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Establishment of Clinical Policy Making in Iran

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ABSTRACT

The worldwide increase in the cost of health services has now become a shared concern for all health managers and experts. Regarding the limited allocatable resources to hygiene and treatment systems and numerous needs in this section, both the politicians and the consumers have to look for the most optimum strategies available. This present study aims to elaborate on how a clinical policy-making module was formed and to discuss its main activities since 2011. The data used in this review study is based on evidence, recorded information, and reports. The very fact that the authors of this article are members of a clinical guidelines standardization and codification bureau can approve for the reliability of the gathered data. Evidence-based scientific products such as guidelines for clinical practice and diagnostic/therapeutic clinical policies that aid health care providers in correct decision-making are currently regarded as an organized set of the latest and most authentic scientific evidences and hold an important position in health service systems.

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Introduction

The worldwide increase in the cost of health has now become a shared concern for all healthcare managers and experts. The non-stop development of new and expensive health technologies, increase in community expectations from health systems, and changes in disease patterns are the major contributing factors.

Furthermore, regarding the limited allocatable resources to hygiene and therapeutic systems and the numerous needs in this section, both politicians and consumers have to look for the most optimum strategies available, which will have dramatic effects on the promotion of community health. To achieve a correct evaluation of the new methods and procedures, precise scientific evidence, particularly on the efficiency, is necessary. It is of utmost importance to investigate if a certain procedure/technology compensates for its cost with its effects on health promotion and opportunity costs compared to alternative methods.

Materials and Methods

The present study investigates the formation of a clinical policy-making module in Iran and its activities since 2010. The incorporated data to this review study is based on evidence, recorded information, and reports.

The very fact that the authors of this article are the members of a Health Technology, Standardization and Tariff Department is sufficient to approve for the reliability of the gathered data.

Formation of Clinical Policy Making

Changes taken place in the last decade, especially in the incorporation of evidence-based medicine into the country's health system, can be regarded as a turning point which has made scientific evidence the cornerstone of policy and decision-making (1). By going through the history of clinical guidelines used in Iran, it becomes apparent that these guidelines did not hold the position they should have until 2003 and were developed in an unorganized fashion in the following years. This was the case until 2010 in which, with the separation of the Deputy Ministries of Health and Medical, a legal and formal structure was defined in Health Technology, Standardization and Tariff Departments of the ministry of health. The Bureau of Clinical Guidelines Standardization and Codification established the national clinical knowledge management system via founding knowledge management units to design and provide the operational bed needed for installing evidence-based health-care systems, in order to guide national knowledge products in specific clinical fields. Also, after reaching agreed-upon frameworks and manuals, codifying different

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kinds of knowledge products which serve important roles in clinical policy-making such as clinical practice guidelines and clinical policies have been set as one of their main responsibilities.

Clinical practice guidelines are sets of clinical recommendations which have been chosen in an organized fashion and with reference to authentic research evidence regarding our native conditions and needs. These guidelines, which are either codified anew or naturalized from previous guidelines, come to aid the health politicians and the health-care practitioners in correct decision-making (2).

Clinical policies are regarded as the main axis for decision-making since they include an extensive source of medical knowledge derived from authentic scientific evidence and the experts' experience that have been converted to practical guidelines and play important roles in the diagnosis, treatment, and management of the diseases. This set was first codified by the American Academy of Pediatrics. The American Congress of Obstetricians and Gynecologists has also played an important role in reinstating clinical policies in health service systems. In the same context, using a 12-section clinical instruction, the American Association of Anesthesia succeeded to significantly improve health-care services and to reduce medical errors. This positive feed-back led to the installation of the first Agency for Health Care Policy and Research (AHCPR) which was put in charge of development clinical guidelines. Similarly, emergency medicine experts of the United States started developing their own clinical guidelines in 1987. Their unison meetings led to naming these knowledge products as "clinical policies". In these meetings, it was decided that certain clinical policies be developed for emergent cases and for risky/expensive services delivered in a short time.

The first example is clinical policies for treating patients with acute chest pain, which showed to have a drastically positive effect in controlling the related costs and treatment management (3, 4).

In addition to providing operational guidelines, clinical policies may have numerous other functions, such as in-service evaluation programs, health research management, pursuing forensic medicine files, and policy-making for clinical affairs. Our article aims to discuss the clinical recommendations positions as the main core of the clinical policies/guidelines, clinical policy-making framework, and the connective structure with executive policies.

Knowledge products in health service systems

1- Policy-making in health insurance: Nowadays, the concepts of evidence-based healthcare service coverage and quality-based purchasing are the main topics considered in health insurance policy-making. Having these guidelines at a national level can be used as the main basis for decision-making in this field.

2- Authentication: Having clinical guidelines which insist on improving quality, promoting the level of safety, and demanding service providers' responsiveness can prepare the settings for having an organized evaluation of health-service providers.

3- Clinical Audit: Clinical Audit is a process for gaining assurance and to guarantee the continuous promotion of optimal health service provided.

Developed guidelines can be of great help in this regard.

4- Realization of Patients' Rights Prism: Guidelines basis on patients' rights function as a kind of reminder for healthcare providers to pay enough attention to this concept.

5- Juridical Forums: One of the main problems in legal and juridical forums is the absence of evidence on which the decisions are based. Approved written guidelines can be used as main evidence in these instances.

6- Revising the regulations for installing new centers: Evidence in clinical guidelines can be used in achieving a more precise framework to codify regulations of centers installation.

7- Navigating the process of education in Medical Sciences: developing clinical guidelines with regards to healthcare services shall elucidate the educational needs and shortcomings.

Framework of Clinical Policy-Making

Regarding the fact that like clinical practice guidelines, the main axis of clinical policies are recommendations which propose a certain intervention for a specific population with a defined outcome, a distinct framework is usually taken into consideration to incorporate the principles of defining the indications, both to have clear definitions on the proposed recommendations and the conditions of having them evaluated/monitored (5). The three principles of the framework are as follows:

▶ The principle of determining the indications: The indications must be specified according to the following 6 points:

1- Effectiveness

2- Cost-effectiveness

3- Complications of the intervention

4- Grand approaches: Three main approaches appoint the indication

- Quality-based approach: aims to promote the quality of offered health services.
- Approach directed at choosing/installing less costly treatment procedures.
- Safety directed approach, which is inclined to safer procedures.

5- Feasibility

6- Accessibility

▶ Principle of explaining the recommendation: Regarding the recommendations' key role in knowledge products, enough attention must be paid to the elements of each recommendation for developing the guidelines. Therefore, any clinical recommendation is considered complete only if they include the

following:
1-indication (denoting the patients)
2- Produced service
3- Amount of received service

▶ Principle of evaluation and supervision on the performance: Ultimately, the patients' identification and determining the outcomes and costs are important in monitoring the system performance.

Connective Structure: Clinical Policy-Making and administration Policy-Making

Development and implementation of knowledge products are to be analyzed and investigated in two different fields:
- Program
- The Standards of codification and execution policies.
- In the first section, three principles must be taken into consideration:

1-Clinical recommendations must be based on authentic scientific evidence.
2-Knowledge products must have the potential to be naturalized.
3-Opinions of experts and specialists must be gathered and taken into account.

Having said this, knowledge products' development alone cannot guarantee promoting the quality of evidence-based medical services and needs appropriate structure and tools for successful performance. The processes of clinical audit (in centers for health service provision) and purchasing policies, previously mentioned as important application of knowledge products, are among the best tools for implementing knowledge products which necessitate a powerful in formatives infrastructures sufficient to identify the patients, the degree of disease severity, and the burden of the disease alongside defining the service and the needed amount with regards to the risks of possible outcomes. The execution costs will also be taken into account. Service Purchasing Policies include the following:

- Payment in form of "fee for service", according to the indication recognition criteria and the response frequency.
- Payment in form of "diagnostic related group/ DRG", according to the service frequency in indication and the process of disease management.
- Global Payment, according to the overall performance in a defined period.

Generally, clinical recommendations which constitute the shared boundary of clinical and executive policy-making, including indications, type of service, and the quality of delivered service, are appointed according to the three influential factors: effect size, side effects, and costs of intervention. The administrative policies are divided to two groups: process-based policies and outcome-based policies, the latter of which can be defined according to the three appointing factors of clinical recommendations.

Service purchasing policies control health system payments in the following way: Payments in forms of fee for service and DRG are related to process-based administrative policies in cases of an accordance between the service and the indication; Global payments can be applied to both process-based and outcome-based executive policies. Outcome-based policies can have a determinant role in choosing resource allocation strategies in health systems (Figure1).

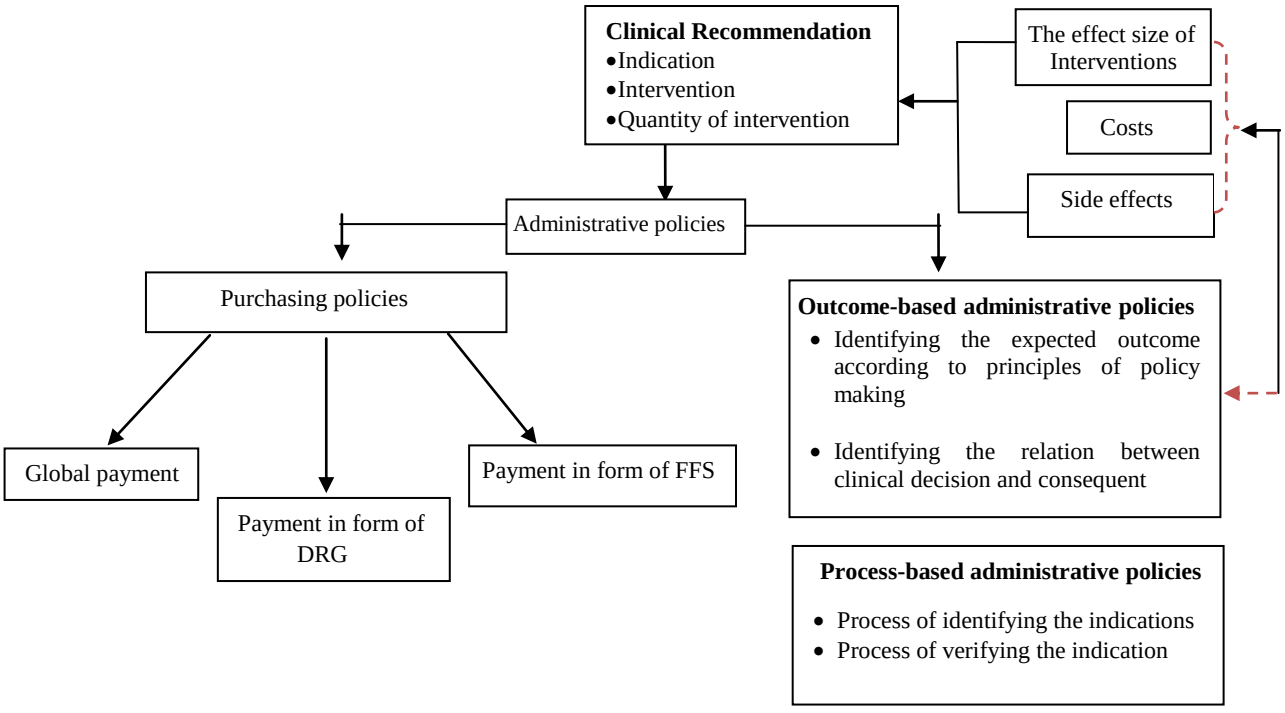

Figure1: Structure and clinical relevance of policy, operational and strategic purchasing of health care system.

The organization of Clinical Guidelines standardization and codification is in charge of managing the codification and execution of knowledge products via its supervision on knowledge management units. This organization has administrative and scientific relations with numerous intra/extra-sectional units (depicted in Figure 2).

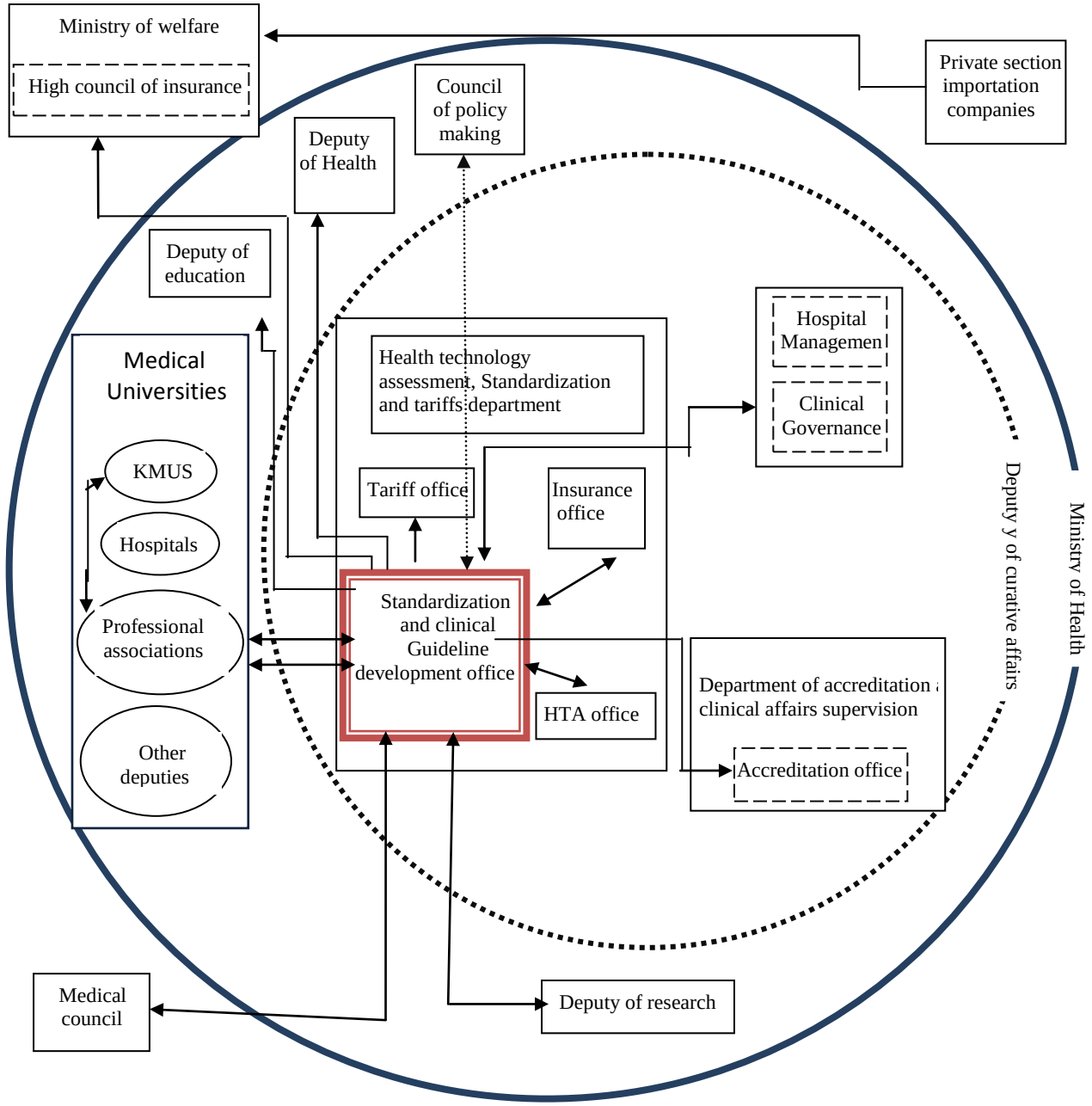

Figure2: Data flow diagram of CPG development in Iran.

Implementing scientific products and reinstating their position in the health system necessitates taking the following into consideration:

- The means of offering scientific products to the target group
- Appointing the role of scientific products as a legal document
- Appointing criteria for monitoring the performances according to scientific products
- Developing purchasing strategies

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