THE MODEL FOR THE AUDIT SYSTEM OF MEDICAL SERVICE QUALITY IN HEALTHCARE INSTITUTIONS

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Summary

Introduction. Audit of medical services is essential means for provision of the qualified medical care to civilian population. The laws and regulations of a particular country should be considered when this means is implemented.

The aim. We have researched the theoretical and methodical approaches to audit system organization of medical service quality in healthcare institutions of Ukraine.

Materials and methods. We have analyzed the ideas of experts according to their clinical effect; goals; results and purposes before and after the implementation and receiving the primary feedback. We have described the precise selection of indices according to their effectiveness, taking into account the theories and empiric investigation of the latest researches and articles. The process assessment would be employed in order to define the most effective components of the audit.

Results. We have distinguished the criteria of medical care in relation to the quality constituents, such as: patient’s orientation, effectiveness, safety, accessibility, economical effectiveness, timeliness. The results of the indicators are entered into the reporting form. In addition, problems which were identified at the stage of processing the results, and prevent the correct interpretation of the obtained indicator values, should be recorded in the reporting form. Definitely, conducting a clinical audit requires significant administrative resources and high motivation of the healthcare institution staff. The personal traits of the head of institution, including abilities to motivate a team, to use the newest data of analytical systems and registries, to know the background of audit, play a key role in this process.

Conclusions. The expediency of regular audits once every 6-12 months was proved. It is suggested that clinical audit be implemented in healthcare institutions in order to ameliorate the procedure and effectiveness of medical care to patients via in-depth analysis of the aid’s constituents in comparison to the defined criteria and implementation of necessary changes.

Key words: clinical audit, medicine, Ukraine, healthcare, criteria of quality

INTRODUCTION

Provision of medical care is one of the crucial aspects of the healthcare system all over the world. The outcomes of successful management in this field serve to increase the quality and accessibility of medical care due to the effective use of limited financial, material, labor and other healthcare resources in a state of increasing competitive healthcare market [1]. The healthcare institutions are defined by specific characteristics, which demand the modification of the main principles of management or changing emphasis in their functions. Nowadays in Ukraine, the heads of healthcare institutions are primarily doctors with significant professional experience and qualifications, who do not possess sufficient qualifications in management.

However, there is a series of problematic issues, associated with the lack of knowledge of the up to date means of diagnostics and treatment, clinical prescriptions along with inappropriate material supplement and
drawbacks of management and organization [2]. Thus, it becomes a primary concern of medical staff to raise their managing skills, to learn the current methods of effective organization in healthcare institutions, to perform the financial and economic activities and employ properly the material, financial and labor resources. All of the above-mentioned issues describe the problematic area of system audit in healthcare institutions of Ukraine [3]. Over the last few years a political interest was focused on the most suitable means of management and control, which contributed to the higher degree of professional autonomy [4]. Nowadays there is a growing trend in healthcare system towards to quality estimation and audit quality as well, in order to support the external reports and enhance the work of suppliers and control over the expenditures [5].

The mentioned issues become of particular relevance in the context of military actions in certain areas of the Donetsk and Luhansk regions of Ukraine. Military and psychogenic losses among the personnel of military formations and law enforcement agencies of Ukraine [6, 7] along with preliminary researches [9, 10] testify to the need of the audit quality of medical services in healthcare institutions.

MATERIALS AND METHODS

The aim of this paper is to investigate the theoretical and methodological approaches according to the organization of the audit system of medical services quality in healthcare institutions of Ukraine. The research aims to evaluate the audit system for the monitoring and improvement of the patient’s safety in healthcare institutions. Taking into consideration that audit is a complicated process, the authors suggest to employ a mixed set of methods for data collection on medical services quality in healthcare institutions at different levels, from patients to personnel and departments. We have analyzed the ideas of experts according to their clinical effect; goals; results and purposes before and after the implementation and receiving the primary feedback. We have described the precise selection of indices according to their effectiveness, taking into account the theories and empiric investigation of the latest researches and articles. The process assessment would be employed in order to define the most effective components of the audit.

REVIEW AND DISCUSSION

Preliminary theoretic researches and findings were partially presented in academic literature as well as practical part of audit organization according to the quality of medical services. This issue and its particular aspects in clinical audit were discussed by Goncharov N. G., Bojchenko Yu. Ya., Oranskaya O. V., Hajrulin I. I., Kurylev V. A., Kapustina I. O., Krishtopa B. P., Gorachuk V. V., Lihtarovich E. E. However, the mentioned works do not consider the complex issues regarding the formation of audit system according to the quality of medical services in healthcare institutions. This fact contributed to the importance of present research and defined its topic and goals.

Audit is a systematic process of collecting, documenting and evaluating information in order to determine, whether a functioning of a particular institution meets established quality standards [11]. The importance of audit in its forms is of significant value in the practice of healthcare institutions. There are scheduled audits (based on a program, reported in advance) and unscheduled audits, with scheduled audits, conducted at least once a year [11].

According to the auditor’s affiliation, there are first, second, and third-party audits. [12]. A first-party audit (internal audit) is carried out directly by the administration of a healthcare institution. The purpose of internal audit is usually to improve the efficiency of personnel management, identify errors in work, and prepare for an external audit. Based on the results of the first-party audit, administrative measures are usually actively used to influence the medical staff and other administrative tools to influence the work of the institution [13].

Second and third-party audits are regarded to external audits. A second-party audit is conducted by a third-party organization for its own purposes. This category includes audits, conducted by healthcare authorities at all levels, by insurance companies as part of departmental and non-departmental control. A third-party audit is conducted by a disinterested organization and includes, for example, a certification audit.

To improve the quality, and therefore the competitiveness of medical services in Ukrainian healthcare institutions, we propose to conduct an annual clinical audit. In accordance with the main principles of clinical audit, it should be appropriate to apply the following scheme for assessing the quality of medical care (Fig. 1). A characteristic feature of this assessment scheme is the implementation of treatment protocols, approved by the Ministry of Health of Ukraine. The scheme reflects the main stages of clinical audit and their sequence. The activity of doctors in providing medical and diagnostic care to patients of the medical institution is assessed.

The clinical audit cycle commences with the preparatory stage.

The preparatory stage includes:
1) planning: formulation of audit goals and objectives, timing of the audit, selection the methods of data collection;
2) development of an audit schedule;
3) distribution of audit responsibilities;
4) preparation of technical equipment and personnel;
5) informing the staff of the institution about the goals and objectives of the audit.
The audit is planned by the head of the healthcare institution. The goals and objectives of the audit are formulated based on already known problems or the results of a previous audit.

In a healthcare institution, it is advisable to conduct a quality assessment annually. This frequency is due to the fact that most of the measures of medical care for patients (lifestyle monitoring, blood pressure measurement, laboratory and instrumental studies) should be repeated every year according to the national provisions of clinical guidelines. Thus, 12 months are enough to collect new data in outpatient records that are used to assess the quality of medical care. Data from the previous calendar year are analyzed at the beginning of the following year.

The period of conducting an audit is determined individually for a particular healthcare institution and largely depends on the methods of data collection and the level of personnel preparation. There are two possible methodologies of clinical data collection:

1) the data are collected within a year;
2) the data are collected in a particular period of time (as short as possible) after the end of a calendar year.

The planning process is finalized with a development of audit schedule and sharing the functional responsibilities. The responsible person is assigned according to the each stage of audit.

In our view, it is expedient to implement the following distribution of responsibilities:

1) a head of an audit (a chief physician) defines the tasks and objectives, and inform the personnel about the received results. The head of the audit also provides the control at all stages of the process.
2) the responsible staff for audit organization (the heads of departments) perform and control the activities at preparatory stage: they plan the schedules of audit, assign the responsible personnel and executors of the further stages of audit, organize and prepare the personnel, participate in taking decisions on improvement and organize their implementation.
3) the responsible staff for data collection (a nurse receptionist, hospital registrar) provides the collection of ambulatory medical records and puts the data into a register.
4) the registrar (a practicing physician who has been trained to work with the registry) – enters patient data into the registry.

5) an audit expert (proficient in clinical audit methodology, with knowledge of the system and statistical analysis skills) – analyzes the results of calculating clinical indicators of the registry, forms an expert opinion, prepares reporting documents based on the audit results, and provides advisory assistance in developing improvement solutions.

6) responsible for the audit (an experienced specialist of the team, who is familiar with the organization of the healthcare institution) – controls the audit process in accordance with the adopted audit schedule, might participate in the organization of the audit and data entry into the registry, prepares draft proposals for improvement based on the results of the audit.

At the preparatory stage, particular attention should be paid to training of the staff who will collect clinical data for analysis. This stage is highly sufficient, as clinical indicators require the presentation of medical information in a formalized (unified) form. Thus, the quality of the formalization depends on the quality of the results obtained by the indicators. Each time an audit is planned, the knowledge of clinical data formalization among the staff members should be assessed, and mandatory training and retraining should be conducted. The process of staff training involves studying clinical guidelines and researching current treatment protocols.

The highest level of clinical audit objectivity might be achieved, when it is conducted on the basis of an information, regarding the quality criteria and indicators, which correspond to its components, developed and approved by the head of the healthcare institution.

The quality criteria should cover all components of quality and serve as guidelines for achieving the planned goals of providing quality medical care (Table 1). The quality criteria are detailed for each department/sub-unit and each staff member, in accordance with the type and scope of medical care, defined by the Regulations on sub-units and job descriptions.

Table 1

<table>
<thead>
<tr>
<th>Quality components</th>
<th>Examples of quality components</th>
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<tbody>
<tr>
<td>1. Patient’s orientation</td>
<td>1.1. The patient’s rights are observed according to existing legislation.</td>
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<td></td>
<td>1.1. The ethical and deontological norms of medical work are followed.</td>
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<td>1.1. The regular sociological surveys are taken in order to reveal the expectations, needs and individual patient’s values.</td>
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<td>2. Effectiveness</td>
<td>2.1. The change of clinical state according to the expected prognosis.</td>
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<td>2.1. Medical care is provided according to the local medical and technical documents, corresponded to the norms and regulations which are specific for a particular area and agree with international medical evidence.</td>
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<td></td>
<td>2.1. In comparison to the previous period, the positive dynamics of deficiency decrease is observed as well as reduce of negative consequences of medical treatment and patient’s complaints.</td>
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<td></td>
<td>2.1. Patient’s satisfaction with the results of medical care and service is regularly estimated.</td>
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<tr>
<td>3. Safety</td>
<td>3.1. Medical care is provided according to the local medical and technical documents, corresponded to the norms and regulations which are specific for a particular area and agree with international medical evidence.</td>
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<td>3.1. License and accreditation standarts are implemented according to the specific functioning of healthcare institution.</td>
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<td>4. Accessibility</td>
<td>4.1. Medical and non-medical staffing is organized due to the existing regulations.</td>
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<td>4.1. Medical equipment of healthcare institution is provided by the facilities charts.</td>
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<td></td>
<td>4.3. Medical employee is enabled to access the local and technical documents, standarts, rules and methods and follow the regulations and instructions of a healthcare institution.</td>
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<td>4.3. It is established the cooperation between the departments of healthcare institutions and other medical or non-medical entities, regarding the organization of medical care to the patients/population.</td>
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<td>5. Economical effectiveness</td>
<td>5.1. Resources capacity are planned due to the specific demands/local medical and technical documents, in order to meet the medical needs of target groups.</td>
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<td></td>
<td>5.1. The types and capacity of resources are used in accordance with the specific requirements/local medical and technological documents.</td>
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<td></td>
<td>4.3. The duration of the treatment, diagnostic process and its individual components correspond to the current standards according to nosology.</td>
</tr>
<tr>
<td>6. Timeliness</td>
<td>6.1. Expectation period is defined and observed:</td>
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<td>– scheduled consultation with a specialist in accordance with the recommended standards;</td>
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<td>– planned hospitalization in accordance with the recommended standards;</td>
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<td></td>
<td>– planned surgical intervention in accordance with the recommended standards;</td>
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<td>– results of laboratory, functional, and other diagnostic tests.</td>
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<td></td>
<td>6.1. The defined procedure for outpatient appointments.</td>
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<td>6.1. The time of arrival of the emergency ambulance crew to the patient/injured is determined, depending on the geographical location and in accordance with the current standards.</td>
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Note. Proposed by authors.
A set of sample (planned) indices of quality is formed for a healthcare institution. They are defined in normative documents, standards, instructions, methodologies and other regulative documents of Ukrainian legislation.

The quality indicators, which are employed as a tool for measuring the quality of medical care, are developed and calculated in accordance with Methodology of developing indicators system of medical care quality, approved by the Order of the Ministry of Health of Ukraine No. 751 on September 28, 2012, registered with the Ministry of Justice of Ukraine on November 29, 2012, No. 2002/22314.

On completion of the preparatory stage, the audit manager informs the staff of institution about the goals and objectives of the audit, familiarizes the staff with the audit schedule, and introduces the personnel, responsible for each stage. (Lihtarovich, 2012).

The next stage deals with clinical data collection about the patients. The data source is outpatient records (form 025/o). At this stage, the data collection officer, who receives instructions from the audit officer on the criteria of selecting outpatient records for review, and a trained registrar participate in the audit.

It is recommended for the healthcare institutions to collect data every three months, including patients with a particular nosology, who made one or two consequent appointments with the doctor [14]. The selected number of patients is defined according to the population served. After the audit is accomplished, a responsible staff checks and controls the credibility of these reports and if some information is lacking, the data collection would be continued.

In case the data is sufficient for reliable processing, the next stage of results processing is followed. At this stage, the person in charge of conducting the audit fills out a report on the audit in a healthcare institution. This form should contain general information about the healthcare facilities, target patient groups, date range, auditor, and a list of clinical indicators [15, 16] for patients with specific diseases and target values of the analyzed clinical indicators.

During the first audit procedure, an interim or final target value is set for the indicator. Subsequently, depending on the timing of the audit and its results, it may be necessary to set additional interim target values and only then the final ones [12]. Next, the results of the indicators are entered into the reporting form. In addition, problems which were identified at the stage of processing the results, and prevent the correct interpretation of the obtained indicator values, should be recorded in the reporting form (e.g., lack of periodic visits to a doctor, lack of data on lifestyle, etc.)

The next stage of the audit is analysis of the results and reports writing. It is carried out with the participation of an audit expert. The audit expert checks the correct processing of clinical information, compares the results of the audit in the healthcare institution with the results, obtained in similar institutions and summarizes the results of the audit. If necessary, the audit results are presented graphically.

The analysis reveals areas of the patient care process, that deviate from the provisions of clinical guidelines, i.e. areas to be improved. After the expert analysis, the audit results are presented to the audit committee of the healthcare institution, which consists of the audit manager, the staff member in charge of organizing the audit, and the staff member in charge of conducting the audit, whose responsibility is to explain and discuss the results.

The crucial part of this stage is that the analysis of the audit results is carried out by an expert, who possesses the knowledge of statistical analysis methodology for obtaining the results of clinical indicators, and who has all the available information about the analyzed problem. Due to correct interpretation of the results it might be possible to find effective means to improve the quality of medical care.

According to the general requirements of conducting an efficient audit, the results of the assessment should be assigned to the staff of the healthcare institutions in compliance with the principles of confidentiality [17]. Fines and other penalties are not provided.

It is highly recommended to employ the highlights of clinical audit in public reports [18]. The responsible person for audit might develop the propositions in order to improve this process and provide a plan of their implementation. The same committee approves the project of propositions and plan of their realization, it also assigns the responsible staff and executors. The objectives, tasks and terms of the following audit are planned.

It is advisable to repeat the audit cycle once every 6-12 months. At this stage, the audit cycle is considered complete. It is recommended to repeat the entire cycle in case of insufficient results or lacking effect of assessment the quality of medical services until the final goal is achieved.

Definitely, conducting a clinical audit requires significant administrative resources and high motivation of the healthcare institution staff. The personal traits of the head of institution, including abilities to motivate a team, to use the newest data of analytical systems and registries, to know the background of audit, play a key role in this process [19]. Implementation of clinical audit principles with use of registries in the practice of Ukrainian healthcare institutions would enable the effective employment of evidence-based medicine data in the treatment of patients, thereby contributing to the achievement of treatment goals and improving the clinical situation in the region.
CONCLUSIONS

Thus, in order to enhance the competitiveness in healthcare organizations of Ukraine, it was suggested the systemic audit of medical services quality, based on a series of criteria and quality indicators. The quality criteria correspond to a particular department/sub-unit and employee according to the type and level of medical care, which are defined by the Conditions on sub-units and job descriptions. Furthermore, it was recommended to provide the clinical audit in healthcare institutions to improve the patient’s treatment via the defined criteria and their adjustment in case the outcomes don’t match the expectations.

We have established the advantages of using the audit of the quality of medical services:

- This mechanism enables monitoring and management of the quality of medical care;
- Encourages socializing and cooperation among the staff of medical institutions;
- This helps to comply with the approved clinical protocols as well as medical and management standards;
- Shortcomings in a staff organization, were revealed and can now be addressed;
- This enhances the institution’s effectiveness and efficiency;
- The institution’s support for quality medical care is highlighted and promoted;
- Effective medical technologies can increase profitability.
- Applying personnel safety principles, identifying risk areas, and preventing medical errors effectively:
  - Encourages and supports the ongoing training of healthcare professionals.
  - Contributes to more effective use of personnel resources, reducing irrational costs.

The regular organization of audit would not contribute to personnel’s overload, but enables them to ameliorate the functioning of healthcare institutions and apply the auditor’s skills in their professional practice.

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COMPLIANCE WITH ETHICAL REQUIREMENTS

Not applicable (no animals or human subjects were used in this study).

AUTHOR’S CONTRIBUTION TO THE ARTICLE


A – Concept and design of the study
B – Data collection and analysis
C – Responsibility for statistical analysis
D – Writing the article
E – Critical review
F – Final approval of the article

REFERENCES


МОДЕЛЬ СИСТЕМИ АУДИТУ ЯКОСТІ МЕДИЧНИХ ПОСЛУГ У ЗАКЛАДАХ ОХОРОНИ ЗДОРОВ'Я
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Вступ. Аудит медичних послуг є необхідним засобом надання кваліфікованої медичної допомоги цивіль-ному населенню. При застосуванні цього засобу слід враховувати закони та правила конкретної країни.

Мета дослідження. Досліджено теоретико-методичні підходи до організації системи аудиту якості медичних послуг у закладах охорони здоров’я України.

Матеріали та методи. Проаналізовано ідеї експертів за їх клінічним ефектом; цілі; результати і цілі до і після впровадження та отримання первинного зворотного зв’язку. Ми описали точний вибір індексів відповідно до їх ефективності, враховуючи теорії та емпіричне дослідження останніх досліджень і статей. Оцінка процесу буде використана для визначення найбільш ефективних компонентів аудиту.

Результати. Проаналізовано міжнародний досвід та розроблено процедуру оцінки якості медичної допомоги. Крім того, ми виділили критерії медичної допомоги по відношенню до складових якості, таких як: орієнтація на пацієнта, ефективність, безпека, доступність, економічна ефективність, своєчасність. Результати показників заносяться до форми звітності. Крім того, у формі звітності повинні бути зафіксовані проблеми, які були виявлені на етапі обробки результатів і перевірено на правильність інтерпретації отриманих значень показників. Безумовно, проведення клінічного аудиту потребує значного адміністративного ресурсу та високої мотивації персоналу закладу охорони здоров’я. Ключову роль у цьому процесі відіграють особисті якості керівника установи, зокрема вміння мотивувати команду, використовувати новітні дані аналітичних систем і реєстрів, знати передумови аудиту.

Висновки. Доведено доцільність регулярних аудитів 1 раз на 6-12 місяців. Пропонується запровадити клінічний аудит у закладах охорони здоров’я з метою покращення процедури та ефективності надання медичної допомоги пацієнтам шляхом поглибленого аналізу складових допомоги, порівняння з визначеними критеріями та внесення необхідних змін у разі невідповідності результатів очікування.

Ключові слова: клінічний аудит, медицина, Україна, охорона здоров’я, критерії якості