Elizabeta ZISOVSKA

FEW BUILDING BLOCKS FOR EVIDENCE-BASED DECISION MAKING

Context and importance of the problem

The main goal within each governmental sector is to achieve good governance. It could be narrow, centralized governance of the activities within the entire sector, or broader multisectoral approach, considering the interlinked problems and common indicators. The health of the population is a very sensitive issue, and therefore multisectoral approach is the best choice, and this policy brief has the main goal to address the main challenges in identification of the building blocks for better health and social wellbeing of the population. The crucial factor standing behind the good governance of health is the evidence-informed decision making. Evidence-informed decision making is a crucial pillar for the governance for health, including inside the whole society and creating the environment for Health in all policy.[1] The main objectives for this concept are included in the Action plan within the Strategy Health2020, part 6, Ensuring Governance for health, as specific Objectives, Improvement of the governance for health,

The author is Director of the Agency for Quality and Accreditation of Health Care Institutions of Macedonia and Professor at the State University Goce Delchev, Shtip

including all key stakeholders of the public sector, business and academic field, civil society and general population.

As a concept, evidence-informed decision making is a global initiative that promotes the systematic use of health research evidence in policy and decision making. It means promotion of national partnerships between policy-makers, researchers and civil society representatives in order to facilitate both policy development and policy implementation through the use of the best scientific evidence available. As a result, different sectors in the country jointly address specific priorities, develop and use specific skills to assess research evidence and to integrate them in policy briefs that provide for evidence-informed decisions by high-level decision makers at both national and local levels.[2] The highest levels of government and society must recognize that health is a common objective and that achieving it requires coherence.[3] It is worth clarifying the difference between "governance for health" and "health governance", using the common definition.[4]

Box 1. Definitions on health and governance

"Health Governance" refers to policy agenda setting processes, implementation and accountability within the health sector. It includes the management and administration of policies and resources in health, including processes for health systems strengthening.

"Governance for Health" describes a far more multifaceted and complex process of intersectoral collaboration and policy agenda setting, formulation, implementation and accountability whereby multiple sectors, groups of actors and levels of action collaborate and intertwine with the goal of fostering equitable health development. "Governance for Health" thus involves a large number of stakeholders in policy processes and transcends the boundaries of not only specific sectors (e.g. health, trade) but also 'levels' of governance (i.e. local, national, regional, international).

Challenges driven by the concept of evidence-based decision making are uncertainties regarding real meaning of the term "**the best evidence"** and the way **"how it could be assessed".** The evidence retrieved out of the research in health is the most powerful tool to support the decision making process in health and health-linked areas, thus accomplishing many of the objectives within the SDGs. Therefore, the activities planned within the Public Health Action Plan aligned with the Strategy Health2020 in a great part are based on Health technology assessment and Evidence based medicine. These two processes need clarification because of the confusion surrounding them.

Health technology assessment

Box 2. Definition on Health technology assessment

Health and technology assessment (HTA) is a multidisciplinary activity that systematically examines the safety, clinical efficacy and effectiveness, cost-effectiveness, organizational implications, social consequences, legal and ethical considerations of the application of a health technology, usually a drug, medical device or clinical/surgical procedure.[5] Health technology can be defined broadly as any intervention that may be used to promote health, to prevent, diagnose or treat disease or for rehabilitation or long-term care. This includes the pharmaceuticals, devices, procedures and organizational systems used in health care. HTA acts as **'a bridge' between evidence and policy-making.** It seeks to provide health policy-makers with accessible, useable and evidence-based information to guide their decisions about the appropriate use of technology and the efficient allocation of resources.

HTA in Macedonia is a pretty new concept, and despite that, certain number of activities are implemented, as listed below:

- Activities related to continuous medical education since 2000
- Improvement of procedures in pharmaceutical sector -regulatory and ethical aspect (procedures assessed and appropriately updated)
- Established Drug and Therapeutics Committees (DTC) in tertiary health care level
- Establishing Drug expenditure control system Database – ongoing process
- Introduced pharmacoeconomic analysis for drugs subject to reimbursement
- Since 2011 in the country exists branch of ISPOR (International Society For Pharmacoeconomics and Outcomes Research)- Macedonia Chapter
- Ministry of Health together with the Agency for Medicines and Medical Devices have developed TORs for DTC (according to WHO recommendations)

DTC is a multi-disciplinary team of doctors, pharmacists, hospital managers and other professionals, and it is expected to improve rational use of drugs and reduce hospital costs by:

-giving advice in all aspects of drug management
-developing drug policies
-evaluation and selection of drugs for Positive list relying on development of and implementing standard treatment guidelines, assessing drug use to identify problems, conducting interventions to improve drug use, managing adverse drug reactions and medication errors, informing all staff members about drug use issues, policies and decisions. All these information should be retrieved if good situation analysis is performed. At the **moment there is no evaluation of the work of DTC.** ISPOR Macedonia Chapter provides an environment where researchers, health care practitioners, and decision-makers interested in pharmacoeconomics and outcomes research can share knowledge at a country level, regionally and internationally. Within these activities, the publication "Health Care Cost, Quality, and Outcomes: ISPOR Book of Terms" was translated into Macedonian and published. This book provides a great contribution to the mission of the ISPOR Macedonia chapter and presents a great value to solving problems related to Pharmacoeconomics.

Evidence-based medicine

The other issue, which has to be better promoted and systematically developed, is ensuring sustainable resources for Evidence-based practice in the country.

Box 3. Definition on Evidence-based medicine

Evidence-based medicine (EBM) is an approach to medical practice intended to optimize decision-making by emphasizing the use of evidence from well designed and conducted research. Although all medicine based on science has some degree of empirical support, EBM goes further, classifying evidence by its strength and requiring that only the strongest types (coming from meta-analyses, systematic reviews, and randomized controlled trials) can yield strong recommendations.[6]

Over the last decade, Clinical guidelines are recognized as particularly important in the context of the current challenges facing the overall health care systems, such as the rising costs of health care, introduction of expensive new technologies, increased demand for care combined with an ageing population, the variations in clinical practice and service delivery patterns among health care professionals, institutions and geographical re-

gions. Although target users of the clinical guidelines are usually considered the physicians, other groups may benefit too, including nurses and midwives, paramedical professions, health managers, policymakers and patients. All of them perceive increasingly clinical guidelines as relevant tools for making health care more efficient, consistent, safer and for eliminating the differences between what clinicians do and what scientific evidence has demonstrated. In this regard, some clarification of the terms are still needed.

Clinical guidelines are used for the following purposes: to inform health care policy for prioritization of needs and support rational and evidence-based health care decisions; to help develop standards for improving quality of care, change the provision of health care, help assess the clinical practice and improve outcomes for patients; to provide information on cost effectiveness and ensure efficient use of resources which is pertinent to modelling health economics; to educate and train health care professionals to deliver high-quality care; to strengthen the position of the patient and enhance patient-provider partnership; to reduce litigation costs by reducing poor clinical practice. What was done within this field?

- The concept was introduced almost ten years ago
- Highly professional working groups established for each clinical field
- Adopted and adapted the most relevant Clinical Guidelines in all disciplines, period for update predefined
- Legal obligation for health care practitioners stated and published in "Official Gazette of the Republic of Macedonia"
- Some Clinical pathways created in accordance with the Clinical Guidelines
- Monitoring and evaluation of the implementation through the Health Insurance Fund and Agency for Quality and Accreditation of Healthcare Institutions
- Regional workshop on Guidelines development/adoption/adaptation and roll out national trainings were continued

The overall goal of this initiative was to contribute towards improving quality of care in the country, trying to achieve it through harmonization and institutionalization of the process of adaptation of existing international guidelines. Furthermore, practical issues around implementation of the national guidelines into clinical practice still are open, and solutions should be found. In the country, the international definitions for Guidelines, protocols, pathways and algorithms are completely accepted as they are internationally:

- **Clinical practice guidelines** are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. Evidence-based clinical guidelines have become an integral part of health care systems and are considered to be essential tools for improving the quality of primary, secondary and tertiary health care. They have been developed to achieve value for money. The principal aim of evidence-based clinical guidelines is to improve the effectiveness and efficiency of clinical care, as well as patient safety by supporting and promoting good clinical practice in the best interest of patients. Although guidelines provide mainly evidence-based advice for clinical care, they can also be used to set standards of care, improve training and influence the research portfolio. Policy makers can also use the recommendations made in the guidelines for commissioning services. Implementation of guidelines also helps to improve communication and shared decision-making between patients and health care professionals. [7]
- **Clinical protocols** are documents at local (institution, department or clinic) health care level, which are used to implement the national clinical guidelines, in order to improve quality of care and reduce inequalities in provision of care and should also be updated regularly. They are derived from the national clinical guidelines and reflect the local circumstances and variations due to different types of clinical care at different levels. Clinical protocols set out precise rules and sequences of activities to be adhered to in the management of specific clinical conditions. They set out specifically what should happen, when and by whom in the care process. They are intended to be applied rigidly and must be followed virtually in all cases in a defined medical situation, allowing little or no flexibility or variation.
- **Clinical pathways** are tools used to guide health professionals at local (institution, department or clinic) health care level, with the aim to improve the quality of care throughout the patient journey. There is still no standardized definition of what a "clinical pathway" actually constitutes. Integrated care pathway is usually used if care pathways are multi-disciplinary and/or across sectors of health care provision. These are a little bit broader mode of direction than the algorithms, which are flow charts of the clinical decision pathway described in the guideline. The algorithm forms the basis of a shorter form of the guideline, intended for quick reference. It is only a summarization of the recommendations and should not include any further detailed

information or advice. It may be necessary to produce more than one algorithm for one clinical guideline, if the recommendations cannot be summarized into one flow chart.

- **Standards** define the exact quantity or the degree of fulfilment of a criterion for an adequate, acceptable or optimal level of quality. Used in this sense, it indicates an objective set to be achieved or considered as being achievable. Standard is the desired level of performance for some process within the health care. Actually, the standard of care is a statement, which provides an overview of relevant evidence in areas that have some influence or effect on day-to-day clinical practice, but does not provide specific recommendations. It expresses the quality of care provided and focuses on care that is effective, safe and provides a good patient experience. In the country, the process of accreditation towards developed Standards for Quality of care, accepted by the Government of Macedonia, was launched in 2014. The standards are based on high level of evidence, gathered by own research and/or found ready for use internationally. Standards are very flexible, and exposed to update and continuous improvement, depending on the new research findings. The use of Standards in the health sector is a model for using the evidence for decision making process. The process of development and implementation of Standards, and therefore accreditation of health care is under the rules and principles of the International Society for Quality of Care (ISQua). The process of decision making based on evidence requires inter-institutional collaboration (Ministry of health, Health Insurance Fund, State Sanitary Health Inspectorate, Agency for medicines and medical devices, Patient Associations and health managers)

Republic of Macedonia has joined EVIPnet since 2014, and its purpose is to provide background on knowledge translation: the synthesis, exchange and application of knowledge by relevant stakeholders to accelerate the benefits of innovation in strengthening health systems and improving people's health. Evidence briefs for policy, formerly known as policy briefs, are one in a core set of tools used to support evidence-informed policy-making. Evidence briefs go beyond the systematic review by not only addressing the question, but also framing the research evidence in conjunction with information that is specifically relevant for health system policy-makers and stakeholders. This is the best way to improve the culture for and practice of research evidence creation, adaptation and use; support the development of evidence brief for policy in public health, con-

vene national dialogues about priority public health challenges, enhance capacity to find and use research evidence and to develop evidence brief for policy and create the platform for knowledge translation in the country.

The research is urgently needed in some fields, as listed below:
- Human resources for Health, including Public health
- Vaccine and Immunization
- Health Insurance coverage
- Access to health services
- Quality of primary health care services- Nutrition
- Patient safety
- Mental health
- Tobacco
- Rare diseases
- Maternal and neonatal mortality
- Gender and health systems

Policy recommendations

In line with the above, issues, the following policy recommendations are given:

Broad research in the area of Public Health and Health care is essential and has to be conducted in order to get strong evidence to be used as basis for decision making.

The evidence should be assessed for its quality and applicability, and good electronic system should be established.

The research should be conducted not only within the entire sector, but multisectoral, aiming to achieve the SDGs.

The desired and expected outcomes of such policies are as follows:
1. Scientists are looking for treatments that cure. Unfortunately, the people who make money on illnesses will not fund the search for cures, so different financing mechanisms should be found
2. In the country, centralized evidence processing is developed. Despite the volume of research expected in the coming years, it is optimal to establish one central, high-quality, evidence-processing source that examines all of the evidence and evaluates it in terms of certain quality criteria. The next step would be to determine which evidence is relevant to particular practice groups and deliver it to them.
3. Information-retrieval systems that are both sensitive and precise are

developed.

4. Highly qualified human-factors specialized to reduce errors are in place.
5. Decision-support systems that integrate clinical data with current, evidence-based, best-practice information are developed. These systems provide information on when and why it may be appropriate to deviate from best practices.
6. Learning systems for busy practitioners that provide them (and the system) with feedback on their performance are developed.

Although all these outcomes sound very futuristic, they should serve as a direction for applying efforts to create environment for evidence-based decision making not only in the health sector, but also in all other sectors relevant for intersectoral approach towards achieving SDGs.

Abstract

The main goal within each governmental sector is to achieve good governance while achieving equitable access to services and welfare for all. It could be narrow, centralized governance of the activities within the entire sector, or broader multisectoral approach, considering the interlinked problems and common indicators. The health of the population is a very sensitive issue, and therefore multisectoral approach is the best choice, and this policy brief has the main goal to address the main challenges in identification of the building blocks for better health and social wellbeing of the population. The crucial factor standing behind the good governance of health is the evidence-informed decision making. The evidence could be retrieved solely by conducting research and situation analysis for priority needs and problems. As part of the research, introducing Health and Technology Assessment and Evidence Based Medicine Practice is of crucial importance, and therefore are part of the Objectives of the Action Plan within the Strategy Health 2020 in Republic of Macedonia. These two processes need clarification because of the confusion surrounding them.

This policy brief on the process of evidence-based decision-making is developed in line with the National Public Health Action Plan linked to the national Health Strategy 2020, proposing some useful recommendations for research, evidence synthesis and analysis, aiming to follow the Evidence-based decision making initiative, which was recently introduced in the country, and still under development. As part of the process, Health and Technology Assessment and Evidence Based Medicine Practice should be explored in their full extent.

References

1. Dzau V.J, McClellan M, McGinnis JM. (2016) Vital Directions for Health and Health Care. Initiative of the National Academy of Medicine. JAMA. 2016;316(7):711-712. doi:10.1001/jama.2016.10692.
2. Green A, Bennett S, eds. Sound choices: enhancing capacity for evidence-informed health policy. Geneva, World Health Organization, 2007
3. Zsuzsanna Jakab, WHO Regional Director for Europe. (2011) Governance for Health in 21-st Century. Regional Committee for Europe, Sixty-first session, Baku, Azerbaijan, 12–15 September 2011 EUR/RC61/Inf.Doc./6
4. Ilona Kickbusch: Global Health Governance Challenges 2016 - Are we ready?, Editorial, in International Journal of Health Policy and Management 2016:5 pp. 1-5
5. Chase D et al. Development of a toolkit and glossary to aid in the adaptation of health technology assessment (HTA) reports for use in different contexts. Health Technology Assessment, 2009, 13:59.
6. Evidence-Based Medicine Working Group (November 1992). "Evidence-based medicine. A new approach to teaching the practice of medicine". *JAMA*. **268** (17): 2420–5
7. Lois Thomas, RN, PhD (1999); *Evid Based Nurs* . 2:38-39 doi:10.1136/ebn.2.2.38. Clinical practice guidelines