Development and Implementation of Clinical Guidelines for Sexual and Reproductive Health

Programme Guidance for Countries in Eastern Europe and Central Asia

UNFPA
Regional Office for Eastern Europe and Central Asia

East European Institute for Reproductive Health

Royal College of Obstetricians and Gynaecologists
Bringing to life the best in women's health care

2012

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Introduction

Evidence-based clinical guidelines have become an integral part of health care systems and are considered to be essential tools for improving the quality of primary, secondary and tertiary health care. Health care policies and systems are being developed increasingly using an evidence-based approach to achieve value for money.

The principal aim of evidence-based clinical guidelines is to improve the effectiveness and efficiency of clinical care, as well as patient safety by supporting and promoting good clinical practice in the best interest of patients. The recommendations made in the guidelines are derived from high-quality evidence and apply to the entire spectrum of health care, namely prevention, screening, diagnosis, treatment/management, rehabilitation and health promotion. Although guidelines provide mainly evidence-based advice for clinical care, they can also be used to set standards of care, to improve training of medical staff and to influence the research portfolio. Policy makers can also use the recommendations made in the guidelines for commissioning services. Implementation of guidelines also helps to improve communication and shared decision-making between patients and health care professionals.

Clinical guidelines can be used for the following purposes:

- To inform health care policy for prioritisation of needs and support rational and evidence-based health care decisions;
- To help develop standards for improving quality of care, change the provision of health care, help assess the clinical practice and improve outcomes for patients;
- To provide information on cost effectiveness and ensure efficient use of resources which is pertinent to modelling health economics;
- To educate and train health care professionals to deliver high-quality care;
- To strengthen the position of the patient and enhance patient-provider partnership;
- To reduce litigation costs by reducing poor clinical practice.

Clinical guidelines are particularly important in the context of the current challenges facing most health care systems, such as the rising costs of health care, introduction of expensive new technologies, increased demand for care combined with an ageing population, the variations in clinical practice and service delivery patterns among health care professionals, institutions and geographical regions.

Although target users of the clinical guidelines are usually physicians, other groups may benefit too, including nurses and midwives, paramedical professions, health managers, policymakers and patients. Clinicians, health managers, policy makers and patients/public perceive increasingly clinical guidelines as relevant tools for making health care more efficient, consistent, safer and for eliminating the differences between what clinicians do and what scientific evidence has demonstrated.

Each clinical guideline is produced and used in a country specific context within the complex environment of the health care system, which is deeply influenced by its political, legal, ethical, economic situation and its societal values. All these aspects should be taken into consideration when planning the development and application of clinical guidelines. In each country the success or failure of implementation of clinical guidelines not only depend on their quality, but also on the social, legal and ethical aspects involved in their development.

Context

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 overall goal of this regional initiative is to contribute towards improving quality of care in SRH services. This would be achieved through harmonization and institutionalization of the process of developing new guidelines or by adaptation of existing international guidelines. Furthermore practical issues around implementation of new national guidelines into clinical practice would be identified and solutions would be proposed.

Building on existing UNFPA experience in this area and the established global collaboration with WHO, including the WHO-UNFPA Strategic Partnership Programme, this initiative was developed in close collaboration with the WHO Regional Office for Europe and will be implemented across the region in partnership by 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, a survey was conducted in 2012 in 16 countries of Eastern Europe and Central Asia, in order to ascertain the current status about the use of clinical guidelines in sexual and reproductive health within the region. Key findings of this survey are highlighted throughout this guidance document.

EECA DATA

The first SRH clinical guideline was published in Turkey (1994), followed by another guideline in Moldova (1998). The process gained momentum after 2003 and most guidelines have been produced after 2005. So far, 190 SRH guidelines had been published in all 16 countries surveyed. Of interest, 114 SRH guidelines were published during the past three years.

Purpose of the Guidance

The purpose of producing this programme guidance is to support stakeholders in countries of Eastern Europe and Central Asia (EECA) to establish a systematic approach to clinical guideline development within a national program on quality improvement. The document provides also advice to policy makers, programme managers and health care professionals who are interested in developing and implementing clinical guidelines. It is acknowledged that health care systems in EECA are undergoing various degrees of reforms, including evaluation of the quality of health care practices. It is conceivable that clinical guidelines may provide best practice references against which such evaluations are carried out.

This guidance document is not intended to be a detailed technical manual on the methodology of clinical guidelines development and implementation. It presents the processes required to be in place for development/adaptation and implementation of clinical guidelines, based on good practices described by several key guideline development groups: the Scottish Intercollegiate Guidelines Network (SIGN)[18], the UK National Institute for Health and Clinical Excellence (NICE)[12], the Royal College of Obstetricians and Gynaecologists (RCOG)[14, 15, 16, 17], the ADAPTE Collaboration and the Appraisal of Guidelines for Research and Evaluation Consortium (AGREE)[2]. The manuals and documents developed by these organizations should be consulted for technical details.

Although this guidance is intended to support development and implementation of clinical guidelines in the area of sexual and reproductive health, the principles described in this document are equally applicable to other specialties as well.

Terminology and Definitions

The terminology used in the area of clinical guidelines includes concepts that are not well defined. The terms used can have many different meanings/interpretations with respect to their degree of rigidity or legal significance. When translated to different languages, specific terms may signify something quite different. It is therefore necessary for all health care professionals, especially those who are involved in the development and implementation of guidelines, to examine the use of different terms in each specific social and language context, to agree on standard and unequivocal terms and definitions and to apply and follow them consistently when communicating with those using the guidelines.

EECA DATA

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".

Clinical guidelines

Broadly defined, clinical guidelines make recommendations for the health care professionals based on the best available evidence, for the care of patients. Guidelines are developed following a comprehensive literature search, review and appraisal of evidence. They are produced at national level using a well defined systematic process and are updated regularly.

Clinical guidelines or clinical practice guidelines were originally defined by the US Institute of Medicine in 1992 as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances". Recently (2011), the Institute of Medicine updated this definition to reflect the essential defining characteristics of clinical 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".[9]

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 is contains recommendations linked directly to their supporting evidence using a rating or grading system that indicates their strength.

Clinical protocols

Clinical protocols are documents at local (institution, department or clinic) health care level, which are used to implement the national clinical guidelines in local specific health care and clinical settings, in order to improve quality of care and reduce inequalities in provision of care. They are derived from the national clinical guidelines and reflect the local circumstances and variations due to different types of clinical care at different levels.

Clinical protocols set out precise rules and sequences of activities to be adhered to in the management of specific clinical conditions. They set out specifically what should happen, when and by whom in the care process. They are intended to be applied rigidly and must be followed virtually in all cases in a defined medical situation, allowing little or no flexibility or variation. They are produced in each health care institution, department or clinic, using also a systematic process and should also be updated regularly.

Clinical/care pathways

Clinical pathways are tools used to guide health professionals at local (institution, department or clinic) health care level, with the aim to improve the quality of care throughout the patient journey. There is still no standardized definition of what a "clinical pathway" actually constitutes. A recent literature review identified 84 different terms that may mean a clinical pathway including "care pathway", "critical pathway", "integrated care pathway", "care map", "protocol" and "guideline".[5] Integrated care pathway is usually used if care pathways are multi-disciplinary and/or across sectors of health care provision.

The US National Library of Medicine introduced the term "critical pathway" in 1996 and is using the definition from Mosby's Medical Nursing & Allied Health Dictionary: "schedules of medical and nursing procedures, including diagnostic tests, medications and consultations designed to effect an efficient, coordinated program of treatment". The European Pathway Association (E-P-A) uses the following definition: "a care pathway is a complex intervention for the mutual decision making and organisation of care processes for a well-defined group of patients during a well-defined period".

Five criteria were identified to define a clinical pathway.[10] These are (1) the intervention is a structured multidisciplinary plan of care, (2) the intervention is used to translate clinical guidelines or evidence into local structures, (3) the intervention details the steps in a course of treatment or care in a plan, pathway, algorithm, guideline, protocol or other 'inventory of actions', (4) the intervention

has timeframes or criteria-based progression and (5) the intervention aims to standardise care for a specific clinical problem, procedure or episode of health care in a specific population.

Algorithms

An algorithm is a flow chart of the clinical decision pathway described in the guideline. The algorithm may form the basis of a shorter form of the guideline, intended for quick reference. It should be only a summarization of the recommendations and should not include any further detailed information or advice. It may be necessary to produce more than one algorithm for one clinical guideline, if the recommendations cannot be summarized into one flow chart.

Standards

The term standard has several possible meanings in health care. A standard may be a statement which is strict, intended to be applied rigidly and must be followed virtually in all cases in a defined medical situation.

It can be also used in the sense of a "norm", or a legal document stating some norms and used in this way it may mean also "protocol". In this meaning, it is similar to "rule", "strict criterion", "strict indication or contraindication", "appropriate or inappropriate practice".

The term standard may be also used to define the exact quantity or the degree of fulfilment of a criterion for an adequate, acceptable or optimal level of quality. Used in this sense, it indicates an objective set to be achieved or considered as being achievable.

A standard of care is a statement which provides an overview of relevant evidence in areas that have some influence or effect on day-to-day clinical practice, but does not provide specific recommendations. It expresses the quality of care provided and focuses on care that is effective, safe and provides a good patient experience.

In legal terms, a standard of care may be defined as the degree of prudence and caution required of an individual who is under a duty of care. A health care provider may be in breach of duty towards the patient if his/her conduct fell short of the standard expected under the circumstances.

Guideline programmes

A guideline programme can be defined as "a structured and coordinated programme designed with the specific aim of producing clinical guidelines".[3] Such programmes are usually national collaborative initiatives, which provide a coherent framework, employ a systematic methodology and use several institutional structures and a network of health providers, managers and patient representatives to produce clinical guidelines. They can improve the quality of the guideline development process by enabling the efficient sharing of resources and expertise.

Guidelines Development

Clinical decisions were traditionally based on experience and skills, but are now increasingly based Guidelines Development

Clinical decisions were traditionally based on experience and skills, but are now increasingly based on evidence. Similarly, the methodology for developing clinical guidelines has evolved from non-systematic informal consensus opinion to evidence-based formal consensus techniques.

The main blocks of a generic guideline process are: topic selection, guideline production, implementation and update. These blocks are not linear, but interdependently connected to a broader set of activities aimed to achieve optimal health care and promote clinical excellence through translating evidence into practice, evaluating the practice, setting and monitoring standards, accrediting services and educating health providers. The whole process takes place in a specific country context, which includes a particular political, economic, legal, professional, ethical environment and involves specific stakeholders such as policy makers, managers, providers, patients, health care industry and others (Figure 1). The World Health Organization recommends that the guideline development process observes the guiding values of population perspective, scientific integrity, sensitivity to local contexts and transparency.[19]

A good guideline development process should be strongly based on systematically and professionally interpreted scientific evidence and complemented with expert opinion when necessary. Relevant evidence should be searched systematically to answer each clinical question selected to be addressed in the guideline. Recommendations should be formulated based on best available evidence and approved through professional expert consensus. Since health professionals are the main target group of the clinical guidelines and those mainly responsible for their implementation, the main responsibility for the development of guidelines should rest with them and their professional organisations. Involvement of patients/public is highly recommended to take account of their perspectives. Participation of other interested parties, such as policy makers, is important as the guideline's recommendations might have implications for policy. Furthermore, research funders and the industry should be invited to contribute whenever appropriate. The guidelines development process should also be transparent regarding the methods used to make the recommendations in the guideline and any potential bias in the process must be adequately described.

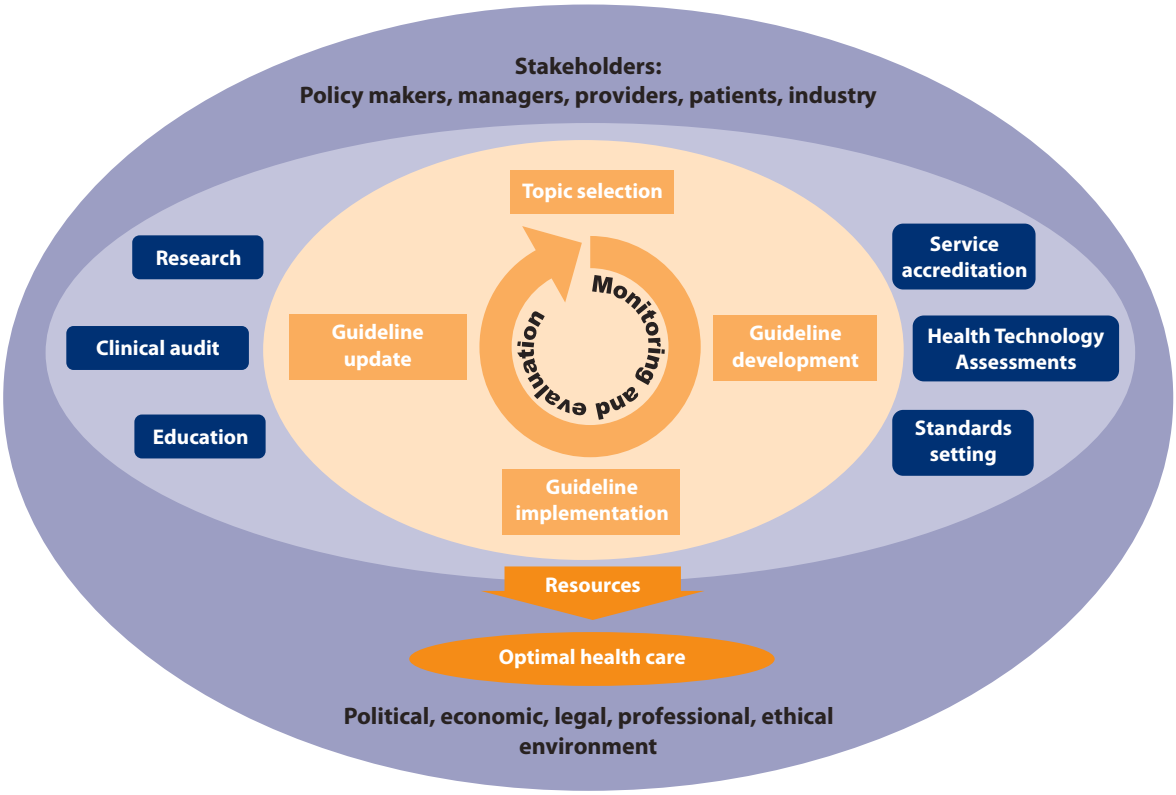

Figure 1. Framework for clinical guidelines development, implementation and update.

It must be recognised that multiple factors, both technical and political, are involved in the clinical guidelines development process. For example, proposals for topics may be submitted by any interested parties, the short listing of the proposals based on a clear set of criteria would be done by a technical body, whereas the ultimate decision about which guideline topic should be considered as part of the broad government health policy. Similarly, although a clinical guideline could be endorsed by professional experts, the formal approval of the guideline, which confers legal value to it, is often or usually done by the Ministry of Health.

The clinical guidelines development process can be implemented with differing degrees of rigour, resulting in guidelines with a variable quality. This programme guidance highlights the key process components which are critical to the development of high-quality and trustworthy guidelines, as they were identified by all major guideline organizations and recommended by Guidelines International Network (G-I-N).

Guidelines topic selection

Selection of appropriate topics for clinical guideline development is a crucial step which is frequently underestimated or performed in an ad-hoc manner. Guidelines can be developed on almost every health topic, condition, procedure or intervention, but since the guideline development process is a resource intensive one, it is critical to decide which topics should be given a priority. The selection of guideline topics needs scientific, technical, financial and political inputs.

Any interested party including health care professionals, Parliament or patients/public, may suggest subjects for clinical guidelines. The institution/organization which develops the guidelines may also be involved in different stages of the topic identification, but the final decision of the topics for which clinical guidelines will be developed should be made by the health authority of the country (the Ministry of Health).

Given the large number of potential areas, formal priority setting exercises should be performed to decide on the topics for guideline development. Proposed guideline topics should be formally assessed, selected and prioritized based on a clear set of criteria scored to rank the relative weight of different topics.

Criteria should prioritise clinical guidelines which address:

- Epidemiology of health problems: areas with high rates of mortality, morbidity or disability, or new/emerging diseases for which there are no existing guidelines;
- Potential to improve patient outcomes or quality of care: areas where effective practice is proven and where guideline recommendations can reduce rates of mortality, morbidity or disability;
- Variations in the provision and quality of care: areas where there is clinical uncertainty, as evidenced by a wide variation in clinical practice, service delivery, or outcomes;
- Health inequalities: areas which may help reduce inequalities in health outcomes in particular vulnerable groups, or which may involve conflicts in choices between individual and societal perspectives;
- Implications across health care system levels: areas where there are implications on and which require inputs and coordination at different levels of the health care system;
- Resource implications: areas with high cost and low number of patients, low cost and high number of patients, interventions of questionable effectiveness used widely, or under-utilized cost-effective interventions;
- Policy priorities: priority health areas of the country and strategic goals of the Government;
- Emergence of new evidence or technologies: areas where new high-quality clinical evidence has been published or new effective technologies have been proven;
- Risks: iatrogenic diseases or interventions carrying significant risks, areas where there is a frequent chance of litigation;
- Other factors: perceived need for the guideline, as indicated by relevant stakeholders, based on an area of clinical need.

The WHO Guidelines for Guidelines[19] recommends that four key questions should be answered during the guideline development process: What is efficacious? What is cost-effective? What is affordable? and What is beneficial for the population?

Guidelines production

Clinical guidelines are developed in and for a specific health care system and in a complex, country-specific environment which includes social, economic, legal, ethical and other factors. Regardless of the setting, guidelines should be produced through a systematic, independent and transparent process, by multi-professional groups and observing appropriate quality criteria. Guidelines should describe clearly and in detail the methods used for the guideline development.

Two strategies are usually applied for producing clinical guidelines:

A. *De novo* development which entails starting from basic principles, that is, starting with a systematic literature review to identify relevant studies and research or with the results of meta-analyses of the literature.

B. Adaptation which entails starting from one or more published foreign clinical guidelines and adapting it according to country specific requirements and in the light of subsequent research findings. The adaptation strategy does not require full systematic review of literature.

Adoption, that is translation and endorsement without any modification of a foreign guideline, is not recommended. Guidelines recommend selected clinical care that is relevant in the context of the health care system of a particular country. They should be therefore critically reviewed and adapted for applicability to a new country taking note of the special needs of its population and environment.

The flow of activities for each of the strategies for guideline development is represented in Figure 2.

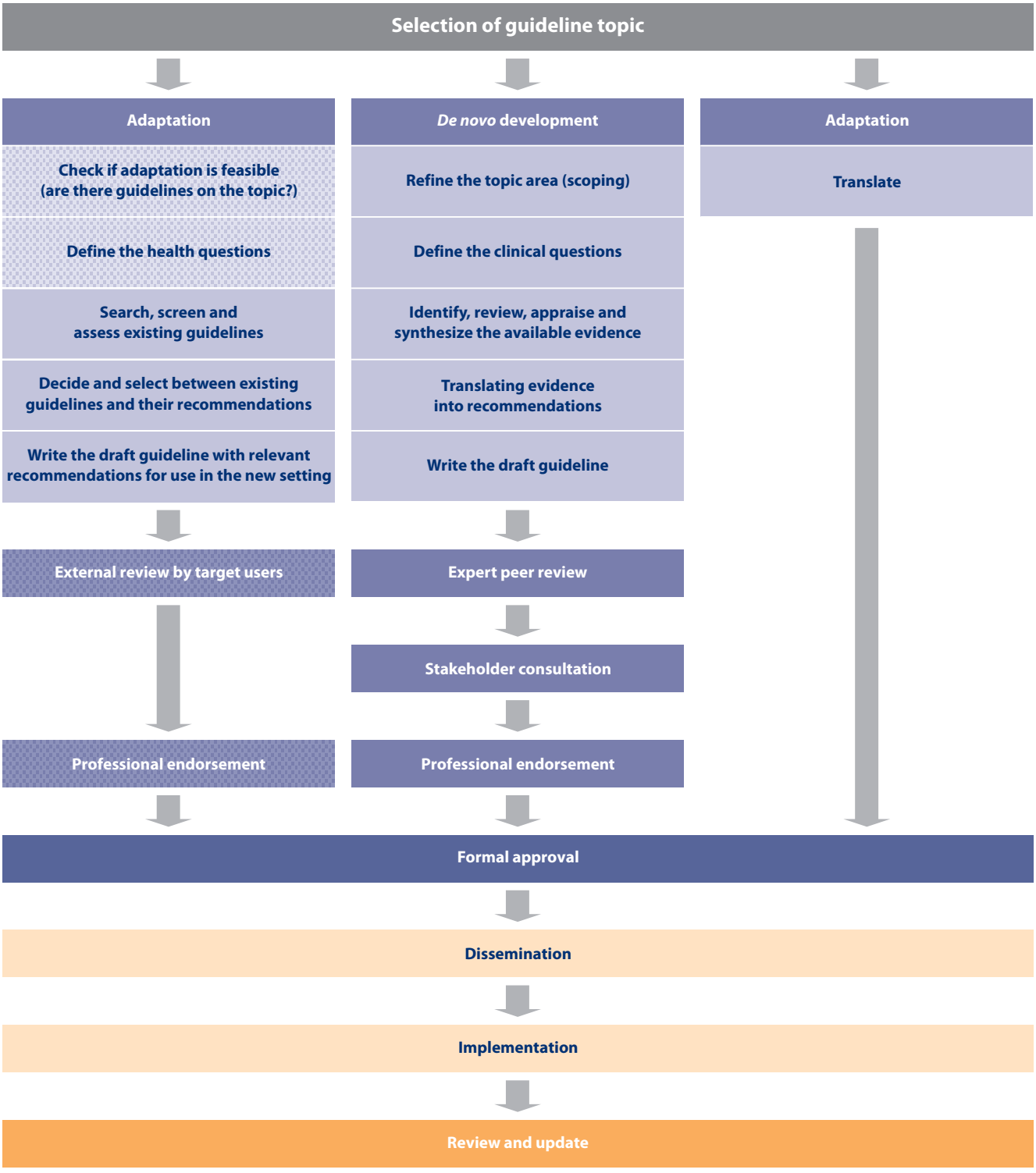

Figure 2. Comparison between the strategies for producing clinical guidelines.

De novo development of clinical guidelines

This strategy requires major costs in terms of expert time, effort needed and support structures that have to be put in place for literature searching, critical appraisal, etc. The time needed to develop a de novo clinical guideline depends on the scope of the topic, the volume of relevant literature to be critically appraised, the amount of feedback received during consultation and peer review and, most importantly, competing pressures on the time of the professionals who produce the guideline. As a reference, in the UK the average time taken by the development of a Scottish Intercollegiate Guidelines Network (SIGN) guideline is 28 months and the development time for a National Institute for Health and Clinical Excellence (NICE) guideline is usually between 18 and 24 months for a standard guideline and between 11 and 13 months for a short guideline.

The Guideline Development Group

Convening an effective Guideline Development Group (GDG) is one of the most important steps in the process of producing a good quality clinical guideline.

The key roles of the GDG are to define the review questions which will guide the search for evidence, to discuss and analyse the evidence, to translate the evidence into recommendations for clinical practice, to analyse and respond to comments received from the stakeholders and peer reviewers during the consultation and to incorporate the necessary changes to the draft guideline and to produce the final draft of the guideline. In some models, the GDG may also contribute to the preparation of the scope. If members have the specialized technical skills required, the GDG may perform systematic reviews of available evidence or health economics tasks but this may be delegated to technical teams or experts within or outside the guideline developing institution/ organization.

One of the strongest recommendations for developing good guidelines is that the GDG should include representatives of all interested parties and disciplines and key groups whose activity would be covered by the guideline or who have other legitimate reasons for having an input into the process. In this way, all stakeholders will see the guideline as a credible one and will cooperate in its implementation. If this principle is not applied, the guideline will risk being criticised for various reasons, from missing some speciality views to being inappropriate for daily practice or not including the views of patients. As a result the guideline might not be implemented.

The GDG should include representatives of all specialities involved in the topic of the guideline such as specialists in the topic in primary and secondary care and generalists. While a single specialty group may be biased in favour of some procedures, a multidisciplinary group may reach different conclusions based on the same evidence. The GDG should include not only senior teaching or academic staff, but also residents or young specialists and nurses/midwives who are involved in the day to day provision of medical care. This would ensure that practical problems related to the use of the guideline are acknowledged and addressed during the development process.

GDG members should not come from only one hospital/department/clinic and health service managers should also be included in the group. Experts in nonclinical disciplines including epidemiologists, statisticians, clinical or social psychologists and economists are important members in the GDG. If available, methodologists with specific expertise in the guideline development process ("guidelineologists") are very useful. Optimally, all members of the GDG should be trained in the methodology of guideline development.

EECA DATA

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.

Patient/public representatives should also be included in the GDG to allow bringing the lay and non-medical perspective into the picture. Representatives of health care industry (pharmaceutical products or medical devices) should not be represented in the GDG to avoid potential conflicts of interest. They may have inputs into the guideline development process during the stakeholder consultation phase.

Members of the GDG, especially the GDG chairperson, should have good team working and group process skills and agree formally before the start of guideline development on the modality of work and of making decisions. Guidelines should describe clearly the process used to reach consensus among the GDG members.

The key steps in the de novo development of a clinical guideline include defining the objectives and scope, conducting evidence reviews, translating the evidence into recommendations, writing the draft guideline, stakeholder consultation and expert peer review.

Refining the topic area and defining the key issues to be covered by the guideline

Following the selection of the topic, the development of a scope is the first stage of the guideline production process. A guideline should specify its objective(s) and scope. A scope is a short document which sets out what the guideline will and will not cover and provides a framework within which the guideline is being developed. The chosen topic for guideline development has to be refined before the scientific evidence can be identified, reviewed and assessed. If the topic is not refined, the subject which is covered by the guideline may be too broad in scope, the effort of developing the guideline may be extremely difficult within the allocated period of time and the guideline produced may be too large. The scope ensures also that the guideline will focus on the particular areas in which clinical practice needs most advice.

Conducting evidence reviews

Once the scope of the guideline has been defined, all available evidence related to the guideline topic should be thoroughly and systematically searched for, identified and evaluated through systematic reviews. This is an essential step which ensures that the guideline is evidence-based. The key clinical issues identified in the scope should be broken down into a limited number of specific questions which will guide the systematic review and the formulation of recommendations. They may usually fall into one of three main clinical areas, intervention, diagnosis or prognosis and may sometimes cover issues of service delivery, although clinical guidelines do not in general cover service guidance. The amount and quality of available evidence reviewed depends on the clinical question and may consist of results of meta-analyses, randomised controlled trials, case control or cohort studies, non-analytic studies, e.g. case reports or case series, qualitative studies or other types of information such as expert opinion. Systematic reviews should extract and summarise the findings in a format easy to use by the guideline writers.

Evidence should be critically appraised and scored or rated according to a system of levels which should indicate its quality. The quality of evidence reflects the degree of confidence or certainty in a conclusion regarding the issue to which the evidence relates.[9]

Translating evidence into recommendations

The process of translating the evidence into guideline recommendations is the core of the guideline production process. Evidence-based recommendations must be based on the appraisal of the body of available scientific evidence, including its quality, quantity, consistency and relevance to particular patients. They should also involve a comparison of outcomes, benefits and harms of potential recommendations, value judgments regarding the importance of specific benefits and harms and if possible an assessment of economic value. Economic factors may refer to patient level out-of-pocket costs or overall health care spending. The recommendations may be influenced also by the ethical, legal, social and economic factors in which the guideline will be applied and should be feasible for practice.

Each recommendation should be concise, clear, accurate, easy to understand and linked directly to the supporting evidence using a rating or grading system that indicates its strength. Strength of a recommendation reflects the degree of confidence that all patients would have so they would conclude that desirable outcomes of a recommendation outweigh the undesirable ones.[9]

Both the level of quality of the evidence and the grade of strength of the recommendation should be clearly identified in the guideline by using one of the standardized and internationally recognized systems of numerals, letters, symbols, or words. Such explicit and standardized systems of rating the quality of evidence and strength of recommendation facilitate the systematic and transparent formulation of recommendations, help avoiding errors in judgment and reduce variability in guideline development.

Writing the draft guideline

The writing of a clinical guideline is an iterative process spread across the development, consultation and review phases. The successive drafts of the guideline should be revised in the light of stakeholder comments, peer reviews and any factual error must be corrected before the guideline is published. A good quality clinical guideline should have a clear logical structure and a reader friendly style, thus allowing easy navigation and location of key data and references. Each recommendation should be clearly graded and accompanied by the supporting evidence and its level.

In addition to the full text guideline, it may be useful to publish an accompanying short or quick reference guide, containing a summary of key recommendations and other essential information from the guideline for easy use by the clinicians. This information may be presented in the format of an algorithm which illustrates the recommended care pathway.

Stakeholder consultation

The consultation of the clinical guidelines stakeholders may greatly enhance the validity of the final guideline and may increase the likelihood that the guideline will be implemented successfully. The consultation phase is also the moment in the development process when the interests of all stakeholders, including health care industry, may be raised. The consultation should take place while the guideline is still under development, in order to allow the guideline developers to benefit from feedback and suggestions and to give stakeholders the opportunity to provide an input to the final guideline and feel ownership. It may be done through circulating the draft guideline to various stakeholder institutions, by posting the draft guideline online for comments and feedback or by organizing open national meetings to discuss the draft recommendations of the guideline.

EECA DATA

It was reported that 72% of the SRH guidelines developed over the last three years were agreed in open meetings/conferences.

Expert peer review

Before publication, the draft guideline should be subjected to independent expert peer review. Peer review is needed in order to ensure that the guideline content is valid, clear, applicable and implementable and that the evidence supporting the recommendations has been comprehensively and accurately interpreted by the guideline developers. It is also needed to ensure that the guideline development process was appropriately applied.

EECA DATA

It was reported that 65% of the SRH guidelines developed over the last three years were reviewed by external reviewers.

The peer review process should be a formal one. All peer reviewers are expected to commit formally to the process, to perform the review in a standardized format within the expected time interval and to send their comments before the set deadline. The process should be open, robust and transparent. The comments should not be anonymous and the guideline developers should know the identity of the reviewers. All comments received from all reviewers should be recorded, addressed and discussed systematically. A decision should be formally made whether to change or not the draft guideline. All decisions and subsequent changes to the text should be documented, including reasons for not making changes. Reviewers should receive a feed-back from the guideline developers regarding the acceptance or rejection of their comments and all comments and decisions should be public.

Expert peer reviewers may be nominated by the professional or specialist societies. It is important to understand that peer reviewers are invited to comment in their individual capacity and not as representatives of their institution or organisation. Official institutional points of view should be raised during the stakeholder consultation process. The draft guideline may be evaluated also by lay reviewers who can judge its usefulness from the point of view of the patients or the beneficiaries of the guideline.

Adaptation of existing clinical guidelines

For many countries, de novo development of guidelines may not be feasible because of lack resources or expertise or because it is time consuming and starting from already existing quality guidelines is more efficient. Adaptation of already developed foreign guidelines to the local context allows achieving considerable savings in time and cost.

There are two levels of the term "adaptation" in the context of clinical guideline development:

A. Adaptation of a clinical guideline from one country (or from an international guideline) to another country (adapting country). In this case, the end product is the new adapting country's national clinical guideline. This process is discussed in this section.

B. Adaptation from the national to the local level (institution, hospital, department or clinic) of a national clinical guideline that exists already in the country, regardless of how it was produced (developed de novo through the full process or adapted from another country or an international guideline). The end product in this case is a local institution specific protocol. This process will be discussed later in the implementation section of this document.

Translation of evidence into the original guideline recommendations takes place in the specific cultural context in which the evidence is interpreted and will be implemented. Adaptation of clinical guidelines from one country to another should subsequently take account of the needs of the adapting country, without affecting the quality and validity of the guideline. This does not involve only translation to a different language, but also a contextual adaptation to a different epidemiological, legal, policy, resource and clinical practice setting. It may be possible that clinical questions not previously considered in the original guideline but relevant to the adapting country may need to be addressed in the adapted guideline.

EECA DATA

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. 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 only in 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.

The guideline should be adapted through a structured process. The Royal College of Obstetricians and Gynaecologists (RCOG) developed a structured yet simplified process of adapting its Green-top clinical guidelines by another country.[17] Another adaptation process was developed by the ADAPTE collaboration, an international initiative based on the Canadian work in this area.[2, 6, 8] Both processes recommend involving and engaging with local stakeholders including clinicians, policy makers and patients/service users, forming an adaptation multidisciplinary group and using formal and transparent consensus methodology. In such approach, the benefits of the original evidence-based guideline are combined with the benefits of the input from the local intended users. Regardless of the process, a high-quality adapted guideline should adhere to the evidence of the original guideline while at the same time reflect the modifications required for the adapting country.

The criteria outlined above in the topic selection section apply also when topics are considered for guidelines adaptation. These include local prevalence and burden associated with the condition, potential to improve patient outcomes or quality of care, evidence of local variations in practice, suboptimal performance, or underuse, overuse, or misuse of interventions and existence of an adequate body evidence about effective and efficient health care interventions in the form of already developed guidelines. The likelihood that the adapted guideline will be effective in influencing practice should also be assessed by analyzing the receptivity or acceptance to change and the availability of resources to implement changes which are required by the guideline.

The Guideline Adaptation Group

When adapting a foreign guideline to a new country, convening a relevant Guideline Adaptation Group (GAG) is a key step. The key roles of the GAG are to retrieve existing guidelines on the topic, assess their quality, content, consistency and how current they are. The GAG has also to determine how applicable and acceptable the recommendations are, to accept, reject or modify/customize recommendations and create the adapted guideline. Members of the group bring their local perspectives to the selection and wording of recommendations, thus ensuring that they are in agreement with the local culture and with available services and interventions.

Like for the development group for a de novo guideline (Guideline Development Group), the GAG should include representatives of relevant health care professions, other relevant professionals, patient/public representatives and technical support staff. The skill mix needed in such a group should be similar to a Guideline Development Group and should include clinical knowledge and expertise in the topic area from relevant disciplines and levels, knowledge of research design, critical appraisal of literature and of databases and in literature searching. ADAPTE recommends that the group members should have personal experience with the topic area, to ensure that issues related to patient/consumer's needs are discussed and that outcomes such as quality of life are considered. In addition, it is essential that the group members have a practical understanding of the adaptation country context and its health care delivery system and policy/administrative expertise to identify the issues related to the implementation of the guideline in local practice, the impact of the guideline on the health care system and to anticipate the resource requirements resulting from the application of the adapted guideline.

Managerial, facilitation, team working and writing skills are important. Consensus among the GAG members may be achieved through formal or informal methods but, like in the guideline de novo development methodology, it should follow strict rules and be both robust and transparent. There are several formal consensus development strategies which may be applied such as the Nominal Group Technique, the Rand version of the Nominal Group Technique, the Delphi Method and Consensus Meetings.

Preparation

RCOG suggests that the preparation phase starts from the selection of the topic to be addressed by the adapted guideline and the decision to adapt an existing Green-top guideline. It includes the establishment of a local adaptation stakeholder group (Guideline Adaptation Group) comprising representatives of disciplines similar to those included in the original guideline development group.

In addition, ADAPTE includes a modality to check whether adaptation is feasible, by checking what guidelines are already available on the chosen topic. If no guidelines exist on the chosen topic, then adaptation is not possible and the guideline has to be developed de novo. After establishing an organizing committee to oversee the adaptation process, ADAPTE methodology aims to identify whether the needed skills and resources to adapt the guideline are available, including qualified human resources, time, financial resources, etc. It also recommends reaching agreements from the start regarding the process and modality to manage decisions through formal or informal consensus, the bodies that will endorse the adapted guideline and the authors of the adapted guideline.

The ADAPTE process involves preparation of a formal adaptation plan and recommends considering the dissemination and implementation strategies from the beginning of the adaptation process.

Adaptation

RCOG recommends a pre-consensus meeting (if time and resources permit) and a formal decision-making process, followed by a formal consensus meeting. The formal decision-making process is done by mailing to the local stakeholder group a consensus questionnaire containing the original guideline recommendations. Stakeholders score their agreement with the original recommendations and the scores are aggregated. This reduces the number of issues for discussion at the "face-to-face" consensus meeting of the GAG, by pre-selecting the agreed and the contentious recommendations.

The face-to-face consensus meeting should involve as many stakeholders as possible and should lead to agreement on some original recommendations, modification of other contentious recommendations to reflect the local circumstances and final agreement on all recommendations through informal consensus. If feasible, a second consensus questionnaire should be compiled containing all the agreed recommendations in the adapted guideline and should be scored by the members of the local stakeholder group to demonstrate that consensus has been achieved for all recommendations in the final adapted guideline.

ADAPTE recommends a more detailed process which includes identifying specific health questions, searching, retrieving, screening and assessing guidelines and other relevant documents and finally deciding which guidelines and recommendations to use to create the adapted guideline. Specific health questions should be defined taking into consideration five items including the population concerned and characteristics of disease or condition, the intervention or diagnostic test, etc. of interest, the professionals to whom the guideline will be targeted, the expected patient, health care system and/or public health outcomes and the health care setting and context in which the guideline is to be implemented. An analysis of the health questions which are already addressed by the published guidelines identified during the preparation phase may be helpful in defining the specific health questions to be answered by the adapted guideline.

Guideline clearinghouses and guideline organizations/programmes websites should be searched for existing relevant good-quality guidelines on the health questions defined. MEDLINE searches may be used, although clinical guidelines may not be published in journals or indexed in bibliographical databases. General purpose Internet searching engines may also help identify relevant clinical guidelines. Identified guidelines should be screened using the Appraisal of Guidelines for Research and Evaluation in Europe II (AGREE II) instrument, thus reducing the number of guidelines to be considered for the adaptation process. Based on the search result, a decision should be made whether to produce the adapted guideline starting from a number of selected good quality published guidelines, from one particular guideline, or to develop de novo a guideline.

Selected guidelines should be appraised from the point of view of their quality, content, consistency and how current they are. This is a systematic and rigorous process which requires that the members of the Guideline Adaptation Group are knowledgeable of critical appraisal of the literature and guidelines. Finally, recommendations made by different guidelines are assessed to determine whether they are acceptable and applicable to the new setting. The context of the implementation

of the adapted guideline in the adapting country should be carefully considered when reviewing possible recommendations.

The results of the assessment, both regarding the selected guidelines as a whole and the particular recommendations, should be used by the Guideline Adaptation Group for making informed and transparent decisions on the recommendations in the adapted guideline. This should be optimally done in a "face-to-face" consensus meeting, considering the decision modality previously agreed and carefully documenting all decisions. The adapted guideline may include recommendations which are not changed compared to the original guideline, recommendations which are refined or reworded and/or recommendations which are significantly different from the original guideline. This does not imply that the process is incorrect, but simply that there is a need for considerable modifications to fit within the new setting. It is essential, however, that modified or new recommendations are linked with the evidence upon which they are based.

Finalization

ADAPTE recommends an external review of the adapted guideline by target users, a consultation with the developers of the original guideline and an endorsement by relevant bodies.

External reviewers should include all those who will be affected by the guideline application such as practitioners mainly, but also health managers, policy makers, or various health organizations representatives. External review gives the future potential users the opportunity to review the guideline and provide feedback, ensuring that recommendations are relevant and applicable and identifying issues which were missed by the Guideline Adaptation Group. It promotes the sense of ownership and commitment of the potential users toward the guideline, provides early information on the potential acceptance and on the impact of the adapted guideline and allows policy makers and managers to start thinking about the resources needed for implementation.

It is recommended that the draft adapted guideline should be sent for information and possible feedback to the original guideline developers, especially when substantive changes were made to the original recommendations. Permissions to use original copyrighted guidelines or guideline recommendations should be obtained and all documents used for the development of the adapted guideline should be appropriately referenced.

The adapted guideline should be endorsed by professional organizations most closely connected to the guideline topic and formally approved by the relevant institutions, according to the country specific context such as the Ministry of Health or its technical bodies.

Although both the RCOG and ADAPTE methodologies do not provide details on guideline dissemination and implementation, they recommend considering the resource implications of implementing the guideline when producing an adapted guideline and including provisions for the aftercare of the adapted guideline from the onset of the adaptation process.

It is important to understand the practical aspects for adaptation as proposed by the RCOG and ADAPTE. The ADAPTE process, as described above, heavily makes a case for a detailed review of the published guidelines. In many countries, with lack of technical support, such approach to adapt guidelines would become a cumbersome process. In these circumstances, the approach recommended by the RCOG is considered more pragmatic and therefore the required results can be achieved more efficiently.

Conflict of interests

Financial or other type of interests related to the health care industry, as well as intellectual and professional preconceptions, may affect guideline developers or reviewers and exert an influence on the interpretation of the scientific evidence during the guideline development process. Potential conflicts of interest may occur at each step during the guideline development process such as topic selection, review of evidence, formulation of recommendations, writing of the guideline, expert peer review and/or during dissemination of the guideline.

Even if it is not possible to completely eliminate any possible bias, guideline programmes should have clear policies and processes for identifying, disclosing, evaluating and managing financial and nonfinancial conflicts of interest of GDG/GAG members and peer reviewers. Guidelines should describe clearly how any identified conflicts were recorded and resolved. The best way to address the issue of possible conflict of interests is to conduct good and transparent systematic reviews of the evidence and to link the recommendations to the evidence in an explicit way.

EECA DATA

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

Interaction with the health care industry may happen both at the individual level and the institutional level. At individual level, it should be a standard requirement that each member of the GDG/GAG and expert peer reviewers disclose their possible conflicts of interest related to each guideline by completing declarations of interests and any individual with conflicts of interest should not be included. At institutional level, guideline development institutions/organizations or programmes should make public all the amounts and sources of funding received directly or indirectly for the development of a guideline. Guideline development institutions/organizations or programmes should not accept direct funding for guideline development from health care industry companies or their foundations. They may, however, accept contributions from private industry sources to a central pool of funds not allocated to the development of a certain guideline and used usually for other activities, such as dissemination. Guidelines should disclose the financial support received for the development of both the evidence review and the guideline recommendations.

Patient/public involvement in guideline development

Patients and in general any individuals potentially affected by the guideline have the right to be provided with relevant information about their health and health care in a format and language they can understand. Moreover, they should be recognized as partners not only in issues regarding their own care but also in the planning, monitoring and development of health care services. The patient/public involvement in guideline development serves two aims. It ensures that the guideline addresses issues of concern to them and guarantees that their perspectives on health care processes, priorities and outcomes are appropriately reflected in the guideline.

The term patient/public may include current or former patients/users of health care services, potential users of health services and their representative organizations. All of these may have a significant input at different phases of the guideline development process.

EECA DATA

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.

Even if there is no tradition and experience of effectively involving patients and public in Eastern Europe and Central Asia, there are several possible modalities to secure their contribution. One option is to work with relevant patient/public representative organizations, if they exist, but guideline developing organizations may also consider establishing special patients/public representative bodies. These special interest groups can help developing patient friendly versions of the guidelines. Such an approach would increase the visibility and penetration of guidelines in clinical practice.

Professional endorsement

Clinical guidelines are an essential part of the professional environment. Guideline development must first and foremost involve the medical profession and should be organized according to professional standards. For the same reason, guideline should be endorsed by the professional bodies which are most relevant to the topic of the guideline. Endorsement may be provided through direct recognition by the relevant organization or through a consensus process. Professional consensus may be achieved through formal or informal methods, but should follow strict rules and be both robust and transparent. Guidelines should clearly mention the endorsement of the relevant professional organizations.

EECA DATA

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%.

The endorsement of a guideline by relevant professional organizations has been shown to enhance the acceptability of a guideline to the organization's members.[7] The professional organization should implement the guideline as a policy within the organization, should promote it as a resource for good practice and should support its implementation including any training that might be needed.

Formal approval

Guidelines may be initiated, commissioned or funded by governmental institutions (Ministry of Health, governmental agencies or institutions) or by other stakeholders and they should mention the formal approval of those institutions. Although guidelines should be seen as recommendations or advice for best practice, they describe practices or procedures which must be regarded as reflecting the accepted professional standards. In this sense, after being endorsed and validated by the professional bodies, they should be also formally embedded in the national regulatory frameworks. Clinical guidelines can be also considered as policy instruments and the role of the Ministry of Health is essential to approve and authorise the guidelines through ministerial orders, decisions or regulations. This will provide the health care institutions with a regulatory basis for their implementation.

Criteria for high-quality clinical guidelines

The quality of clinical guidelines can be extremely variable and some guidelines may even fall short of basic standards. To be qualified as a valid and usable clinical guideline, a guideline has to satisfy several criteria. Several groups or institutions have proposed various standards for high-quality and trustworthy guidelines.

According to the US Institute of Medicine[9], trustworthy clinical guidelines should be based on a systematic review of the existing evidence, should be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups and should consider important patient subgroups and patient preferences, as appropriate. They should be based on an explicit and transparent process that minimizes distortions, biases and conflicts of interest, provide a clear explanation of the logical relationships between alternative care options and health outcomes and provide ratings of both the quality of evidence and the strength of the recommendations. They should be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.

In an attempt to promote a set of international standards for guideline development, Guidelines International Network (G-I-N) has proposed recently a set of 11 key components which are important minimal criteria for high-quality guidelines.[13] These criteria include composition of guideline development group, decision-making process, conflicts of interest, scope of the guideline, methods, evidence reviews, guideline recommendations, rating of evidence and recommendations, peer review and stakeholder consultations, guideline expiration and updating, financial support and sponsoring organization.

EECA DATA

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.

The Appraisal of Guidelines for Research and Evaluation in Europe (AGREE) instrument is a widely used tool that assesses the methodological rigour and transparency in which a guideline is developed and includes a set of criteria widely used by guideline programmes. The AGREE instrument and guidelines were developed to address the issue of variability in guideline quality and were recently refined, resulting in the new AGREE II, which has 23 items grouped in the 6 domains of Scope and purpose, Stakeholder involvement, Rigour of development, Clarity of presentation, Applicability and Editorial independence.

As a tool that assesses the methodological rigour and transparency in which a guideline is developed, the AGREE II instrument may be used by various stakeholder groups for different purposes:[1]

- By guideline developers to follow a structured and rigorous development methodology, to conduct an internal assessment to ensure that their guidelines are sound, or to evaluate guidelines from other groups for potential adaptation to their own context;
- By policy makers to help them decide which guidelines could be recommended for use in practice or to inform policy decisions;
- By health care providers who wish to undertake their own assessment of a guideline before adopting its recommendations into their practice;
- By educators and trainers to help enhance critical appraisal skills amongst health professionals and to teach core competencies in guideline development and reporting.

Guidelines Implementation

Dissemination

Clinical guidelines should be disseminated as widely and through as many channels as possible. They can be disseminated both in printed and electronic formats. Electronic publishing is easily updatable and less expensive than paper publishing. As each format has its advantages and disadvantages, both should be used together to achieve optimal dissemination.

Various formats used for disseminating clinical guidelines should convey the same messages through different mechanisms. These include the full guideline, a quick reference guide containing only a summary of the key recommendations and an algorithm illustrating the recommended care pathway and a patient version of the guideline.

It is essential that dissemination of a guideline and the necessary resources are planned for at the production stage. Guidelines should be distributed free of charge, both through the structures of the professional organizations and of the Ministry of Health.

Although implementation of a clinical guideline starts with its dissemination, it had been clearly demonstrated that passive strategies such as distribution of a guideline do not lead to change in clinical practice. Guideline production, dissemination and implementation should go therefore hand in hand.

Implementation strategies

Successful implementation of a clinical guideline into practice requires a combination of technical and political decisions at different levels. The Ministry of Health should play a key role in deciding which guidelines to implement and with what priority. Health care institutions should participate in decision making and also in choosing which guideline should be actively implemented first.

Health policy makers, managers or clinicians who choose a particular guideline for implementation should first assess its quality, as the potential benefits of using guidelines are directly linked to the quality of the guidelines and using bad guidelines may do more harm than good. In choosing the right guideline to implement, criteria outlined by AGREE, G-I-N or IOM (see section on Criteria for high-quality clinical guidelines) may be used.

A clearly defined plan is essential for the successful implementation of guideline recommendations and for applying correctly the implementation strategy. Strategies for successful implementation may include educational interventions (conferences, hospital/institutional based meetings), organizational interventions (initiated by the institution or part of service commissioning), financial interventions (rewards or penalties) and regulatory interventions.

EECA DATA

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%).

Educational interventions may include presenting materials developed from the guideline in professional conferences, interactive workshops which allow discussions and practical sessions, outreach visits by managers, supervisors, or mentors giving advice directly to clinicians and using the clinical guidelines in the process of training the health professionals. The support of medical universities through getting guidelines into undergraduate or residency curricula may be very useful and helps promoting their implementation. Guidelines should also be included in the continuing medical education (CME) programmes to assist in the continuing professional development of health care providers. Guidelines may be used also as tools for testing professional competence for specialist qualification examinations.

Organisational interventions may include reminders (manual or electronic) of new practice issues, influencing of opinion leaders, establishment of multidisciplinary teams, local consensus building and patient/public mediated interventions. Audit and feedback, changes in facilities, medical records or information systems, revision of professional roles and of case management may also help guideline implementation.

Financial interventions to promote guideline implementation may include incentives, rewards and penalties. Economic incentives may be offered to the health care provider, the health care institution, or the health care funding organization. At the health care provider level, other types of rewards, such as professional acknowledgement and recognition, may help implementation of guidelines. While incentives or rewards may be useful, penalties for non-compliance with the guidelines should be avoided, since guidelines are not definitive directives on the correct treatment.

Regulatory interventions may include use of accreditation, licensing and management of complaints. Health authorities may use the existence and the application of clinical protocols within an institution as criteria for accreditation or licensing of service providers. Guidelines and protocols can be linked

also to the commissioning or procurement of services from health care providers. The evidence to support adherence to the clinical protocols can be assessed by the results of the clinical audits carried out within the institution.

EECA DATA

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

However, in order to implement a guideline successfully and achieve change in practice, different strategies and methods should best be combined into multifaceted interventions.

Development of local institutional clinical protocols based on national guidelines

Although guidelines provide evidence-based recommendations for practitioners in a digested and friendly form, a key step in the implementation is the adaptation of the guideline to each local setting. In this context, the term "local" may include a multitude of settings within the health system of a country, extending from a hospital or department to a clinic. Customization of a clinical guideline to a local setting in the form of a local protocol defines clearly who does what, when and where. While a great deal of effort has been invested in developing processes that lead to high-quality national clinical guidelines, less work has been done to understand how national guidelines can best be adapted to a local context of health care through specific protocols.

EECA DATA

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.

Development of local clinical protocols based on the national clinical guidelines should be a structured, systematic and participatory process and should take place in each health care institution. The process is different from the national one, but should follow similar principles. An in-house discussion should take place to ensure that issues and concerns relevant to local circumstances have been identified and addressed adequately. Factors to consider may include limited treatment options, equipment, or human resources (variations in the availability, training, experience and skills of clinicians). The process must preserve the scientific integrity of the national guideline evidence-

based recommendations, while in the same time adapt them in accordance with the specific local context of use, needs, priorities, policies and resources.

Local protocols should be preferably based on existing national clinical guidelines. They may also use other relevant guidance documents and may contain recommendations which do not come from national clinical guidelines. If local protocol development groups intend to modify a recommendation of a national guideline based on any evidence not considered at the national level, they should inform the national guideline developers about the proposed modifications and their supporting evidence. Finally, the local protocol should be approved by a local consensus process and endorsed by the health care institution management.

The local Protocols Development Group

Local adaptation of national clinical guidelines requires organizing Protocol Development Groups in each department/section/clinic. It is essential that the process of organizing these groups offers all interested parties an opportunity to be involved and takes into account their views. Implementation of a national clinical guideline at local level is a responsibility of each individual health care institution and takes place in each department, clinic and ward. Properly developed local protocols improve acceptance, adherence and uptake through a sense of ownership from the end-users, thus making it easier to implement changes in clinical practice.

Protocol Development Groups should involve local practitioners, health managers and financial officers and, if possible, representatives of the patients. The groups should have formally appointed coordinators and clearly agreed terms of reference. Members of the Protocol Development Groups should be trained in the methodology of developing their own clinical protocols.

Guidelines Review and Update

Clinical guidelines should be regularly updated as new evidence emerges on effectiveness, benefits or harms from newly published literature or from advances in therapies and technology. The optimal interval for updating a guideline depends on the topic and other factors, but is usually between three to five years. The review date could be advanced if recommendations are no longer valid in the light of new information. Too frequent review of a guideline should be avoided, since it may affect continuity of implementation. Guidelines should include a review date and should describe the process which should be used to update the recommendations.

The process of updating a guideline includes similar fundamental steps like those used for the de novo development of the guideline including systematic literature search, critical appraisal and formulation of recommendations. It needs careful planning in order to avoid conflicting priorities and is made easier when the original production process has been systematic. To facilitate this process, it may be useful to set up a mechanism through which alerts and requests for update may be received continuously from guideline users.

EECA DATA

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.

Guideline Programmes

For the clinical guidelines to achieve their maximum effect and impact, they should not be developed and implemented in isolation, but in a structured environment and should be integrated in a broader strategy designed to promote and improve the quality of care at both the national and local level. Almost all countries in Eastern Europe are member states of the Council of Europe. A policy document issued by the Committee of Ministers of the Council of Europe (Recommendation Rec(2001)13) has been in place since 2001, recommending that the governments of member states develop a coherent and comprehensive national policy framework for drawing up guidelines on best medical practices.[4]

There are many initiatives for the development of clinical guidelines in almost all countries in the EECA Region, but only some countries have managed to build structured and co-ordinated approaches. In many countries in the region, guideline-related activities seem to be scattered, or have just begun to be co-ordinated.

EECA DATA

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. 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.

Developing good quality clinical guidelines is a time-consuming and expensive process which can be performed by institutions or organizations of different sizes. Large national institutions or organizations may have the capacity to develop series of clinical guidelines, but smaller organizations may develop only a few guidelines occasionally. Guidelines can also be sometimes developed by ad-hoc groups, which may not have the resources and infrastructure for a good quality evidence-based process.

Strong guideline programmes should have national bodies dedicated to producing clinical guidelines, including institutions capable of conducting systematic reviews and synthesizing evidence. Suitable infrastructure and incentives to deliver care guided by recommendations of guidelines and clinical auditing functions should be available in order to assess the uptake and adherence to guideline-based care. In Eastern Europe and Central Asia, although the development of clinical guidelines is being promoted and supported by governments and professional organizations, only a limited number of countries have institutions dedicated to synthesizing evidence and producing guidelines and fewer have policies in place designed to support clinical governance and practice guided by guideline recommendations. Local adaptation of guidelines through institutional level local protocols is still rare and the use of clinical audit more so.

Given the complexity of the processes and of the resources that have to be involved, it is essential that a systematic approach to planning, developing, disseminating, implementing and updating clinical guidelines is followed. Countries which intend to develop a structured guideline agenda should consider planning, managing and monitoring a coherent guideline development programme as a part of the country's health care development strategy.

Phases in developing a guideline programme

A guideline programme should be established through a structured process including the following suggested phases.

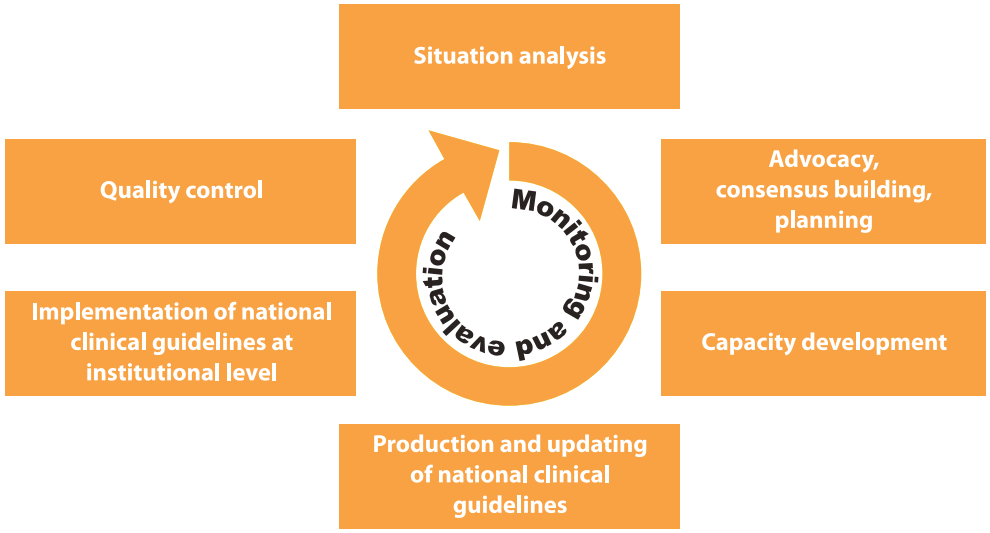

Figure 3. Phases in developing a guideline programme.

Situation analysis

Laws, policies and regulations

A situation analysis should be conducted at the beginning of the process of setting up a guideline programme. The analysis should aim to identify existing laws, policies and regulations related to clinical guidelines, protocols and audit. If gaps are identified, plans to clarify, streamline, or develop adequate laws, policies and regulations should be developed.

Stakeholders

The situation analysis should also identify all key stakeholders who may have an interest or involvement in the development and implementation of the guidelines. This includes key institutions which may provide coordination, technical support, facilitation and backstopping, but also funding. It may also be useful to identify in the country individuals who consistently and energetically advocate, promote and support the process of developing and implementing clinical guidelines, protocols and audit. Such "champions" may be instrumental in pushing forward the guidelines agenda in the country.

Key stakeholder institutions involved in clinical guideline development and implementation can belong to several categories and have each a well defined role in each phase of the guideline development and implementation process. (Figure 4)

Parliament	Defines the legal framework for quality in health care.
Ministry of Health, Government agencies	Define priority health care topics; endorse legally the guidelines; define guidelines-based quality assurance regulations; allocate budgets.
Physicians' representative organizations (professional bodies, specialty or disease specific associations)	Produce and update evidence-based guidelines, set professional standards, ensure physicians' compliance, analyse the noncompliance and act to improve practice.
Medical universities and academic institutions	Produce evidence-based guidelines, support the process, and implement guidelines-based education.
Public or private technical institutions, quality improvement organizations	Produce evidence-based guidelines, support the process.
Public or private health care provision institutions	Develop and apply local clinical protocols starting from the national guidelines, implement quality management programmes.
Health professionals	Apply the guidelines and protocols in daily practice and guarantee high-quality health care.
Civil society organisations that represent patients or potential health consumers	Participate in guidelines and protocols development and dissemination.
International development partners	Support the guideline development process or may develop guidelines
Private health care industry	May support the guideline development process

Figure 4. Key stakeholders for clinical guidelines.

The input of particular institutions/organizations involved in the development, implementation and evaluation of clinical guidelines differ depending on the political context and the health care system of a particular country. The leadership role of the Ministry of Health in the guideline programme as the Government body in charge with the health of the population is essential. The role of professional bodies representing the medical profession is equally important, as the clinical guidelines regulate the professional conduct. The role of medical universities and other stakeholders also needs to be defined.

EECA DATA

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%).

Existing guidelines and protocols

The situation analysis should identify existing SRH guidelines developed by different organisations in each country. Guidelines should be entered on a centralized inventory and clearinghouses should be established in order to guarantee easy access and transparency, to allow evaluation of guideline quality and to assist in prioritizing the guidelines to be developed. Clearinghouses may also offer access to guidelines published on similar topics in other countries or by international bodies, provide advice on methodologies and facilitate access to bibliographies and tools for critical appraisal of guidelines. They may also serve as a discussion forum for users and developers. Advanced clearinghouses may also perform evaluation of the methodological quality of guidelines, without recommending which one to be used.

Capacity analysis for development needs

The situation analysis is also an opportunity to identify not only which are the key stakeholders, but also what are their capacity gaps, development needs and to analyse other attributes which play a key role for the development of a guideline programme. This would also help define the characteristics of the stakeholders who would take forward the task. A robust organisational structure, a responsible and motivated team of stakeholders with authority, adequate human and financial resources, autonomous decision making and learning and communication abilities are key ingredients of a successful guideline programme.

Advocacy, building consensus, planning

Establish policy/coordination structures

A clear understanding of the country's needs should inform the development of the guidelines programme from its outset. This requires the full understanding of the challenges faced by the country in order to improve the standards of health care and the outcome indicators. Therefore, policy dialogue between key stakeholders is needed in order to secure the political participation and reach agreement on common goals.

No programme would succeed without the endorsement of the Ministry of Health, therefore the policy makers should be fully briefed on the value for money of the guidelines programmes and how their implementation would bring measurable benefits. In that respect, briefings, orientation and brain storming meetings/workshops with stakeholders would be instrumental in clarifying all aspects of the process.

Good practice may be to establish a formal policy/coordination structure for the guideline programme at national level, such as a National Clinical Guidelines Programme Steering Committee, comprising of a group of representatives of key stakeholders. All policy decisions needed for the setting up, running and evaluation of the clinical guideline programme should be agreed between all relevant stakeholders, especially between the Ministry of Health and the physicians' professional bodies, but also the medical universities and technical institutions. The political process of building consensus between all stakeholders before starting the technical process would lead to ownership of the process by the national institutions.

EECA DATA

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%).

Set strategic direction

Setting realistic goals and feasible targets for the guideline programme is important and a strategic planning exercise should take place from the beginning. It should take into account various factors such as epidemiological and health data, structural configuration of the health care system, ethical, social and financial issues. In setting goals, it should be recognised that the purpose of a guideline programme is to improve quality of care by reducing variation in clinical practice within existing financial constraints. Clinical guidelines should be considered in the context of national policy decisions on prioritisation of health care needs.

Decide institutional structures

In order to implement a successful guideline programme, a decision should be made at the outset regarding which health care institution/organization (governmental agency or professional organization) will lead the guideline programme. Institutions which will provide the functional roles needed for the process, including technical assistance, facilitation, backstopping, etc. should be also identified and their financial support should be secured, preferably from public/governmental sources.

There are two models which could be considered regarding the delivery of a guidelines programme: a centralized programme for the development of guidelines in one strong institution/organization, or a multi-institutional approach. The world wide experience of developing guidelines favours a functional mix of both models. It would be prudent to suggest that in the EECA countries there should be a state-funded central body with executive body membership from all the stakeholders and whose function would be to define the programme, set out rules for the production of guidelines and how the guidelines developers' performance would be measured. Thereafter the guidelines programme could be devolved to the institutions/organizations who meet the criteria set out by the central body. Developing and using a large community of guideline developers would in this context have advantages in terms of constituency and ownership of the professional organisations that could play a key role during the implementation phase. A mechanism for regularly reviewing the activity and procedures of the guideline developing organizations should be developed and implemented, so that adherence to quality development standards can be certified.

To successfully develop quality clinical guidelines, it may be necessary to set up new structures in a country, or reassign specific tasks to existing structures, in order to meet the distinct functional roles which have to be undertaken at policy and technical levels. Some functional roles can only be assumed by some particular institutions/organizations. For example policy setting, topic decision and formal approval should be the prerogatives of the Ministry of Health. Some of these roles may be played by entities/structures within the same institution/organization, but some should be performed by independent structures. Some roles should not be combined. For example, development and review of the guideline should not be performed by the same entity/structure.

Allocate resources

A guideline programme may take one to three years to fully develop. Building up the structures, securing funding and training the professionals require sizeable efforts at the beginning of the process. Decisions regarding the sources, amounts and destination of funds should be agreed and budgets should be planned and allocated well in advance in accordance with the fiscal year procedures. Such planning is especially important when multiple sources of funding, including government, professional bodies, international partners, should be combined and leveraged

to support one coherent programme and to achieve specific targets. Financial needs should be anticipated and planned not only for the guideline development process, but also for dissemination and implementation of the guidelines.

The process of developing a clinical guideline requires funding for several types of costs: information support (online searches, library and copyright fees to obtain copies of articles for review, systematic review, etc.), professional time involved in guideline development, meetings (of the guideline development group and other structures/bodies established for the programme, consultation meetings, consensus meetings, other), technical editorial support, printing and dissemination. The average budget to develop de novo a single guideline may vary from 10,000 USD to 200,000 USD, not including dissemination costs.[3] The major expenses in the guideline production are usually related to the in-depth evidence systematic reviews and syntheses. Some guideline developing organizations or programmes may not afford this level of resources, so adaptation may be the only alternative.

Guideline development costs may be covered by the government in the case of publicly funded programmes, by guideline organizations themselves (professional bodies, universities, etc.), or by international development partners. A guideline programme may also be partially funded from other funding sources or related sources of income such as sale of guidelines, training courses, etc. To avoid conflict of interests, guideline programmes should not accept funding from health care industry sources for guideline development.

EECA DATA

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.

A decision should be made regarding the payment of the members of the guideline development/adaptation groups and other different bodies involved in the process. Normally, the professional time spent by the GDG/GAG members should be covered by their employing institutions and this activity should be included in their job description. They should not receive additional payment for their activity, but should be reimbursed for the travel expenses incurred by attending the group meetings. As an incentive for their participation and work in the guideline development activities, they may be awarded continuous professional development credits/points or other professional recognition incentives. Depending on the country specific situation, honoraria may, however, be paid to GDG/GAG members.

Agree on the guideline development methodology

Before initiating the guideline development process, an agreement should be reached on the guideline development methodology that will be used (adaptation or de novo development). The agreement and the methodology chosen should be documented in a formal guideline development handbook, or "guidelines for guidelines", agreed by the Ministry of Health, governmental agencies, professional organizations and other stakeholders. The handbook should address and detail the steps of the guideline development process. It has been reported that guidelines produced within a structured environment, using a systematic methodology agreed by all stakeholders, are more likely to be of higher quality.[3]

EECA DATA

Guidance documents for good practice in guideline development ("guidelines for guidelines") were developed and published only in 19% of the countries.

Prioritize health topics

There is a wide range of topics and clinical problems could be addressed through clinical guidelines. However, just one guideline may consume many months of work and the number of experts qualified to generate valid recommendations about a topic is limited. Therefore, setting priorities is an essential step for the guideline programmes. It should be done through regular, formal, structured and transparent priority-setting exercises, involving all interested parties. Based on the priority setting exercise, a subject map may be constructed and updated at regular intervals. Ranking of the potential guidelines topics should reflect the health strategy of the country and the goals of the programme.

Capacity development

Develop capacities

Capacity gaps of key stakeholders may exist in various areas, such as: assessing situation and defining vision, formulating policies and strategies, engaging with other stakeholders, managing and implementing budgets, monitoring and evaluating. Any identified capacity development needs for key stakeholders should be addressed through a capacity development plan. The plan should address the key general components of capacity (policy and legal issues, accountability, human resources, financial resource allocation, management and oversight, access to information and knowledge, systems and technology and participation, equity and empowerment), as well as any technical capacity gaps identified during the capacity analysis.

Most often, technical capacity gaps may exist in the area of identifying, evaluating and interpreting scientific evidence, which requires substantial resources and expertise. This can be done within the guideline developing institution/organization, if it has or can develop the appropriate resources. It may also be delegated to a specialized institution or to external experts trained in systematic reviews, who evaluate the evidence in discussion with the clinical experts. There are also international institutions, most notably the Cochrane Collaboration, dedicated to improving health care decisions through development of systematic reviews of health care outcomes evidence. There are also specific tools aimed to assist easy retrieval of SRH evidence, such as the WHO Reproductive Health Library. Technical capacity gaps may also exist in the area of planning and managing the clinical guideline development process and the support of institutions which successfully facilitated such processes in other countries may be considered.

Networking

Networking between guideline programmes, developers, reviewers and users may provide practical support, decrease unnecessary repetition of work and should be encouraged both within and between EECA countries. Guideline programmes and institutions/organizations may consider joining the Guidelines International Network (G-I-N), a global network which represents 46 countries from all continents. G-I-N aims to lead, strengthen and support collaboration and work within the guideline development, adaptation and implementation community. It provides a network and partnerships for guideline organisations, assists members in reducing duplication of effort and improving the efficiency, effectiveness, patient safety and outcomes of evidence-based guideline development, adaptation, dissemination and implementation and promotes best practices.

Production and updating of national clinical guidelines

Once the national structures are in place and have the required capacities and after the priority topics have been identified, a systematic process of producing national clinical guidelines may be initiated. More details on the process are outlined in the specific sections of this guidance document.

Guideline programmes should include clear policies and responsibilities for the review and update of the published guidelines to ensure that guidelines are continuously updated at the date set or when new evidence on the guideline topic becomes available.

Time, resources and funding should be clearly earmarked for production and update. Since limited resources compete for both guideline development and review/update, it is important to identify those topics which require updating and decisions have to be made between developing new guidelines and updating existing ones.

Implementation of national clinical guidelines at institutional level

Developing local clinical protocols in all health care institutions is the key link between national clinical guidelines and local clinical practice. Clinical guidelines are instrumental for evidence-based practice, performance monitoring and health care management. Institutional clinical protocols make national clinical guidelines relevant to the local setting and provide an opportunity to develop locally specific standards which can be used as quality improvement tools and as a basis for clinical audits.

This process may require resources, capacity development, technical assistance and backstopping support at a much wider scale than the national process of clinical guidelines development. Therefore, in developing a national guideline programme, one should always be aware of the intensive resources required for developing local clinical protocols at a nationwide scale.

As with national clinical guidelines, guideline programmes should have mechanisms for ensuring constant updating of local clinical protocols and for informing all providers about the new recommendations.

Quality control

As the programme develops and more and more guidelines are produced in a country, some addressing similar or related topics, clinicians will face challenges in reviewing and identifying trustworthy guidelines developed through a high-quality process. A regular mechanism for quality control should be created at guideline, institution or process levels. Quality control may be done by evaluating individual guidelines produced against defined quality standards (see section on criteria for high-quality guidelines), by evaluating on a regular basis the guideline developing institutions and their organizational procedures, certifying their adherence to quality standards and accrediting them, or by evaluating the proposed guideline development processes for each planned guideline.[9]

Monitoring and evaluation of guideline programmes

The ultimate goal of clinical guidelines programmes is to improve health care practices and health outcomes. However, even the best recommendations based on strong evidence and sound judgement and implemented by motivated providers may not fully produce the intended changes. Guideline programmes should therefore incorporate mechanisms to check whether the objectives of the programme were accomplished, to determine the extent to which the guidelines influence the practice and health outcomes and to identify any factors that may lead to non-compliance with the guidelines. Such information may inform the development of more effective implementation strategies. The monitoring process should be designed and put in place from the beginning of the guideline programme development process.

It should be noted that a guideline programme is usually responsible for the production and dissemination of national guidelines, but not also for their implementation into practice, since factors outside the programme, such as national policies and local ownership, are essential for successful implementation. Guideline programmes may be involved however in the development of national policies that regulate and facilitate local guideline implementation activities.

On a longer time frame, it is also important to monitor the impact of the guidelines programmes and to establish whether they produced the desired and anticipated health outcomes on a wider scale. In order to achieve this, once the guidelines are implemented, routinely monitoring of health outcomes through clinical indicators should be an integral part of guidelines programmes. To monitor the intermediate and the true health outcomes of the interventions recommended in the guideline, high-quality indicators should be developed and validated. Such indicators should be available from regular records, easily measurable, comparable between health care institutions and indicative of true health outcomes.

Legal issues in guidelines development

Legal issues related to clinical guidelines may refer to the clinicians who use the guidelines or to the guideline developers.

Some clinicians may be concerned about their potential legal liability if they do not act according to the clinical guidelines and something goes wrong. Guidelines may indeed be referred to or used in courts as evidence of what constitutes recommended medical practice, but the extent of using them as evidence depends on their medico-legal status conferred through their formal approval. If developed by professional bodies or technical institutions, they are not legal regulations per se, but may acquire legal significance if formally incorporated into binding regulations issued by the Ministry of Health. Legal status of the guidelines may also depend on their quality, determined by how evidence-based they are, the rigour of the development process, the level of professional consensus on the recommendations and whether or not they are updated or not in line with new evidence.

Although clinical guidelines do not substitute sound professional judgement, using guidelines confers a degree of protection to the clinician. Deviation from the recommendation of the guideline does not by itself imply malpractice, but the clinician must document and be able to provide good reasons if he/she does not act according to the guideline and the decision may need to be justified in court, especially if the patient is harmed. It is important that any decision to not comply with the recommendations and the reasons for doing so must always be clearly documented in the medical records.

Regardless of the strength of evidence, it is the responsibility of the clinician to interpret the guideline recommendation, to make the best decision and to act in the best interest of the patient. As a good practice rule, clinicians should always give information to patients about the available treatment options and their risks and encourage them to take their own decisions. Information should be provided in a lay language, correlated with the patient's level of education and culture and respecting the patient's values and rights. The patient's informed consent must be clearly recorded.

EECA DATA

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".

The risk to guideline developers being held liable for any negative consequences arising from the implementation of guidelines is low. The decision to implement a particular guideline is made by health policy makers, managers and service providers. Guidelines offer recommendations and do not replace the clinicians' professional judgment in a particular case. Each country should decide on the medico-legal status of guidelines depending on the specific legislation, interpretation and practice. In any case, guidelines should not be seen as definitive directives on the correct treatment and should not be used to legally mandate or outlaw different treatments or procedures.

Each guideline should include a disclaimer clearly stating that the recommendations may not apply in all situations and that individual patient or setting specifics have to be considered. It should be made clear that guidelines should not be used as a substitute for the clinician's informed clinical judgment and decisions regarding an individual patient and that the ultimate responsibility for clinical care lies with the clinician who uses the guideline. No responsibility can be accepted by the authors of the guidelines for any lack of benefit or harm that may occur by following the guidelines.

Monitoring Guidelines Use and Improving Practice

Institutions/organizations or programmes which develop clinical guidelines should monitor and evaluate the impact of their guidelines on clinical practice. This should be best made through clinical audits which check if the process of care at the institution level reflects the recommendations from the guidelines and derived protocols.

Clinical audit was defined by the National Institute for Clinical Excellence as 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.[11]

EECA DATA

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 audits were reported as taking place in the last three years in topics belonging to the areas of SRH in 50% of the countries. Topics included 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.

Each guideline should include several key auditable criteria, which should allow the objective evaluation of the effect of guideline recommendations implementation on processes and, if possible, on outcomes of the interventions. Given the fact that outcome indicators are influenced also by other non guideline-related factors, such as lifestyle, compliance, socio-economic factors, etc., it is more appropriate to measure the success of the implementation of a guideline through process indicators.

In order to improve the quality of health care delivered, the guideline and protocols development process should be connected with the national and local clinical audit processes. Clinical guidelines provide the evidence base for setting quality of care standards, which are audited.

Clinical audit can be regarded as a systematic cycle or spiral rather than a linear process. It does not involve only monitoring guideline use and measuring care against specific criteria, but it also includes identifying solutions and taking action to improve care if necessary and monitoring the change process in order to sustain improvement. As the change process progresses and each new clinical audit cycle moves to a higher level of the spiral, improved quality of health care is achieved.

Clinical guidelines and clinical audit are elements of professional self-regulation and should operate in a cultural environment in which openness is encouraged, errors or failures are reported and investigated without fear of punishment and lifelong learning and creativity are supported. Thus, they become essential components of the larger framework of clinical governance, in which health care institutions are accountable for continuously improving the quality of their services and safeguarding high standards of care.

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