

# DEVELOPMENT OF PRACTICE PROTOCOLS AT HOSPITAL LEVEL IN ROMANIA

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## INTRODUCTION

From a structural and functional point of view, hospitals are the most complex medical units as units characterized by a diverse activity, in which efforts are concentrated around the provision of specialized medical services, which respond as appropriately as possible to the specific diagnostic and treatment needs of patients. In this regard, the volume of hospital activity needs to be projected and planned so that hospitals can meet (from an organizational and functional point of view, through adequate resource planning) the current and future challenges. Hospitals must also be seen as waiting systems, which must always be prepared, depending on the limits of their competence, to respond promptly to requests from the population served, regardless of the frequency or variability of requests. Hospital medical services involve high associated risks, compared to the care provided in other levels of care in the health systems.

The consumption of resources is extremely diverse in a hospital, and the diversity depends on a multitude of factors common to all hospitals, or specific depending on the profile, typology, level of competence of the hospital. Most of this consumption is reflected in the consumption of resources needed to provide the actual medical act (direct costs, respectively clinical examinations, investigations, treatments, various maneuvers and procedures, monitoring, specialized counseling, etc.). In addition to these, there is a consumption of resources associated with various support activities, non-medical, which supports the actual medical activity and which generates indirect costs (eg hotel and administrative services provided to patients in the hospital). Resource consumption and both direct and indirect costs must be recorded correctly and properly by the hospital, so that, at discharge, the patient can receive the statement of his hospitalization episode, in addition to the discharge sheet and the medical letter.

The analysis of hospitalization costs must take into account all resources consumed (that must be recorded); this step must be followed by the calculation of costs, by types of costs (fixed/variable, direct/indirect, unitary/total, capital/operational, supported by health system/patients and their families /other sectors) and in a well-established step-by-step algorithm (identifying resources by relevant consumption categories, establishing unit cost, measuring consumed resources, totaling costs and updating/adjusting

→ cost over time), which allow finally a realistic calcu-

*The benefits of standardizing medical practices are obvious and known, both at the level of the patient and hospital or health sector. Knowing the clinical pathways that a patient can follow during his hospital stay can simplify the case management of the hospitalized patient only if the standard algorithm for diagnosing and treating each pathology is known, mastered and applied at hospital level. The existence of national guidelines or standardized protocols for certain pathologies can guide the medical practice (where local conditions allow the application of the guidance) or the development of practice protocols adapted at the local level (ward/hospital).*

*In Romania, hospitals are required by law to apply a therapeutic standard (national, European or international) adapted to the local level for each pathology, but this often becomes impractical due to the real gaps for the implementation of this goal.*

*Political will is needed to be translated into support in promoting the standardization of hospital medical practices (by types of hospitals/specialties) so that the costs generated at the hospital sector or health system level can be predicted, based on cost standards related to the standardized medical activity.*

*There is a need for professional discipline in exercising the roles of actors and those responsible with the development and implementation of practice protocols at the hospital level, but there is also a need for strategic measures to ensure that hospital medical practice is processed, declared, known, mastered and applied locally, taking into account the local specificities.*

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lation of the cost at the level of the hospitalized patient or of the hospitalization episode.

The diversity of consumption and costs is directly proportional to the specific needs of the patient (depending on the severity and complexity of the case) and the variability of medical practice; in the same direction, the consumption and thus costs can be identified by analyzing medical practice protocols (for diagnosis and/or treatment) development and implementation, for hospitals where they are developed and implemented. Less variability in practice is expected to lead to less diversity of consumption and to a better cost standardization; and the implementation of practice protocols in a medical unit will direct consumption for an inpatient to a well-established clinical route, for which the necessary resources in solving that hospitalized case that follows that clinical route are known.

## SCOPE

The main objective of the article is to present a summary of the regulatory framework for the development and application of diagnostic and treatment protocols in hospitals in Romania.

## METHODOLOGY

The present study is a revision of the specialized literature and of the main legislative documents that regulate the elaboration and application of the practice protocols at the level of Romanian hospitals: LAW no. 95 of April 14, 2006 on health reform, Order of the Ministry of Health no. 863 of June 30, 2004 for the approval of the attributions and competences of the medical council of the hospitals, National Strategy for quality assurance in the health system, for the period 2018-2025 "Quality in health".

## RESULTS

*Current state of development of diagnostic and treatment protocols*

Currently, the provision of hospital care in Romania is based on the regulations provided in Law 95/2006 on Health Reform, which defines the concept of guidelines and protocols of medical practice and defines the responsibilities for developing and implementing protocols in hospitals [1].

The support of the Ministry of Health also consists in the elaboration/adaptation of guidelines and standardized protocols for certain pathologies, by the specialized Commissions, within a consultative process with the specialized medical companies and having the approval of the Romanian College of Physicians.

*Thus, according to Law 95/2006, hospitals are required to apply a therapeutic standard (national, European or international) adapted locally for each pathology.*

Despite all these regulations, compliance with this obligation sometimes becomes a rather laborious and resource-consuming task, often impracticable due to the lack of links for the implementation of this goal.

On the other hand, at local level (ward, hospital), the current practice must be standardized taking into account, on the one hand, the general benefits of standardization and on the other hand the local specificities and particularities (particular pattern of hospitalized morbidity, different complexity of hospitalized cases, different competence of the hospital, different level of endowment, etc.); in this context, given that the efforts of the practice protocols development at the hospital level must be translated into major benefits, and the only one who can procedure the hospital activity at the level of a certain hospital can only be the one who knows best these particularities, then it is clear that the hospital should ensure a good functionality of this process of developing guide and protocols for medical practice at hospital level.

*The national guides and standardized protocols developed by the specialized commissions of the MoH have the role of guiding the elaboration of practice protocols at local level, while the practice protocols developed at local level have the role of adapting and integrating local particularities (demand, endowment, administrative aspects etc.) to the national/European/international standard.*

Since 2004, the hospital's medical council is the structure that "establishes rules on professional activity and medical practice protocols at the hospital and is responsible for their application and compliance" (ORDER No. 863 of June 30, 2004 for approval of the responsibilities and competencies of the medical council of hospitals) [2].

The central and local authorities in the field are concerned with the inclusion of this topic on the work agendas, by including strategic measures within a comprehensive strategy in the field of quality in health [3], in which one of the sections is dedicated to the development and implementation of clinical protocols at the hospital level.

Thus, starting with the middle of 2020, at the level of each hospital in Romania is established (based on Order no. 1,312/250/2020 on the organization and functioning of the quality management structure of health services within health units with beds and ambulance services, in the process of implementing the quality management

system of health services and patient safety), the structure of quality management of health services, led by a doctor responsible for quality management at the hospital level; among other functions, this doctor has responsibilities in the field of practice protocols at the hospital level, such as: "monitors the elaboration of diagnostic and treatment protocols and procedures aimed at medical assistance, following the observance of the rules for their elaboration; monitors and analyzes the implementation of procedures and protocols governing healthcare; monitors the planning and development of health care activities according to the procedures, protocols and care plan"[4].

Therefore, the head of the quality management structure of health services is responsible for developing, monitoring, analyzing, updating and implementing clinical protocols in a hospital. The activity of this structure must ensure that any medical staff in the ward/hospital is informed, knows, has assumed the responsibilities and implements the stipulations of the available protocols. In the absence of these protocols, medical practice in that hospital should be performed according to national/European/international standards. Also in this situation, this aspect must be known and declared, so as to ensure that the medical staff of the respective department/hospital knows has mastered and applies the national/European/international standard applicable at the level of the hospital/department. On the other hand, by standardizing the practice, each patient with a certain pathological condition will receive hospital services at the same standard (same quality and safety of medical act); by having data on potential cases and the standard of care, the management team will be able to predict and plan the activity much more effectively and efficiently.

For the current context in the hospital sector in Romania, a series of chained and coordinated actions is needed, materialized by:

- approaches in order to standardize the medical practice, which should include among the first steps the standardization of the way of elaborating the practice protocols which should highlight, for each clinical route, the level of resources consumed,

- including the practice of elaborating and implementing practice protocols as mandatory hospital management tools, It is needed the stimulation/development of a motivating work framework materialized by local changes through which to ensure the fulfillment of some relevant requirements for a good implementation of the process of elaboration and implementation of the standardized medical practice at local level, such as:

- at least one person per hospital to have specific competencies (possibly specific training in the elaboration of practice protocols) so as to ensure the necessary consultancy/support and revision of all materials developed by the technical staff involved in the elaboration of protocols at the hospital level; this expert will also ensure the adaptation to the local context: the standard structure of the protocol, the establishment of responsibilities, the choice of appropriate measures depending on the availability of resources, auditable standards, review and monitoring of the protocol, administrative issues, etc.

- the obligatory inclusion of the algorithms for the clinical management, on pathologies, which →

should clearly highlight teach possible clinical route relevant for approaching an adequate clinical management to the respective hospitalized pathology.

- the level of detail of the protocol must allow the identification of all identified Resources, Responsibilities, Locations, Periods, and Care possible to be applied locally.

- clear stipulation (within a dedicated section of the protocol) of how the protocol is monitored and evaluated; the auditable standards section should contain SMART indicators that can be used to evaluate the protocol in various ways.

- clear stipulation (in a dedicated section) of how the protocol should be revised (periodicity, responsibilities, reasons for revision, method of revision, etc.)

- identification of incentive measures for the staff involved in the development and monitoring of practice protocols at the hospital level, in order to increase the degree of information, knowledge and application of the protocols.

- modifying or updating or adapting any information used from guides to the local context and specificities, so as to ensure the specific identification of the responsible, actions and resources that are available and feasible to be applied in the local given context.

## DISCUSSIONS. CONCLUSIONS

Practically, the practice protocol is a document that regulates the way in which the medical staff proceeds or would be recommended to proceed when providing medical services, in this case at hospital level.

The target population of a protocol is diverse (medical staff, administrative staff, audit staff, etc.); the protocol must contain all the elements of identification of the document, but also of improvement (the way of elaboration, references, conditions of deviation from the protocol, the way of revision, auditable standards), considering the fact that the medical practice is frequently improved being a process in dynamics. In addition, the practice protocol can be an effective managerial tool through the information related to the consumed resources and their planning, but also through the possibility of organizing and planning the activity, or the systematic evaluation of the results obtained (by standardizing the practice and resource consumption provided in protocol). For the patient, the benefits can be accounted for an informed choice of the doctor or hospital that provides services at a certain standard, but also by ensuring greater safety given by the improved standardization of the activity of a certain provider [5].

In the hospital sector in Romania, without an in-dept analysis of how to develop and implement practice protocols it is impossible to know whether medical practice is performed based on the knowledge and experience of medical

teams treating patients or by rigorous application of local protocols/guidelines/standardized protocols.

In the absence of a common template for practice protocols, it is expected that hospital medical practice, in this case the diagnosis and treatment of hospitalized patients, will be very little proceeded by well-structured, appropriate, adapted and updated practice protocols that present the defining aspects of medical practice adapted to the specificities at the local level (ward, hospital, etc.) [6].

Wide variability of medical practice complemented by ignorance and especially by the lack of importance granted to practice protocols requires the development, by experts, of a model (reference) of diagnosis and treatment protocol for hospital, by type of hospital (eg levels of competence); there is a need for developing a standard document to be completed in a professional, correct and appropriate manner by all development teams, as well as unitary and coordinated training of hospital medical staff for the development activity, and review of medical protocols, so that they can become well-documented practical tools, used, analyzed and periodically reviewed by specialists; subsequently, they can document and support the medical practice, cost standards and variations in practice registered in Romanian hospitals.

In this sense, it is expected that there will be a great variability of medical practice, for each pathology, a variability that determines, in the same sense, a great diversity of resources consumed for diagnosing and treating patients, respectively a great variability of costs at the level of a hospitalized patient.

In contrast, in emergency medical practice, where each emergency unit has the same structure, resources, facilities and the same practice protocol (by a better regulation), with small differences, the optimal cost options for each pathology can be more easily detected due to the fact that the protocols provide algorithms for diagnosis and treatment.

Political will is needed to be reflected in providing a regulatory framework that stimulates and promotes the standardization of medical practice so that the costs generated at sector level or health system can be predicted based on cost standards related to the medical standardized activity.

Support and sustained efforts are needed to ensure that the level of the hospital can guarantee a certain standard of quality, effectiveness and safety of the medical act.

There is a need for professional discipline in exercising the roles of actors and those responsible for the elaboration and implementation of practice protocols at the hospital level, but there is also a need for strategic measures to ensure that hospital medical practice is processed, declared, known, mastered and applied locally, taking into account the local specificities.

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