries. Similar effects of limited magnitude are expected for implementation costs. An increasing number of laboratories are adopting the *European Committee on Antimicrobial Susceptibility Testing* – (EUCAST) guidelines. In addition, EARS-net is set to strengthen its support and methodological guidance toward better cross-country harmonisations. In this sense, it is expected that laboratory capacity would continue to improve even in the absence of specific policy measures. This might have a mild

[91] ECDC, 'Antimicrobial resistance surveillance in Europe 2014'. http://ecdc.europa.eu/en/publications/publications/antimicrobial-resistance-europe-2014.pdf

reflection on laboratory costs but a more-than-proportional gain in terms of data quality.

On the other hand, there would remain significant limitations to the use of this indicator in MS policy processes, because of the numerous and substantial methodological caveats affecting their comparability across countries, and of the poor relevance of MRSA as compared to other resistant pathogens in various MS.

As regards PPS, precise data on the coverage trends between the two waves are not available, but anecdotal evidence suggests there is a growing interest in this exercise, especially among healthcare providers and public health institutes, which might translate into a spontaneous greater participation, hence a greater investment and possibly a greater return, although time series are still short and real benefits will likely materialise on a longer run. However, at present there are issues with the funding of these exercises that may slow down or neutralise this growing trend.

Sustainable System Scenario. Council Recommendation 151/2009 clearly recognised the utility of having robust indicators on healthcare associated infections in place. The EARS-Net operates under the auspices of ECDC and its legal basis. In this sense, this indicator seems well-established and sustainable and does not require additional recognition or a stronger status. Its current weaknesses are – as seen – mostly of technical nature, and would be solved by further investment in quality and harmonisation. This would help redress the paradox of a higher incidence correlated to better detection capacities. Compared to the current situation, an increase of coverage by 10% per year would already represent a major leap over the past trends. But as seen the benefits would be geographically skewed, given the different incidence of MRSA across countries (in some cases below 1%).

The PPS-based HAI indicator seems to have a greater benefit potential. In principle it would enable: (i) measuring the effectiveness of the introduction of individual measures (e.g. isolation rooms etc.); and (ii) measuring in economic terms the benefits of a reduction in HAI incidence. More information in these areas may further spur the uptake of these indicators at policy-making level. Needless to say, this would require not only more investments on population coverage (as indicated above) but also more granular data not only by type of infection but also by type of providers and geographical breakdown. In addition, better mechanisms for the restitution of the information to the raw data collector should be envisaged. Some industry players concur that a stronger institutionalisation and 'policy recognition' of this survey may contribute to a greater use of these indicators also in the field of health outcome assessment.

A structural problem that goes well beyond the scope of this analysis is the lack of appropriate electronic recording mechanisms in some hospitals, which makes both the raw data collection and the following treatment more laborious than necessary. Some big digitalisation projects are ongoing in various countries, but 'manual' rather than automatic processing is still widespread. Investments in this respect may eventually reduce in the medium run the current implementation costs.

	No Change Scenario		Sustainable System	
Implementation costs/burden	**0**	Very slow increase of coverage of MRSA, and budget constraints for PPS	**+1**	Investments are required to increase coverage in some countries / regions and harmonisation (especially to overcome MRSA incidence technical disparities)
Analysis and reporting costs/burden	**0**	Marginal and non-indicator related increase in quality of processes	**+1**	More efforts are required to enhance both the utility and the analysis and dissemination
Use and	**0**	Limited significance for policy	**+1**	There is some room to expand

benefits for policy process		benchmarking, and for country-level assessment in general		the use of indicators in HAI and patient safety policies, but there are intrinsic limitations for broader policy use.
Use and benefits for other knowledge purposes	**+1**	Possible improvements in the meaningfulness of data due to improved quality processes	**+2**	Better analysis and more focussed comparison b/w similar context may results into more widespread best practices.
Estimated net effects of change	**Overall:** Neutral or marginally positive. ECDC provides already a solid implementation framework. Investment in quality may provide a return in terms of data comparability that is at present largely missing. **Medium-term evolution**: Fairly positive. Especially as regards PPS that is a relatively recent exercise and whose data series are not yet usable. The sustainable scenario may (partly) offset in the medium terms the tendency of certain MS to disinvest on MRSA indicator. **Distributional effects**: Fairly High. MRSA surveillance efforts are different across countries, and so is the coverage of PPS. An optimal implementation would require scaling up investments especially in certain context. There are even more marked differences across individual providers. **Sensitivity (level of uncertainty)**: Low for MRSA incidence (well-established process), medium for PPS-based HAI (still relatively new, and not yet very much exploited)			

7.5.6 Waiting times for elective surgeries

'No Change' Scenario. There is a positive trend in the collection and reporting of this indicator that is not expected to be reversed in the coming years. The indicator is part of the OECD Health Statistics database and is reported in *Health at a Glance*. In the latest edition (2016) some 10 EU countries (plus Norway) reported waiting times data on the three surgical operations selected (cataract, knee replacement and hip replacement), against seven in 2010 and six in 2006 (respectively six and five for knee replacement). Therefore, some moderate increase of the overall collection costs can be expected as the territorial coverage expands. The OECD indicator actually includes two metrics: waiting times from specialist assessment to treatment and waiting times of patients on the list. For both indicators the established variables are: mean, median, and percentage of all patients waiting more than 3 months. Actually, most countries seem in the position to report only waiting times from specialist assessment to treatment, therefore the second indicator is currently not analysed by OECD and it is unclear if it will be maintained. Similarly, the median is considered the most informative variable and the others may not be calculated in the future.

The utility and use of the indicator is constrained by several harmonisation obstacles that make data poorly comparable across countries. No major overhaul is expected in the near future, therefore there seems to be limited potential at hand for a greater use for benchmarking and policy-related initiatives, outside of entirely domestic processes – where the indicator is used to measure the effectiveness of guarantees and other incentives to 'productivity' of care providers.

Sustainable System Scenario. A comprehensive and harmonised implementation of the indicator EU-wide would require major resource investments. In the first place, the countries currently not reporting the indicator shall face the burden setting up a data collection and reporting system. Such costs may differ significantly based on the availability of a comprehensive country-wide information system already tracking data on waiting lists, or the need to actively retrieve raw data from multiple sources. In

addition to these one-off costs, there will be evidently an increase in the recurrent implementation costs proportional to the increase of reporting countries from 10 to 28 (plus, possibly, EFTA and EU candidate countries). Secondly, the harmonisation of the indicator would require efforts also in currently reporting countries due to the current disparities or uncertainties on how the waiting times are actually calculated.

When it comes to policy use of the indicator, stakeholders agree that the indicator is more informative for same-country trend monitoring (and possible comparison of trends) than for immediate comparisons between countries, and it is unlikely this perception would change as a result of larger coverage or better data quality, since the differences due to the national context and policy frameworks would persist. This suggests that – if retained as an EU sustainable indicator – it should be supported by a robust in-depth analysis to prevent misleading interpretations.[92] National bodies who collect this indicator seem interested in fostering cross-country exchanges on this theme, including on the efficacy of the different measures adopted. It was underlined that this would in principle support a better implementation of the EU Directive on patient mobility, which contains a reference to waiting times. In principle, this indicator may contribute to the analysis of access to care where, at the moment, the data collected mostly relate to waiting times for medical examinations (i.e. prior to referral) and are collected by means of survey. There is interest in this area also in MS that do not participate in the above OECD indicator[93].

	No Change Scenario		Sustainable System	
Implementation costs/burden	**+1**	The number of reporting countries will continue increasing.	**+2**	Significant investment needed to achieve full coverage and harmonisation
Analysis and reporting costs/burden	**-1**	Possible reduction in the metrics collected and computed	**+1**	Possible greater demand for analysis to properly interpret trends.
Use and benefits for policy process	**0**	Limited use for policy, due to harmonisation issues	**+1**	Comparison of same-country trends may produce evidence on effective policies.
Use and benefits for other knowledge purposes	**0**	Also limited use for other knowledge purposes, due to harmonisation issues (partly mitigated by extended coverage)	**+1**	Better quality data and analysis may increase the use of the indicator for public accountability and communication.
Estimated net effects of change	**Overall:** Neutral or marginally negative. Pushing the implementation and harmonisation of the indicators in all countries (including where this is not perceived as a policy problem) may translate in a burden that the expected benefits would not necessarily offset. The potential use in the field of equity of access is not yet demonstrated. **Medium-term evolution**: Fairly Positive. The cost/ benefit balance would be on the negative side especially in the initial phase, due to one-off set up costs. Also, benefits depend on the comparison of time series, so they will increase as these become longer and more robust. **Distributional effects**: High. Mostly countries not currently reporting the indicator would be affected. **Sensitivity (level of uncertainty)**: Medium. It is in particular difficult to			

[92] See Siciliani, L., V. Moran and M. Borowitz (2013), "Measuring and Comparing Health Care Waiting Times in OECD Countries", OECD Health Working Papers, No. 67, OECD Publishing. http://www.oecd-ilibrary.org/docserver/download/5k3w9t84b2kf.pdf?expires=1476169844&id=id&accname=guest&checksum=FE36A51EEAD0F9E944ABA6BFFD3CCBEA

[93] For instance, France has launched a waiting times survey in the framework of the Constances cohort project. This survey on waiting times involves appointments made with private practitioners (GPs and specialists) and at the hospital (excluding elective surgery and emergencies). The data collection begun in June 2016 and will concern about 40,000 people. It will be performed through four waves of three months each, each of them will interview approximately 10,000 people.

	quantify the level of efforts necessary to conduct quality control on the data collected at national level and the efforts needed to ensure comparability. Also, there is a significant uncertainty as regards the possible implementation costs in non-reporting countries, since they greatly depend on the current information system and the need or not to conduct active searches.

7.5.7 Share of day cases

'No Change' Scenario. The indicator has gained some popularity over time as a consequence of the project conducted by OECD and the following report published at the end of 2012. Since 2014 it is included in the Health at a Glance, with reference to two types of operations, cataract surgery and tonsillectomy. However, data on the number of surgical operations used to be routinely reported by most of EU countries as part of the statistics on health care activities. Limited change of coverage was reported over the past ten years for these two variables, with only a handful of EU MS not reporting (three for cataract and six for tonsillectomy in 2013). In the strict sense, the coverage does not represent a relevant cost factor, in perspective, since administrative data are anyway collected by caregivers and transmitted to the competent authorities.

A major step in the standardisation of the indicator was the adoption by OECD, EUROSTAT and WHO of a common definition and the inclusion in the 'joint questionnaire on non-monetary health care statistics'. There were disparities in the data reported previously by the three organizations, which have been levelled today. To comply with the specifications, various countries have addressed the existing inconsistencies in the data reported, e.g. with respect to the 'double counting' issue due to the unit of measurement used. However, the evidence from fieldwork shows that the national reporting entities are not always in the position to properly check and validate the data received from hospitals or from regional-level authorities. More importantly, disparities persist with (i) the classification of surgical procedures used, (ii) the definition of 'day case' applied, which makes data poorly comparable across MS.

Certain stakeholders foresee that the quality of the indicator is likely to decrease in the next few years under the 'no change' scenario. For instance, as a result of the new EU regulations on the personal data protection, some Statistical Offices already anticipate that it will no longer be possible to process microdata for double counting or even have access to raw data from the competent authority when these are coded by means of personal IDs.

Sustainable System Scenario. At hospital level, the main possible improvement concerns the efficient collection and transmission of data by means, e.g. of a better digitalisation and automation of reporting – a system that is already in place in some countries but not in others. However, this falls outside the scope of this specific indicator and concerns broader investment on national health information systems. In some countries, data are aggregated at intermediate levels, which may cause loss of some information that may be useful for more granular analyses.

The major challenge in terms of coverage is, however the coverage of outpatient cases. At present, Member States are requested to report outpatient cases only for two types of operations, which means that a significant share of day cases that are currently and increasingly performed in ambulatory settings (and possibly funded by primary care) are not monitored by the indicator. Actually, various countries are not currently able to report outpatient cases and do not think it is likely or feasible to have a reliable source in the near future. The raw data are in principle available (e.g.

through payment systems) but there is no system in place for the transmission and aggregation of the information. Expanding the coverage of the indicator to outpatient cases for additional types of operations (taking into account that several types of operations are not permitted in outpatient settings) may increase the utility of the information, but might imply a certain additional investment.

	No Change Scenario		Sustainable System	
Implementation costs/burden	**0**	No relevant change expected	**+1**	A proper implementation requires more widespread coverage of procedures especially as concerns outpatient data.
Analysis and reporting costs/burden	**0**	No or minor relevant change expected (countries better aligning with the joint definition)	**+1**	Comparability requires more efforts as regards the validity of raw data from registries. Especially if coverage of outpatient operations is increased.
Use and benefits for policy process	**+1**	There seems to be a growing interest in this kind of non-monetary healthcare indicators.	**+2**	More and better data would likely accelerate their policy use. Direct cross-country comparison would remain difficult.
Use and benefits for other knowledge purposes	**0**	There is limited evidence of possible use outside of healthcare system management process and related policy framework.	**0**	Same as for the 'no change' scenario
Estimated net effects of change	**Overall:** Neutral. To enhance the significance of the indicator it is necessary to invest in harmonisation and to effectively deal with gaps for outpatient procedures, which affect the interpretation of data. This may enhance benchmarking, although the usual limitations in comparing different health system may mitigate benefits. **Medium-term evolution**: Fairly positive. No major leaps in costs expected, but the utility of newly monitored procedures and/or the benefits of more informative data would increase with time. **Distributional effects**: Medium. Harmonisation efforts and quality improvements required are strictly connected to the specificities of national health system and the information system in place. **Sensitivity (level of uncertainty)**: Fairly low. No major impact on the production of raw data is expected (raw data are ruinously collected). No major change in policy use (and benefits) is likely.			

8. CONCLUSIONS AND RECOMMENDATIONS

8.1 Summary of Key Findings

The current state of the health information system. The current EU Health Information System comprises several health and health system-related indicators developed over time under different frameworks. In addition to the indicators regularly collected by Eurostat and other EU agencies (ECDC, EMCDDA) in the framework of existing policies and regulations, numerous EU-funded projects *ad hoc* initiatives have defined and implemented multi-country health indicators on a temporary basis. The ECHI initiative was the first and most structured attempt to set up an integrated information system and EU-wide data platform on health. However, the evidence from previous evaluations - confirmed in the current Study – indicates it is scarcely used as a reference source for cross-country comparative assessments. The ongoing BRIDGE-Health project, which pulls together the most relevant EU-funded initiatives in this area, is expected to produce a rationalisation and consolidation of the existing framework and to possibly contribute to the transition toward a more integrated EU health information system.

From the perspective of national data providers, the fragmentation of sources is multiplied by the various existing health databases and projects run e.g. by OECD, WHO-EURO and other international partners. This contributes to a proliferation of indicators that is sometimes felt as causing unnecessary duplications of efforts. The situation has, however been improving, and there is evidence that today the level of coordination is higher than in the past. A concrete example is the case-study indicator on the share of day cases operations, whose data are collected in a harmonised way through the OECD, Eurostat and WHO's joint questionnaire on non-monetary health care statistics.

Various Member States also maintain domestic non-harmonised indicators covering the same areas of internationally-harmonised indicators as part of their national health information systems. Domestic indicators usually respond to the specific information needs of the country and to the diverse characteristics of health systems, but sometimes also reflect reservations as to the relevance, reliability and utility of certain harmonised indicators in their current definitions. This is the case, for instance, of the current indicators on hazardous alcohol consumption, which some Member States (MS) collect separately. All in all, health information maintains a strong national dimension. National-level databases and analytical work remain by far the preferred source of access to health information among stakeholders.

The implementation status of EU health indicators and related burden. The findings of the case-studies indicate that the level of MS adoption of harmonised indicators and the compliance with data requests are generally satisfactory and on an increasing trend. This is evident for indicators backed by data collection regulations (EHIS) or specific policies (e.g. the Council Recommendation 2009 on healthcare-associated infections) but holds true also for indicators supported by gentlemen's agreement like OECD's indicator on waiting times for elective surgeries, whose number of reporting countries has been steadily increasing over time. There remain gaps in the territorial coverage and/or the level of detail for some indicators, but the issue seems more severe for *ad hoc* indicators collected under specific and time-bound projects. The 'fatigue' caused by the proliferation of such initiatives and budgetary constraints are increasingly constraining MS capacity to take part in pilot initiatives.

On the other hand, despite a steady increase in coverage, there are persisting weaknesses and implementation disparities affecting the perceived and actual robustness and comparability of certain harmonised indicators. This concerns, for instance, survey-based indicators (EHIS and EU-SILC), due to a widespread scepticism

towards self-assessed health and cultural bias factors. Furthermore, it emerged that comparability is affected by various other factors including disparities in the implementation and processing methods (e.g. MRSA incidence), diverging national classifications and definitions (e.g. share of day cases), different collection and quality control capacity (e.g. cancer incidence), specific policy-induced alterations of data (waiting times) etc. Reliability and comparability issues emerged with virtually all the indicators analysed in-depth. However, these issues do not necessarily associate with a perceived lack of potential for future use, once the indicator will be fully and consistently implemented.

The costs of producing health information at the country level is still a poorly investigated area, and only gross estimates could be calculated, using a mix of appraisals of data producers, analysis of the chain of underlying activities, and extrapolations from similar tasks. The structure and the level of costs vary significantly, especially in relation to the source and methods selected. Registry-based indicators are particularly burdensome due to overhead costs and when active search is required. Population surveys are also on the expensive side but sample sizes and the implementation method chosen (e.g. CATI, self-administered etc.) can make a significant difference. Indicators based on administrative data that are collected routinely for other purposes (e.g. hospital discharge registries, health fund reimbursement tables etc.) are among the cheapest raw data sources.

The costs of following data treatment and reporting – when it is carried out at MS level and not by international organisations – present smaller variations. They generally consist of the activities needed to gather raw data from source points (caregivers, local/regional authorities etc.) or survey datasets, to validate them through appropriate quality control, and reporting them to the competent international databases. Sometimes MS have to face additional burden that is not strictly implied by the implementation mechanism of the indicator but is caused by its broader operational context. This primarily consists of effort duplications caused by the parallel implementation of domestic non-harmonised indicators in the same policy areas and/or to a much lesser extent by non-coordinated requests for data from multiple entities.

The use and benefits of EU health indicators. Implementing an indicator (i.e. collecting and reporting data) is generally not sufficient to ensure the expected benefits do materialise. This requires in the first place that better information translates into MS-level strategies and policies that better tackle country's health priorities and improve health systems performance, reducing also the geographical imbalances and inequalities across segments of the population. The policy process (in broad sense) is the key driver for contributing to the ultimate goals of improving population health and the sustainability of health systems. Health information is essential to contribute to specific stages of the policy cycle, i.e. from problem analysis to the evaluation of policy impact, but can also contribute to it indirectly, e.g. via a comparison of policies and performances between countries, or through more general support to research and innovation, citizens' awareness, and other specialised monitoring and knowledge purposes.

The degree of uptake and use of harmonised indicators in Member States may depend on a number of factors, which concern the indicator itself and the national context, and eventually determines the extent to which their perceived value outweigh or not the implementation costs. The Study showed that on average EU health indicators are underused in policy-related process, due *inter alia* to:

- 'mismatches' between the information produced and the actual national needs and priorities (including possible inconsistencies with the specificities of national systems);

- insufficient awareness among decision-makers and associated limited commitment for use of indicators in the policy process;
- perceived redundancy with other domestic or international indicators;
- 'usability' aspects, such as accompanying analytical work and guidance on how to interpret the information, and timeliness of data.

Some of the case-study indicators analysed are used in the policy process, but more for background analysis and general monitoring of trends rather than for establishing specific policy targets and commitments. Cancer incidence, for instance, is sometimes used as a benchmark for long-term strategies but strictly speaking the evaluation of policies is more often done through outcomes (survival rates) and/or prevention (screening) indicators. The health system indicators may have a greater potential in this respect. The link with target-setting (e.g. reduction of waiting times, increased share of day cases) is often explicit since these indicators often originate from policy reform processes (e.g. waiting time guarantees). The results showed also persisting limitations in the use of harmonised indicators for the quantification of disease burden and the measurement of health system performance. There are initiatives ongoing at the international level, as well as a growing body of scientific literature, but only in few countries this type of analyses has just been mainstreamed in the policy process.

As regards the other drivers of the value of indicators, there is convincing evidence that certain harmonised indicators have a knowledge value that justifies their implementation, irrespectively of their direct impact on policies. The healthcare-associated infections (HAI) indicator collected by ECDC is a case in point in various contexts. Analogously, cancer incidence and prevalence indicators are largely and usefully used to describe and analyse broader epidemiological trends. Other indicators, like waiting times, have a potential for general public interest although the OECD version seems still underused in this respect. Conversely, the widespread issues affecting the true comparability of data across countries severely hinder their use for benchmarking purposes (i.e. comparing policies and performance). While direct comparisons between countries are therefore hardly feasible or significant, more valuable opportunities are offered by trend comparisons. This approach maintains that irrespectively of national specificities, the stable and consistent measurement of the same indicator over time may allow meaningful comparison of trends across countries.

Scenario analysis and comparison. The evidence collected indicates that in the absence of any major intervention on the current EU Health Information System the ongoing process towards a greater cross-country harmonisation of health indicators may slow down but only for indicators that are perceived redundant or poorly relevant for country needs. In other cases, rather a spontaneous increase in coverage and quality of the information is expected. Budgetary constraints may impose containments of expenditure, but this may affect primarily *ad hoc* indicators rather than harmonised ones. If proper maintenance is not ensured, the utility and relevance of the EU indicators and platforms like the ECHI Data Tool would likely decline, and stakeholders would increasingly refer to other national or international sources for their information needs. Imbalances between the implementation costs and the actual benefits for some of the EU harmonised indicators may worsen.

In order to achieve a full harmonisation and satisfactory implementation of EU indicators in a sustainable manner, significant investments seem necessary. In particular, most indicators seem to need interventions to increase their robustness and true comparability in view of their use for benchmarking and policy purposes. In various instances these seem pre-conditions for the potential benefits to materialise. At the same time, there is no guarantee that the investments required for a full and sustainable implementation of indicators would pay-off, since there are various degrees of uncertainties between the availability of robust information, its consistent use for better interventions and the actual materialisation of the desired effects. In the first place, it is essential that the selected indicators respond to concrete and pressing

policy needs and are designed to this end, which was not always the case in the past. Before investing in this area, it is also important to consider that – as case-study indicators showed – costs would mainly increase in the short-run, while benefits may materialise in the medium/long-run. Moreover, the burden would not distribute equally, but would be borne by certain Member States more heavily than others.

8.2 Conclusions and Recommendations for the Way Forward

Enhancing the consolidation and coordination trends. The future development of the EU health information system appears linked to various ongoing processes whose outcome is difficult to forecast at the moment. The ongoing BRIDGE-Health project has taken up the legacy of ECHI as well as other EU-funded health information projects, with a view to ensuring an appropriate follow up and to improve coordination and synergies. The EGHI group, with the support of BRIDGE-Health, is promoting a transition from ECHI towards a European Research Infrastructure Consortium (ERIC), which would subsume the development and maintenance tasks related to health and health system indicators in the EU. In parallel, DG SANTE is collaborating with OECD, the European Observatory on Health Systems and DG EMPL (JAF-Health) to build a model and a set of agreed indicators for the development of 'State of Health in the EU', as a major tool to promote policy dialogue with Member States. At the same time, at the international level, WHO/EURO is progressing with the implementation of the European Health Information Initiative (EHII), which is currently joined by some thirty countries.

Any possible intervention in the field of the EU health information system has to duly take stock of the complexity of this scenario and its rapid evolving. The priority is to contribute to integrating the existing sources and governance mechanisms rather than setting up new ones. No matter how well the mechanism is designed, the situation is at present still too fluid and too saturated to allow for another initiative or governance layer. On the other hand, there is scope to further enhance both the consolidation of health information projects and the integration / synergies of the main existing processes, in particular 'State of Health in the EU', HSPA, JAF-Health, and the would-be ERIC on ECHI. In fact, while there are obvious differences of scope and purpose, it is important to minimise through effective coordination any efforts these processes may require to national counterparts. The same approach should be taken towards international coordination with e.g. EHII and other ongoing initiatives, so as to enhance synergies and avoid redundancies. There is a clear demand from MS to further accelerate a cooperation process that has already produced encouraging results.

Enhancing policy-related use of harmonised indicators. In principle, all stakeholders agree on the potential of health information systems to steer policy processes and improve health outcomes and/or healthcare system efficiency. However, the views on the adequacy of the mechanisms in place through which this potential translates into a concrete use of these indicators for policy-making and the underlying drivers may differ from case to case and tend to be more negative. Two main factors have been highlighted.

In general, there is a certain consensus about the limited availability or effectiveness of the tools for the dissemination of this information, its limited visibility in the policy debate, and a limited appreciation of its direct significance for policymaking purposes, since the production of indicators is not always supported by explanatory comments or in-depth analysis. Most of the information available to policymakers comes from national sources and only marginally from EU-level comparative analyses.

Redressing these shortcomings would require taking action at multiple levels including more rapid production of information on emerging challenges, more policy-oriented

"knowledge-based" products complementing the provision of indicators with analysis, adequate visibility and communication actions, as well as mechanisms for restitution of the information to raw data producers. As regards visibility an interesting benchmark is the mechanism put in place by EMCDDA, which often release its European Reports based on the harmonised indicators along with the national reports, in joint events, to increase echo and visibility for both. Most importantly a better dissemination should be supported by more updated data, i.e. a significant reduction of the time-lag in the publication of indicators, as it frequently happens that European indicators are crowded out and neglected in the debate by the more recent appearance of national versions.

A second key area of improvement concerns the emphasis on what should be achieved by comparability and where efforts should aim at. As seen, despite harmonised specifications, there remain significant implementation disparities or country-specific biases, which may prevent their meaningful use for cross-country benchmarking. Leaving aside technical aspects, which pertain to the statistical dimension of the indicator, the direct and punctual comparison of country data points is generally considered as poorly informative *per se* and potentially contentious. Much more promising is instead the use of harmonised indicators for same-country assessment of trends and for the comparison of these trends across countries.

Some stakeholders actually raised the issue of whether and under which conditions EU harmonised indicators can be considered fit for policy comparison, especially when they have been originally proposed and collected for different purposes. This is the major challenge the 'State of Health in the EU' package has to face, as it is expected to become the framework of reference for benchmarking the performance and the outcome of national policies and systems. In order to respond to stakeholders' needs and be perceived as credible, this tool should demonstrate the capacity to take into account the specificities of the national contexts and needs. To this end, the 'State of Health in the EU' will require a supporting health information system, capable of adapting to evolving needs more rapidly and flexibly than the current process for establishing harmonised indicators at EU level.

Adopting incremental measures to mitigate the burden of indicators. The assumption that the added value from comparability and harmonisation would be self-evident is not fully supported by the findings from this exercise and the argument would deserve some reconsideration and better qualification. The comparative analysis of the development scenarios above has shown that the achievement of truly comparable and fully implemented health indicators might sometimes require substantial investments that are not necessarily justified or whose rationale is not immediately apparent unless ways are found to increase related benefits from their enhanced use and make them more tangible to prospective users.

The need to supplement indicators with comparative data analysis and interpretation should be regarded as a precondition before any resource-intensive strengthening of the indicators is ever proposed. Otherwise the rationale for further investments might appear particularly weak, especially since national health information systems are under financial pressure because of the budget cuts reported in many MS. This is even more so when the benefits from this strengthening would eventually require long periods of time before materialising and would be subject to a certain degree of uncertainty because of other external factors that cannot be fully controlled. To further discourage any hasty initiative it should be borne in mind that in a number of cases these costs would not be evenly distributed but would affect some players more than others, and those likely to be affected the most may also be those who have taken the least advantage from the current system.

Conversely, there is already room to increase value-for-money of the current information system by pursuing burden-mitigating and cost-saving approaches

through the provision of enhanced governance mechanisms. In particular, the following possible drivers for savings are worth mentioning: (i) the consolidation of *ad hoc* initiatives on health information should continue, by also envisaging mechanisms to effectively filter proposals to launch pilot indicators based on actual needs; (ii) there is room to explore the opportunity offered by 'big data' (primarily administrative information) and semi-automated surces for collecting health indicators in a more cost-effective way than surveys and other resource intensive methods (where feasible).[94] This would require a common and coordinated governance providing a vision, assessing concrete feasibility in given cases and outlining a European strategy to this aim; (iii) much of the data gathering and reporting costs from primary sources would be significantly cut by the adoption of (semi-)automated systems. This however would require a governance mechanism to create a link with parallel developments in the area of e-health that is currently not there.

[94] In this area, a seminal study on possible use of 'big data' for public health purposes, has been commissioned by DG SANTE and published at the end of 2016. Among the case studies reported, it is worth mentioning the Hospital Episode Statistics (HES) in the UK, that is a data warehouse containing detailed information on admissions, outpatient appointments and accident and emergency (A&E) attendances for secondary non-clinical purpose use, including the basis for hospital payment. The HES is used among other thing to develeop national clinical quality indicators. Gesundheit Österreich Forschungs - und Planungs GmbH, "Study on Big Data in Public Health, Telemedicine and Healthcare", December 2016. https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

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