DECISION MAKING IN HEALTH SYSTEMS WORLDWIDE: AN OVERVIEW REFLECTING INNOVATIONS, OPPORTUNITIES AND CHALLENGES

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Abstract. Innovations and new health technology can significantly improve the clinical practice, health outcomes, and life expectancy. However, governments must make a decision about which intervention is of the best value, offers the best improvement in terms of health gain, fewer adverse events, and all of that in the frame of the restricted resources. Exploring the literature we can see that by using decision-making science and Health technology assessment (HTA) a lot of countries had achieved the balance in the innovative health care world. Their approaches, framework, and development give us an insight of limitations and strengths that decision-makers and HTA agencies face to assess and optimize outcomes and the benefit-harm balance of new medicines and diagnostic tools. Bringing HTA in countries in development is also a concern that has economic and political restrictions and it raises a lot of questions and challenges for development of decision making sciences itself. Our findings suggest that within all the limitations and future challenges that are to come and even we do not have the perfect information, decision must be made. In most health care situations clinical and economic evidence must be extrapolated through time or space, transferred from one study to another, or combined and linked in a way that they can demonstrate a balance between the costs and consequences and capture the benefits of new technologies, overcome uncertainties, and recognize the value of innovation, all within the limits of overall health resources and constrained health budgets of the respective country.

Key words. health systems, Health technology assessment (HTA), Health care, Pharmacoeconomics, National Institute for Clinical Excellence (NICE).

Introduction. Throughout the twentieth century health systems have developed at different speeds, and with different degrees of complexity, reflecting the diverse political and social conditions in each country. As a result, national health care systems have become more advanced, introducing a range of technological innovations such as new medicines and diagnostic tools, telemedicine, and surgical equipment that have brought remarkable improvements in terms of health gains, better quality of life, and fewer adverse events. Adopting innovations in clinical practice provides a major opportunity for health professionals to improve the effectiveness, safety, and quality of treatment. Although many innovations have the potential to bring a range of benefits to patients and the health care system, their spread can cause problems when there are constraints on resources as some innovations bring the same or improved effectiveness and quality of care at significantly lower costs, while other innovations increase overall health expenditures. Even though innovations can significantly improve clinical practice, the rapid growth of medical technology and the increasing volume of new knowledge have made it virtually impossible for providers to keep pace with new treatments. As a result, inappropriate practices and variations in how technologies are used have become part of health care provision across the world, indicating that the most effective and efficient technologies are not always being used. Physicians often hesitate to change long standing practices, which may stop the uptake of new and more effective interventions [1]. Many countries face the challenge of utilizing the benefits of innovation while managing health care budgets and following the basic principles of equity, access, and choice. Considering the rapid growth in health technology and other changes in health care, governments must manage their limited resources by making a decision which interventions are of the best value and how they should be used. So, decision making already became essential part of health care systems [1,2]. Decision making involves choosing an action after weighting the risk, benefits, and costs of the options available to the individual patient or the patient population [1,3].

Innovations and new health technology can significantly improve the clinical practice, health outcomes, and life expectancy. However, governments must make a decision about which intervention is of the best value, offers the best improvement in terms of health gain, fewer adverse events, and all of that in the frame of the restricted resources. Exploring the literature we can see that by using decision-making science and Health technology assessment (HTA) a lot of countries had achieved the balance in the innovative health care world. Their approaches, framework, and development give us an insight of limitations and strengths that decision-makers and HTA agencies face to assess and optimize outcomes and the benefit-harm balance of new medicines and diagnostic tools. Bringing HTA in countries in development is also a concern that has economic and political restrictions and it raises a lot of questions and challenges for development of decision making sciences itself. Our findings suggest that within all the limitations and future challenges that are to come and even we do not have the perfect information, decision must be made.

Discussion. Achieving the balance in health care. Adopting new health technologies has a huge impact on the limited national budgets resulting in tensions between delivering cost effective health care and improving or sustaining a country’s manufacturing and research base. It is therefore increasingly important to have a balance between affordable health care and innovative health technologies. To meet this end, it is necessary to consider the value of a product both in medical and economic terms and also to consider who benefits from innovations, its optimal usage, and the appropriate placement in health care [1,2,3,5]. Moving further, to conduct all this diversity of data and to provide a unique input into the decision making process of the health systems, a lot of countries have developed multidisciplinary field of policy analysis agencies known as Health technology assessment (HTA) agencies [6]. As defined in International Society for Pharmacoeconomics and Outcomes Research’s (ISPOR), HTA is “a form of policy research that examines short and long term consequences of the application of a healthcare technology. Properties assessed include evidence of safety, efficacy, patient-reported outcomes, real world effectiveness, cost and cost-effectiveness as well as social, legal, ethical, and political impacts” [7]. HTA has shown its improving role in growing the national priority-setting and health policy processes [6]. A lot of countries had developed systems to evaluate innovations. In the United Kingdom, for example, the National Institute for Health and Clinical Excellence (NICE) was one of the first review bodies to provide faster access to modern treatments through a systematic review process and evidence-based decision-making [8]. HTA contributes in many ways to the knowledge base for improving the quality of care, in supporting the development and updating of clinical practice guidelines and health service standards [9]. Without good evidence, the spread of technologies is more likely to be influenced by social, financial, professional-al, and institutional factors, and may not produce the best outcomes or the most efficient use of resources [1,2]. However, Kristensen et al. (2009) in their reports for the EUnetHTA work have suggested that despite its policy goals, HTA must always be firmly rooted in research and the scientific methods [10]. Considering the increased uses of pharmaceuticals and other technologies, decision-makers have been encouraged to rely on HTA while determining the reimbursement status and pricing of interventions and pharmaceuticals. HTA with their evidence can reduce or eliminate interventions that are unsafe and ineffective, or whose cost is too high compared to the benefits. As an example, McNeil et al. (2001) reported the use of HTA in identifying technologies that are underused (eg, preventive screening, smoking, cessation interventions) and identifies the reasons for that [11]. Battista and Hodge (1999) called HTA also “the bridge between evidence and policy making”, because it provides information for health care decision-makers at macro-, meso-, and micro-levels [12]. Parts and approaches of HTA. HTA involves different parts and broad range of approaches. Part of HTA report can be clinical effectiveness evaluations as well as economic evaluations, while approaches could be divided in qualitative (narrative review and evidence tables) and quantitative (meta analysis and decision analysis). Adequately, HTA reports go beyond qualitatively reviewing and summarizing the evidence of published international studies and nowadays use decision-analytic methods also to ensure that the results reflect the context of the investi-
gated country’s health care system [1,2]. According its broad concept of technology, the principles and purview of HTA include medical interventions it self, as well as organizational interventions, and even of health care reform, since all of them could be considered as interventional in the health system. HTA can offer to decision-makers the broad picture of assessment of the potential effects on health, the consequences for the health system, the society in which a technology is to be introduced or excluded, and the different options from performing a health care reform [3,13]. In reviewing systematically the evidence on a health technology, HTA uses a multidisciplinary framework to ask four main questions (UK National Health Service R&D Health Technology Assessment Program 2003) as: “Is the technology effective? For whom does the technology work? What costs are entailed in its use? How does the technology compare with available treatment alternatives?” [14]. Framework and Development of HTA. In Europe, the first organizations dedicated in evaluating health care technologies were set up in the 1980s, initially at the regional and national level in Europe and from then on, on the regional level in Sweden in 1987 [15,16]. Further on, over the following next 10 years countries set up HTA programs, either by providing new agencies or institutes, or by setting up academic units or governmental and non-governmental entities. These groups were generally independent review bodies that produced and disseminated assessment reports on a range of different topics. However, as characteristic of the overall management of health care, the bodies producing guidelines and orphan drugs, even if they have poor cost effectiveness ratio usually are permitted to provide input, how results are communicated, how HTA are operated, and how HTA must be reviewed constantly when considering the changes of cost effectiveness ratios in different settings. The European Network of HTA offers a better cooperation among stakeholders, particularly HTA staff, government officials, industry representatives, health providers and patients, starting from the adequate level of understanding of the HTA process. In the interest for HTA to be of optimal benefit, the assessment process needs to be linked with innovation and other aspects of policy-making, and it must recognize the complexities of decision-making, where subjective and normative concerns are considered. Otherwise, HTA could be limited in its power to impact on the policy process and subsequent access to new and effective products [18,24]. Although the difficulty HTA has faced in the past and there will be a lot of them in the future, it is likely that the impact on the innovation exists and that strengthens the future work that it should be more based on research on the technology, process and outcome of HTA systems [18,24]. The European Network of HTA offers a better cooperation among assessment groups and can help in developing those new methodologies, enhance the transferability and transparency of HTA recommendations, and potentially improve the efficiency and account-
bility of the HTA process [29]. This is a European level project established to create an effective and sustainable network for HTA across Europe that could bring all the experiences, data, evidences, strengths and limitations of European countries in a collaborative work in supporting and improving national HTA processes. As defined by EUnetHTA its objective is “to increase the impact of HTA, strengthen the link between HTA and healthcare policy making in the EU and its Member States, and support countries with limited experience in HTA” [10,29]. Kristensen et al. (2009) discussed and reported in detailed structures, methodologies, and tools developed by EUnetHTA. They report also that based on the results of the working process during the project itself EUnetHTA can already be considered as a concrete achievement of transnational decision making and HTA work in Europe. This structure is planned to build a solid foundation for concrete European collaboration in HTA [17,29]. And as a project in progress is the EUnetHTA Joint Action 2 (2012-2015) with its aim “to strengthen the practical application of tools and approaches to cross-border HTA collaboration” [30]. Bringing HTA in countries in development is also a concern that has a huge number of limitations (political, economic and social) and it raises a lot of questions and challenges for development of HTA itself. Beside that, remains the fundamental idea of HTA to guide the healthcare systems in spending their limited budgets in maximizing value of health, and this remains the future challenge for those countries [31]. One of the most important requirements of HTA is leadership, not only among government officials, but among individuals in professional organizations, including the academics and research centers. Ethical aspects of HTA. The most important parts of ethics in HTA are the actual consequences of applying the chosen technology. The HTA analyses itself is an ethical question even from the moment when we start the point of choice in the area we want to focus our decision [31]. INAHTA’s reports that handle ethical issues discusses the different understandings of the consequences of HTA, as it could refer to the value of the HTA results from the ethical perspective, i.e. the relevance of HTA assessments for making and justifying decisions; also it could be the actual ethical implications of an HTA appraisal, assuming the recommendations that the HTA reports give us. As defined by Duthie et al. (2011), “ethical analysis requires systematic reflection and reasoning about what is of fundamental importance to those developing, using, and affected by a particular technology and moves systematically to some course of action that best reflects this importance” [31]. The aim of ethics in HTA is to HTA by making it more comprehensive, transparent, transferable, and more useful to HTA users. In its report, Duthie et al. (2011) highlighted the weaknesses of those issues that exist in the current literature and they offered three steps forward to help improve them: “acknowledge and use relevant expertise, further develop models for conducting and reporting ethics analyses, and make use of untapped resources in the literature” [31]. On the other hand, the INAHTA’s final reports give us an insight of the questions that arise in different aspects of ethical analyses of HTA evaluations, it discusses every question separately and gives recommendations of steps that could every HTA agency undertake in order to develop and share improved skills related to an ethical analyses [32]. Conclusions. The application of this framework within the landscape of health care innovations can inform the development of decision making sciences in societies confronting the challenges of supporting economic growth and providing basic health care. Within all the limitations and future challenges that are to come and even we do not have the perfect information, decision must be made. In most health care situations clinical and economic evidence must be extrapolated through time or space, transferred from one study population to another, or combined and linked in a way that they can demonstrate a balance between the costs and consequences. The findings of our review suggest that decision making and HTA can play a valuable role in health care and it has improved to be a focal point of an ongoing struggle across a range of countries. However, the process must include transparency, relevance, depth, and usability. Assessments need to use robust methods and be supplemented by other important criteria in the decision-making process. By maximizing the potential of HTA in health care system, decision-makers will be able to implement decisions that capture the benefits of new technologies, overcoming the weaknesses of issues that exist in the current literature and recognize the value of innovation, all within the limits of overall health resources and constrained budgets. This article is not attempt to resolve different issues, rather than its aim is getting familiar, articulating, comparing, and contrasting different experiences in health care systems and processes. This template can be seen as useful for purposes when implementing a research, changing a health system, building an HTA agency, and across the areas of science, policy, and population in the countries in development that aim to get familiar with innovations in health care systems.

Reference.