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INTERNATIONAL QUALITY AUDITS IN THE MEDICAL FACILITY

Summary
The qualitative research was carried out in multidisciplinary medical facility in Ukraine. It was established that audit quality management system according to ISO Standard is more formalized and universal, than clinical audit. The advantage of clinical audit is a direct support of continuous professional development of medical staff through additional training and gain experience in problem solving by recognized leaders.

Keywords
Quality management in health care, external quality audit, health care facilities.

Healthcare quality improvement is an urgent priority for many public health systems. There is not enough research-based evidence for quality management tools, while using modern healthcare technologies [5, 9, 10]. Assessment of effectiveness and other quality-related components of obstetric and gynecological care is a complex technological task [2, 3, 7, 9]. The World Health Organization (WHO) reproductive health department defines three main approaches to assessment of obstetric care quality. Those are mortality audit (maternal or perinatal), severe morbidity audit (or near-miss), and clinical practice audit. Analytical methods can be quantitative (e.g., surveillance) or qualitative (e.g., case review) [10, 13].

The audit is based on medical care criteria (standards), which can be direct or indirect. The National Institute for Health and Care Excellence (NICE) in UK defines audit as «the process of quality improvement, which is aimed at improving care and results through systematic matching of medical care against direct criteria and changes implementation». Aspects of structure, processes and results of medical care are chosen and being systematically assessed against direct criteria. The changes are introduced on the individual, team level or on the level of service, if necessary, and the following monitoring is used to confirm improvement of care [12].

For the last 20 years, clinical audit has been spread widely. It is used in various specialties in many countries [1, 2]. Due to clinical audit, one can trace processes of diagnostics, treatment and patient care, use of various resources, effects of medical interventions and impact of medical care on a patient's life quality [6, 9, 11]. Thus, clinical audit, covering all the aspects of patient care, became an essential and an integral part of clinical management in some countries. Clinical audit can be carried out by non-medically qualified audit assistants who screen patients' medical records and collect relevant data. Standardized criteria for assessing high-quality care are determined beforehand [3, 7]. Criterion-based clinical audit assumes that recorded activities have been actually performed, while non-recorded have not. Incomplete definition of case files, missing files, as well as case files filled in an improper form a potentially serious problem for studies using criterion-based audit that needs more accurate staff profiles, training and data collection methods and tools. According to the systematic review W. Graham et al., we can use a lot of criteria for optimum management of obstetric practice [3]. Criteria-based clinical audit consists of five standard steps: to establish good practice standards, to assess the current practice, to collect feedback and to set local objectives, to implement changes into practice, if applicable, and to reevaluate practice and feedback data.

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To a certain degree, clinical audit is very much alike any quality audit in accordance with the ISO 9000 Standards Series. Quality audit is defined as systematic, independent and documented process for acquiring audit evidence and unbiased assessment of the aforementioned data to determine the extent of audit criteria fulfillment [8]. The ISO 9000 Series is applicable in a wide range of business activities. It has been recognized in Ukraine since 1997. The current national accreditation criteria for medical facilities set the dependence of awarding the accreditation category to healthcare providers of secondary and tertiary healthcare services from holding a certificate of the quality management system in conformity with the requirements of the ISO 9000 national standard (ДСТУ ISO).

Objective: comparative scientific analysis of clinical audit specifics and conformity audit for a quality management system to requirements of the ISO 9000 Series, which were sequentially introduced into practice of medical facility management.

Materials and methods

The qualitative research was carried out in an inpatient department of a multidisciplinary private medical facility of the highest accreditation level in Kyiv city. There was an in-depth study of obstetric and neonatal departments, while engaging a specialized team to car-

ry out clinical auditing activities. The team consisted of three specialists: two general practitioners, leaders of relevant departments at university clinics and the chief of the nurse service in one of the clinics. The audit of quality management system conformity to requirements of the ISO 9000 Series was carried out by a team of three auditors, with two of them being general practitioners. Auditors from both teams were representatives of the European Union countries. The subject of the research was as follows: methodological aspects of implementing external quality audit into Level II healthcare facilities. The authors conducted active observation activities and received feedback from the auditors and medical staff of the departments that took part in the audit.

Results and discussion

In the healthcare system of Ukraine, clinical governance has been traditionally paying its major attention to control and expertise of healthcare quality or performance indicators over a period of time. Clinical audit, while being a tool for healthcare quality improvement, is significantly different from control and expertise procedures [1]. The system of indicators is used as a mechanism of internal quality improvement and not as a tool for accountability or punishment. The result is overall cover and expanding with the help of the indicators at all stages of standards' implementation for structure, process and results of medical care aimed at continuous healthcare quality improvement [4, 12]. The Ministry of Health is only slightly engaged in forming legal framework. Those tools are the Order of the Ministry of Health of Ukraine №795 «On monitoring clinical indicators of healthcare quality» as of 11.09.2013, and the Order of the Ministry of Health of Ukraine №751 «On drafting and implementing medical and technological documents related to standardization of healthcare within the system of the Ministry of Health of Ukraine» as of 28.09.2012. The drafting process of the national list of healthcare indicators has just begun.

The medical center, as the research object, has eight year experience of preparing and conducting external quality audits. Quality audit includes examination of management system and processes, with their quality criteria specified in our own internal documentation. While drafting internal documentation, we considered the norms of the current Ukrainian legislation in the first place; specifically, the orders of the Ministry of Health of Ukraine. They define a strict scope of medical care in various cases. A doctor cannot fail in following an order of the Ministry of Health of Ukraine without facing strict legal consequences. The Medical Center is allowed to extend the scope of services that must be provided in some cases, but it has no legal right to limit the scope in its own discretion. For example, the list of laboratory tests is a must for pregnancy. European, as well as World Health Organization guidelines or research and publication data are taken into consideration on the second priority basis and only IF they do NOT contradict the current norms of the national legislation. So, while carrying out quality management system conformity audits to requirements of the ISO 9000 Series, we checked conformity of processes and resources organization to developed and set quality performance criteria. Auditors did not dwell deeply into the process of healthcare decision making or its reasons.

Last year, we conducted several experiments using external audit for healthcare quality. At first, we performed a testing audit, while engaging an independent Ukrainian expert, who carried out audit of medical documentation in an obstetric department. According to the documents, this type of audit improves relevance of criteria selection (criteria actually apply to a given context) and reduces unnecessary variability (e.g., unclear wording in criteria definitions, differences between sites) [3, 7]. We also carried out an external international clinical audit in two departments: obstetrician and neonatology. The clinical audit was aim at checking medical issues only: reasons for medical decision making, while taking into account modern healthcare trends and guidelines, evidence based healthcare data, assessment of safety issues for life and health of a mother and a child in a long-term perspective, economical consequences of medical decisions for the Medical Center, as a service provider. The results of the audit were discussed in the form of sharing our experience with invited specialists. Audit appliance is a form of feedback, which helps the personnel to build their professional capacity indirectly [1].

Clinical audit is usually implemented by qualified supportive audit assistants who screen patients' medical records and compare them with previously determined and set criteria [6]. As qualified supportive personnel can take part in clinical audit, training of such personnel (availability of sufficient training) is necessary to guarantee accuracy and reliability of an audit. However, we think that such a criterion is more appropriate for conformity audits of a quality management system, as the process of its implementation and reporting are more formalized in this kind of audit. According to our experimental observations of a clinical audit, an individual approach in selection of auditors is necessary. Healthcare facilities of the highest level must be checked by specialists of the relevant highest level.

Apart from important information and sharing valuable experience, we acquired very interesting results from the point of view of personnel's attitude towards such events, comparison with quality audit and comprehension of auditors' recommendations.

The comparison between the audit types implemented in 2013 is provided in the Table below.

After the clinical audit was over we conducted inquiry of engaged personnel. Doctors' comments included the following: «the purpose of the audit is unclear, as its results have no legal force», «it is just a visit and experience sharing», «the purpose of the invitation is unclear», «there is no plan and time for preparations, that is why one doesn't know what to expect»; «an auditor's personal point of view is not always evidence-based and that evidence includes documents»; «this piece of

advice is worth attention but it is not obligatory for execution»; «there is an impression that the process is creative and there are no standards of its performance»; «the absence of language barriers is useful».

The clause was introduced into job descriptions for doctors and chief nurses; it was obligatory for the employees to take part in development and implementation of the ISO Standard in a specific department. Job descriptions, providing local and personal regulations of interrelations between an employee and a medical institution, provide an opportunity to define rights and obligations of a healthcare employee with his/her participation in a clinical audit. In our opinion, there must be a decision on financial and moral incentives for an employee's participation in this type of work on the local level.

The issue of the language barrier requires a specific discussion. Unfortunately, the level of the English fluency, which could provide direct communication with colleagues and access to original sources for the doctors, who worked at the research object, was better than the average level over the country, but still far from adequate. During the international quality audit with English as its working language, a management representative (in our case – a quality manager) plays two roles. On one hand, he/she is an interpreter, which means that he/she both helps with understanding direct speech of the auditors and transfers some cultural and business notions of the country, the language of which is used at the moment (so called «background knowledge»); on the other hand, he/she is plays the role of the «moral support» for the employees. A quality manager controls the whole system; he/she knows the content of each specific process and all the levels of interrelations between various processes. During the clinical audit, employees had an opportunity to express their opinion without fear of being punished, but they still felt uncertain, as according to them, it was unclear what exactly the auditors wanted to see.

During an audit, an auditor's personality plays an important role. Our observations and comparisons of behavioral types and personal attitude towards an auditor are presented below.

The chief auditor, an expert in healthcare facility management, who carried out the quality audit in conformity to the ISO Standards, was friendly but emotionless. He asked questions regarding the program, received and noted answers but commented nothing, gave neither assessments, nor examples from his own experience.

The medical auditor from the quality audit team on conformity to the ISO Standards did not ask any questions on the rules of healthcare decision-making process, nor did he have any doubts on conformity of the guidelines of the Ministry of Health of Ukraine to Eu-

Table. Comparison between the audit types

	Quality audit (conformity to the ISO 9001: 2008 Standard)	Clinical audit
Team	The chief auditor (a specialist in healthcare facility certification from Germany); a healthcare expert (head of the clinic, obstetrician-gynecologist from Switzerland); hygiene expert/ healthcare facility manager from Russian Federation.	Three healthcare experts from Lithuania: a neonatologist, an obstetrician-gynecologist and a medical nurse.
Role of a healthcare auditor	A healthcare auditor is a member of the team; an expert selected by a certification body (usually, a head of a relevant department).	The leader of the healthcare auditing group is an international expert selected by the client, who doesn't have any language barriers with the personnel.
Management staff participation in the audit process	A representative from the management team or a quality manager is necessary to accompany the auditors.	Auditors worked with the personnel directly that encouraged more frank approach.
Specifics of the preparation	Dates of the audit are known beforehand, the heads of the department have additional time for preparations under the control of a quality manager.	Dates of the audit are known beforehand. There was no additional time given. Additional documents were not prepared.
Report form	Accurate and formalized structure of the report, which has been used for several years. The only adjustments were those important from the auditors' point of view.	The report consists of the description of actual findings, as well as suggestions about the structure improvements.
Objective	Assessment of effectiveness and relevance of those processes used for fulfilling quality-related tasks set by the organization. Assurance of evidence concerning reducing, removal and prevention of nonconformities.	Improvement of healthcare quality effectiveness of healthcare practice. Focus on validity of medical interventions, level of application of the last evidence based medicine data, readiness to work with complex clinical cases.
Auditing technology	Assessment of availability of necessary internal documents. Evaluation of relevance of personnel's knowledge on the order of actions in specific cases to those set in internal Standard Operation Procedure algorithms. Monitoring the relevance of process description in internal documentation to performed actions during service provision.	Observation, inquiry, medical records analysis, medical activity reports analysis, evaluation of utilization of equipment, assessment of organization charts and staff schedule.
Recommendations/ Guidelines content	Changes of organization chart and subject's intercommunication aimed at process optimization in a medical facility. Guidelines are based on an auditor's own experience regardless of relevance for medical decisions.	Optimization of medical staff intercommunication systems in accordance with current clinical guidelines and protocols. Introducing changes into current clinical protocols. Relevance of medical technologies application. Guidelines are based on an auditor's own experience and may cast into doubt appropriateness of medical intervention. Guidelines on group and personal needs in professional capacity building.
Audit consequences	The audit report considers a possibility of issuance, prolongation or annulment of a certificate or time rendering for nonconformity correction.	The audit report may be used or ignored by the owner and management staff of a facility without any direct legal consequences. The necessity of a re-audit aimed at changes assessment shall be defined by the management team.
Activities of continuous professional capacity building	Audit does not involve any personnel training by the members of the audit team.	A joint conference with a workshop and training event for the healthcare staff of one of the departments was carried out.

ropean practice. He took them as the basis for quality management system. He didn't criticize doctors' work. The personnel had more confidence in his judgments and comments, as his recommendations could lead to «punishment» in the form of quality certificate annulment and that is why they were to be met. The quality management system in his clinic, which is certified by the same procedure, is alike the research object and that is why his recommendations on improvement of processes organization were comprehensive enough. He was not argued with, as «he knows better». The auditor used the approach: «not criticize but observe».

An obstetrician-gynecologist from the clinical audit team was friendly; he accepted other employees' points of view, who could argue with him regarding some issues. The auditor used the approach: «to express his opinion».

The personnel of the healthcare facility did not accept the medical nurse as an equal member of the team. Their communication was very friendly, but due to non-obligatory nature of European norms with possible adjustments to them, if necessary for a hospital, the personnel didn't express any extreme interest in their colleague's guidance.

In conclusion, though the clinical audit was implemented with the focus on experience sharing and not on control, the personnel was inclined to have more trust to the results of the quality audit. Healthcare facilities are an object of increasing number of inspections in their activities. Those inspections are mostly aimed at «revealing nonconformities» and «punishing culprits». Despite seven years of experience in implementation of quality audits at the research object, the personnel considered the event only as a marketing advantage and an attempt of their management to find nonconformities and to punish those responsible.

We also think that a quality audit is less dependable on an auditor's personality and it can be used for assessment of a quality management system in healthcare facilities of different level and in any kind of medical care.

Both types of audit are tools for healthcare quality management. One cannot say that this or that kind of audit gives any better picture of what is going on, but a quality audit, in our opinion, looks more formalized and universal, and the undeniable advantage of a clinical audit is its opportunity for personnel's capacity building through exposure to the experience of medical leaders.

As mentioned above, in case of poor understanding of an audit methodology or when an organization's environment has no support to it, chances of a successful implementation of an audit are lower [12]. Our experience confirmed the thesis that a clinical audit has a chance to be successful, if an owner and a CEO express their support and the personnel involved is properly trained. At the moment, a lot of efforts must be invested to form the culture of modern methods of healthcare quality management in healthcare facilities in Ukraine.

Conclusions

An external audit is an advanced tool for assessment and improvement of healthcare quality. The focus on quality improvement and assessment of conformity to set criteria is common for both types of an external audit. However, quality audit is more formalized and universal, and the undeniable advantage of a clinical audit is an opportunity for personnel's training, acquisition of experience from the medical leaders.

Selection of the leaders and an audit team has a considerable impact on the possible successful use of this tool for comprehension and an opportunity to implement any changes.

Conformity to the ISO Standard is less dependable on the personality of an auditor and it can be implemented in different kinds of medical practice.

Wide practical implementation of modern methodology of healthcare quality management involves policy, educational, informational, economical and cultural aspects, while each of them requires further studies. Optimization of a clinical management system must involve wide engagement of healthcare employees, qualified supportive experts and experienced patient leaders to participate in any clinical audit activities.

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