

Health Systems Impact Assessment and the High Level Group on Health Services and Medical Care

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“L’acteur n’existe pas en dehors du système qui définit la liberté qui est la sienne et la rationalité qu’il peut utiliser dans son action. Mais le système n’existe que par l’acteur qui seul peut le porter et lui donner vie, et qui seul peut le changer.”

Michel Crozier and Erhard Friedberg, in “*L’Acteur et le Système*” ed. du Seuil, Paris 1977.

Abstract

The High Level Group on Health Services and Medical Care was established by the European Commission in 2004 to endorse and implement the recommendations issued from the Patient Mobility reflection process. Amongst these, arose the need to develop and explore an assessment on social grounds (along the economic and the environmental) where the impact of non-health EU policies on health systems effectiveness should be detailed. In this paper we review the mandate and role of the High Level Group in putting forward a mechanism specifically addressing Health Systems (HS), within the integrated impact assessment current methodology. The proposed model (and assessment tool) is presented and discussed along the key function elements, priorities and objectives of HS in formulating and implementing EU legislative initiatives and policies.

Introduction

Health systems impact assessment (HSIA) is complementary to health impact assessment (HIA) in decision-support processes, sharing a common concern about the potential effects of pending decisions on health systems, health determinants and the health of the population. In this particular, HSIA looks into the effects of non-health policies on health systems and their functions, namely governance or stewardship, financing, resource generation and delivery, and objectives or priorities, such as access, quality and sustainability. HIA, on the other end, analyses the potential effects of a pending decision on the health of the population. It is “a combination of procedures, methods and tools by which a policy, program or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population”¹. Both HIA and HSIA are building on common methodological approaches.

The Commission has been a long standing promoter of such Impact Assessments, supporting initiatives aimed at congruent political options which maximize positive

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¹ Gothenburg consensus paper on health impact assessment, European Centre for Health Policy, WHO-Euro, Brussels, 1999.

health impacts of non-health policies, while minimizing the downturns, in the context of what is generally known as *Health in All Policies*.

The ensuing paper delineates the chronological framework which guided the activity of the *High Level Group on Health Services and Medical Care sub group on HIA/HSIA*, putting in context the Commission’s tenet for these impact assessments.

Special focus on health systems within impact assessment is increasingly recognized as an important response to the link between health and care in response to the challenges of changing needs and expectations of citizens/consumers/patients; health inequalities and inequalities in health care access; population ageing process; high prevalence of chronic diseases and co-morbidities, just to name a few. Thus, the need to develop this new approach.

Framework and mandate for the working group on HIA and HSIA

The *High Level process of reflection on patient mobility and health care developments in the EU*² followed the conclusions of the Health Council in June 26th 2002, where the Commission was encouraged to address the cumbersome interconnection of health systems and policies across the EU. The need of sharing a common vision was pursued in order to “enhance cooperation in the field of health and medical care to better meet citizen’s expectations and provide patients with improved access to care and a wider choice of health providers”³, while observing each member state pervasive responsibility over its own health system. Concerns regarding the promotion of opportunities for high quality health care while maintaining financial sustainability of the health systems were expressed, and the interest in involving in the high level reflection process in addition to health ministers, the European parliament, and a number of civil society stakeholders from the health sector such as mutuals, insurance, health management and professional associations.

The methodology, objectives and duration of the reflection process were drawn, aiming at a closure by the end of 2003. At the end of this period a report on the patient mobility process was issued⁴, exploring five areas, amongst which, under Reconciling National Objectives With European Obligations one recommendation (among nineteen) was issued “inviting the Commission to consider the development of a permanent mechanism at EU level to support European cooperation in the field of health care and to *monitor the impact of the EU on health systems and to bring forward any appropriate proposals*”. In response to such a request, the Commission took the decision of establishing a High Level Group on Health Services and Medical Care⁵, under the provisions of Article 152 of the Treaty establishing the European Community⁶, with the

² Minutes of the meeting of the High Level Process Reflection on Patient Mobility and Healthcare Development in the European Union, 3 February 2003.

³ idem

⁴ Outcome of the reflection process of the High Level Process of Reflection on Patient Mobility and Health Care Development in the European Union, 9 December 2003.

http://ec.europa.eu/health/ph_overview/Documents/key01_mobility_en.pdf

⁵ Communication from the Commission on the follow-up to the high level reflection process on patient mobility and healthcare developments in the European Union (COM(2004)301 final, 20 April 2004).

⁶ Article 152 of the Amsterdam Treaty states: “A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities. Community action, which

particular aim of promoting cooperation between the member states on health services and medical care, enforcing high quality health care to patients while fostering health system's effectiveness and efficiency.

The setting up of the High Level Group on Health Services and Medical Care⁷ was followed by the creation of five working groups dedicated to examine the following specific questions: cross-border healthcare purchasing and provision (including rights and duties of patients); health professionals; European reference networks; patient safety information and e-health (including data protection) and finally, that concerned with Health Impact Assessment and Health Systems⁸.

Within its mandate, the working group on HIA thoroughly examined the links between the HIA and health systems, exploring its different aspects in order to develop a dedicated methodology for estimating the impact of new policies on health systems, as opposed to analysing the impact on health determinants and hence, on the population health status. One of its set aims was to produce an operational tool for use by officials evaluating specific proposals or policies, in addition to setting up a thorough network of contact points at the European level in order to provide information and support the development of the policy assessment.

The working group on Health Impact Assessment and Health Systems convened for the last time in September 2006, having fulfilled its main goal of producing the policy assessment website application tool, and hence discontinued its regular meetings⁹. Its activity, to which this paper is addressed, drew on the Commission expertise on Impact Assessment, going back for at least a decade.

The Impact Assessment in the EU Commission

In an effort to integrate and replace sectoral impact assessments with partial screening on employment, trade, or environment policy proposals, to name a few, the EU Commission developed an integrated mechanism, the Integrated Impact Assessment (IIA). Building on this considerable prior experience, it was intended to provide a common set of fundamental questions, an analytical standard and a common reporting format, so to improve the quality and coherence of any policy development process. The introduction of impact assessment in the policy development process followed the publication of a Communication from the Commission¹⁰ and the issuing of terms of reference, procedural rules and practical guidelines for impact assessment, in 2002 ("Impact Assessment in the Commission - Guidelines" and "A Handbook for Impact Assessment in the Commission: How to do an Impact Assessment") which were condensed and further developed into full implementation with the technical Impact Assessment Guidelines of June 2005¹¹. These guidelines include reference manual, technical annexes, outlining tools and the assessment methodology covering which

shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to human health"

⁷ Commission Decision of 20 April 2004 setting up a High Level Group on Health Services and Medical Care (C(2004) 1501).

⁸ This working group included representatives from the following Member States: BE,FI, FR,DE,NL, PT(Chair), SE, UK, LT, LV.

⁹ Draft Report on the Work of the High Level Group in 2007, 2 October 2007 (HLG/2007/3).

¹⁰ Communication from the Commission on Impact Assessment (COM (2002)276 final, 5 April 2002).

¹¹ Impact Assessment Guidelines (SEC(2005)791, 15 June 2005).

procedures to follow, while elucidating each actor’s role along the process and straining inter-service cooperation.

It should be stressed that the IIA is currently required for all the major initiatives presented by the Commission in its annual Policy Strategy (from 2004 onwards) or Work Programme, which include regulatory proposals (directives and regulations) proposals under the form of White Papers, expenditure programmes or guidelines for international agreement negotiating procedures. The periodical executive decisions, technical updates, statutory decisions or Green Papers were excluded, following an overarching purpose of simplification and regulatory improvement.

The Directorate General for Health and Consumer Protection took action on its part, promoting a “Scoping Paper”¹² where the essential elements of impact assessment were to be taken into consideration when developing new legislative and non-legislative initiatives, internal to the directorate. The *Scoping Paper* includes a screening of likely economic, environmental and social impacts, with a degree of engagement proportionate to the political and legal nature of the proposal. Ahead of analysing unintended consequences and impacts on consumers, on food and food safety, for example, a clear case is made for assessing impacts on public health and health systems in particular. The *Scoping Paper* is composed of two parts. One, put forth as an appraisal, or “quick and dirty Impact Assessment” procedure, gives evidence on possible policy options, providing the elements for managerial decisions to be made, regarding alternative options to carry on. The second, a delivery plan, where these elements are summarized for the case one policy option has been chosen and is to be conveyed.

The Council of the European Union, on its side, endorsed the Commission’s new impact assessment Guidelines and produced an Interinstitutional Common Approach to Impact Assessment, in order to bring to unison the assessment of potential impact of the legislative work that the European Parliament, the Commission and the Council process and adopt¹³.

By early 2006 the Commission had already conducted 120 impact assessments of this sort, at which point a comprehensive independent evaluation procedure was launched, in order to scrutinize the setting up, the implementation, the results and the evolution of the Integrated Impact Assessment System from its inception in 2002¹⁴.

It should be underlined that Environmental Impact Assessment (EIA), where human health is explicitly tackled as one of the key factors to be assessed, is already statutory in the EU, through directive 2001/42/EC¹⁵. Even though the directive is fully

¹² Directorate General for Health and Consumer Protection, “Preparing a Scoping Paper: the First Step”, Brussels, European Commission, 2005.

¹³ Better Regulation-Handling of Impact Assessments in Council, Report from Presidency, Doc. 8894/06 COMPET100, May, 2006.

¹⁴ Evaluation of the Commission’s Impact Assessment System, Tender Specifications-Invitation to Tender n° SG/2006-01/PO.

¹⁵ Directive 2001/42/EC of the European Parliament and of the Council on the Assessment of the effects of certain plans and programmes on the environment, (OJ L197, 27.06.2001).

implemented since 2004, human health has been seldom considered, as often pointed out¹⁶.

Other institutions have played a role in introducing or endorsing a system of health impact assessment. Such is the case of the World Health Organization (WHO) promoting HIA as a method to be used in the political decision-making process. A “HIA web gateway”¹⁷ has been put forth in order to ease the exchange of international examples of HIA practice and promote easy access to relevant documents.

In addition, the European Observatory on Health Systems and Policies (former European Centre for Health Policy) has continually promoted HIA in sectors outside the health sector and published on various aspects of HIA, such as up-dates on HIA development at each country level; the institutionalisation of HIA, or the effectiveness of such an approach, to name a few¹⁸.

The Working Group on HIA/HSIA: what has been done

The activity of the working group on HIA/HSIA centred its activity on exploring and analysing the context of interdependence of HIA and the Health Systems, namely covering the dimensions of non-health policies on the health systems and their functions. A first report by the Working Group¹⁹ introduced terms of reference in what pertains HIA and its underpinning values and principles; the basic steps it undergoes, the screening of the main policy areas where HIA is deemed more relevant; the gathering of evidence to support the assessment process at regional, national and at the Union level and, at the same time, acknowledge the availability of procedures the Commission has been putting in place to enforce integrated impacts on the policy process.

The uniqueness of a needed methodology designed to approach Health Systems was clear, since it should examine “systematic impacts on organizations (health systems) which in turn may affect the way health care is organized and delivered, and thus, would have impacts on the health status of the population through influencing the ability of health systems to achieve their objectives of improving health”²⁰.

The need of a dedicated tool for such measurements of impact was clearly assumed at this point in time and fashioned the ensuing activity of the group until 2005, when a methodological approach was put-forward under the model: the “Health System Impact Assessment Cube” with the collaboration of the European Observatory on Health Systems and Policies.

¹⁶ John Kemm, “Health Impact Assessment and Health in All Policies,” in Stahl, T.; Wismar, M.; Ollila, E.; Lahtinen, E.; Leppo, K. (eds). *Health in all policies: prospects and potentials*. Helsinki: Finnish Ministry of Social Affairs and Health, 2006, pg.189.

¹⁷ <http://www.who.int/hia/en/>

¹⁸ Wismar, M.; Blau, J.; Ernst, K.; Figueras, J. (eds). *The Effectiveness of Health Impact Assessment: Scope and Limitations of Supporting Decision-making in Europe*, Copenhagen, World Health Organization on behalf of European Observatory on Health Systems and Policies, 2007.

¹⁹ Report from the Sub-Group on Health Impact Assessment and Health Systems, High Level Group on Health Services and Medical Care: Anna Deltour, Anna Hedin, Arto Koho, Birte van Elk, Eero Lathinen, Ruta Liaudanskienė and José Pereira Miguel (Rapporteur) 02/12/2004.

http://ec.europa.eu/health/ph_overview/co_operation/mobility/docs/high_level_wg_002_en.pdf

²⁰ *idem*

In 31 January 2006 the working group promoted a HSIA Workshop in Brussels, with the aim of bridging the gap between the conceptual model, the practical applicability of HSIA, while achieving a consensus on the technical approach and concrete assessment mechanism leading to the impact assessment “cube” endorsement. Hosted by the European Observatory, the meeting engaged a wide variety of stakeholders: academic experts, country experts, international NGOs, the European Commission and WHO (European Observatory on HSP, Office at the EU), emphasising the required external input from stakeholders and experts for developing/updating the information in the cube (to be used by the lead service and DG SANCO to base their assessment upon).

That same year the working group, with the assistance of the European Observatory, produced an operational web-based assessment tool supported by a manual designed for non-health desk officers; putting forward a pilot policy assessment on Community policy on social Policy, Education, Vocational Training and Youth, and, finally establishing an initial network of experts amongst the Member States, in order to exchange assessment outcomes and expertise on national health systems²¹.

The web-based IA tool

The web-based assessment tool, which is now publicly available²² and largely due to the work of Matthias Wismar and co-workers, offers under the developed Health Systems Impact Cube depicted in Figure 1, an outward *do-it-yourself* approach to HSIA, guiding the non-dedicated evaluator or desk officer through interactive links. In practice, the exhaustive set of questions: *why is health important in EU Policies, what are health systems, what is a HIA, why should I do a HSIA, what is the difference between a HIA and a HSIA, how do I use this tool, who can I contact for help*, endow the user with an effective manual and an easy access to personal support, in addition to a rich repository of prior assessments. The wholesale purpose is to facilitate a practical and meaningful assessment of policy proposals, while providing comprehensive evidence on health systems impacts.

The tool analytical framework incorporates rich concepts and notions, explicitly the objectives of the health systems, their principles and values (meaning different things to different countries), covering accessibility, quality and overall sustainability. Also the health system functions are depicted in one of the faces of the cube, comprising stewardship, resource generation (financial and human resources), service provision focused on personal health services (prevention, diagnosis, therapeutic and rehabilitation) and the health system financing (collecting, pooling and purchasing functions). The main face of the cube portrays the European Community 21 Policies (19 are non-health) stipulated in the Treaty of the European Community, and leads to policy assessment documents and specific information on policy impacts on health systems. This unequal-faced model cube (Fig.1) quite visually depicts the interlinking of these strands, underpinning and binding each evaluation to concepts of health systems impacts, to sources and targets of the impacts, but also to the priorities of the assessment²³.

²¹ Report on the work of the High Level Group in 2006, 10 October 2006 (HLG/2006/8 FINAL).

²² http://ec.europa.eu/health/ph_overview/co_operation/high_level/index_en.htm

²³ Matthias Wismar, “Proposal for Developing Health Systems Impact Assessment,” European Observatory on Health Systems and Policies, Draft, June 2005.

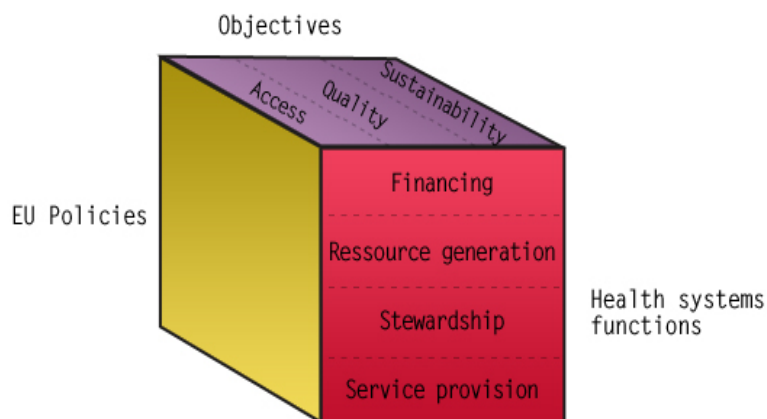


Figure 1. Schematic of the Health Systems Impact Cube, used by the Commission as an online tool.

One realises that factoring all the individual items depicted in the cube would result in 252 junctions (21EU policies x objectives x functions), or more suggestively, an analogy can be drawn with virtual building blocks or drawers, where incremental information can be gathered for the overall assessment. For a single impact evaluated or reported in the past, the respective “drawer” will contain a brief “fact sheet” (*impact news alert*). These policy assessments are indeed the most important information the model-cube provides.

The policy assessments are short documents giving an overview of a specific non-health policy (the source of the impact), establishing the nexus to health systems by target (the health system function) and priorities (the principle and values); identifying the instrument of the impact (eg.legal) while providing (historical) examples of policies which had impact in different country systems in the past. A reference list provides resources for further exercises: content matters to be considered, conclusions and recommendations; references and other information sources retrievable at a touch. In addition, a responsible expert is designated²⁴.

In summary, the health systems impact assessment cube offers a quick check on all pending decisions, the prescriptive advice given to the desk officer who may not have background knowledge in health being supported by the best updated, available, evidence. However, it needs yet to be completed by filling its multiple drawers.

A pilot exercise²⁵, putting to test the tool’s performance, was undertaken on policy assessment addressing the Community Policy on Social Policy, Education, Vocational Training and Youth²⁶. Despite being a very wide policy area with most significant links to health systems, the area of Health and Safety at Work was chosen, and in particular, DG Employment up-coming regulations on musculoskeletal disorders. This exercise introduced an *impact news alert*, giving examples of specific pieces of work (legislation or policy documents) within the broader policy assessment area that have had a

²⁴ idem

²⁵ M. Wismar and K. Ernst,” Policy Assessment on Social Policy, Education, Vocational Training and Youth: a part of the Health Systems Impact Assessment Tool,” Draft, 25 October 2006.

²⁶ Art.136-150, Treaty Establishing the European Community.

particular effect on health systems. Pre-pilot exercises preceded, using precursor work pertaining the 1990 Handling of Loads Directive²⁷. This directive has been in place for a considerable length of time, offering an opportunity to validate the effectiveness of the tool, comparing to the directive’s actual impact. It should be mentioned that the tentative network of experts in the Member States (18 members were nominated by Sept 2006) commented on this first policy assessment.

Contribution of the Portuguese Presidency

On 5 November 2007 the Health Systems Impact Assessment web-tool was launched in Lisbon, at the Portuguese Presidency European Meeting on Health and Health Systems Impact Assessment²⁸. The meeting proved influential in instilling the notion the tool as a working process, to which further policy assessments in every single policy area should be added, until the tool is completed. A particular emphasis was given to the incoming disclosure of a second policy assessment on the subject of Migration, a priority topic during the Portuguese EU Council Presidency health agenda (a theme addressed by the European Conference “Health and Migration in the EU - Better Health for All in an Inclusive Society” that was held in Lisbon, September 2007²⁹).

The overarching aim of the November meeting was to strengthen the development and implementation of HIA/HSIA, by providing a unifying forum around impact assessments, grown apace on European, national and regional levels. The scientific workshop strengthened the network of experts from EU Member States - advocated by the HLG - in order to deepen the understanding of the many factors outside of the health sector that have an effect on the health of a population and their health systems, while making the case for a strong intersectoral cooperation. Dedicated workshops covered *Quality of prediction in HIA and organisational constraints; health inequalities and HIA; health issues in the different sectors, and mental health and HIA*.

HSIA was acknowledged as an effective means to bridge the challenges cast upon both the health systems and the EU policies, and a clear marker of the consequences such policies have for health systems. HSIA continued effort was put in context of the wake of prior presidencies’ issues, namely Social Inequalities and Health, addressed during the UK Presidency and Health in All Policies; the main theme of the Finnish Presidency. A number of case studies on European initiatives were shared, to conclude on the stringent need of a systematic capacity building for HIA/HSIA, making full use of the assessment tools, methodologies and guidelines available, and facing the new challenges ahead, such as further the predictive quantitative dimension of the impacts, with the use of evidence based (epidemiological, toxicological, others) and probabilistic modelling approaches.

In addition, health stakeholders and communities involvement in designing alternative policies better tuned with societal dynamics was seen as cornerstone in achieving the goals of the Lisbon Agenda.

²⁷ Council Directive 90/269/EEC of 29 May 1990 on the minimum health and safety requirements for the manual handling of loads where there is a risk particularly of back injury to workers (OJ L156, 21.6.1990, p. 9-13).

²⁸ <http://www.eu2007.min-saude.pt/PUE/en/conteudos/programa+da+saude/technical+initiatives/Conferência+HIA.htm>

²⁹ <http://www.eu2007.min-saude.pt/pue/EN/>

Concluding remarks

HIA and HSIA, in particular, are entering the political lexicon and discourse, backing policy makers growing awareness of its potential on clarifying various political options at stake. There is clear value in assessments being established as early in the political formulation processes as possible, the usefulness of the recommendations assessors put forth in order to optimize future policies, and the pedagogical precedence it opens influencing key decision procedures.

Because the HSIA evaluation procedures, endorsed by the HLG working group, are likely to involve a broad set of experts (nongovernmental, and voluntary organizations, interest parties, local authorities, media, professional and social groups), HSIA should be regarded as an effective communication instrument increasing the public engagement and learning. All stakeholders need to understand the uncertainty inherent to the scientific process of gathering and producing evidence and output, as well as the highly complex political process of decision, where non-scientific evidence like historical, cultural or social-economic *acquis* should be appropriately valued and taken into the deliberations.

Even though the sub group on Health Impact Assessment and Health Systems convened for the last time in September 2006³⁰, having fulfilled its main goals addressing HSIA and producing the policy assessment website application tool presented in this paper, its vision on commitments for the future are shared. These are namely, to increase relevance of EU internal attention to health issues; broaden the use of the tool and widen its application to several policies while testing and validating the current methodology and, finally, strengthen the network of international experts and Member State focal points for effective exchange of knowledge on least elucidated linkages between policy proposals, health systems and health determinants impacts. Now, the way ahead, namely the implementation of procedures and recommendations, is for politicians to decide.

³⁰ Draft Report on the Work of the High Level Group in 2007, 2 October 2007 (HLG/2007/3).