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RESEARCH

MEDICAL PRACTICE PROTOCOLS. THE EXPERIENCE OF HOSPITALS IN ROMANIA

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The standardization of medical practice is necessary to ensure effective and quality medical care, and for hospitals, the implementation of practice protocols sometimes becomes a rather laborious and resource consuming task, often impracticable due to missing links for the implementation of this goal.

The aim of the study was to analyze the diagnostic and treatment protocols for 20 of the most common pathologies treated at the level of some pilot hospitals in Romania.

RESULTS.

The medical practice analyzed at the level of the pilot hospitals within the CAPESSCOST project is to a very small extent processed through well-structured practice protocols, which should contain relevant aspects and adapted to the specificities at the local level. Hospitals choose rather to take over information from national or international reference guidelines in their own protocols, without any adaptation.

CONCLUSIONS.

In order to standardize the practice and to establish cost standards for the selected pathologies and not only, it is necessary a model (reference) of diagnosis and treatment protocol for the hospital, by types of hospitals, with a basic structure that has to be correctly and adequately completed by all development teams, according to a typical methodology, including clinical pathways and the level of consumed resources for each pathway. At the same time, a regulatory framework is needed to stimulate and promote the standardization of medical practice among the main actors in the hospital medical sector, a first recommendation in this regard referring to the inclusion of the elaboration and implementation practice of practice protocols as a mandatory tool for hospital management.

Keywords: protocols, standardization, medical practice, hospitals, Romania

INTRODUCTION

The provision of high-performance and quality hospital health services involves, among other things, the application of therapeutic standards by medical staff, established by nationally approved guidelines or by standards recognized by the medical community of that specialty [1]. To support the adoption and application of such standards, the Romanian health system has regulated roles and responsibilities for various actors in the system on the protocols development and implementation at the hospital level.

Thus, the support of the Ministry of Health consists in the elaboration of guidelines and protocols for certain pathologies, by the specialized Commissions, with the consultation of the specialized medical companies and having the approval of the Romanian College of Physicians. These guidelines and protocols are intended to guide the development of practice protocols at the local level.

The National Authority for Quality Management in Health (ANMCS) meets this goal by including measures on the issue of diagnostic and treatment protocols at the hospital level in a comprehensive strategy in the field of health quality, and by developing accreditation standards in this regard. Accreditation standards recommend that the hospital activity should be based on diagnostic and treatment protocols, which should be developed in accordance with the principles of evidence-based medicine, as well as based on the technical and material capacity of the hospital and its clinical experience. According to them, the protocols need to be reviewed, updated and improved based on the recommendations developed following a clinical audit.

On the other hand, at the level of the hospital, recently, the quality management structure of the health services has been regulated, which has among its attributions the analysis of the elaboration and implementation of the diagnostic and treatment protocols and of the procedures concerning the medical assistance.

Despite all these regulations, the standardization of medical practice at the hospital level (a unit with specific characteristics in terms of skills and equipment, which treats pathologies with different complexities, in different conditions of organization and operation) sometimes becomes a rather laborious and consuming resources task, being often impracticable due to missing links for the implementation of this desideratum.

However, the variability of the practice, regardless of the hospital, should not exceed the procedural framework, where it is defined for a particular pathology. Thus, within the same hospital or group of hospitals with the same level of competence (I, II, III, IV, V), each patient with a certain pathology should benefit from standard services, defined by a medical practice protocol, so that a standard quality can be ensured for each patient. The development of hospital activity based on well-developed protocols can lead to reduced variability, and in cascade, to improve, streamline and increase the quality of services provided, with positive benefits on patients and hospital functioning.

PURPOSE OF THE STUDY

To evaluate the way in which medical practice is performed in hospitals, an activity of the project CaPeSSCoSt – "Improving the Quality and Performance of Hospital Services through Cost Assessment and Standardization ", code 724/129170 was dedicated to the study of diagnostic and treatment protocols for 20 of the most common pathologies treated at the level of pilot hospitals, selected within the project [2].

SPECIFIC OBJECTIVES OF THE STUDY

The main objectives were:

- identification of the currently used protocols for the selected pathologies

- descriptive and comparative analysis of the identified diagnostic and treatment protocols

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METHODOLOGY

Obtaining information on diagnostic and treatment protocols was done through the CaPeSaRo application, managed by ANMCS, where hospitals uploaded the required protocols.

The transmission of the protocols by the hospitals was done on a list basis, made available to them, with the 20 pathologies, namely:

I50.0	Congestive heart failure	O82	Single cesarean delivery
J84.9	Interstitial lung disease, unspecified	F20.0	Paranoid schizophrenia
Z38.0	Only child born in hospital	J44.0	Chronic obstructive pulmonary disease with acute lower respiratory tract infection
J18.9	Pneumonia, unspecified	A49.9	Bacterial infection, unspecified
I34.0	Mitral regurgitation (valve)	J44.1	Chronic obstructive pulmonary disease with acute exacerbation, unspecified
K76.0	Fatty liver degeneration, not elsewhere classified	F33.2	Recurrent depressive disorder, severe current episode without psychotic symptoms
I63.3	Cerebral infarction due to cerebral artery thrombosis	O20.0	Imminent abortion
I10	Essential hypertension (primary)	K74.6	Other cirrhosis of the liver and unspecified
P59.9	Neonatal jaundice, unspecified	Z50.8	Care involving other rehabilitation procedures
M51.1+	Disorders of lumbar disc and other intervertebral discs with radiculopathy (G55.1 *)	I42.0	Cardiomyopathy with dilation

The analysis was performed on a number of 556 protocols transmitted by 87 hospitals (representing over 20% of all hospitals in Romania).

For the unitary collection of data and information from the protocols, a model elaborated within the project was used, based on the recommendations from the specialized literature [3-12] regarding the structure of the diagnostic and treatment protocols. Thus, the information extracted from the protocols and entered by the project experts in the collection template for each protocol referred to:

• issues regarding the identification of the protocol and the addressed pathology;

• the correspondence of the protocol with the targeted pathology - assessed by the degree of inclusion in the protocol of the diseases included in the respective ICD10 disease code / pathology, considering that they constitute, in fact, clinical pathways within the selected pathology, grouped in common clusters; for each pathology, the box with the conditions included in the respective ICD10 disease code was extracted from the List of diagnostic codes (Tabular list of diagnoses_RODRGv1);

• degree of updating of the protocol / seniority of the protocol;

• purpose of the protocol;

• elaboration methodology;

• responsibilities;

• situations of deviation from the protocol;

• reasons for revising the protocol;

• the presence or absence of clinical pathways;

• aspects regarding diagnosis, treatment;

• administrative issues;

• auditable standards;

• bibliographical references

• evaluator conclusions.

The analysis included all the elements of the model, which were descriptively and comparatively analyzed, in order to highlight the common and specific aspects, which will be the basis for issuing recommendations for improving the medical practice procedure in hospitals. The conclusions of the evaluator / team of evaluators who assessed the pathology were included in a summary of that pathology, which contains information on the number of received, analyzed and excluded protocols from the analysis, as well as specific pathology patterns extracted from the evaluator's general opinions. In order to an analysis as completely as possible, a series of documents were researched, such as: normative acts that regulate the field of medical practice protocols; national guidelines and protocols for the 20 selected pathologies; ANMCS standards, requirements and indicators that refer to diagnostic and treatment protocols. The recommendations were formulated considering the opinions of the project experts obtained through a brainstorming session, the value judgments derived from the results of this analysis and the strategic measures contained in the "Health Quality Strategy 2018-2025".

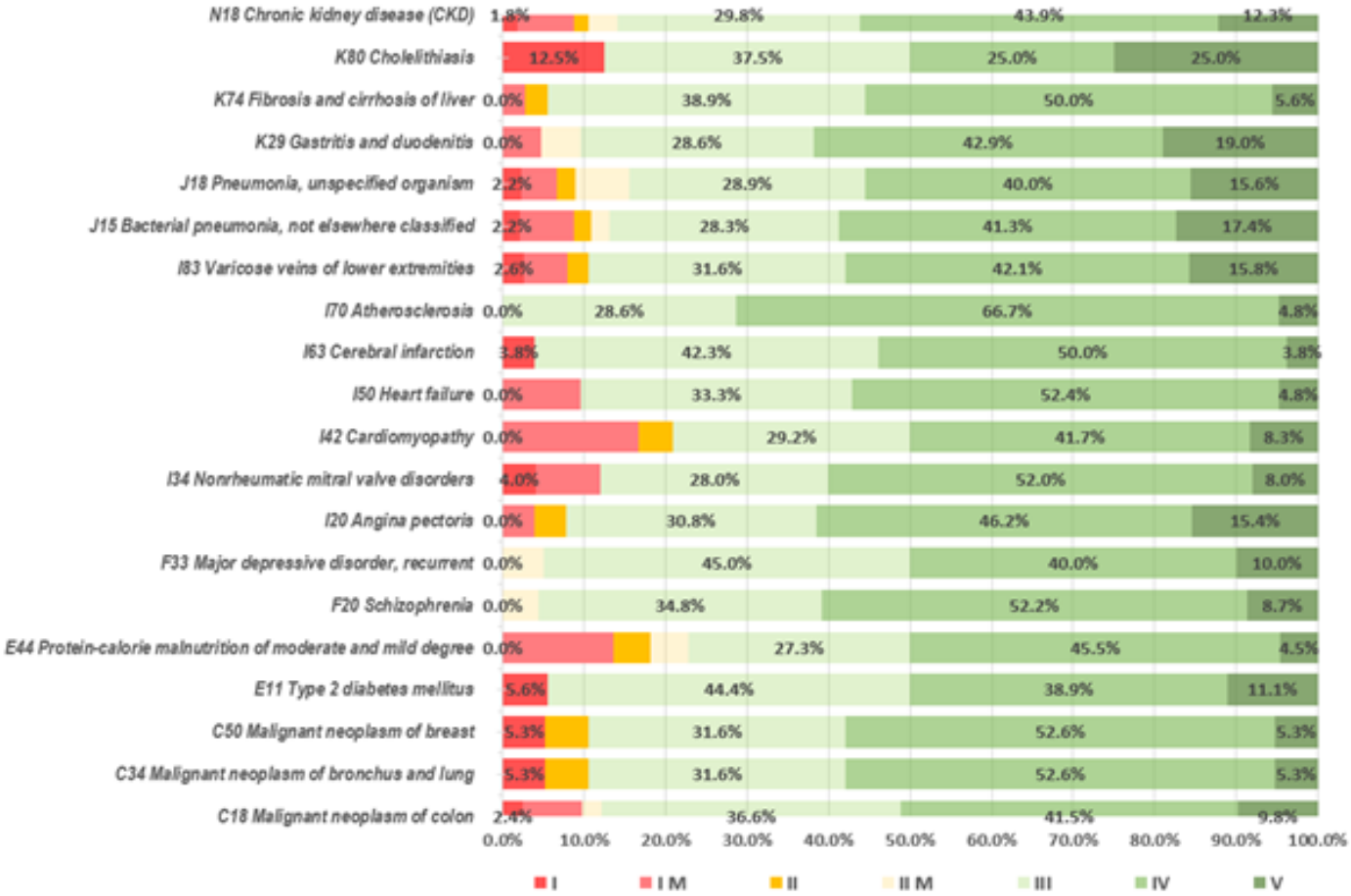
RESULTS

The situation of the protocols, on pathologies and hospitals levels of competence, summarized in graph 1, shows a great variability, which could be determined by factors such as the specificity of the pathology and the capacity of the hospital to treat that pathology. Level III, IV and V hospitals sent protocols for all 20 selected pathologies. However, the absence of protocols for atherosclerosis, schizophrenia and recurrent depressive disorder can be found in level I and II hospitals, the last ones being pathologies that require specialized assistance in specialized hospitals.

The average per hospital of the sent protocols was 6.4 (representing 32% of the number of selected pathologies), this ranging between 0.6% (IIM level hospitals, with an average of 1.2 protocols transmitted / hospital) and 57 % (level III hospitals, with an average of 11.4 transmitted protocols / hospital) - graph 1. Although the highest response rate was recorded for level III and IV hospitals, the documents do not contain all the relevant information specific to a protocol, as it is seen in the vision of the project. The protocols received from the level I and IIM hospitals had the highest degree of approach to the relevant aspects such as: deviations from the protocol and reasons for revision, diagnostic and treatment algorithms, respectively responsibilities, resources, but the assessment of these results must be done with caution because, at the level of each selected pathology, the number of these protocols is quite small.

Thus, it can be appreciated that there is a low rate of medical activity through diagnostic and

Graph 1. Status of protocols received from pilot hospitals, by hospital competence and targeted pathology



treatment protocols, which can lead to a wide variability of medical practice, consumption and results. The analysis of the protocols uploaded in the CAPESARO application by the pilot hospitals highlighted a great diversity in terms of their size, content and structure, as there is no common template.

*The size***.** In terms of size, the number of pages contained in submitted documents varies between 10 and 100 pages, in some cases the lack of content making it difficult to easily find the sections of the protocol and implicitly the information to complete the collection layout.

Content and structure of protocols. Most protocols contain information about the team that developed, verified, and approved the protocol, including the signatures of its members. However, there have also been identified protocols that do not contain information on their assumption by the staff involved in their implementation (not being signed for acknowledgment).

Very few protocols include diagnostic / treatment algorithms, the clinical pathways that patients can follow being very difficult to identify. There are some protocols that have rather the format and content of a guide. Most protocols have a structure similar to the quality management control system operational procedures, which is not perfectly applicable to a medical practice protocol, as many of the relevant elements of a protocol are missing (presence of clinical pathways, deviations from the protocol, administrative issues, auditable standards, etc.).

The most appropriate protocols in terms of structure and contained information (according to the model developed in the project) are those for cardiovascular disease, common pathologies, and usually well documented by clinical guides available at national and internationl level. Thus, their analysis highlighted: a high degree of correspondence with the targeted pathology; a detailed description of the disease and the clinical forms that allow the differentiation of clinical pathways and a high degree of updating (with recent revisions of previous versions).

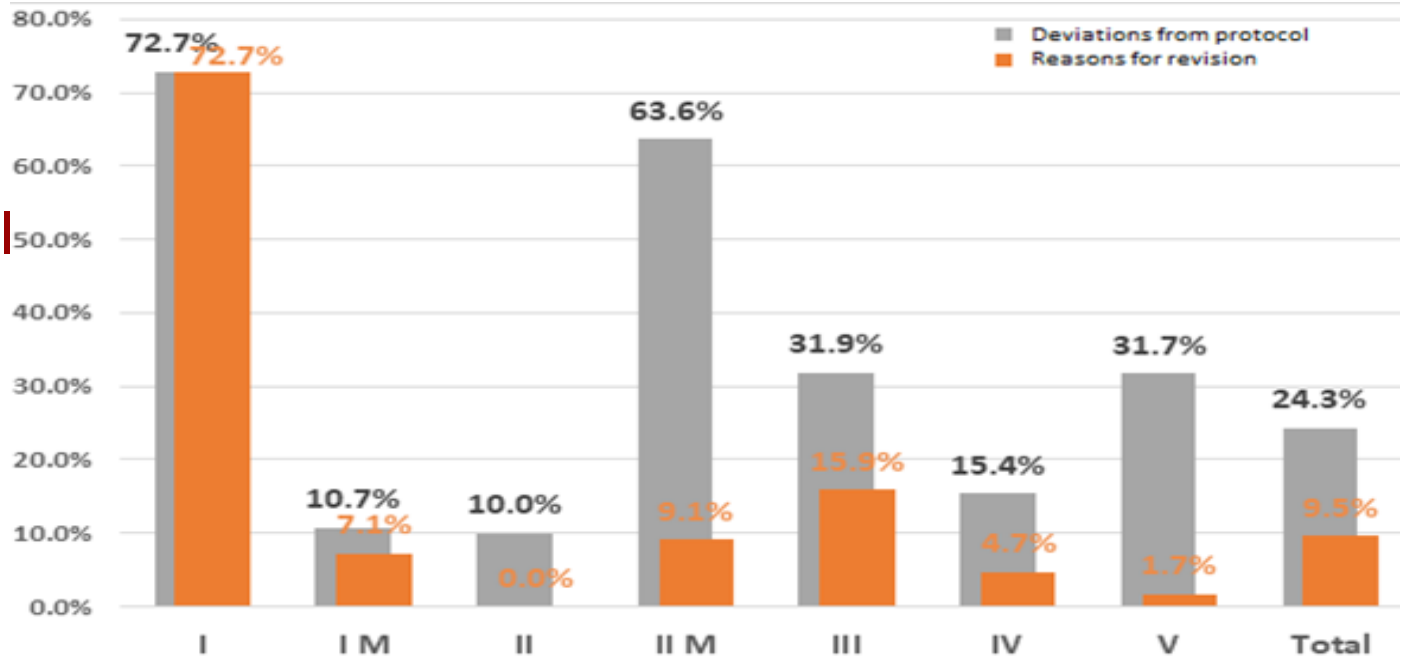
Age. Most protocols are up to one year old, some with a one-week pre-release date.

The degree of correspondence of the protocol with the targeted pathology. The most comprehensive in this respect were the protocols from hospitals of higher level than IIM (respectively IIM, III, IV and V), in which over 60% of the protocols correspond entirely to the pathology in question, in the sense that the protocol addresses the whole palette of diseases and clinical forms of the respective pathology. The correspondence rate for level I, IM and II hospitals was 45.5%, 39.3% and 30% respectively.

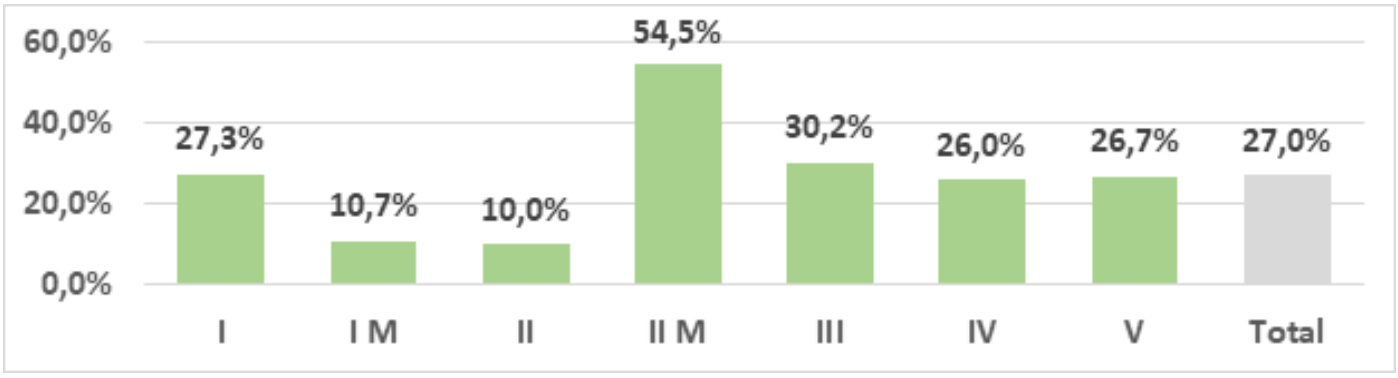
The results regarding the correspondence of the protocol with the targeted pathology must be interpreted in relation to the overspecialization and high complexity of cases treated in level I and II hospitals (institutes, clinical hospitals, monospecialty hospitals, etc.), on the one hand, and in the context of a wide variety of cases. treated in level II, IV and V hospitals, on the other hand.

Degree of protocols updating. The years of the protocols last revisions varied from 2012 to 2021 (the year of the present study). For all Level II hospitals that

Chart 2. Share of protocols describing the reasons for the revision and deviations from the protocol



Graph 3. The share of the use of national guidelines in the elaboration of protocols



submitted protocols, the year of the last revision of the protocol is not specified.

The vast majority of protocols, among those that provide information about the date of the last revision, have a recent revision date (January 2021 or autumn 2020), in most cases being equivalent to the first and last edition / version of the protocol. If we consider that many of these protocols were transmitted without the registration, verification and approval team of the protocol as well as the persons involved in its implementation, it can be suspected that the purpose of developing the protocols was to respond to the request of the project team. This could suggest the idea that the medical activity has been carried out so far, for the vast majority of hospitals, for the requested pathologies, without the existence of a protocol assumed by the hospital management.

Declared purpose of the protocol, elaboration methodology, responsibilities. Only one of the transmitted protocols (from a level III hospital) clearly set out the objectives of the protocol and the categories of staff protocol is addressed to (doctors / nurses / etc), describing the steps taken in developing the protocol (choice of topic, team for protocol development, documentation) and responsibilities.

Only 14 protocols (eight - level III hospitals; one - level IV hospital; three - level V hospitals) totally present the steps of the protocol elaboration. The lack of a description of the development methodology for many of the protocols makes it difficult to monitor and even update the existing version of the protocol.

Although the three elements (the stated purpose of the protocol, the methodology of elaboration, responsibilities) were found only in the protocol of a single hospital, this can demonstrate that the correct procedure of medical practice is possible for the current context of hospital activity in Romania.

Deviations and reasons for the protocol revision. The analysis of the presentation of deviations and reasons for revising the protocols shows a low rate of inclusion of these aspects in the protocols, with high variability depending on the hospital level of competence.

Less than a quarter (24.3%) of the protocols have a section devoted to deviations from the protocol, while less than one tenth (9.5%) of the protocols list or describe the reasons for the revision (Chart 2).

The highest rate (72.7% of protocols) for describing deviations and reasons for revising protocols is recorded among level I hospitals (but this figure must be interpreted

Table 1. Situation of presentation of diagnostic and treatment algorithms in protocols

Do they have clinical algorithms / pathways?	Hospital level (Nr. of Protocols)								Hospital level (% protocols)							
	I	I M	II	II M	III	IV	V	Total	I	I M	II	II M	III	IV	V	Total
DIAGNOSTIC ALGORITHMS																
YES	8	9	0	5	39	46	19	126	72.7%	32.1%	0.0%	45.5%	21.4%	18.1%	31.7%	22.7%
No, but they can be deduced	1	6	2	3	60	83	13	168	9.1%	21.4%	20.0%	27.3%	33.0%	32.7%	21.7%	30.2%
NO and can NOT be deduced	1	7	5	2	67	106	20	208	9.1%	25.0%	50.0%	18.2%	36.8%	41.7%	33.3%	37.4%
IT IS NOT A DIAGNOSTIC PROTOCOL	1	6	3	1	16	19	8	54	9.1%	21.4%	30.0%	9.1%	8.8%	7.5%	13.3%	9.7%
TOTAL	**11**	**28**	**10**	**11**	**182**	**254**	**60**	**556**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**
TREATMENT ALGORITHMS																
YES	9	11	1	4	42	50	15	132	81.8%	39.3%	10.0%	36.4%	23.1%	19.7%	25.0%	23.7%
No, but they can be deduced	1	10	1	3	70	84	22	191	9.1%	35.7%	10.0%	27.3%	38.5%	33.1%	36.7%	34.4%
NO and can NOT be deduced	1	7	6	3	62	104	21	204	9.1%	25.0%	60.0%	27.3%	34.1%	40.9%	35.0%	36.7%
IT IS NOT A THERAPEUTIC PROTOCOL	0	0	2	1	8	16	2	29	0.0%	0.0%	20.0%	9.1%	4.4%	6.3%	3.3%	5.2%
TOTAL	**11**	**28**	**10**	**11**	**182**	**254**	**60**	**556**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**	**100.0%**

in the context of the small number of protocols received from hospitals at this level), followed by IIM level hospitals (63.9% for deviations, respectively only 9.1% for reasons). At the opposite pole there are the level II and IM hospitals with low weights of 10% or less than 10%.

Diagnostic and treatment algorithms. Clinical pathways. The clear, distinct highlighting of all the clinical pathways of a patient with a certain pathology during the hospitalization episode is an essential element in understanding the clinical problem determined by the particularities of that pathology. Moreover, the allocation, planning and distribution of resources according to the route followed by the patient can lead to increased effectiveness and efficiency of the medical act. Even if the practice protocol has the role of recommendation, guidance of medical practice, highlighting in the protocol the clinical pathways and steps (algorithms) followed by the patient can guide the diagnostic and therapeutic conduct, in a standardized way that can ensure a certain standard quality of medical care (patient benefits), effective management of the disease and the resources involved.

Almost half (about 45%) of the protocols do not show the possible pathways to be followed by the patient, or they cannot be deduced from the information contained in the protocol.

Level I hospitals present to a greater extent these diagnostic and therapeutic algorithms (72.7% for diagnosis and 81.8% for treatment, respectively), followed by level IIM hospitals (45.5% for diagnosis and 36,4% respectively, for treatment) - table 1.

Resources needed for each identified clinical pathway. The information regarding the resources involved in the completion of each identified clinical path is non-existent, thus, for any of the pathologies selected, the consumption of resources could not be identified. Thus, one of the indirect objectives of the analysis, that of identifying patterns of resources use, in order to assess the variability in resource consumption for certain pathologies, and for certain hospitals, could not be achieved. In the current context of the procedure of the hospital activity in Romania, it is necessary a standardization of the way of elaborating the practice protocols in order to highlight, for each clinical pathway, the level of the consumed resources.

Administrative Asp`ects and Auditable Standards. 26.8% of the protocols set out very clearly the standards / indicators by which the effectiveness and

efficiency of the protocol can be measured, ensuring that the existing protocol sets a desired standard at the health unit level. As for the administrative aspects, they were very clearly set out in only one protocol.

Bibliographical references. The references on the basis the protocols were developed can be easily identified. The development of approximately 20% of the practice protocols was based on information taken from and adapted from scientific documents other than practice guidelines, while only 8.6% of the protocols were based on national medical practice guidelines (Figure 3). However, the bibliographic references were not specified in more than one third of the analyzed protocols. There is a high level of compliance with the recommendations of the relevant scientific forums, as evidenced by the tendency to use national guidelines (where they exist) and European or international guidelines or other scientific documents.

Analyzing the use of national guidelines by hospital level, level IIM and III hospitals stated the use of national guidelines as references in the elaboration of the sent protocols, to a greater extent (54% of the protocols of the level IIM hospitals, respectively 30.2% of the hospital protocols level III) than other hospitals; only 10% of IM and II level hospitals are based on national guidelines developed by the specialized commissions of the Ministry of Health.

CONCLUSIONS AND RECOMMENDATIONS

The medical practice analyzed at the pilot hospitals level within the CAPESSCOST project is to a very small extent processed through well-structured practice protocols, which should contain relevant aspects and adapted to the specificities at the local level. Rather, hospitals choose to take over information from national or international reference guidelines in their own protocols, without any adaptation.

The variability of practice identified for the selected pathologies, but especially the lack of relevant information within the protocols, such as: algorithms or clinical pathways, resources needed to implement the protocol, clear responsibilities (who does what in the protocol on each clinical path), standards and indicators evaluation, makes difficult to estimate the costs involved in diagnosing and treating the targeted pathologies and consequently setting cost standards for these pathologies.

In order to standardize the practice and to establish cost standards for the selected pathologies and not only, it is necessary a model (reference) of diagnosis and treatment protocol for the hospital, by types of hospitals, with a basic structure to be correctly and adequately completed by all development teams, according to a typical methodology, including clinical pathways and the level of resources consumed for each pathway.

In order to make this model as easy as possible in practice, it is obviously necessary to provide unitary and coordinated training of hospitals staff (medical and non-medical) assigned by hospitals for the development and revision of medical protocols so that they can become well-documented practical tools, used, analyzed and periodically reviewed, and subsequently to be able to document medical practice, cost standards and practice variations.

In the same time, a regulatory framework is needed to stimulate and promote the standardization of medical practice among the main actors in the hospital medical sector, a first recommendation in this regard referring to the inclusion of the practice of elaboration and implementation of practice protocols as a mandatory tool for hospital management.

In order to easily implement all the proposed aspects, it is necessary to identify incentive measures for the staff involved in the development and monitoring of practice protocols at the hospital level.

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