Unified Methodology for Development of Clinical Guidelines, Standards of Medical Care, Unified Clinical Protocols of Medical Care, Local Protocols of Medical Care (Clinical Pathways) on the Principles of Evidence-Based Medicine

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Current approach to the improvement of the health care quality aims to control and improve the activities of the health care system, improving its efficiency through evidence-based practice, and use of high-quality clinical studies as the basis of clinical information. Best international practices show that the implementation of evidence-based medicine involves consideration of safety, efficacy, cost of medical services and technologies. Up-to-date medical practice requires from physicians to use the most reliable evidence, from patient — active informed participation in preventive programs and during the treatment.

In Ukraine, the mechanism of development of medical technological and regulatory documents according to the principles of evidence-based medicine is realized according to the Quality Management Concept in Health Care of Ukraine until 2010, approved by the Orders of the Ministry of Health of Ukraine № 166 of 31.03.2008, № 340 of 25.06.2008 «The Plan of Actions to Promote the Quality Management Concept in Health Care of Ukraine until 2010», № 341 of 25.06.2008 «On Approval of the National Standardization Program of Health Care until 2010».

The National Program of adjustment of Ukrainian legislation to European Union legislation (Law of Ukraine № 1629-IV of 18.03.2004) envisages harmonization of the national standardization system in accordance with the European principles. According to the Quality Management Concept in Health Care of Ukraine until 2010, standardization of health care in Ukraine will be realized through the development and implementation of clinical guidelines (recommendations) and clinical protocols in routine medical practice, harmonization of (medical) care standards with the international standardization system, etc. The basis of health care standards should be scientific evidence of effectiveness and safety of medical interventions, obtained during clinical and epidemiological trials based on the unified methodology (evidence-based medicine), or in case of data unavailability — on the best medical practice.

Development of strategy and practical implementation of these standards in health care system are imposed on the National Centre for Development and Monitoring of Medical Standards Compliance headed by the Ukrainian Institute for Strategic Studies of the Ministry of Health.

Methodological basis of the activity in standardization of health care are the up-to-date scientific approaches to the principles and requirements for elaboration of medical and technological regulatory documents, including recognized by the international questionnaire AGREE (Appraisal of Guidelines for Research and Evaluation in Europe) — a tool of examination and appraisal of clinical guidelines for the unified assessment of their quality. AGREE is designed for assessment of the data quality shown in clinical guidelines, namely, to determine risk of possible bias in during development of clinical guidelines. In addition, these guidelines are based on SIGN:50: A guideline developer’s handbook (Scottish Intercollegiate Guidelines Network (SIGN) Publication № 50) that is a «gold standard» for national health care systems in the development of clinical guidelines. In Ukraine, the above-mentioned document with amendment of certain statements is presented in two publications: «Guide for developers of clinical guidelines/medical standards» (NICARE, 2006) and «Guide for developers of clinical guidelines/medical standards (short version)» (NICO, 2007). «Guides ...» were worked out by international and Ukrainian experts on the Order of the Ministry of Health of Ukraine under the auspices of the European Union in the TACIS (Technical Aid to the Commonwealth of Independent States) project «Promotion the development of medical standards in Ukraine» (2004–2006 estimates).

Development of the clinical guidelines is a long-term and expensive process, so, there is no need for each country to do it. Information on clinical guidelines development in the leading scientific centers, such as GIN (Guidelines International Network; http://www.g-i-n.net), SIGN (http://www.sign.ac.uk), NICE (National Institute for Health and Clinical Excellence; http://www.nice.org.uk); US National Guideline Clearinghouse (http://www.guideline.gov) national database of clinical recommendations of the U.S.A. GIN partner and others. This information is available to all. Moreover, by the agreement between them it is not duplicated in recent years. This allows working out more documents and efficiently using limited resources in health care systems around the world.

For countries that do not have their own centers on clinical guidelines development, an adjustment of clinical guidelines to the institutional foundations of the medical care in the national health care system is an acceptable way. This way is used in France for adjustment of clinical guidelines in ADAPTE project (http://www.adapte.org).

Nowadays, an adjustment of clinical guidelines is an optimal way for Ukraine to form high-quality clinical practice, which was developed in the world’s leading centers on the principles of evidence-based medicine, and further development on this basis of standards and protocols of medical care. There are certain prerequisites, and in the first place — experience of clinical guidelines adjustment — gained by technical assistance of the TACIS project during two years.

Both development (full cycle) and adjustment process of clinical guidelines occur
The essence of differences of the above-mentioned documents can be represented as follows:

- clinical guidelines answer the question: «What can be done?» (reference version of clinical practice based on recent achievements of medical science);
- standards of medical care, unified clinical protocols of medical care — «What should be done under the conditions of the country?»;
- local protocols of medical care (clinical pathways) — «How this should be done in a particular health care institution?».

Elaboration of these documents occurs in two ways:


There are two ways to further development of unified clinical protocols of medical care due to specific functions of standards of medical care that provide managerial arrangements to solve health problems. Moreover, they take into account national peculiarities of health care system and socio-economic situation in the country.

Standards of medical care are developed in limited amount, depending on the social and health priorities, including groups of diseases or conditions that affect large population groups, inc. able-bodied people, and result in considerable losses in the economy of the country.

- «Classic» way includes development of unified clinical protocols of medical care on the basis of clinical guidelines and standards of medical care in the priority-oriented areas of health care, which, by definition of the Ministry of Health of Ukraine, require well-defined rules and criteria for control of health care quality.
- «Direct» way allows using basic clinical guidelines in developing of unified clinical protocols of medical care without development of standards of medical care. The Ministry of Health of Ukraine approves unified clinical protocols of medical care, basic principles of medical care according to the best practices provided in clinical guidelines.

Local protocols of medical care are developed by the institution of health care to resolve multidisciplinary tasks, to establish effective cooperation between regional health care institutions, the units of one institution, to determine «clinical pathways».

Furthermore, clinical guidelines, standards of medical care, unified clinical protocols of medical care differ in terms of their legal status. Clinical guideline is a professional document that is approved at a forum of association or by other organization of specialists.

Standards of medical care, unified clinical protocols of medical care are normative documents that are approved at the state level by the Ministry of Health of Ukraine.

The health care institution approves local protocols of medical care (clinical pathways). Thus, the development of medico-technological standards of medical care in the standardization of health care involves the following steps:

1.1. Development/adjustment of clinical guidelines;
1.2.a. Development of standards of medical care and (or)
1.2.b. Development of unified clinical protocols of medical care;
1.3. Development of local protocols of medical care (clinical pathways).

These methodological guidelines represent the first part of a complex methodology, which is devoted to the development/adjustment of clinical guidelines (1.1) and standards of medical care (1.2.a).

The second part of the complex methodology is represented in particular methodological guidance on unified clinical protocols of medical care (1.2.b.) and local protocols of medical care (clinical pathways) development (1.3).

The purpose of methodological guidance. Methodological guidance is issued for the purpose of dissemination of technology and process of justified choice, adjustment of clinical guidelines to evidence base, development of standards of medical care on the basis of clinical guidelines, according to the Order of the Ministry of Health of Ukraine № 341 of 25.06.08 «On Approval of the National Standardization Program of Health Care until 2010».

Terms and Definitions
Adjustment of clinical guidelines — a process of prototypes analysis in terms of their compliance to the national resource and regulatory base, the possibility of their realization in Ukraine, financing, used terms and medical specializations, the list of authorized in Ukraine medicines and equipment, with further justification of the measures required for implementation of clinical guidelines with high level of evidence.

Implementation of clinical guidelines and standards of medical care — system of measures on distribution and using of standards of medical care, developed on the basis of clinical guidelines.

Evidence-Based Medicine — fair, accurate and deliberate using of best results of clinical studies for choice of the treatment for patient.

Indicator of quality care — quantitative or qualitative indicator, to which exists evidence or consensus as to its direct impact on the quality of health care. It is determined retrospectively.

Clinical audit — is the process of improving the quality of medical care through systematic examination of provided treatment, using clearly defined criteria, and ensuring
further changes. On the base of examination and retrospective evaluation of structure, process and outcome of the medical care necessary alterations for quality improvement at the individual, collective, or organizational level are determined. Further prospective monitoring confirms or denies the feasibility of current rules of health care.

Clinical pathway — is a regulatory document of regional and/or local level. It is aimed at ensuring continuous, efficient and economically rational health care in specific diseases and other pathological conditions, according to unified clinical protocols of medical care. It provides coordination and streamlining of the technology and methods of health care of multi (inter-) disciplinary content according to the schedule. It regulates registration of medical information and clinical audit. The chief of health care institution approves it.

For the purpose of organization, coordination, scientific and methodological support of clinical guidelines adjustment process and standards of medical care development at the national level National Center of Development and Monitoring of Standards of Medical Care Compliance was established. It is headed by Ukrainian Institute of Strategic Studies of Ministry of Health of Ukraine, whereas the Institute is principal institution responsible for the organization and public health management in Ukraine. Activities on clinical guidelines adjustment and development of standards of medical care is provided by thematic working groups. They were established according to the Order of the Ministry of Health and function on the base of the National Center of Development and Monitoring of Standards of Medical Care Compliance.

These guidelines development groups include representatives of professional medical organizations and associations, research institutes of the Ministry of Health and Academy of Medical Sciences of Ukraine, medical universities and academies of medical postgraduate education, the main external experts of the Ministry of Health of Ukraine, leading specialists of health care institutions, patients and other non-governmental organizations, whose activity is directed on health care improving.

Nowadays, clinical guidelines, elaborated according to the principles of evidence-based medicine, are scientific basis of standards of medical care and unified clinical protocols of medical care. In case of using other approaches to development (expert evaluation, retrospective statistical evaluation), standards of medical care are usually prohibited documents and have the status of prohibited documents and have the status of medical guidelines with high level of evidence.

The process of selecting clinical guidelines topics is integrated to the national health care system and medial science. It is usually consists of 3 stages:

I stage — initiation of clinical guidelines adjustment. Any person or group representing the interests of medical professionals and/or patients can realize it. Initiators fill application form and submit it to the National Centre of Development and Monitoring of Standards of Medical Care Compliance, when competition will be announced;

II stage — examination of applications for the adjustment of the clinical guidelines. According to the Order of the Ministry of Health of Ukraine, clinical guidelines development groups for primary expertise and consultation on clinical guidelines development under the auspices of the National Centre of Development and Monitoring of Standards of Medical Care Compliance should be composed:

- General Practice/Family Medicine;
- Internal Diseases;
- Infectious Diseases;
- Medical emergency conditions;
- Children diseases;
- Obstetrics and Gynecology;
- Surgical Diseases;
- Dentistry.

If it is necessary, in addition to the thematic groups permanent or temporary groups can be composed to ensure target clinical guidelines and/or clinical guidelines, which require an interdisciplinary approach (e.g. cardiovascular diseases, oncology, blindness, deafness, HIV infection, tuberculosis, etc.).

III stage — consideration and approval of clinical guidelines topics by the Ministry of Health of Ukraine. At this stage the National Centre of Development and Monitoring of Standards of Medical Care Compliance is responsible for:

1) Consideration of the applications recommended by thematic groups;
2) Approval of the type of work on clinical guidelines;
3) Approval of the composition of guideline development group, responsible institution (organization), plan, implementation schedule, and financing of activities.

While passing all stages, appointed clinical guidelines topics will be included to the National program of clinical guidelines development.

The working group should include representatives from all medical specialties — potential users of clinical guidelines, patients, and their representatives.

Each member of the working group before start of working must provide information about possible conflict of interests, both personal and group. Details on conflicting interests of any member of the group must be available at the request of representatives of the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine.

Ключові слова: TACIS, SIGN 50, клінічні настанови, медичні стандарти, клінічні протоколи, розробка, доказова медицина.

Уніфікована методика по розробці клінічних рекомендацій, медичних стандартів, уніфікованих клінічних протоколів медичної допомоги, локальних клінічних протоколів медичної допомоги (клінічних маршрутів пацієнтів) на принципах доказової медицини

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