In 2011, the UNFPA Regional Office for Eastern Europe and Central Asia (EECARO) has started a regional initiative on standardization and institutionalization of quality national clinical guidelines in sexual and reproductive health (SRH), in order to address gaps in quality of care existing in the countries of the region.

The initiative is developed in close collaboration with the WHO Regional Office for Europe and implemented in partnership with the Royal College of Obstetricians and Gynaecologists (RCOG) in the UK and the East European Institute for Reproductive Health (EEIRH) in Romania.

Within the framework of the regional initiative, this survey was conducted in 2012 to provide a better understanding of the situation of sexual and reproductive health clinical guidelines in the countries of the region. This survey was coordinated and managed by the East European Institute for Reproductive Health with funding from UNFPA.

This survey was completed by a UNFPA Country Office staff member with the best available information after consultation with key stakeholders in the area of SRH clinical guidelines and clinical audit. 16 of the 20 Country Offices belonging to the UNFPA Regional Office for Eastern Europe and Central Asia responded.

The results of this survey will serve as a basis to support the regional initiative, including a programme guidance document and a regional training course on the methodology of adaptation/development and implementation of clinical guidelines.

To date, 190 guidelines have been published in the area of sexual and reproductive health, the majority of which (114) were in the last three years and covered mostly the area of antenatal, perinatal, postpartum and newborn care (73). Other topics included prevention and management of HIV and AIDS, contraception/family planning, prevention and management of STIs, safe abortion, early diagnosis and management of cervical cancer, prevention and management of gender-based violence (GBV) and early diagnosis and management of breast cancer.

<table>
<thead>
<tr>
<th>Number of clinical guidelines published in the last 3 years by areas of sexual and reproductive health</th>
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<tbody>
<tr>
<td>Antenatal, perinatal, postpartum, newborn care</td>
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<tr>
<td>HIV and AIDS prevention and management</td>
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<tr>
<td>STIs prevention and management</td>
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<tr>
<td>Contraception/family planning</td>
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<tr>
<td>Safe abortion</td>
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<tr>
<td>GBV prevention and management</td>
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<tr>
<td>Cervical cancer early diagnosis and management</td>
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<td>Breast cancer early diagnosis and management</td>
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It was estimated that only 57% of the developed SRH guidelines include levels of evidence, 56% include graded recommendations linked to evidence and 46% show an explicit link between recommendations and supporting evidence.
Terminology and Definitions

The terminology used in the area of clinical guidelines is not well defined. The terms used may have different interpretations with respect to their degree of rigidity or legal significance. When translated to different languages, specific terms may signify something quite different.

Differences between the terms “clinical guideline” and “clinical protocol” were recognized in 81% of the countries. Many other terms which were considered to have similar meaning to that of “clinical guideline” and “clinical protocol” include “clinical diagnosis and treatment guideline”, “national guideline”, “service guideline”, “practical guideline”, “unified national clinical protocol of medical care”, “local protocol of medical care”, “algorithm”, “management algorithm”, “standard”, “medical standard”, “standard of medical care”, “standard of quality”, “clinical recommendation”, “national recommendation for clinical practice”, “clinical directive”, “instruction”, “scheme”.

Legal documents which make explicit reference to clinical guidelines were identified in 94% of the countries. In 88% there are clear criteria for a document to be legally titled and recognized as a “clinical guideline”.

Health care professionals, especially guideline developers, should agree on standard and unequivocal terms and definitions, which should be consistently applied and followed when communicating with those using the guidelines.

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. (US Institute of Medicine, 2011)

Clinical protocols set out precise sequences of activities to be adhered to in the management of specific clinical conditions in a specific health care institution, department or clinic. They are derived from national clinical guidelines and reflect local circumstances and variations due to different types of clinical care at different levels.

It is important to make a difference between a guidance document issued by various international bodies, which may be labelled as “guideline” or “clinical guidance” and may come in various forms and shapes and a clinical guideline. The defining characteristic of a clinical guideline is that it contains recommendations linked directly to their supporting evidence using a rating or grading system that indicates their strength.

The survey identified a broad range of terms which are perceived to have the same meaning to “clinical guideline” or “clinical protocol”, and in some cases “guideline” and “protocol” are used synonymously.
Guideline Programmes

More than half (56%) of the countries reported that they had a structured and coordinated guideline programme designed with the specific aim of producing SRH clinical guidelines.

Coordination of the guideline development process is done by the Ministry of Health alone in 69% and by a group of institutions in 31% of the countries. If established, the coordinating group includes governmental institutions (44%), universities and academic institutions (22%), health care institutions (17%), professional bodies (professional associations or medical specialty societies, 11%) and international partners (6%).

The purpose of these programmes is primarily to improve quality of care in all countries and in 44% of the countries it is also to control costs.

In all countries the scope of guidelines is treatment and management, in 94% is diagnosis and in 69% prevention and screening.

The targeted levels of health care include primary and secondary care in all countries and tertiary care in 81%. Public health was mentioned as a target in 63% of the countries.

The targeted users include physicians in all countries, nurses/midwives in 88%, health care managers in 75%, policymakers in 38% and paramedical professionals in 13%. Patients were mentioned as target users in 44% of the countries.

Stakeholders

Institutions which have the mandate to develop clinical guidelines include governmental institutions (46%), health care institutions (27%), universities/academic institutions (15%) and professional bodies (e.g. associations or societies, 12%).

<table>
<thead>
<tr>
<th>Institutions developing clinical guidelines</th>
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<tbody>
<tr>
<td>Governmental institutions 46%</td>
</tr>
<tr>
<td>University/academic institutions 15%</td>
</tr>
<tr>
<td>Health care institutions 27%</td>
</tr>
<tr>
<td>Professional bodies 12%</td>
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</table>

National professional bodies that represent physicians/clinicians in general exist in 81% of the countries, while specialized professional bodies in SRH exist in 88% of the countries. In addition, professional bodies representing physicians interested in a certain condition/disease relevant for SRH exist in 47% of the countries.

However, professional bodies are responsible for developing clinical guidelines only in 12% and part of the coordination mechanism of the guidelines development process only in 11%.

Professional bodies are considered stakeholders in the development of clinical guidelines in only 12% of cases and are part of the coordination mechanism of the guidelines development process in only 11% of cases.
Topic Selection

Selection of appropriate topics for clinical guideline development is a crucial and frequently underestimated step. Guidelines can be developed on almost every health topic, condition or intervention, but since the guideline development process is a resource intensive one, it is critical to decide which topics should be given priority.

SRH national priorities are explicitly set by the government in all EECA countries. The top priority is improving the antenatal, intrapartum and postnatal care in 50%, followed by family planning and prevention of unintended pregnancy and abortion in 19%.

The presence of a formal process for selecting and deciding the priority topics for SRH clinical guidelines was reported only by 44% of the countries.

In 86% of those countries, the process was described as being open to proposals from any interested stakeholder. In most countries, the process includes the key institutions and decision makers, but in some countries, guideline topics are decided by a single academic institution.

Criteria for selecting topics for clinical guidelines include burden of disease, associated morbidity and mortality rates, population affected, social significance of conditions/diseases, resource implications and political importance.

Only one third (32%) of the guideline developers received training on guideline development methodology.

Guideline Developers

In all countries, teams of SRH guideline developers include physicians from medical specialties relevant to the topic of the guidelines. The teams also include individuals from other disciplines, such as: nurses or midwives (50%), clinical epidemiologists and statisticians (44% each), communication and information specialists (31%), social scientists (psychologist, sociologist, etc.) in 25%. Health economists were reported as members of the teams in 19% of the countries.

Only one quarter (27%) of the guideline developers signed declarations of interests to avoid conflicts of interests.

Existence of training courses on the methodology of developing clinical guidelines was reported in one third (33%) of the countries. It was estimated that only 32% of the guideline developers received such training.
Methodology

Clinical guidelines are developed for a specific health care system and within a complex, country-specific environment which is influenced by social, economic, legal, ethical and other factors.

Adaptation and new development

Two thirds (62%) of the SRH clinical guidelines published in the last three years in EECA were adapted from foreign published guidelines to the country specific circumstances and needs.

Methods used for guideline development

A quarter (22%) was developed starting with a literature review or results of existing meta-analyses. Adoption (that is, translation and endorsement without any modification of a foreign published guideline) was used as a method in only 3%. 13% of guidelines were developed in a simplistic fashion based on a small scale research of individual institution or centre, or on the basis of an expert opinion.

Peer review and consultation

It was reported that 65% of the SRH guidelines developed over the last three years were reviewed by external reviewers and 72% of the guidelines were agreed in open meetings/conferences.

Formal approval

All countries reported the existence of a process of formally approving and authorizing the SRH clinical guidelines. In all cases, the authority which approves the SRH clinical guidelines is the Ministry of Health through a decree or an order.

Review and update

The existence of a formal procedure for the revision of a published guideline was reported by 63% of the countries. Only 28% of the guidelines explicitly stated a revision date and 29% of those guidelines have undergone a process of revision at the date set.

Patients’ involvement

Organizations or associations which represent patients or consumers in the area of SRH were reported to exist in 25% of the countries. However, patients, public or their representative associations were involved in the development of only 14% of the SRH clinical guidelines which were published in the last three years. Only 9% of these guidelines were accompanied by a patient friendly version.

Two thirds of the SRH clinical guidelines, produced in the last three years in Eastern Europe and Central Asia, were adapted from already published guidelines.
Implementation

The most common methods of implementation of SRH guidelines were distribution of printed guidelines (94%) and presentations in medical conferences (81%).

Other methods included using guidelines in formal medical education/training programmes (75%) or for the development of educational materials (69%), electronic dissemination on websites/online databases (56%), influence of local opinion leaders in support of guideline implementation (50%), by presentation in the media (31%) and through reminder systems (25%).

Local Clinical Protocols

In 38% of the countries there is a requirement that each SRH health care institution develops its own specific institutional clinical protocols based on the national clinical guidelines. In these countries, a formal mechanism for assessing the quality of the SRH local institutional clinical protocols was reported. However, there is very limited information in these countries about the number of SRH health care institutions which have actually developed their own institutional clinical protocols.

Adaptation of a national clinical guideline to a local institutional setting in the form of a local clinical protocol defines clearly who does what, when and where.

Although guidelines provide evidence for practitioners in a digested and friendly form, a key step in the implementation is the adaptation of the guideline to each local setting of use. In this context, the term “local” may include a multitude of settings within the health system of a country, extending from a department, section, clinic to a hospital.

Accreditation of SRH health care institutions is conditioned to the use of SRH clinical guidelines and/or protocols in 40% of the responding countries.

Funding of the health care institutions is conditioned to the use of clinical guidelines and/or protocols in only 6% of the countries.
Funding

Approximately half (51%) of the SRH guidelines developed over the last three years were funded by international development partners/agencies and 44% by governments. In only 4% of the cases, guidelines were funded by an institution’s own budget. International partners/agencies that support the development of clinical guidelines for SRH are present in 94% of the countries. Analyses regarding the cost implications of applying the recommendations of the published SRH clinical guidelines were reported in 19% of the countries.

Analyses regarding the cost implications of applying the recommendations of the published SRH clinical guidelines were reported in 19% of the countries.

Funding for guidelines development

<table>
<thead>
<tr>
<th>Source</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Institutions own budget</td>
<td>4%</td>
</tr>
<tr>
<td>Other sources</td>
<td>1%</td>
</tr>
<tr>
<td>International development partners/agencies</td>
<td>51%</td>
</tr>
<tr>
<td>Government</td>
<td>44%</td>
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</tbody>
</table>

Clinical Audit

Many terms are used and considered to have the same meaning as “clinical audit”, such as “medical audit”, “service audit”, “audit of clinical cases”, “case clinical review”, “quality assessment”, “quality control inspection”, “monitoring of efficiency implementation”, “monitoring”, “supervising (control)”, “medical quality control”, “external quality control”.

Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team, or service level and further monitoring is used to confirm improvement in healthcare delivery. (UK National Institute for Clinical Excellence NICE, 2002).

Clinical audits were reported as taking place in the last three years in topics belonging to the areas of SRH in 50% of the countries. In those countries, 25% of the SRH institutions have conducted at least one clinical audit in topics belonging to SRH areas such as premature labour, uncomplicated labour management, hypertension and haemorrhage. Audits were reported also on topics like maternal mortality, near miss cases and perinatal mortality.

A formal and structured national clinical audit programme in the areas of SRH was claimed to exist in 36% of the countries.

AGREE (Appraisal of Guidelines for Research and Evaluation in Europe) is a tool originally published in 2003 that assesses the methodological rigour and transparency in which a guideline is developed and includes a set of criteria widely used by guideline programmes.

Quality Control

A system for monitoring the quality of the SRH guidelines was reported by 69% of the countries. The Appraisal of Guidelines for Research and Evaluation in Europe (AGREE) instrument was used for appraising the quality in 44% of the guidelines published over the last three years. Revising guidelines based on comments from the professional community was reported in 37% of the countries. In 19% of the countries, guidance documents for good practice in guideline development (“guidelines for guidelines”) were developed and published.
The principal aim of evidence based clinical guidelines is to improve the effectiveness and efficiency of clinical care, as well as patient safety and outcomes by supporting and promoting good clinical practice.

The Way Forward

Evidence-based clinical guidelines are fundamental to quality improvement in modern health care systems whether at a primary, secondary or tertiary level. Health care policies and systems are being developed increasingly using an evidence-based approach to achieve value for money.

The survey identified several key issues which positively influence the process of development of SRH clinical guidelines in the countries of Eastern Europe and Central Asia such as existing laws, health care strategies, policies and best practices, principles of training, stakeholder interest, public pressure and international support.

A number of key issues were reported to challenge the process of development of SRH clinical guidelines in these countries, including limited capacity, lack of understanding of evidence-based medicine, the resistance to change, limitation in English language and in information technology, lack of knowledge in methodology, inability to achieve full implementation of guidelines, inadequate monitoring and evaluation systems in addition to limitation of funding opportunities.

Policy recommendations

Advancing the clinical guidelines agenda in the countries of Eastern Europe and Central Asia will need strengthening of advocacy for well structured strategies, policies and legal support. In addition, the establishment of national programmes for clinical guideline development and the appropriate funding will be a major contributor to its success. Furthermore, conditional accreditation of health care providers and their funding on the basis of their practice of evidence based guidelines and protocols will further enhance the process and lead to a more widespread application of evidence-based medicine in health care. An increased role of national professional bodies in the process of guideline development in SRH should be promoted.

Technical recommendations

Capacity building, including training on evidence-based medicine and clinical guidelines development and implementation, the use of appropriate methodologies for guideline adaptation or development, the improvement in implementation of national guidelines through development of local protocols and monitoring the results of their application through clinical audit are essential for achieving a high quality clinical service in SRH.