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

Development centres:
State Institution «Ukrainian Institute of Strategic Studies» Ministry of Health of Ukraine
Public Enterprise «State Pharmacological Centre» Ministry of Health of Ukraine

Authors:

Reviewers:
V.M. Lyekhan, Y.S. Bereznytskyi

With the support of experts of the European Union project «Support to Secondary Healthcare Reform»:

G. Ross, E. Novichkova, M. Bews

Introduction
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 determinate 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 according to the same methodological principles. The main difference is that in adjustment, the step of search and data processing for clinical research, which is the most expensive in terms of finance and time, is missed.

In European countries, the methodology of development (adjustment) of clinical guidelines is unified.

Further implementation of clinical guidelines occurs at two levels: national and regional level. At each of these levels there are other than clinical guidelines medical and technological documents that are developed on the base of clinical guidelines. International experience shows that standards and protocols of health care are based on clinical guidelines, which is a source of evidence base and best medical practice. This is an important methodological principle for the development of medical and technological documents.

Development of health care standards largely depends on the policy of health care in particular country, its economic development, cultural and historical peculiarities.

Implementation of clinical guidelines at the national level involves development of medical care standards and unified clinical protocols of medical care. At the regional level — local protocol of medical care (clinical pathway).

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)** answer the question «How this should be done in a particular health care institution?».

Elaboration of these documents occurs in two ways:

2. **«Direct»** (reduced way without standards of medical care) clinical guidelines — unified clinical protocols of medical care — local protocols of medical care (clinical pathways).

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 (see Section 7).

• **«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».

### 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.

**Fig. 1**

<table>
<thead>
<tr>
<th>Standards of medical care</th>
<th>Unified clinical protocols of medical care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Local protocols of medical care (clinical pathways)</td>
<td>Clinical guidelines</td>
</tr>
</tbody>
</table>

**Table 1**

<table>
<thead>
<tr>
<th>Role and functions of each of these documents at the national and regional levels</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Research level</strong></td>
</tr>
<tr>
<td>Clinical guidelines and standards of medical care — national level, monitoring of the health care system activity</td>
</tr>
<tr>
<td>Clinical guidelines and unified clinical protocols of medical care — monitoring and clinical audit</td>
</tr>
</tbody>
</table>
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 changes 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 includes 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. This document can be integrated with local protocols of medical care.

Methodology of clinical guidelines development — is a complex of methodological, information and organizational measures, based on systematic consolidation of scientific evidence, which were obtained during the high quality clinical studies (especially randomized controlled trials).

Systematic review of clinical research data — is an effective scientific technology of detection and generalization of data on interventional. It allows evaluation of generalization and reliability of the results of clinical studies and identifying data, which are not consistent.

Medico-technological documents in health care
Clinical practice guidelines — is a document that contains systematized statements regarding medical care. It is developed by using the methodology of evidence-based medicine based on confirmation of their reliability and evidence. It aims to assist a physician and a patient in making considerable decisions in various clinical situations.

Standard of medical care — is a legal document of the national level, which determines rules, requirements and criteria of the organization and quality of medical care, as well as indicators, on which audit is performed at different levels of quality system ensuring management. It is developed on the basis of clinical guidelines, taking into account possibilities of health care system. It is approved by the Ministry of Health or by central executive authority of the health care system.

Unified clinical protocol of medical care — is a regulatory document of the national level. It is developed on the base of clinical guidelines, taking into account possibilities of health care system (in case of availability of standard of medical care, according to the standard). It determines provision of health care systematic, volume and results in a certain disease. It is approved by the Ministry of Health or by central executive authority of the health care system.

Local protocol of medical care (clinical pathway) — is a regulatory document of the regional level. It is aimed at ensuring continuous, efficient and economically rational medical care in specific diseases and other pathological conditions according to unified clinical protocol 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.

1. Ukrainian National Network of Clinical Guidelines Adjustment and Development of Standards of Medical Care

Ukrainian network of clinical guidelines adjustment and development of standards of medical care includes 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.

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 the medical 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.

Methodological and technical measures on adjustment and processing of clinical guidelines, development of standards of medical care, publication and dissemination of relevant documents is provided through budgetary allocations within budget of the Ukrainian Institute of Strategic Studies of the Ministry of Health of Ukraine. It may be funded through arrange financing from other sources not prohibited by law. Time that members of thematic working groups and involved experts spend on clinical guidelines adjustment and development of standards of medical care is not covered.

2. Key Stages of Clinical Guidelines Adjustment

2.1. General provision

Clinical guidelines are an information source, which accumulates the best (reference) data on medical care (prevention, diagnostics, treatment and rehabilitation), as well as psychological, social, and other relevant aspects concerning certain pathological processes, using evidence of interventions effectiveness according to gradation system. 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 analysis) standards of medical care are usually prohibited documents and have the status of consensus.

Elaboration of high-quality clinical guidelines (according to the principles of evidence-based medicine) requires significant financial and time resources. Adjustment of clinical guidelines, in contrast to their initial development, devoid of most laborious, long-term and expensive stage — conducting a systematic search, critical appraisal, data synthesis and systematic review of clinical research. Adjustment of clinical guidelines for Ukraine, like for other countries with limited resources, is a possibility to form a bank of clinical guidelines, according to the principles of evidence-based medicine, and thus providing the prerequisites for improving the quality of health care. Adjustment of clinical guidelines is a process of prototypes analysis in terms of their compliance to the national resource and regulatory base, the possibility of their realization in Ukraine, and financial security, used terms and medical specializations, the list of authorized in Ukraine medicaments and equipment, with further justification of the measures required for implementation of clinical guidelines with high level of evidence.

The process of adjustment, application, and revision of clinical guidelines has no linear sequence. It is submitted by interrelated and interdependent series of steps that are components of the process of implementing results of clinical research into practice, setting standards and monitoring of their implementation, progress in improving of clinical practice. (Fig. 2).

The average time, needed to elaborate documents (including adjusted clinical guidelines, standards of medical care, unified clinical protocols of medical care), does not exceed 1 year and consists of the following stages: composition of guideline development groups — up to 3 months, systematic review of clinical guidelines, developed by the world leaders of this direction, reasonable choice of prototype and clinical guidelines adjustment, development of standards of medical care and (or) unified clinical protocols of medical care — to 8 months, consultations and peer review — up to 3 months, publication — up to 2 months (Table 2).

An important condition of ensuring the actuality of clinical guidelines is a publicity of adjustment process, discussion of clinical guidelines at professional congresses and other forums, consultations and review by specialists. The internal review is provided by the National Centre of Development and Monitoring of Standards and Standards of Medical Care Compliance; external review should involve at least three independent experts.

2.2. Criteria for selecting clinical guidelines topics

The scarcity of health care system resources predetermines certain amount of
clinical guidelines, which simultaneously can be adjusted within the framework of the national standardization program. Clinical guidelines topics are determined primarily with regard to the importance of social and medical problems, possibility of improving clinical outcomes through the implementation of practice based on scientific evidence. Criteria for examination and justification choice of clinical guidelines topics for adjustment are divided into key and additional.

Key criteria
1) Importance of the problem for public health. The problem, proposed for solution by adjusting clinical guidelines, should belong to priority and meet the strategic objective of health care system.

2) The importance of the problems for health care. It should be clear formulation of health care problems, which can be solved by using adjusted clinical guidelines with obligatory tentative realization of a) the analysis of existing regulatory documents and its impact on medical practice; b) the assessment of state of the arts in that area and arrangements held to solve problems or lead to its aggravation.

3) Existence of high quality clinical guidelines and evidence on the problems. You must show the existence of clinical guidelines with the requirements of evidence-based medicine (as evidenced by using of the evidence scale), as well as literary sources, according to the principles of evidence-based medicine (systematic reviews, meta-analysis, publications of controlled clinical studies). There is a need of a preliminary search of developed clinical guidelines in the scientific literature and electronic databases, as well as assessing the quality of clinical guidelines by using questionnaire AGREE.

4) There is a need to unify approaches to solving problems. It should be determined the existence of the unified approach or differences of existing medical practice to assess of the existence of iatrogenic problems.

5) Potential possibility to achieve an effect of intervention. In detected during the preliminary search clinical guidelines (perhaps some scientific publications with high level of the evidence) there should be given the real ways for improving of medical practice in Ukraine (e.g., diagnostic methods of proven effectiveness, which significantly improve accuracy and reduce the period of examination, treatment methods, which have impact on the frequency of complications, lethality and mortality rate).

6) The need of these clinical guidelines development is supported by relevant granting organizations. Clinical guidelines adjustment may be carried out according to the order of the legal entity or individual, which defrays the expenses.

Additional criteria:
• Availability of clinical audit data for use during the topic development;
• High cost of medical technology (for example, as an argument in favor of clinical guidelines adjustment may be identification of the ways of reducing the cost of health care or its particular stages without loss of quality);
• Predictable increase of the role of the primary health care or other level of health care due to clinical guidelines adjustment.

2.3. The process of selecting clinical guidelines topics is integrated to the national health care system and medical science. It 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 (see Table. 3) 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. The National Centre of Development and Monitoring of Standards of Medical Care Compliance perform initial examination of applications for clinical guidelines adjustment. It includes assessing of their accordance to key and additional selection criteria, up-to-date scientific approaches and needs of the health care system. The National Centre of Development and Monitoring of Standards of Medical Care Compliance is responsible for ensuring the fundamental principles of the second stage of clinical guidelines topic selection: democracy, publicity, transparency of the application processing, displaying all stages of review and their results on public websites of the Ministry of Health of Ukraine and the National Centre of Development and Monitoring of Standards of Medical Care Compliance, providing applicants the possible
bility of alternative choice of thematic groups, ethics committees, public organizations and individual experts.

Expertise of applications is the most crucial stage in developing of clinical guidelines topics. It is directed at ensuring the high scientific value and social need of the clinical guidelines topics. Thus, the selection of topics is on a competitive basis.

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.). The expertise of the projects is provided by commissions of the Ministry of Health of Ukraine, the Ukrainian Academy of Medical Sciences, scientific councils of research institutions of the Ministry of Health, the Academy of Medical Sciences of Ukraine, and the main external experts of the Academy of Medical Sciences, professional medical and public organizations.

The objectives of the thematic groups are to consider the applications, covering public opinion at least of three independent experts and members of the group. In addition, groups have to make decisions through open vote. In case of approval of proposed clinical guidelines topic compliance to selection criteria by thematic group, an application is directed to the next stage.

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:
   - adjustment of clinical guidelines developed by international organizations or in other countries to the health care system;
   - review of existing national clinical guidelines;
   - update (partial review) of existing national clinical guidelines;
   - change the time restrictions (planned term of review or update);
   - recognition of clinical guidelines as obsolete and must be annulled.
3) Approval of the composition of guideline development group, responsible institution (organization), plan, implementation schedule, and financing of activities.

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

3. Functions of the Clinical Guideline Adjustment Group

3.1. Composition of clinical guideline adjustment groups

Up-to-date clinical guidelines are a multidisciplinary information product. For the purpose of full and rational use of clinical guidelines, to ensure effectiveness of clinical guidelines adjustment (or other type of work), and to continue it further development on their basis standards of medical care and unified clinical protocols of medical care, set up a working group at the National Centre of Development and Monitoring of Standards of Medical Care Compliance. It includes representatives of all interested professional and community organizations. Composition of the working group should be approved by the Order of the Ministry of Health of Ukraine.

The working group should include representatives from all medical specialties — potential users of clinical guidelines. Inclusion of representatives from different regions is obligatory. For possible participation in the working group, it should be provided consultation with the Ministry of Health of Ukraine, all interested professional medical organizations, leading research medical institutions, etc. Inclusion in the group of representatives of different specialties and geographical regions guarantees:

- availability of experts for all stages of medical care;
- identification and critical appraisal of scientific evidence on the subject;
- identification and consideration of the issues of practical application of clinical guidelines;
- consideration of possible range of views;

Among additional criteria for specialists, involvement is knowledge of all or some of the following skills:

- clinical expertise (e.g. medical, surgical, nursing, etc.);
- other specialist expertise (e.g. health economics, social services);
- practical understanding of the problems faced in delivery of care;
- critical appraisal of information. The number of group members can vary within 10–20 persons. It is required to find compromise between the ideal number of stakeholders, specialists, and optimal composition of the group that will ensure effective activity.

3.2. Participation of patients in the clinical guidelines adjustment

Involving patients in the process of clinical guidelines adjustment plays an important role, because their experience and perspectives on health care and its results are often significantly different from the views of health care professionals. In addition, patients significantly influence the possibility of implementation of certain provisions of the clinical guidelines.

Participation of patients or their representatives is as follows:

- being full members of the group;
- ensuring taking into account specific problems of patients in clinical guidelines adjustment;
- studying materials on the results for patients and make sure that they were considered in text;
- helping in identifying other patients, who may be invited to an open discussion and national meetings, or to participation in external review of the draft of clinical guidelines;
- helping in identifying issues that are relevant to patients and should be taken into account and placed in the clinical guidelines.

If patients’ issues will not be covered in clinical guidelines, this fact should be specially marked and explained.

3.3. Training for members of guideline adjustment group

All members of working group should be questionnaire to identify the level of knowledge of up-to-date methodology of evidence-based medicine and clinical guidelines adjustment before working. According to the results of survey of the working group members is suggested training. There are two levels of training — basic and advanced, developed to avoid unnecessary duplication for trained professionals.

List of suggested topics for training:

1. Introduction to the evidence-based medicine: interrelation between evidence and clinical practice.
2. Formulating of clinical questions and development of search strategy.
3. Critical reading skills.
5. Systematic reviews and interpretation of their results.
7. Planning of approbation in the pilot regions.

3.4. Statement on competing interest

Each member of the working group before start of working must provide information about the 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.

3.5. Contents of the overall protocol of the working group activity

In order to ensure publicity and transparency of the development, adjustment, and review of clinical guidelines, activity of the working group should be carefully documented. All meetings, discussions, official correspondence of the group members re-
Regarding the text of clinical guidelines, work with information sources, assessment, additional materials, evidence, educational seminars, and trainings should be displayed in the protocol of the working group. This document is composed while events are in process. When clinical guidelines will be completed, general protocol of the working group activity serves as an appendix to the report on finance using and stored in the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine.

4. Working with Information Sources

4.1. Search and selection of data

Search of clinical guidelines for adjustment is conducted among databases (libraries), including existing national clinical guidelines and regulatory documents (guidelines on the best clinical practice and standards of medical care), as well as clinical guidelines and standards of medical care international electronic databases. Clinical guidelines, which are in such bases, as SIGN, NICE, NZGG, GIN, AHRQ, and some others, based on systematic reviews and meta-analysis of clinical research results and related evidence (Table 4).

Search in the Internet is performed by search engines of the first and second generation: Alta Vista (http://www.altavista.com), Google, Yahoo, Bing, etc.; and also by engines of the first and second generation: Alta Vista (http://www.altavista.com), Google, Yahoo, Bing, etc.; and also by agents: Lycos, Excite, Golisano, etc. Search in the Internet is conducted among databases (libraries), including existing national clinical guidelines and regulatory documents (guidelines on the best clinical practice and standards of medical care), as well as clinical guidelines and standards of medical care international electronic databases. Clinical guidelines, which are in such bases, as SIGN, NICE, NZGG, GIN, AHRQ, and some others, based on systematic reviews and meta-analysis of clinical research results and related evidence (Table 4).

Table 4

<table>
<thead>
<tr>
<th>Country and resource name</th>
<th>Internet address</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>United States of America</strong></td>
<td></td>
</tr>
<tr>
<td>Centers for Disease Control and Prevention (CDC)</td>
<td><a href="http://www.cdc.gov">http://www.cdc.gov</a></td>
</tr>
<tr>
<td>Agency for Healthcare Research and Quality (AHRQ)</td>
<td><a href="http://www.ahrq.gov/clinic/cpgsia.htm">http://www.ahrq.gov/clinic/cpgsia.htm</a></td>
</tr>
<tr>
<td>Health Services/Technology Assessment Text (HSTAT) and National Library of Medicine (NLM)</td>
<td><a href="http://www.ncbi.nlm.nih.gov/books/bv.fcgi?id=hstat">http://www.ncbi.nlm.nih.gov/books/bv.fcgi?id=hstat</a></td>
</tr>
<tr>
<td>AMA (American Medical Association)</td>
<td><a href="http://www.ama-assn.org">http://www.ama-assn.org</a></td>
</tr>
<tr>
<td>American Society of Health System Pharmacists (ASHP)</td>
<td><a href="http://www.ashp.org/s_ashp/index.asp">http://www.ashp.org/s_ashp/index.asp</a></td>
</tr>
<tr>
<td>Institute for Clinical Systems Improvement (ICSI)</td>
<td><a href="http://www.icisi.org">http://www.icisi.org</a></td>
</tr>
<tr>
<td>Primary Care Clinical Practice Guidelines</td>
<td><a href="http://medicine.ucsf.edu/education/resed/etm/practice_guidelines.html">http://medicine.ucsf.edu/education/resed/etm/practice_guidelines.html</a></td>
</tr>
<tr>
<td>American College of Physicians (ACP)</td>
<td><a href="http://www.acponline.org">http://www.acponline.org</a></td>
</tr>
<tr>
<td>National Institutes of Health (NIH)</td>
<td><a href="http://www.nih.gov">http://www.nih.gov</a></td>
</tr>
<tr>
<td><strong>Canada</strong></td>
<td></td>
</tr>
<tr>
<td>Canadian Medical Association InfoBase (CMA InfoBase: Clinical Practice Guidelines (CPGs))</td>
<td><a href="http://www.cma.ca/index.cfm/ci_id/54316/la_id/1.htm">http://www.cma.ca/index.cfm/ci_id/54316/la_id/1.htm</a></td>
</tr>
<tr>
<td>Canada Task Force on Preventive Health Care (CTFPHC)</td>
<td><a href="http://ctfphc.org/guide.htm">http://ctfphc.org/guide.htm</a></td>
</tr>
<tr>
<td>Medical Services Plan of British Columbia / Guidelines &amp; Protocols</td>
<td><a href="http://www.health.gov.bc.ca/gpac">http://www.health.gov.bc.ca/gpac</a></td>
</tr>
<tr>
<td>Health Information Research Unit (HIRU) / McMaster University</td>
<td><a href="http://hiru.mcmaster.ca/hru">http://hiru.mcmaster.ca/hru</a></td>
</tr>
<tr>
<td><strong>Great Britain</strong></td>
<td></td>
</tr>
<tr>
<td>National Institute for Health and Clinical Excellence (NICE)</td>
<td><a href="http://www.nice.org.uk">http://www.nice.org.uk</a></td>
</tr>
<tr>
<td>NHS Quality Improvement Scotland</td>
<td><a href="http://www.nhshealthquality.org/nhsqg/CCF_FirstPage.jsp">http://www.nhshealthquality.org/nhsqg/CCF_FirstPage.jsp</a></td>
</tr>
<tr>
<td>National Library of Guidelines Specialist Library (NLH)</td>
<td><a href="http://www.library.nhs.uk/guidelinesfinder">http://www.library.nhs.uk/guidelinesfinder</a></td>
</tr>
<tr>
<td>PRODIGY Knowledge</td>
<td><a href="http://www.prodigy.nhs.uk/home">http://www.prodigy.nhs.uk/home</a></td>
</tr>
<tr>
<td>Scottish Intercollegiate Guidelines Network (SIGN)</td>
<td><a href="http://www.sign.ac.uk">http://www.sign.ac.uk</a></td>
</tr>
<tr>
<td>Core Library for Evidence Based Practice</td>
<td><a href="http://www.shf.ac.uk/scharr/ir/core.html">http://www.shf.ac.uk/scharr/ir/core.html</a></td>
</tr>
<tr>
<td>Royal College of Physicians (RCP)</td>
<td><a href="http://www.rcplondon.ac.uk">http://www.rcplondon.ac.uk</a></td>
</tr>
<tr>
<td>TRIP Database</td>
<td><a href="http://www.tripdatabase.com/index.html">http://www.tripdatabase.com/index.html</a></td>
</tr>
<tr>
<td>Bandolier</td>
<td><a href="http://www.medicine.ox.ac.uk/bandolier/">http://www.medicine.ox.ac.uk/bandolier/</a></td>
</tr>
<tr>
<td><strong>Germany</strong></td>
<td></td>
</tr>
<tr>
<td>Leitlinien.de/German Guideline Information Service (GERGIS)</td>
<td><a href="http://leitlinien.de/english/english/view">http://leitlinien.de/english/english/view</a></td>
</tr>
<tr>
<td>Evidence Based Medicine Resource Centre</td>
<td><a href="http://ebmmy.org/cpg.html">http://ebmmy.org/cpg.html</a></td>
</tr>
<tr>
<td>Australian National Health and Medical Research Council (NHMRC)</td>
<td><a href="http://www.nhmrc.gov.au/guidelines/health_guidelines.htm">http://www.nhmrc.gov.au/guidelines/health_guidelines.htm</a></td>
</tr>
<tr>
<td>Monash University/Medicine, Nursing and Health Sciences/Centre for Clinical Effectiveness</td>
<td><a href="http://mhnrs.monash.org/cee">http://mhnrs.monash.org/cee</a></td>
</tr>
<tr>
<td><strong>New Zealand</strong></td>
<td></td>
</tr>
<tr>
<td>New Zealand Guidelines Group (NZGG)</td>
<td><a href="http://nzgg.org.nz">http://nzgg.org.nz</a></td>
</tr>
<tr>
<td><strong>Russia</strong></td>
<td></td>
</tr>
<tr>
<td>Межрегиональное общество специалистов доказательной медицины (ОСДМ) / Russian society of Evidence-based medicine specialists (OSDM)</td>
<td><a href="http://osdm.org">http://osdm.org</a></td>
</tr>
</tbody>
</table>

**International databases of clinical guidelines**

- The Cochrane Collaboration: http://www.cochrane.org/resources/training.htm
- The Cochrane Library: http://www.thecochranelibrary.com
- International Network of Agencies for Health Technology Assessment (INAHTA): http://www.inahta.org
- Health Evidence Network (HEN), World Health Organization (WHO): http://www.euro.who.int/hen
- WebMD: http://www.webmd.com
- eMedicine from WebMD: http://emedicine.com
- Medscape from WebMD: http://www.medscape.com
- The heart.org from WebMD: http://www.theheart.org
- MedicalMatrix: http://medmatrix.org/rex/login.asp
- ScHARR Netting the Evidence: http://www.shef.ac.uk/scharr/ir/netting
- The Community Research and Development Information Service (CORDIS): http://cordis.europa.eu/guidance
- Global Index Medicus WHO: http://www.who.int/gho/medicus/en
- Index Medicus – abbreviations of journals titles: http://www2.bg.am.poznan.pl/czasopisma/medicus.php?lang=eng
- The Community Research and Development Information Service (CORDIS): http://cordis.europa.eu/guidance
- Global Index Medicus WHO: http://www.who.int/gho/medicus/en
- Index Medicus – abbreviations of journals titles: http://www2.bg.am.poznan.pl/czasopisma/medicus.php?lang=eng

Clear definition of the target population, identification of current interventions (diagnostic, therapeutic, etc.), criteria of clinical outcomes evaluation, and types of applicable control is achieved through distribution of specific problems on a number of key clinical issues. These questions are the basis for search criteria for inclusion/exclusion of the information materials. Manual search is possible, but it requires large expenditures, significant efforts, and characterized by low efficiency, since there is apparently a systematic error of data selection. In some cases, manual search is required (e.g. Index Medicus).

Search is performed by using several bases to minimize systematic errors and to ensure adequate coverage of the literature on the topic, including general and specific to certain key issues databases. Period of search depends on the nature of key issues and needs discussion in the working group.

Member of the working group, who searched, provides primary screening of the search results. At this stage are removed the documents that do not clearly relate to the key issues. Summaries of the remained documents should be analyzed in terms of their design studies and other specific methodological criteria. In case of doubt about compliance with methodology, reliability and uniqueness results, the documents should also be excluded.

At least two members of the working group perform secondary screening of the documents. Their authority includes exclusion of materials that are not meeting the criteria of inclusion/exclusion, designed before search. In this case, all stages of the search results testing will be fully completed and remained documents should be involved in the preparation of clinical guidelines (Table 5).

4.2. Data evaluation
Selected clinical guidelines are assessed according to the international questionnaire AGREE (Appraisal of Guidelines Research and Evaluation). By means of this tool unified analysis and evaluation of clinical guidelines, complex quality assessment of clinical guidelines considering their development methodology, clinical content and factors associated with implementation are provided.

Key requirements for clinical guidelines formulated in AGREE:
• openness and transparency of the development process;
• accommodation of interests (and opportunities) of consumers and providers of medical services;
• compliance of recommended technologies, diagnostic and preventive methods with up-to-date state of medical science;
• objectivity and reliability of data;
• choice of the most effective cost for realization of medical technologies.

The main purpose of the AGREE questionnaire is to justify decisions on applicability of the clinical guidelines in medical practice. By using AGREE, guideline development group can:
• ensure that considered in clinical guidelines issues meet unified standards of quality;
• systematically focus attention on methodology issues and content of clinical guidelines;
• putting marks during the assessment divergence of opinions of experts, need of further discussion of interpretation and formulation of clinical guidelines, should be identified;
• systematize and document the process of clinical guidelines adjustment.

In order to minimize the possibility of systematic errors associated with varying degrees of subjective evaluation of the methodological quality of each document, which was included in the final analysis, at least two members of the working group should rate it. Any differences of assessment should be discussed in the group. In order to obtain additional criteria of clinical guidelines quality, experts, who were not members of development group, should review particular parts of clinical guidelines. Conclusions should be also compared.

5. Wording of Final Clinical Guidelines
5.1. Data generalization
Results of research, processing and selection of information materials are presented in generalized tabulated form. This table shows all selected clinical guidelines and additional publications of clinical studies results, found through systematic literature review on each key issue (extension of Table 5). Formed tables of data generalization are an important part of documenting process of clinical guidelines adjustment, as they identify transparency of the origin and justification of clinical guidelines.

5.2. Evidence statements and grades of recommendations
Determining of evidence gradation of some statements of clinical guidelines (in case of its absence in prototype and if appropriate) should be implemented with the participation of all members of the working group under the data of Table. 6. If the working group does not reach consensus, differences of opinion of members of the working group and their reasons should be reflected.

In case of absence of evidence on some important clinical questions concerning obvious aspects of health care, that could not be contested, but require coverage in clinical guidelines, the following statements should be icon as «Recommended best practice of clinical experience developers of clinical guidelines». Similar statements are not alternative to clinical guidelines based on evidence and may be used only in case of extreme need.

5.3. Considered judgment
Improving of transparency in the development process of full text of clinical guidelines by using so-called «considered judgment».
i.e., disclosure of the views of working group members concerning evidence for each key issue, as listed in clinical guidelines, selected as prototype, and as in selected additional information materials. «Considered judgment» should reflect the following aspects:

• Methodological quality of adjusted clinical guidelines evaluated according to the questionnaire AGREE;

• Applicability of the clinical guidelines to the target population;

• Clinical impact (i.e., expected effects on the target population and resources that are necessary to ensure a particular intervention).

In assessing, the applicability of clinical guidelines to the conditions of Ukraine it should be taken into account:

• Peculiarities of the population. Working group should determine, whether there are biological mechanisms that under the conditions of Ukraine could affect on effectiveness of diagnostic tests and treatment in another way, than it was in the study population, which proof, that included in clinical guidelines evidence was selected for prototype. For example, in Ukrainian population there may be different basic level of risk, sex, age or ethnic structure.

• Peculiarities of health care. When considering foreign clinical guidelines, the financial, material, and technical condition of health care system, qualification of personnel and availability of medical technologies and medicines should be taken into account.

• Peculiarities of culture and mentality. In some situations cultural peculiarities could be a barrier for adjustment and implementation of foreign clinical guidelines. For example, obligatory provision of information of patient about his diagnosis in pessimistic prognosis, or researching sexual behavior. «Considered judgment» should be processed as separate document. The most important statements could be presented as «Comments of working group» in the text of clinical guidelines.

5.4. Requirements for the content of clinical guidelines

All clinical guidelines developed by the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine must contain introduction, which explains necessity of development of clinical guidelines, standards of medical care, and unified clinical protocols of medical care, defines the scope of their use, including the target group of patients, physicians, other medical personnel, and also scheduled update period.

The final structure of clinical guidelines should meet content of the general protocol of the working group and include:

1) clear and precise wording of clinical guidelines topics (clinical issues) based on analysis of the problem;

2) brief description of available options of health care and wording of key clinical issues, description of search, systematic review and analysis of found clinical guidelines with assessment of their methodological quality according to AGREE (see subsection 4.2);

3) summary of conclusions obtained as a result of critical evaluation of data («table of generalization» with comments on the level of evidence and links), discussion of effective methods of health care, effectiveness of which are not confirmed by evidence (the latter should be clearly stated and presented as an «expert opinion on effective methods of health care » and justify the inclusion of statements marked as «Recommended best practice of clinical experience of developers of clinical guidelines») (see subsections 5.1, 5.2);

4) text of clinical guidelines, adjusted by the working group with the addition of information and obligatory indication of the evidence level;

5) brief description of important practical aspects (e.g., for the successful implementation of clinical guidelines in a particular region it is necessary to take into account physical or geographical conditions) (see subsection 5.3);

6) text of clinical guidelines for patients developed in form that is accessible, clear and useful for self-use form. It should be written in a simple non-medical language. It should explain general aspects of health care and prevention of diseases and/or conditions.

5.5. Summary and key recommendations

Summary of clinical guidelines includes laconic information on key recommendations, preferably in a form of algorithms. Summary should be published as a part of clinical guidelines and as a leaflet; abstracts—algorithms very popular among practicing physicians. It should be noted, that the key recommendations are not considered those that have the highest level of the evidence, but those that from point of view of working group may make a major impact on important clinical results.

5.6. Documenting the process of clinical guidelines adjustment

At the final stage of the development/adjustment (or other works) of clinical guidelines working group should include to the general protocol set of documents, namely:

1. The Order of Ukraine on establishing of the working group;

2. The Declaration of Competing Interests;

3. Table of generalized data (if generalization was made);

4. «Considered judgment» of the working group;

5. Text of clinical guidelines with comments of the working group;
6. Minutes of proceedings and other meetings of the working group, which influenced on the final wording of clinical guidelines (see subsection 3.5).

6. Dissemination of Clinical Guidelines

Full text of clinical guidelines should be disseminated, as well as detached abstracts.

As part of common information space, the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine distributes clinical guidelines in printed form, free of charge in public and communal institutions of the health care system through the Departments of Health Care of regional public administrations.

The electronic version of clinical guidelines placed free access on the website of the Ministry of Health of Ukraine and subordinate institutions.

Full information on the clinical guidelines (see subsection 5.4) should be available on the website the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine.

7. Development of Standards of Medical Care

The Ministry of Health of Ukraine regulates and determines the number and topics to establish standards of medical care.

It should be noted that the number of standards of medical care is usually limited. It is determined by the Ministry of Health of Ukraine according to diseases and other medical conditions that affect large population groups, cause considerable social and economic losses and social tension.

Standard of medical care is a basis of accreditation of health care institutions and administrative control, as it contains quality criteria and indicators. Thereby, they should be developed for providing of health care through national and sectoral programs of the most important areas (cardiology, oncology), and for the primary and/or secondary levels of health care, taking into account national peculiarities of health care, traditions of clinical practice and the economic situation in the country.

Each standard of medical care should be supported by system of automated monitoring of health care, taking into account the criteria of health care and indicators of quality approved by the standard of medical care.

After development of draft of clinical guidelines, while discussing and reviewing, working group proceed to the formulation of statements of standards of medical care (see Table. 2). Standards of medical care (regulation of practice) are developed on the base of adjusted clinical guidelines (reference practice, supported by scientific evidence). Adjustment of clinical guidelines and development of standards of medical care project is realized by one working group that determines necessary properties of standards of medical care, namely: scientific validity, practicability, integrity of set of criteria and indicators of quality of health care.

Differences between reference standard and real practice in terms of the Ukrainian health care system determine existence of two levels of quality criteria of standards of medical care: obligatory level that should be achieved, and desirable level — can not be achieved, because of objective reasons, but achievement of this level are designed, as it will ensure improvement of quality of health care.

Structure of standards of medical care: A. General
- Diagnosis
- Code according to the ICD (The International Classification of Diseases)
- Developers (surname, name and patronymic, academic rank, position, place of work, institution/organization)
- Referees (surname, name and patronymic, scientific degree, academic rank, position, place of work, institution/organization)
- Date of update

B. The standard of medical care

Sections «Provisions of standards of medical care», presented in the table are obligatory (section 4 is not developed in the case of outpatient care), they can be detailed by subsections.

Justice «of standards of medical care provisions» formulates laconically according to the text of clinical guidelines: justification of each section of standards of medical care should reflect statements of adjusted clinical guidelines, developed according to the principles of evidence-based medicine.

In the column «Criteria of quality of health care» should be indicated criteria of minimal level of medical care, below which it can not be provided and desirable (to determine the direction of improving of quality of medical care).

The criteria are numbered for ease of work and evaluation. Numbering of criteria is not the evidence of their priority. Priority is defined as obligatory in contrast to desirable criteria.

C. Indicators of quality of medical care

Monitoring of implementation/compliance with standards is provided by using quality indicators, developed according to the special technique based on the principles of the evidence-based medicine and reflect quality of medical care that meet the criteria specified in standards of medical care. In this context, indicator is an element that can be measured, and which enable evaluation of health care quality level. It should be noted, that indicators used to assess compliance with standards of medical care should include structure, process, and results in health care system.

Ensuring of effective and adequate monitoring of compliance with standards of medical care requires implementation of information technology based on registration of health care according to medical records.

D. Literature
- Primary source — adjusted clinical guidelines, which were selected for the prototype
- Other scientific literature used in the development of clinical guidelines, including electronic documents
- Existing regulatory documents on the issue, devoted to clinical guidelines.

The main condition for the working group is development of standards of medical care that can be achieved (this level should be provided by obligatory criteria). However, they can be completed by using desired criteria

8. Consultation and Review

8.1. Review
All intermediate versions of clinical guidelines and standards of medical care are reviewed by independent reviewers (who do not belong to the working group). In the review the following aspects should be observed: completeness, accuracy and precision of interpretation of clinical guidelines, and quality criteria of health care offered to standards of medical care at the national level.

Reviews are discussed at the special meeting of the working group. The discussion should be published.

8.2. National Open Meeting
Guarantee of effectiveness increasing in standardization of health care is public proceedings of clinical guidelines formulation and openness of scientific bases of standards of medical care. In this regard, the National Open Meeting of intermediate versions of clinical guidelines and standards of medical care for each set of documents conducted. The electronic version of standards of medical care submitted for review and approval to the Ministry of Health of Ukraine is available for discussion on the websites of the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine, the Ministry of Health, and certain subordinate institutions within 1 month. Publishing of run-time versions of clinical guidelines and standards of medical care in mass media is also allowed.

During the National Open Meeting of intermediate versions of clinical guidelines and standards of medical care, physicians, general practitioners, specialists and other medical professionals speak about precision, understandability, benefits, and possibilities of implementation of clinical guidelines and standards of medical care at the primary and secondary levels of health care.

Comments and suggestions of all participants of the evaluation process are accepted in writing by e-mail, by post, and by fax. They should be grouped and thoroughly discussed at a special meeting of the working group on adjustment of clinical guidelines and
standards of medical care. Each proposal must be reviewed, considering changes that were made in clinical guidelines according to the discussion, or reasons, why making corrections were denied.

8.3. Approval of the final version
After the National Open Meeting and making appropriate corrections and clarifications, each member of the working group officially certifies their agreement to publish the final version of clinical guidelines and approval of project of standards of medical care.

9. Approval (Pilot Testing) and Further Implementation of Standards of Medical Care
9.1. Strategic approaches to testing
Clinical guidelines, standards of medical care, and unified local protocols of medical care developed on the principles of the evidence-based medicine, help «build bridges» between scientific research and clinical practice. Extremely important is election of the right strategy for their implementation in practice of public health. The basic principles of testing are:
1. Support by developers and clear management of process (leadership);
2. Provide reminders and training;
3. Support by multidisciplinary team;
4. Systematic approach to financial planning;
5. Systematic approach to the validation process;
The approval of standards of medical care provides not less than in 3 regions. Number of pilot «sites» for implementation in regions involved in testing, certain health care institutions, general/family practice, etc. is determined depending on the topic of clinical guidelines and standards of medical care to ensure statistically significant number of cases of health care, indicators of quality and indicators of compliance with standards of medical care.
The Ministry of Health of Ukraine provides conditions for motivation of regions to participate in programs of the pilot testing of standards of medical care, their interest in implementation of health care strategies with proven effectiveness and development of multidisciplinary approaches to management of patients.
Responsibility for the accuracy of the results of testing of standards of medical care relies on the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine, as well as on the regional, municipal, district health administrations, heads of health care institutions. At the local level, commissions for pilot testing of standards of medical care are created. They include head specialists, heads of health care institutions or their deputies, employees of «Health» centers. The main task of the commissions is organization, training and awareness among medical professionals and patients, audit and evaluation of clinical effectiveness of testing results.
Planning of approbation start from the beginning of clinical guidelines topics development (see Table 2). Preparation of approbation needs:

1. Composition of team for the pilot testing;
2. Open discussion of the clinical guidelines and project of standards of medical care at the local level;
3. Identification of possible obstacles of the pilot testing;
4. Identifying pilot «sites of implementation»;
5. Cascade training for participants of the pilot testing team;
6. Development of local documents to support implementation of standards of medical care and unified clinical protocols of medical care, namely: local protocols of medical care-clinical pathways, algorithms, etc.;
7. Solution of organizational issues concerning data collection for analysis of the testing results (publication of relevant orders on management of health care and health care institutions);
8. Implementation of special forms for accounting information of the pilot testing;
9. Solution of issues concerning staff and logistics of collecting and processing data for analysis of the testing results (to ensure the pilot «sites» office equipment and related information technology).

It should be emphasized that guidelines drawn up with regard on accurately studied and sensible experience of approbation in Ukraine (health care institutions in Kharkiv, Poltava and Zhytomyr regions), international experience of development of clinical guidelines and standards of medical care according to the principles of the evidence-based medicine. Note, that examples of approbation indicate presence of external and internal barriers to the implementation of standards of medical care with evidence base. Among external barriers, there are lack of necessary medical resources (equipment, chemical reagent), financial constraints, and lack of legal support to the process of implementation. Internal barriers include «controlled» reasons: existing defects in the organization of health care, insufficient training of medical personnel, medical staff’s conservatism, which often do not want change the habitual tactic of patients management; polypragmasy (available and common form of physicians «protection» from patient complaints). These reasons usually determine the lion’s share of nonfulfillment of standards of medical care.

9.2. Practical steps
Pilot testing of standards of medical care based on clinical guidelines should be systematic:
Step 6: to evaluate the process through audit and give feedback to team of pilot testing.
The implementation of this mechanism provides the necessary documentary support to pilot testing:
• Order of the Ministry of Health of Ukraine, which determines purpose of pilot testing, pilot regions and regulates start of approbation stating the date;
• Order of the regional health care administration, which determines specific health care institutions, their tasks, functions and interactions during the pilot testing;
• Orders of particular health care institutions that regulate composition and activity of multidisciplinary teams of implementation during the pilot testing stating the date;
• Clinical guidelines + standards of medical care + indicators of quality unified clinical protocols of medical care;
• Local documents (local protocols of medical care-clinical pathways, algorithms, etc.);
• Clear distribution of duties between all team members;
• Recording of cases, data collection;
• Protocol of the pilot testing and report forms.
Recommended composition of team of pilot testing:
• Registrars,
• Physicians of various specialties,
• Nurses,
• Medical attendants,
• Representatives of administration of health care institution,
• Representative of the regional health care administration,
• Technical staff.
Recommended training topics to support process of the pilot testing:
• Planning and plan of evaluation of the pilot testing in the region;
• Evaluation of the possible obstacles of approbation and to overcome them;
• Evaluation of region specifics and its taking into account for plan on realization of further implementation of standards of medical care based on clinical guidelines after pilot testing;
• Evaluation of methods and strategies of implementation and their possible realization at the local level.
9.3. Report on the pilot testing
The pilot testing of compliance of standards of medical care is provided to confirm their applicability in real conditions of the health care system, determine reasons of their failure, further measures for correction (if necessary) and implementation.
The pilot testing protocol should include relevant documents (see subsections 9.1, 9.2) and results of compliance and deviations of standards of medical care:
1. Description of patient population (sex and age structure, domiciliary, diagnosis, social position, preferential status);
2. Coverage of patients by medical technologies that are regulated by standards of medical care and unified clinical protocols of medical care;
3. Results of analysis of used medical services identified in standards of medical care and unified clinical protocols of medical care at the level of region, institution, particular physician;

4. Analysis of the applicability criteria and quality indicators;

5. Number of deviations from management of unified clinical protocols of medical care;

6. List of deviations from unified clinical protocols of medical care and level of care, at which took place deviation;

7. List of the deviations reasons from unified clinical protocols of medical care;

8. Identifying causes of failure of standards of medical care.

Thus, according to the results of the pilot testing of standards of medical care, which was carried out as part of the TACIS project «Support to the development of standards of medical care». The following causes of failure of standards of medical care:

- Patient disclaimer because of high cost;
- Patient disclaimer because of service remoteness;
- Other factors of patient disclaimer;
- Individual intolerance to medication;
- Late patient referral;
- Lack of timely access to services;
- Lack of service in health care institution;
- Lack of necessary expendable materials in health care institution;
- Failure of patient transportation;
- Subjective opinion of physician on irrationality compliance with standards of medical care;
- Other organizational obstacles of access to services;
- Lack of consultant with needed specialization.

9. List of issues that arose during testing (organizational, conflict situations related to information support, etc.).

10. Conclusion on the possibility of adjustment and recommendations for further implementation of standards of medical care with list of quality indicators for the audit.

9.4. Monitoring of the pilot testing

Monitoring of the pilot testing of standards of medical care at the state level is provided by the National Centre of Development and Monitoring of Standards of Medical Care Compliance Ministry of Health of Ukraine, at the regional level — health administration (through commission of the pilot testing).

9.5. Implementation of standards of medical care

According to the results of the pilot testing, the Ministry of Health of Ukraine decides on the approval and implementation of standards of medical care at the state level. If case of positive decision, should be issued Order of the Ministry of Health of Ukraine, according to which standard of medical care become regulatory document mandatory to implement in health care institutions, regardless of departmental subordination and ownership.

9.6. Unified clinical protocols of medical care, local protocols of medical care (clinical pathways)

Number of unified clinical protocols of medical care should meet requirements of medical practice. Local protocols of medical care should meet requirements of health care institutions. In this regard, the number of unified clinical protocols of medical care, local protocols of medical care are determined by needs of improvement, and streamlining of health care in health care institutions, and in contrast to the limited number of standards of medical care may be numerous.

Methodological principles of unified clinical protocols of medical care and local protocols of medical care (clinical pathways) will be presented in the second part of a unified methodology.

10. Audit of Compliance with Standards of Medical Care and Update of Evidence Base

10.1. Audit of clinical guidelines and standards of medical care

Dissemination of clinical guidelines, implementation of standards of medical care and their impact on the quality of health care is followed up and evaluated through audit. Audit of standards of medical care compliance provides data collection on structure, process and outcomes of health care for their improvement, and accreditation of services and health care institutions. Audit is directly related to evaluation of provided health care according to the criteria presented in standards of medical care. Compliance of health care quality is measured by quality indicators, which are quantitative «signs» of health care.

The working group defines key points of the audit as quality indicators during development/adjustment of clinical guidelines and development on their basis standards of medical care. During the pilot testing a final list of indicators, specific to the standard of medical care should be composed. These indicators represent a minimum set of data according to the national standards of medical care.

List of data, that is collected routinely, is formed with the participation of information units, including the Centre of Medical Statistics of the Ministry of Health of Ukraine. In addition, selective fundamental audit of compliance with standards of medical care at the local level is carried out. State and local authorities, health authorities of various levels, administration of health care institutions make decision on the audit in health care. Main stages of the audit:


2. Choice (development) of documentation forms (and if necessary — information technology) for receiving and processing data.

3. Training of personnel, activities on control of data quality that should be collected and analyzed.

4. Collection and analysis of data, using procedures of standardization.

5. Providing data to stakeholders.

6. The analysis results and planning of activities to improve quality.

7. Reaudit.

10.2. Monitoring of regulatory documents in the standardization of health care

Alongside with audit effective form of assessment of adequacy and relevance of clinical guidelines, standards of medical care, and unified clinical protocols of medical care is current monitoring in the form of passive collection of opinions and active polls of physicians, medical staff, and patients regarding clinical guidelines, standards of medical care, and unified clinical protocols of medical care. All received comments concerning published clinical guidelines, approved standards of medical care or information on important new evidence in this field should be sent to working group on adjustment of clinical guidelines for urgent response or considering it during planned processing of clinical guidelines.

10.3. Updating/revision of regulations in the standardization of medical care

All clinical guidelines, standards of medical care, and unified clinical protocols of medical care should contain information regarding scheduled date of the update or complete revision. Clinical guidelines contribute to their improvement according to new evidence that emerged later, and exclusion of outdated information. Improving of clinical guidelines, standards of medical care, and unified clinical protocols of medical care is determined their relevance and compliance with task of improvement of health care quality.

Information on clinical guidelines scheduled for review, should be posted on the website of the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine. Original scheduled update/revision do not envisage mandatory compliance. Clinical guidelines could be revised earlier in case of significant change of evidence, or postpone review in case of absence of such changes. The National Centre of Development takes decisions regarding need of extraordinary update/revision and Monitoring of Standards of Medical Care Compliance Ministry of Health of Ukraine based on interrogation of specialists.

Any updates and additions to clinical guidelines, up-to-date in interim period before release of new planned version of clinical guidelines, should be published on the website of the National Centre of Development and Monitoring of Standards of Medical Care Compliance of the Ministry of Health of Ukraine.

Standards of medical care are reviewed and updated according to decision of the Ministry of Health of Ukraine, which issued by relevant order.

Literature


10. NHS, Lincolnshire Care Pathway Partnership.

Mailing address: Alla V. Stepanenko of. 205; 40, Ushinskyi St., 03151, Kyiv, Ukraine
E-mail: clin_trial@ukr.net
Olena M. Lischyshyna
40, Ushinskyi St., 03151, Kyiv, Ukraine
State Pharmacological Centre of the Ministry of Health of Ukraine, Medical Service Standardization Board
http://www.pharma-center.kiev.ua
E-mail: omlpharm@gmail.com; public@pharma-center.kiev.ua