Essential levels of health information in Europe: An action plan for a coherent and sustainable infrastructure

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The European Union needs a common health information infrastructure to support policy and governance on a routine basis. A stream of initiatives conducted in Europe during the last decade resulted into several success stories, but did not specify a unified framework that could be broadly implemented on a continental level.

The recent debate raised a potential controversy on the different roles and responsibilities of policy makers vs the public health community in the construction of such a pan-European health information system.

While institutional bodies shall clarify the statutory conditions under which such an endeavour is to be carried out, researchers should define a common framework for optimal cross-border information exchange.

This paper conceptualizes a general solution emerging from past experiences, introducing a governance structure and overarching framework that can be realized through four main action lines, underpinned by the key principle of “Essential Levels of Health Information” for Europe.

The proposed information model is amenable to be applied in a consistent manner at both national and EU level. If realized, the four action lines outlined here will allow developing a EU health information infrastructure that would effectively integrate best practices emerging from EU public health initiatives, including projects and joint actions carried out during the last ten years.

The proposed approach adds new content to the ongoing debate on the future activity of the European Commission in the area of health information.

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1. Introduction

Timely information is required to support health monitoring, research and governance in Europe.

During the last ten years, the European Union (EU) invested substantial resources to pave the way for a common health information infrastructure through the second health programme (“Generate and disseminate health information and knowledge”) [1] and the FP7 research framework (“Optimising the delivery of health care to European citizens”) [2].

As a result, a stream of initiatives allowed translating seminal ideas into useful products, including analyses, policy recommendations, and working prototypes for the automatic production of specific indicators. After 14 years of continuous work (1998–2012), the action on European Community Health Indicators (ECHI) delivered an example...
of implementation of a core set of public health indicators in Europe, concluding that “further efforts at DG SANCO and Eurostat are needed towards a permanent health monitoring system” [3].

Exploiting the results of more EU projects may help achieving this end. Specific work conducted by the EUROREACH project [4] recommended interfacing best practices from BIRO [5], EUBIROD [6], EUROHOPE [7] and SHARE [8] as a sustainable strategy for the continuous production of comparative indicators.

A common problem is that there is no mechanism in place to embed the above results in the European Statistical System (ESS) according to what has been envisaged by the Regulation 1338/2008 on Community statistics on public health and safety at work [9]. The Regulation puts Eurostat in charge of providing adequate information for all EU Member States (MS). However, it does not indicate how the different areas therein specified may be efficiently covered [10], taking also into account other sector-specific monitoring systems managed by the European Centre for Disease Prevention and Control, the European Monitoring Centre for Drugs and Drug Addiction, and the European Environment Agency.

As a result, there is a high risk that successful achievements from previous projects would be not included in the information system that will be operated by Eurostat on a rolling basis.

An overarching framework is needed for public health monitoring in Europe.

To this end, a recent paper [11] urged the public health community to convince politicians to undertake concrete action on the roadmap agreed by the European Commission (EC), WHO and the OECD.

A relevant step was made in the reflection process on health systems leading to the Council Conclusions on 10 December 2013 [12], which invited the EC and MS to “cooperate with a view to establishing a sustainable and integrated EU health information system...exploring in particular the creation of a European health information research infrastructure consortium as a tool”.

These conclusions clearly attributed the identification of coherent solutions for health information in Europe as a joint responsibility of the public health community and national authorities.

The goal was tackled at meetings organized by DG-SANCO at EC premises, where representatives of EU-funded projects and MS involved in the Expert Group on Health Information (EGHI) were invited to discuss the contents of a “scoping paper” [13] finally delivered in 2014.

The document illustrated the potential benefits of a European Research Infrastructure Consortium on Health Information (ERIC-HI) as a springboard for the realization of a coherent EU health information infrastructure (EU-HII).

The primary aim of the ERIC-HI was to link individual researchers and networks in the area of public health and health systems through better information sharing and coordination.

Although based on a comprehensive vision, the scoping paper included an operational plan made up of many horizontal tasks derived from past projects (e.g. injury surveillance, disease registries, etc). Consequently, the document missed the opportunity of identifying an overarching framework where all activities and different methods could be vertically integrated.

This result clearly showed that while MS request precise objectives and a solid sustainable infrastructure, public health leaders generally prefer maintaining their own networks, and fulfil separate tasks in relative isolation, rather than identifying interoperable solutions that would require potential mergers of different projects.

This way, it will never be possible to gain added value through an expanded collaboration in the following areas:

- efficient use of modern information technology (by engaging specialized professionals as peer designers of advanced solutions)
- legislative boundaries (privacy and data protection issues to guide the design of the system)
- practical gains of international collaboration (consultation with different types of users as a key to evaluate the practical advantages of a EU-HI)

So, what can the different actors do to help responding to the challenge of health information in Europe?

The EGHI meetings highlighted the need for MS and researchers to focus on the following aspects:

- agree common objectives
- define their precise roles and responsibilities
- fix the scale of the effort and source of funding

In this paper, we aim to provide the public health community with key action lines to deliver the following:

- a comprehensive vision to harmonize societal goals with technical and legislative issues in the cross-border exchange of health information in Europe

The following sections will propose a general framework and introduce the “Essential Levels of Health Information” (ELHI) as a key concept for implementing this vision.

2. A new governance model for health information in Europe

The production of many indicators requires using multiple sources and data elements, in order to apply advanced techniques e.g. multivariate risk adjustment, in a unified manner across Europe.

The Regulation 1338/2008 requested MS to collect and transmit micro and aggregated data, in compliance with high quality criteria, standard metadata specifications, and data protection principles laid down in Directive 95/46/EC [14].

However, the content of the Eurostat portal six years after its approval [10] still lacks the expected degree of “greater accuracy and reliability, coherence and comparability, coverage, timeliness and punctuality” [9].

To fulfil these tasks, the information infrastructure of MS needs to be substantially strengthened.
The top-down approach of the Regulation, already not ideal to accomplish complex tasks in a highly heterogeneous framework, has become particularly difficult to make progress with under the current financial restrictions.

In many countries, the systematic organization of standardized databases needs to be improved first. Better data quality strategies (particularly for coding practices) are needed for the routine application of computerized data linkage, also hampered by a heterogeneous implementation of the EU Data Protection Directive [15].

2.1. Overcoming these problems requires strengthened collaboration at different levels.

The methodological support that can be provided by international projects might be reinforced through the creation of a new entity e.g. an ERIC-HI, which could be in charge of Art.5 of Regulation 1338/2008 on methodology. However, such a structure would not relief MS from a significant informative burden that would still rely on their internal capacity.

Expert networks financed by several Research Framework Programmes and Public Health Actions have demonstrated that they are generally unable to reach the level of self-sufficiency expected to contribute to a permanent health information system.

Therefore, a bottom-up approach relying on the capacity of networks would be difficult to implement with limited resources.

One example of effective international collaboration that demonstrated to work in an institutional setting is the experience of the OECD “Health Care Quality Indicators” (HCQI) Project [16].

Over a decade of continuous activity, the HCQI has been able to deliver an expanding set of indicators, periodically reported in the publication “Health at a Glance” [17], now also released with a EU focus [18]. Countries involved in the HCQI liaise with the OECD secretariat to improve methods and algorithms, and as necessary, adapt national systems to fulfill the requirements of the biennial data collection, which now involves over 70 indicators. The HCQI is an open forum for the exchange of best practices, including relevant methodological contributions from EU projects. In 2013, the secretariat initiated a process of devolution of methodological activities (R&D studies) to MS.

The successful model of participative engagement realized in the HCQI is worth to be considered for European collaboration, taking note of the following:

(a) the activity builds upon a well specified conceptual framework [19], in which quality represents only one dimension in the comparative evaluation of health systems performance. This allows countries to see the relevance of indicators in the broader perspective of benchmarking for continuous improvement.

(b) the direct participation of MS to various activities, including taking decisions on methodological issues, data collection and mode of publication of the results, create positive spin-offs through a virtuous competition between MS. The participative model allows for targeted adjustments to be ported to the national level, so that an increasing number of indicators can be delivered. Over time, countries unable to deliver indicators will have a lesser role in highly regarded international reports.

The EU should draw upon HCQI experiences to define a new participatory governance structure for health information in Europe (see Fig. 1).

In such a new organization, the EGHI should be transformed into a structural entity with its own financial budget e.g. a EU Agency on Health Information (EAHI). A central secretariat with strong technical and managerial capacity should coordinate discussions on a rolling basis, using various means (meetings, teleconferences, workshops) and leading the workplan for the establishment of a functioning EU-HII. The coordination shall assist DG-SANCO and MS in taking rapid decisions on all elements of the common infrastructure, from plans for national implementation, to appropriate legislation as deemed necessary.

Participation of MS should also involve representatives of National Data Protection Authorities, to take privacy and data protection into account while shaping the information infrastructure.

Increased collaboration between authorities may smooth the various interpretations and improve public health monitoring, particularly in the case of disease registries and data linkage [6]. In fact, unless the data subject has given his/her explicit consent, the processing of sensitive/health data is in principle prohibited by Art.8.1 of Directive 95/46/EC [14]. However, consent shall not be required if “processing of the data is required for the purposes of preventive medicine, medical diagnosis, the provision of care or treatment or the management of health-care services” (Art.8.3). Consent would be instead required for any further secondary use of the same data, including statistics and health research. Art.8.4 and Recital 34 envisage the possibility for MS of providing additional exemptions to the general prohibition of processing sensitive data for important reasons of public interest e.g. public health, scientific research and government statistics. However, very few MS have translated this possibility into national laws/regulations [20]. As a result, MS that have not used the possibilities ex Art.8.4 of Directive 95/46/EC, have implemented more stringent privacy provisions. The uneven interpretation of the Directive has made data processing for public health and research purposes more difficult in several countries [21].

In the above described governance framework, the ERIC-HI should be given a strong independent advisory and consulting role for research and innovation, to continuously support the EAHI through the provision of targeted recommendations and/or tools/approaches that can be specifically funded for the scope.

The governance structure should also include a “community forum”, including representatives of patients and citizens involved as a focus group that would help evaluating the various options, with particular regards for public reporting.
Two elements will be strategic for such governance structure:

- identifying a conceptual framework for the definition, transmission and publication of health information in Europe. The framework should foster the integration of relevant experiences, ensuring consistency and elimination of duplicated efforts.
- ensuring an equal baseline ability in each MS for the provision of all data elements required for indicators, with appropriate quality and reliability for comparative analysis. The common features of such fundamental baseline will be called “Essential Levels of Health Information”.

Fostering the availability of public health indicators in Europe will require stronger coordination at EU level and firm commitment from MS, as well as an equal capacity within MS to act towards agreed goals. The main characteristics of the proposed overarching conceptual framework are presented in the following sections.

The EAHi shall orient all its activities towards the production of clear specifications and strict guidelines to be duly implemented by EUROSTAT, taking into account and avoiding any potential duplication of work conducted by other EU agencies, for the realization of a sound and efficient EU-HII.

3. An integrated approach to the EU health information infrastructure

The production of health information spans across a continuum linking input data elements to the outputs that shall be communicated to the public. In between, there are all processes required to transform raw data into useful information.

The most natural and efficient way to identify a common framework is through the integration of approaches from successful EU projects conducted on field over the last 20 years.

The task of identifying a common model for different cases may be particularly challenging.

An example from the end of data inputs is given by the case of multiple chronic conditions. Although keeping indicators for each individual disease would be still relevant, new composite indicators are needed to investigate the compound condition. Their calculation will require either ad hoc surveys or linking data for the same subject across multiple sources. The latter case would allow automated calculation, but require disease registers that are structurally interconnected. Such an approach, partially experimented by EUROHOPE [7] in five countries (Finland, Hungary, the Netherlands, Norway and Sweden), seems almost impossible to realize widely across Europe.

One aspect that raises particular concerns is compliance with EU privacy legislation [22–24]. According to the latest draft of the revised EU Data Protection Directive, the processing of personal health data for historical, statistical or scientific purposes shall be allowed only with the consent of the data subject or if the processing serves an exceptionally high public interest, cannot be performed otherwise and is legally authorized [25].

At the opposite side of the process, a common model for the communication of the results would also require integrating views and perspectives of different categories of users. Starting from EU projects on health information may only partially help in this regard, as they have been conceived primarily by researchers, whose views and priorities are very specific compared to others e.g. health professionals and the public.

Recent experiences in the public provision of health information show that targeted efforts are needed to make dissemination more effective [26]. A multidisciplinary approach is required to entail scientific integrity into a broader communication strategy that would allow for results to be used by different categories of users.

This aspect cannot be overlooked, as health professionals and the public have their right to shape future health information for Europe.

Therefore, both the design of data specifications as well as their use by different users must be formally evaluated using objective criteria.

A coherent and sustainable infrastructure that can adequately represent different needs and priorities is outlined in Fig. 2.

The diagram envisages a set of interrelated components, classified as follows:
• "content domains":
  o general principles of policy goals, ethical and social values (represented with black rectangles);
  o subjects of public health monitoring and health systems organization (grey rectangles);
  o statistical methods and information technology (white rounded rectangles)

• “action levels”:
  o four vertical dimensions, including: common EU standards, implementation in MS, cross-border information exchange and the central health information system

This way, any change may trigger adjustments in one or more aspects of the overarching framework. Arrows included in the diagram show the main interconnections occurring between the different components of the system.

The scheme can be particularly useful to fulfil Directive 24 on the cross-border provision of health services [27]. For its implementation, the routine use of health information will require standardized EU definitions, structurally linked to clinical guidelines and underlying data elements, to be routinely applied to national systems of data collection, in compliance with privacy and data protection laws.

4. An action plan on four levels

An action plan to realize the proposed EU-HII shall focus on four different action levels.

4.1. Action level I. Definition of common EU content standards

The definition of health needs and priorities should be a primary scope of the governance structure identified above. This structure will need to specify common criteria that must be agreed among MS to perform national public health monitoring and data transmission to the EU on a routine basis. The complete set of specifications will form the EU Essential Levels of Health Information (ELHI) towards which all MS shall comply.

A useful starting point for the definition of ELHI will be offered by an examination of all relevant public health projects conducted and official EC reports targeting health system monitoring [28,29]. Ranking target indicators according to criteria of relevance, validity, feasibility and actionability should result into a shortlist of indicators and derived data elements [30].

This process would allow defining the initial content for the EU-HII, including standardized definitions and technical specifications for all indicators, as well as specific
methods for their analysis. A relevant example is offered by the OECD HCQI Technical Guidelines for Data Collection: every two years, a set of manuals are distributed to MS, including basic references for indicators by section (e.g. acute care, primary care, etc.), specific criteria to map different data sources, items and classification schemes towards common definitions, and algorithms, including flow charts and software distributed for quality control and on site statistical analysis.

Specific tools shall be planned and duly implemented by Eurostat to aid database design at all levels. It will be possible to optimize the approach by defining ELHI that will allow using the same structure of the database for both national and EU analyses.

A rigorous taxonomy of all data elements involved in the automatic calculation of target indicators will be also required.

So far, duplicated efforts have left room for inconsistent data (e.g. different blood pressure ranges in cardiology and diabetes), resulting in measures that are either misaligned, or lack any mechanism to ensure regular update. A structured inventory of these elements (“data dictionary”) is needed to set common terms of reference for the EU-HII. Relevant EU projects shall be also screened and systematically assessed, making sure that indicators can be produced consistently and reliably over time.

A ”meta-registry” is needed to record information on all relevant data sources, specifying their content, and how the data elements included in the dictionary can be extracted at both national and EU level.

A central repository of open source software shall be maintained as a shared library of useful instruments for interoperable analysis, e.g. mapping tools to link definitions across different classification systems (e.g. ICD9 vs ICD10) or statistical software for computerized reporting.

4.2. Action Level II. National implementation of data collection and reporting

Here the provision of ELHI will be verified at national level. This would mean not only providing the data elements required to fulfil EU obligations, but maintaining a system of public health information that regularly uses the ELHI to report back to the citizens in each country.

The quality and completeness of available information can be substantially strengthened through the active use and feedback from local users.

To share common principles, it will be essential that each MS specifies how they will use the ELHI to respond to public health challenges e.g. diseases and risk factors at high prevalence; multi-morbidity and ageing; integrated care; pay for performance schemes, systematic evaluation of structures, processes and outcomes; patient reported outcome measures; patterns of health expenditure; equity.

Consistently with EU agreements, MS shall be left free to implement the national practices in the use of the ELHI, ensuring that the same levels are safeguarded across Europe. An evaluation of these practices by EU authorities may be foreseen for the scope.

Innovation in national systems may also trigger amendments in the EU priority settings, generating new content for the whole system.

To realize reporting systems in each country, data linkage across multiple sources shall be made possible. This shall allow for advanced statistical methods e.g. risk adjustment to be applied, and computer programs to be developed in accordance with minimal requirements agreed at EU level.

In the national implementation of the ELHI, a particular attention shall be given to the compliance with privacy legislation. All data and analytical processes shall be subject to a process of privacy impact [5] and performance assessment [6], envisaging changes in the local implementation e.g. risk mitigation strategies (including distributed databases, fragmented data analysis, etc.).

The overall approach is summarized by the principle fully endorsed by the EC of “privacy by design”, according to which privacy and data protection should be integrated into the design of Information and Communication Technologies, which should not only maintain security, but be designed and constructed in a way to avoid or minimize the amount of personal data processes [31].

National privacy and data protection authorities shall be involved at this level. This process shall ensure that interpretations of the EU Data Protection Directive are not too restrictive to impede the provision of ELHI.

A series of blueprints and technical manuals will be needed to underpin the implementation of ELHI in MS.

4.3. Action Level III. Rules for cross-border exchange of ELHI

At this stage, precise specifications shall be provided on how to compile national results (macro and/or micro and/or meso aggregates), and which formats and security rules (e.g. encryption) shall be used for cross-border data transmission.

This step will require stewardship of the EC (particularly Eurostat) in consultation with MS and data protection authorities.

A key regulatory aspect of data transmission and storage will be data ownership, in agreement with the rights of different actors that will be directly or indirectly contributing to the EU-HII. Transmitted data that are de-identified may still belong to a person, group of individuals, care provider, region or country. Health information can be processed and published in various ways, raising ethical issues on the rights of groups of individuals, professionals or citizens of entire territories, who can legitimately request control over own records.

The issue on who can legitimately claim rights over the data sent to the EU must be also clarified. This topic often neglected should be carefully discussed and clearly resolved in the interest of governmental institutions, data custodians and individuals.
4.4. Action Level IV. Construction of a central health information system

At this level, results from MS will need to be pooled, analysed and publicly reported. To make this possible, a central database shall be organized, including all data elements required to compute EU indicators, through the application of advanced statistical routines.

The structure of the central database will strictly depend from the formats agreed for cross-border transmission, which in turn will determine the specific statistical techniques that will be used to deliver standardized estimates, e.g. using subject-level data in mixed models, or aggregating cell counts to apply logistic regression, or pooling model coefficients in a meta-analytical fashion. Compliance with statistical requirements may impose changes in the structure of the EHI.

In fact, in many cases the selection of specific statistical methods may require the specification of more complex data collection schemes, which may impact on: (a) technical complexity (additional data to be extracted); (b) sustainability of data operations (higher costs); (c) privacy risks (potential new threats for data anonymity). The final decision on the best method required for data selection and transmission shall be based on the joint evaluation of social benefits, technical complexity and privacy risks.

The central system shall also include effective ways for public reporting, as well as means to provide data feedback to MS (e.g. raw data to allow benchmarking national/sub-national results against international averages [32]). To identify the best solutions, the EC shall take advantage from focus groups included in the governance structure above specified at EU level.

The entire system should be submitted to an independent ethical assessment and overall evaluation, whose results may trigger a revision of the outputs and/or parts or even the entire information infrastructure.

5. Conclusion

The proposed approach attempts shaping the future activity of the European Commission in the area of health information.

In this paper we reported the limited results achieved during multilateral discussions held at EC premises, and propose clear mechanisms and innovative solutions to overcome the current stagnation in the development of a fully functional health information system for Europe.

To this end, we have specified a new participative governance model, complemented by an integrated conceptual approach for the EU health information infrastructure and four action levels to carry out a range of strategic tasks.

This way, results from public health projects and joint actions carried out in the past may be integrated with emerging best practices from MS and future EU initiatives.

The proposed structure revolves around the central notion of “Essential Levels of Health Information”, which will need to be officially endorsed to ensure that complete, high quality data can be made available centrally on a routine basis. This will be only possible through the use of an appropriate legislative instrument e.g. a “EU Directive on Essential Levels of Health Information”. Such legislation should enshrine the general principle of a uniform provision of health information as a key driver for equitable and high performing health systems in Europe, leaving its implementation to the participative process presented here.

Whether these arguments will be ever implemented should depend not only on the vision of politicians and EU officers, but also on the support of the public health community, and how they will orient future collaborations in this field.

For greater transparency, the construction of a new EHI should be based as much as possible on plain language, to favour sharing across the community, including policy makers, health professionals, patients and all citizens.

Disclaimer

The opinions expressed here are only personal and in no way reflect those of participants involved in meetings of the Expert Group on Health Information, including national authorities, international project networks, and the European Commission.

Contributors and sources

The paper takes inspiration from a recent position expressed by public health leaders on the European Journal of Public Health, highlighting the need to get the politicians involved in the realization of a European health information system.

Between 2013 and 2014, the EU Directorate DG SANCO has invited Member States and representatives of EU projects to contribute to a long term working plan regarding the EU information infrastructure, resulting into background materials and text of calls that will finance related activities in 2015–2017. Health professionals and citizens have the right and interest to follow these plans closely.

The author of the paper is a Member of the Bureau of the OECD Health Care Quality Indicators Project, who has been involved in discussions at the EGHI meetings as the former technical coordinator of the EUBIROD project, a public health project funded between 2009 and 2012 by DG-SANCO, Health Information Strand.

He has used his personal experience and the background material available at the official EGHI web page to conceptualize the overarching framework included in this paper.

Fabrizio Carinci is the author nominated as the guarantor of the article.

Conflict of interest statement

None declared.

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