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Legal Regulations of the Health Statistics System and Reflections on the Creation and Implementation of Health Policy in Kosovo

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ABSTRACT

Background: Health professionals and health institutions document their professional activities with patients based on health policy and legal framework. This creates valuable medical records not only for health institutions at the three levels, but also for scientific research purposes and government agencies that design policies, laws and strategies and implement and monitor these policies based on the health statistics that form the basis of these policies, as well as for the health system not only at the national level, but also at the regional and local levels. **Objective:** To analyze the impact of the legal framework for health statistics in Kosovo on the planning of health system needs, human and financial resources and other components related to the collection, analysis and processing of data and health statistics, and on the basis of these statistics, to develop sectoral strategies, but also other key strategic documents for decision-making in the health system of Kosovo. **Methods:** Decision-makers and stakeholders, as well as other staff involved in the system of health statistics at the three organization levels of the health system in Kosovo, including inspectors from the Health Inspectorate, were interviewed through specific questionnaires. **Results:** The analysis of the laws, bylaws and other provisions that regulate and directly influence the data system and health statistics in Kosovo revealed that the institutional role is unclear, the legislation is insufficient and in many cases regulations are missing, which are an essential prerequisite for the implementation of the legislation and consequently influence the insufficient decision-making process. **Conclusion:** The research and findings provide sufficient evidence that the Kosovo's system for health data and statistics has serious shortcomings, starting with the legal framework, organizational structure, functional organization, segregation of duties and responsibilities, pronounced lack of staff, professional profiles and required technology, which in turn affects unreliable decision-making and health policy.
Keywords: health statistics, decision-making, health policy.

1. BACKGROUND

The design and management of public health policy in the modern era is inconceivable without reliable official statistics. A country's health system at all levels of its organization, including all health institutions, carries out its activities based on laws, regulations, protocols and ethical principles that characterize each segment of its work. There are definitions, but also many assessments of health statistics and their role in decision-making and health policy in general.

Health statistics data and information are used to understand some risk factors for communities, to track and monitor diseases, health system organization and activities, to monitor the impact of policy changes, and to assess the quality and safety of health care. Health statistical data and information are a form of evidence, i.e. facts that can support a conclusion. Evidence-based policy-making is "an approach to policy-making designed to ensure that decision-making is based on the best available research" and evidence-based medicine (1). Not all evidence is or should be equally convincing to support a conclusion. The quality of evidence and its applicability to a particular situation varies. Health statistics are figures that summarize information about health. Researchers and experts from government, private and non-profit agencies and organizations collect health statistics. They use statistics to learn more about public health and health care. In addition to

the major role statistics play in health planning, policy making and decision making, they also show us which claims about factors affecting our health are not valid, are not supported by the data or are based on flawed experimental designs and observation (2).

When formulating health policies, health system reforms and sectoral strategies, especially in transition countries such as Kosovo, accurate, transparent and well-analyzed statistics based on scientifically verified methods have a great impact on proper decision-making for a sustainable health system. Evidence-based health policy is an approach to policy-making that aims to ensure that decision-making is based on the best available research. It is characterized by systematic and transparent access to and evaluation of evidence that informs the policy-making process (3).

Current trends in public health policy-making and decision-making generally require close collaboration between health professionals, experts in medical statistics and similar profiles, and decision-makers. The growth of the public health sector is placing increasing strain on available resources. As in other areas of social policy, health statisticians and health data are increasingly expected to provide keys to rational decision-making. To achieve this goal, statisticians and decision-makers increasingly need to work together (4). Analytics is a tool or set of methods that transform raw data into meaningful and useful information that is then used to enable health organizations to gain effective, strategic and operational insights for decision-making and setting their vision for the future (5). This complex but important approach to appropriate health policy requires expertise, human resources, advanced technologies and sustainable financing, which are often lacking in transition countries such as Kosovo.

Public health is a very broad and complex field of specific health care. Therefore, the analysis and processing of health statistics takes place at many levels to ensure that policies and decision-making in this field meet the requirements and needs of the community or population for which these policies are intended. Multilevel analysis has many features that can be useful for public health research methods widely used in current trends in health policy in general and in public health in particular (6). Modern trends, the advancement of information technology in the collection, processing, analysis and presentation of public health statistics, have created a system that transcends national boundaries and is referred to as public health informatics. Public health informatics is a specialized field of informatics concerned with the provision of public health services and population health surveillance, both domestically and globally (7).

Policy-making and decision-making in health care and public health is usually based on statistics produced by professionals for specific segments of the health system. In setting health policy, policy-makers are usually assisted by experts using previous scientifically validated results that are used to support a particular policy decision. Unfortunately, scientifically validated outcomes are not always available/appropriate for all situations (8). Therefore, for appropriate decision-making that meets the health needs of the population and the health system at all three levels, combined and practical methods are often used, especially in the field of public health, known as public health decision making. The complex, cross-sectoral and multi-level nature of public health means that, unlike defense for example, it is not possible to speak of an explicit, all-encompassing national health policy in any country. However, it is possible for governments (at the national or regional level, depending on the distribution of responsibilities within the country) to develop policies that lead directly to action by the state or those acting on its behalf, and facilitate action by others that promotes public health (9). In this context, the organization of the health system is also organized on three levels, which coincides with the relevant institutions that collect and process health data and statistics, which is also characteristic of the institutional organization of the Health Statistics Network in Kosovo.
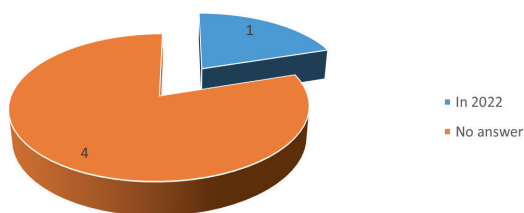
2. OBJECTIVE

The objective of the study is to analyze the impact of the legal framework for health statistics in Kosovo on the planning of health system needs, human and financial resources and other components related to the collection, analysis and processing of data and health statistics, and to design sectoral strategies based on these statistics, but also other important strategic documents for decision-making in the health system of Kosovo.
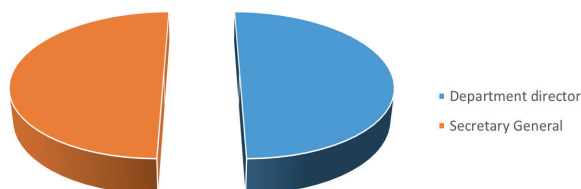
3. MATERIALS AND METHODS

This research is mainly based on a combination of qualitative, quantitative, deductive, analytical and comparative methods developed with representatives of the Assembly of Kosovo – the legislative and supervisory aspect–and the Ministry of Health of the Republic of Kosovo – the executive and implementing aspect. Data, opinions and assessments were obtained from policy makers, health policy implementers, the Health Inspectorate, health professionals from all three levels of the health organization and IT experts actively involved in the system of health statistics of Kosovo. First, we analyzed the published materials, laws, bylaws and action strategies related to the field of our study. This is referred to, in qualitative methodology as the analysis of documents and policies in relation to the hypotheses established (10). Then, using three questionnaires addressed to the focus groups of our study (five members of the Parliamentary Committee on Health, Labor and Social Welfare from the legislative branch, members from the executive branch, the Secretary General of the Ministry of Health of the Republic of Kosovo, the Director of the Department of Health Information System, the Director of the Department of Strategic Health Development) and applying the quantitative method (extraction of research statistics), we reflected on the results of our study.

Q: When do you think the Law on Health Information System will be processed and when do you think the implementation of HIS can be expected in Kosovo?

- In 2022
- No answer

Graph 1. Expectations of respondents regarding the adoption and implementation of the Law on HIS in Kosovo

Q: Do you consider that capacities such as human resources and technologies for analysis, processing and effective use of medical data and statistics are sufficient to improve the quality of health care?

- Department director
- Secretary General

Graph 2. Responses related to the adequacy of the capacity of the health statistics system

4. RESULTS

4.1. Answers to the interview questions for the members of the Parliamentary Committee on Health, Labor and Social Welfare
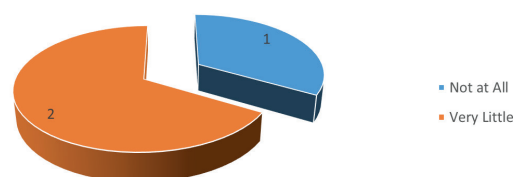
The questionnaire for the members of the Parliamentary Committee on Health, Labor and Social Welfare consists of 6 questions. To the first question, "As a functional committee of the Assembly, have you discussed the role of health statistics and medical data and their importance in health policy formulation and forecasting during this legislative period?", all respondents answered no. To the second question, "Is the field of health statistics in Kosovo covered by the necessary laws and regulations?", 60% answered "no" and 40% answered "partially". To the question "To what extent do you assess the bylaws (regulating health statistics): The Health Information System and the Report on Health Statistics, and do these by-laws fully regulate this area?", 60% answered "partially", 20% answered "yes" and 20% of the respondents answered "no". To the question that is the main topic of this project: "When do you think the Law on Health Information System will be processed and when do you think the implementation of HIS can be expected in Kosovo?", 80% of the members of the Parliamentary Committee on Health, Labor and Social Welfare had no answer, while 20% of them believe that this will happen after 2022, data that speaks volumes about the state of this public health sector in particular, but also of the Kosovo health system in general.

Regarding the last question: "Do you consider it is important to provide this health sector with the necessary legal framework to advance and improve health statistics and public health?", 60% answered "Yes", 20% answered "Partly" and 20% of the respondents gave no answer.

4.2. Responses to the interview questions for the Secretary General of the Ministry of Health and the Director of the Department of Strategic Health Development
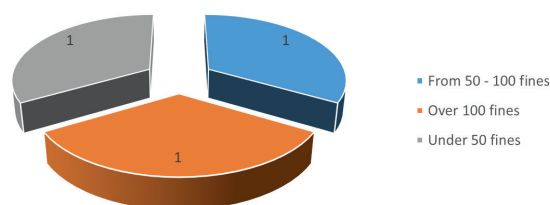
The purpose of this questionnaire was to obtain the necessary information on the creation and implementation of laws and bylaws in the field of medical data and health statistics, the progress cycle from collection to reporting to the Ministry of Health. The questionnaire consists of five questions. To the first question "Do you think the laws regulating the field of health statistics are sufficient to advance health policy?" there were different answers, i.e. one answered "No" (Secretary) while the other (Director) answered "Yes". To the question "Do you consider the collection of medical data and statistics within the health sector, NIPHK, regional public health centers and the three levels of health organization in both sectors functional and sufficient for health policy planning, formulation, analysis and evaluation?" Both senior ministry officials answered "No". To the third question, "Do you consider there are procedural and bureaucratic obstacles in the reports you receive from the institutions that are obliged to report to the Ministry of Health?" The answers were "many" and "yes", which also indicates the state of this important link in the statistics of Kosovo's health system. To the fourth question: "Should there be

Q: To what extent do you consider the legal framework for the health statistics system to be sufficient for collecting, analysing and reporting accurate and reliable medical data and statistics?

- Not at All
- Very Little

Graph 3. Responses to the question on the adequacy of the legal framework for the health statistics system

Q: How many fines, sanctions and other legal actions have you imposed on all health institutions, both in the public and private sectors, in the last two years?

- From 50 - 100 fines
- Over 100 fines
- Under 50 fines

Graph 4. Responses on fines and sanctions imposed on health institutions in Kosovo in the last two years

legal, procedural and technical changes in the form and manner of processing and dissemination of medical data by reporting institutions?" both respondents answered "yes". To the last and most important question for the focus of our work, "Do you consider that capacities such as human resources and technologies for analysis, processing and effective use of medical data and statistics are sufficient to improve the quality of health care?" the answers were "no" and "partly".

In the comment section of this questionnaire, the Secretary General of the Ministry of Health made two important comments that relate to the thesis of our study. He estimates that: "The functionalization of the infectious diseases surveillance system, the "early warning system", the interoperability of the statistical module in the existing systems, the definition of the indicators and their harmonization with Eurostat and their credibility for Eurostat, i.e. in general the aggregation, collection and analysis of data for the purpose of evidence-based policy making are only a few basic requirements for the future development of the health system in Kosovo.

4.3. Responses to the interview questions for the Director of the Department of Health Information System of the Ministry of Health

The questionnaire for the Director of the Department of Health Information System of the Ministry of Health contains eight specific questions relevant to the issues addressed in this research.

In response to the first question, "Do you consider the legislation that regulates the field of health statistics is sufficient to advance health policy?", the Director of HIS Department answered "partly". The next question, which is important for the topic we are dealing with, "Do you think that there is appropriate interaction between the three levels within the system of health statistics (health facilities, regional public health centers and NIPHK)?" the answer was "partly". To the seventh question, "Do you think that the current structure of the health statistics system ensures the protection of personal data?" the answer was "somewhat", which is also an important indicator of the state of Kosovo's health statistics system and the security of patients' personal data.

To the last question of this questionnaire, "How do you assess the security standards of the statistics to protect health data at all three levels of the health system?", the answer was "partly secure".

4.4. Responses to the interview questions for the Health Inspectorate

Purpose of the questionnaire: to inspect, advise, recommend and take legal action against any health facility that violates the standards of the administrative regulations, Health Information System and reporting of statistical data.

Regarding the first question, "To what extent do you consider the legal framework for the health statistics system to be sufficient for collecting, analyzing and reporting accurate and reliable medical data and statistics?", 66.7% consider it "unreliable", while 33.3% assess it "not reliable at all", which is a serious indicator that

legislation in this health sector in Kosovo needs to be changed urgently.

To the second question, "Do you consider that the legal sanctions imposed on health institutions, managers and staff regarding the recording and reporting of health data and statistics are adequate?", 100% of respondents answered "somewhat".

To the last question, "How many fines, sanctions and other legal actions have you imposed on all health institutions, both in the public and private sectors, in the last two years?", 33.3% indicated that they imposed more than 100 fines, 33.3% between 50 and 100 fines and 33.3% less than 50 fines.

5. DISCUSSION

Carefully analyzing the "architecture" of the health statistics system, the legal framework regulating this area of the health system in Kosovo, the implementation of this legislation and the institutional coordination, we can justifiably state that it is a fragile system with many gaps and legal ambiguity of institutional responsibilities. This statement is confirmed by the content of one of the sectoral health strategies, which states that: "An accurate picture of Kosovo's health profile is questionable, due to the limited scope and accuracy of the data. Moreover, the Health Information System (HIS) is not yet complete, so any conclusions that can be drawn from data analysis should be taken with caution (11).

From the analysis of eleven laws, the administrative instruction specifically aimed at regulating this sector, and the three strategies, two of them sectoral and one exclusively for HIS, that cover this area of the health system with a legal framework, we can understand that the unenviable situation of the health system in Kosovo is also a consequence of a system of amorphous health statistics that is disorganized, without a strict hierarchy and with mixed responsibilities at the legislative and executive levels. These findings support the hypotheses and research questions of this project that planning, designing, managing, forecasting and creating health policies and strategies that meet the requirements of modern parameters is unimaginable without an organized system of data and health statistics collection, processing, analysis, management, storage and distribution data by the institutions responsible for this activity.

This lack of coordination and clarification of responsibilities between the legislative and executive branches of government and between the three levels of health institutions for the collection, updating, processing and regular reporting of health statistics has certainly resulted in unsustainable decision-making, budgeting and inaccurate staffing.

6. CONCLUSIONS AND RECOMMENDATIONS

6.1. Health Statistics System of Kosovo

Research and findings provide sufficient evidence that Kosovo's health data and statistics system suffers from serious deficiencies ranging from the legal framework, organizational structure, functional organization, segregation of duties and responsibilities, to a pronounced

lack of human resources, professional profiles and the necessary technology to perform the basic tasks.

6.2. Laws and bylaws

The analysis of laws and bylaws that regulate and directly affect Kosovo's data system and health statistics revealed that the institutional role is unclear, the legislation is insufficient and in many cases bylaws are missing, which are an essential precondition for the implementation of laws.

Of the eleven laws passed that regulate this area of health system, only one administrative instruction is in force that specifically regulates this area, indicating a significant lack of specific legal infrastructure and practical implementation of these laws.

The absence of the Law on Health Records is a major lack of legal infrastructure for health data and statistics in the health system of Kosovo.

6.3. Findings from the interviews with representatives of the legislative, executive and the health inspectorate

From the analysis of the interviews with five members of the Parliamentary Committee on Health, Labour and Social Welfare of the Assembly of Kosovo, we can conclude that:

There were no discussions in both the Functional Committee and the Parliament about the role of health statistics and medical data and their role in health policy formulation and implementation.

They estimate that the legal framework covering the area of health statistics partially regulates this health sector.

These findings speak about the lack of political will of the institutions responsible for the further development the health statistics system, but also of the legislator's negligence in addressing this issue in a meritorious manner.

6.4. From the analysis of the interview with the Secretary General of the Ministry of Health and the Director of the Strategic Health Development Department, it can be concluded that:

Both officials consider the collection of medical data and statistics within the health system, the NIPHK, the regional public health centers and the three levels of health organization in both sectors to be dysfunctional and insufficient for health policy planning, design, analysis and evaluation.

They believe that immediate changes are needed in the legal, procedural and technical aspects, as well as changes in the form and manner of processing and dissemination of medical data by reporting institutions.

They also believe that capacities such as human resources and technologies for the analysis, processing and effective use of medical data and statistics are insufficient to improve the quality of health services, decision-making and health policy development.

6.5. From the analysis of the survey, of we have drawn the following conclusions from the Director of the Health Information System Department of the Ministry of Health:

He estimates that the legal framework for the area of health statistics partially covers this sector with the necessary laws and by-laws.

He evaluates the security standards of health statistics of data protection at all three levels of the health system as partially secure and the protection of personal data from the current system of health statistics of Kosovo as less secure.

6.6. From the analysis of the survey for the Health Inspectorate we can conclude that:

The health inspectors surveyed consider the legal framework covering the area of health statistics to be insufficient and not reliable enough.

They are not sure whether the fines and legal sanctions for institutions, managers and health workers regarding the recording, processing and reporting of health data and statistics are sufficient.

Regarding inspectors' knowledge of health statistics and their skills, they indicated that they have these skills to some extent. More than 2/3 of them said that they encounter many violations of the law by professionals and health institutions in their work.

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