Developing and implementing guidelines for health policy and clinical practice in Estonia: interim appraisal of progress

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EXECUTIVE SUMMARY

WHO defines guidelines as

....systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions. Health interventions are defined broadly to include not only clinical procedures but also public health actions. Guidelines are formal advisory statements which should be robust enough to meet the unique circumstances and constraints of the specific situation to which they are being applied (1).

Well-developed and high-quality guidelines provide the basis for promoting quality of care in a health system. If the guidelines are based on evidence, accepted by local health professionals, and linked with performance indicators and implementation strategies, they can lead to improved quality of care and health outcomes. According to the Institute of Medicine, "When rigorously developed using a transparent process that combines scientific evidence, clinician experiential knowledge, and patient values, CPGs [clinical practice guidelines] have the potential to improve many clinician and patient healthcare decisions, and enhance healthcare quality and outcomes" (2). In fact, there is no viable alternative to evidence-based development of tools like guidelines that support decisions at a clinical, population or system level.

Guidelines can be used in different ways and, thus, have multiple pathways in influencing and improving care. Development and debate around developing, adapting and applying guidelines will contribute to health professionals’ continued medical education and knowledge, and may be focused at universities as part of health professional development. When used in health insurance systems to decide what will be reimbursed, guidelines can contribute to cost-containment, and when used in quality assurance and audit at a local level, they can improve quality. If a country wants evidence-informed policy and guideline development to improve health outcomes, then a guideline development process needs to be embedded in the health system at all levels. From national policy through to public health programmes, this process needs to include hospital and primary care implementation, financing, auditing and health professional education, with all professional groups accepting and engaging in the principles and practice of the approach.

The Estonian Health Insurance Fund (EHIF), with support from partners including WHO, has invested in the development of a clinical guideline development process since 2011 that has resulted in:

- five completed high-quality clinical guidelines, of international standard, and 10 in progress, which were developed with reference to the Estonian handbook for guideline development (3), and with local ownership by health professionals participating in guideline panels and guideline development;
- completion of patient guidelines on six topics;
- over 200 health professionals in Estonia trained in evidence-based guideline development;
- developments linking the new guidelines with effective and appropriate quality standards;
- progress in transforming health professional workforce capabilities to practice evidence-based medicine using best practice internationally;
- effective links between the Ministry of Social Affairs, the EHIF and academic institutions such as the University of Tartu and the National Institute for Health Development in Estonia;
- changes to the reimbursement of some items and services funded by the EHIF to promote better quality of care; and
- an operational framework to improve the quality of care delivered in Estonia, particularly by family medicine practitioners.
Based on information provided about salary support, meeting costs and production costs, we estimate the financial investment by the EHIF to produce these impressive results has been less than half a million euros. This is a model for many other countries aiming to develop similar programmes. Provided the guideline process is maintained and the linkage to quality improvement (especially clinical indicators and audit processes) and reimbursement continues to strengthen, we expect that over the next few years, there will be evidence of the cost-effectiveness of the guidelines, as well as data supporting the improvement in quality of care. In addition to the EHIF that has led this process, these developments are a tribute to the leaders driving the process, the staff involved, and the health professionals and societies who have participated and continue to do so.

When this review was commenced, these gains appeared to be under threat. There was considerable uncertainty about how the transition of two key full time staff from the EHIF would be managed. Skills developed by these two staff have been a major contributor to the success of the work to date, and maintaining their networks and contacts will be essential. Over the course of the review, it became apparent that the EHIF’s management were taking urgent steps to ensure that continuity of the programme would be maintained. We strongly support the need to do so, to avoid any risk of a major hiatus in the system of guideline development. The effects of this change, if not properly managed, could be a loss of the goodwill with the medical professional community that has been built up over the last five years, a loss of the credibility of the guideline programme and potential loss of the improvements in quality of care.

We see that over the last five years, increases in the human resources available in Estonia for guideline development have been substantial. To take this forward, the core system requirements for guideline development are:

- systems to identify topics, drawing on analysis of health services data, to help prioritize areas where good policies and guidelines properly implemented are likely to improve health outcomes;
- capacity to co-ordinate and manage the process of guideline development;
- teams that can carry out evidence synthesis and prepare material to guideline panels;
- expertise and systems to produce and disseminate a variety of guideline products; and
- systems that oversee implementation strategies and monitor progress.

The resources to undertake these functions in Estonia already exist for the most part, as a result of the work over the last 4–5 years, but they are scattered throughout different organizations and centres. If the guideline process is to continue, commitment is needed now to ensure a core of at least 2–3 full time equivalent (FTE) staff to co-ordinate guideline development, five FTEs to provide technical material and possibly another 2–3 FTEs for production, dissemination and implementation. These functions could be located in the EHIF, the Ministry of Social Affairs, the University of Tartu or the National Institute for Health Development (NIHD), but an effective coordinating mechanism is needed if they are not in one place. The location of the unit or units is a political and managerial decision, depending on budget, flexibility and existing staff. Our detailed suggestions on options are set out in the main body of this publication. The additional direct investment of resources required is relatively small when compared to the potential impact on quality of care and health outcomes. We note that there are plans for the development of an overall quality of care strategy, and clearly, the guideline development process and the guidelines will need to be embedded as a core part of that initiative. While currently the EHIF has provided the majority of funding for development of clinical guidelines on disease treatment, we suggest that there is an appropriate role for the Ministry of Social Affairs to play with respect to funding guidelines related to public health interventions.

The review panel received mixed signals about the level of political support for guidelines, and some people were not fully familiar with what the guidelines process entails. This is not unusual given the relatively short history of development within the country, but a process is clearly required nationally.
The process of guideline development requires time, energy and resources, but this process is key to ensuring local ownership by health professionals who will contribute to effective implementation and improved quality of care. Efficiencies can be introduced into the current process with amendments to the handbook. But if the EHIF wishes to ensure quality of care delivered to its clients, the guideline development process needs to be supported by a small team of professional staff. The guidelines then need to be implemented through use of appropriate derivative guideline products, such as clinical pathways, training, audit and feedback, linkages with quality indicators and where appropriate, pay for performance arrangements.

**Key recommendations**

1. **Build on the process that has been successfully established in Estonia for guidelines.**  
   **This will require:**
   - articulating the value of guideline development in Estonian health policy as a core component for quality improvement; and
   - demonstrating political commitment to guideline development by providing resources for staff required for the core system requirements outlined in recommendation 3.

2. **Further advance guideline development based on the latest international best practice.**  
   **This will require:**
   - improving the topic selection process, by choosing guideline topics based on the needs of the Estonian health system;
   - adopting, adapting and developing local guidelines with local ownership using international guidelines where appropriate;
   - formalizing the use of the grading of recommendations assessment, development and evaluation (GRADE) process and other key aspects of guideline quality such as reporting of conflict of interest throughout the guideline process; and
   - designing and targeting systematic implementation strategies with greater care.

3. **Establish and organize the core system requirements in the country for guideline development.**  
   **We considered certain options.**
   - Increase substantially the staff and resources involved in guideline development at the EHIF to take over complete management of all aspects of guideline development and implementation; as noted previously, this would require approximately 10–12 FTEs based at the EHIF.
   - Have EHIF continue to play a coordinating role through slightly increased staff numbers to coordinate the guideline process (especially maintaining established clinician networks) but outsourcing the evidence synthesis functions through contracts with either the University of Tartu or NIHD to provide technical support to guideline panels. The coordination needs to include links with the EHIF clinical indicator process, as well as audit activities and utilization review.
   - Establish a separate permanent unit independent of the EHIF for ensuring quality of care by consolidating existing capacity in Estonia in one centre, with roles and functions that include the guideline development process, provide technical support and link guidelines with implementation and monitoring activities.
INTRODUCTION

In 2010, Estonia started revising its national clinical guideline development process as part of an overall programme of quality improvement in health care. WHO, the EHIF, the Medical Faculty at the University of Tartu, and selected national and international experts carried out a comprehensive assessment of guideline development in Estonia in an effort to streamline and harmonize the principles and processes of guideline development. As an outcome of a two-year preparation process, the Estonian handbook for guidelines development (3) was developed. The handbook aimed to bring together the experience and internationally accepted methods for developing guidelines covering all aspects of guideline development, including a consistent approach. This process was tested through a pilot project consisting of development of a new guideline during 2010–2011 on the management of hypertension in primary care. Furthermore, beginning in 2010, annual training has been conducted to support the EHIF’s work. This training included 2–5 day courses in evidence-based health care, guideline development and systematic reviews.

The new process of guideline development is now well under way, with 15 guidelines in different stages of development; three are complete and approved. The completion of the development cycle provides a good opportunity to review how the process has been implemented, whether it delivers guidelines of improved quality and according to evidence-based medicine standards, and whether it has resulted in the improved uptake of guidelines in the everyday practice of health professionals.

During the first five years of implementation, great progress has been made, but further development is still needed, as well as a need to attend to concerns and questions raised to help guide and support further development and implementation. Some challenges were identified.

- Some view the process to develop a guideline de novo to be too long and resource intensive, and question whether this is realistic and the degree to which internationally available guidelines can be adopted and adapted.
- Sustainability concerns exist due to the low turnover of guidelines and the resource-intensive process.
- Whether the use of existing (human and financial) resources and capacities (including secretariat skills) is optimal is questioned.
- Guidelines may not have been developed for the most relevant health problems.
- The uptake of guidelines is still perceived to be low, and their use is not well integrated into clinical practice and the decision-making process.
- Incentives supporting use of the guidelines are lacking.
- Capacity building is still required to ensure that participants and stakeholders have the required capacities, and understand and accept the methods.
- How to achieve equal participation of different health professional groups (including nurses and other auxiliary staff) and how to engage patient representatives in the process remain challenging.

The areas that need further development are the processes of adapting and updating guidelines, and the development of guidelines products, such as patient pathways, that depend on recommendations from standard guidelines on the whole.
EVALUATION OBJECTIVES

The terms of reference for the evaluation are in Annex 1. The aim of the evaluation is to review the progress made with clinical guideline development in relation to the process and outcomes, and to gain an understanding of potential or actual impact on improvements in quality of care and the health care system as a whole. The evaluation is expected to provide recommendations for updating the guideline development and implementation process, including changes, if needed, to the handbook and other institutional arrangements to support the development and usage of clinical guidelines.

The evaluation considered specific questions.

- Are the guidelines following international standards?
- In what ways can the guidelines be further improved?
- How to handle the development of non-conventional guidelines such as updating patient pathways and adapting existing guidelines within the process of guideline development?
- How could production and use of the guidelines be further improved and institutionalized in the health system?
- What are the barriers to use, and what is best to improve uptake by health staff?
- Have the guidelines impacted on integration and patient flow between levels of care?
- What has been the process of implementation of clinical guidelines into the clinical practice, and what options further support the usage of clinical guidelines (including the potential of e-tools, patient management guidelines and training)?
METHODS

The evaluation was based on two components: preparatory work carried out by staff from the EHIF in collaboration with the WHO Country Office, Estonia, and a site visit by a team of three external experts. The programme for the site visit is in Annex 2, and the list of persons met is in Annex 3.

Preparatory work

The preparatory work consisted of:

- a survey of the experience of participants in the guideline development process, including secretariats and panels (findings in Annex 4);
- a survey of clinicians’ opinions and perceptions about clinical guidelines, based on an update of the survey published by Taba et al (⁴) (findings in Annex 5); and
- a quality assessment of three completed guidelines translated to English by external reviewers using the Appraisal of Guidelines for Research and Evaluation (AGREE) instrument.

Site visit

The three external reviewers spent one week (24–28 August 2015) in Estonia, conducting stakeholder interviews and focus groups. We prepared a report and draft recommendations, which were then discussed in a meeting with the EHIF staff.

We assessed the implementation of the guidance in the handbook, and the outcome of the guideline development process. In addition, we assessed the number of guidelines produced, the resources and time spent, the cost per guideline, and obstacles and opportunities in relation to the process and sustainability. We used recent developments and current literature (⁵) in guideline development methodology to inform our assessment.
FINDINGS

EHIF leadership in clinical guideline development

The EHIF, with support from partners including WHO, has invested in the development of a clinical guideline development process since 2011 that has resulted in the completion of:

- five high-quality clinical guidelines, of international standard, with a further 10 in development, according to the handbook, with local ownership by health professionals; and
- patient guidelines on six topics.

We estimate the direct financial investment to produce this very impressive outcome has been less than half a million euros, with two FTE staff in the EHIF. The majority of funds have been invested by the EHIF; the Ministry of Social Affairs has paid for two guidelines related to public health topics, which are outside of the scope of care covered by the EHIF. Clinicians and academics have provided in kind contributions, with particular support coming from professional medical societies such as the Family Medicine Association. This approach is a model for many other countries aiming to develop similar programmes. Provided the guideline process is maintained, we expect that over the next few years, there will be evidence of the cost–effectiveness of the guidelines, as well as data supporting the improvement in quality of care.

The effective development of this system is due to the leadership shown by the EHIF. This is consistent with the EHIF’s mandate to ensure that it pays for high-quality health care. Although there has been some debate about whether the EHIF should retain a leading role in quality improvement rather than, for example, the Ministry of Social Affairs, we recommend that given the available funding, staff, the established networks with clinicians and academics, and the general acceptance by stakeholders of the appropriateness of the role of the EHIF in quality of care, the lead responsibility should remain with the EHIF, at least in the medium term.

While other structures that manage quality of care, such as a dedicated unit in the Ministry of Social Affairs, are envisioned, they do not exist yet.

When this review was commenced, these gains appeared to be under threat. There was considerable uncertainty about how the transition of two key full time staff from the EHIF would be managed. Skills developed by these two staff have been a major contributor to the success of the work to date, and maintaining their networks and contacts will be essential. Over the course of the review, it became apparent that the EHIF’s management were taking urgent steps to ensure that continuity of the programme would be maintained. We strongly support the need to do so, to avoid any risk of a major hiatus in the system of guideline development. The effects of this change, if not properly managed, could be a loss of the good will with the medical professional community that has been built up over the last five years, a loss of the credibility of the guideline programme and potential loss of the improvements in quality of care.

By establishing a systematic approach to guideline development and investing in staff, training and resources, the EHIF has established its authority, widely accepted by all stakeholders, for development of Estonian clinical guidelines.

Various stakeholders felt that, on the whole, the process worked well and was appropriately implemented based on the handbook. The benefits of participating in the process were considered to be broader than just creating a guideline. For example, it enhanced the understanding of approaches to evidence-based health care. However, it was accepted that modifications to the process will be required. Detailed recommendations for updating the handbook are in Annex 6.

Findings and suggestions for improvement are summarized as follows.
Progress on strategies to institutionalize and sustain the process

Coordination of the process worked well. However, it was recognized as being driven by highly energetic and committed individuals, raising questions about the sustainability of the process. Furthermore, the secretariats created individually for each guideline were understaffed and, therefore, creating a so-called professional secretariat, i.e. dedicated staff, emerged as a consistent theme.

While some participants felt that initial meetings of the panels were slow, overall the number and frequency of the meetings were appropriate. In particular, panel members and members of the secretariat felt that it was good to meet repeatedly. However, making time available and ensuring consistent participation in panel meetings, which led to some repetition of information provided, were difficult. Participation would be facilitated by a system that recognizes contributions either through financial reimbursement (with broad consensus for this option), continued medical education credits or academic recognition, such as authorship on guidelines.

Some participants felt that lack of time was the main reason for insufficient preparation for meetings. Changing the timing of meetings (currently often held in the evening) may increase willingness to participate as the need for additional trust-building with clinicians, including groups other than family physicians, was recognized and could be overcome through more active involvement and accommodation of their needs. University involvement was seen as a positive aspect of the development process, particularly by university faculty members. A guideline is important for clinicians as a source for summaries of evidence. It is also the link between education and medical care. Professional societies need to be even better integrated in the process although, for some guidelines, this had already worked well.

Handbook and areas where further guidance is needed

There was broad recognition that having a handbook to follow was critical. The primary reasons were that the handbook:

- provided a resource for how to develop guidelines
- was logical and made sense
- clearly described a beginning and an end to the process
- lent the necessary support
- was of high quality.

An overarching theme that requires clarification and/or modification is related to the choice of guideline topics and priority setting. This is addressed in the subsections on guideline relevance and quality.

Establishing how best to adopt or adapt existing (international) guidelines needed further development. The reasons were mainly based on recognition of limited direct financial and human resources. While stakeholders sometimes indicated these other guidelines were sufficient, upon further questioning, they indicated some process of national and local adaptation was needed. Thus, most international guideline recommendations will need, at a minimum, a review for their utility and applicability in the Estonian context, for example, to determine the availability of recommended interventions and resources. De novo development of guidelines was not a high priority for some interviewees, but local or national input is needed for any type of guideline, even if an international guideline is adapted. Interviewees also agreed that existing guidelines would have to be assessed for quality before adoption or adaptation for Estonia.

The need for some flexibility with regard to changing questions during the process of guideline development was emphasized. This was recognized because relevant questions that make a guideline more complete often emerge as part of the process, and the process should allow this modification.

Generally, adherence to declaration and consideration of conflicts of interest were appropriate, but documentation of these conflicts needs to be better; the guideline appraisal highlights this. The pharmaceu-
tical industry’s influence on one guideline was suspected with regards to the type of questions that were addressed (see also suggestions for updating the handbook).

Training in guideline development for panel members

Over 200 clinicians have been trained for the guideline development process, primarily through the annual workshops and during the initial panel meetings. While the workshops were appreciated, participants felt training could be improved by providing better directions to online training material and more targeted material, in particular for patients who participate in the process.

A few members of the Guideline Advisory Board were concerned about the duration of time for developing a guideline. However, many panel members did not endorse this perception, and valued the opportunity to consider guideline questions and evidence summaries over the course of a number of meetings.

Guideline relevance

We assessed three guidelines and examined minutes of the Guideline Advisory Board that selects topics and has oversight.

The guidelines completed to date include a wide range of topics, mostly proposed by clinicians and considered by the Guideline Advisory Board. Only a small number of proposals are approved for development, which given the size of the task of guideline development and the available resources seems appropriate.

The published guidelines have a focus on primary health care: asthma, hypertension, anxiety and care of venous ulcers for example. Asthma and cardiovascular diseases are important causes of death in the country, and seem appropriate topics for guidelines to establish best practice.

The topics chosen are often very broad, so it may be that a more targeted approach in the future may better focus on the evidence and the recommendations. For example, statin use appears low in Estonia (although contested by cardiologists), and cardiovascular mortality is high; but no guideline has yet been considered in this area. Thus, it would help if the Guideline Advisory Board considered the size of the potential effect of interventions, as well as the size of the problem in their assessments.

The examination of options to detect and manage alcohol problems arose out of the Institute of Health Research obtaining funds to develop services in this area. Thus, the guideline process fed into policy development in a public health problem with a focus on primary health care. Indeed, the use of evidence-informed approaches currently used in clinical guidelines could easily be further extended to areas of public health concerns.

Guideline quality

We appraised three guidelines from translated English versions, with reference to the Estonian original: hypertension from 2012 (6); and asthma from 2014 (7); and in the adoption of the surgical safety checklist from 2015 (8). These were independently assessed against AGREE criteria by two members of the review panel, including one who has not been involved in the Estonia guideline development. Two of the checklists were targeted at primary health care staff and the third at hospital surgical teams.

The guidelines show that considerable advances have been made in adopting evidence-informed, transparent guideline development in Estonia. The guidelines are short, use standard icons and coding to help the reader navigate the text, and seem to cover the main topic areas in primary care. The AGREE assessment scores underline this progress and provide three clear areas where, in the next round of updating, guideline development could be improved.
Editorial independence

While conflict of interest declarations have been collected, these are held by the secretariat and are not published in the main guideline document, partly for reasons of space. We noted a number of potential conflicts of interest such as receipt of funds from drug companies for carrying out trials in the areas considered by the guidelines. While the secretariat may have made judgments about whether these interests were important, a central principle is to publish all declarations. We **strongly recommend** the secretariat follow the handbook and publish this information in guidelines.

Rigor of development

The secretariat have clearly been diligent in searching for existing guidelines and evidence from systematic reviews, but where they have formulated recommendations, there needs to be a much clearer link to the evidence, to the reference to the GRADE table and to the publication of the Evidence to Decision Framework.

Our discussion with panel members suggested that for many recommendations, there has been considerable controversy. This is an important part of the decision-making process, but is not recorded in the guideline or annexes. The panels appear to need to consider more carefully the trade-off between benefits and harms. This is not always clearly expressed. A more structured approach to recording the panel discussions is required and, therefore, we recommend that the secretariat start using the new GRADE evidence to decision frameworks that are now available. These have only recently been developed, so their introduction will help ensure Estonia stays in a leadership position in the region.

Clarity of presentation

While the guidelines have commendable icons and colour coding, the clarity of the presentation could be considerably improved. The guidelines have considerable amounts of text that are difficult to negotiate. The text often considers evidence, but it is not always clear if a recommendation is linked to it, and why it is there, for example, with influenza vaccine in asthma.

We recommend the secretariat work with panels in reducing the amount of explanatory text, and really focus on the key recommendations they make and the evidence considered to reach this decision.

Further extension of use of standard templates will help, and in addition, publishing these guidelines electronically, with more detailed information layered behind different sections (and, in a book, placed in an annex).

Other issues

The **scope** of the two guidelines examined is broad: treatment of hypertension and treatment of asthma. While these provide a clear clinical manual for practitioners in these areas, the topics are very broad and unmanageable in terms of efficient guideline development and also implementation.

We recommend that future guidelines have much more focused questions around an area of equipoise or uncertainty, or where considerable health benefits may be gained from a recommendation. For example, a guideline group could consider the role of statins after acute myocardial infarction or the use of nurse practitioners in asthma care. Each of these topics requires substantial investment of time and is sufficient for one guideline group.

**Stakeholder engagement** – engaging patients – in guideline panels is not straightforward. The secretariat have ensured patient representation in the Guideline Advisory Board, and it would be helpful to
continue to seek ways of ensuring patients have a voice in panels, particularly to provide input on the importance of different outcomes. For example, tuberculosis specialists may advocate long treatments in people who have been diagnosed with tuberculosis meningitis on the basis that any risk of recurrence, however small, outweighs the risk of extending treatment, whereas patients may prefer a shorter regimen and avoid the toxic effects of long treatments of antituberculosis drugs.

**Experience and reflections of guideline developers**

**Personal development**

The people we met who had completed guidelines described what they personally had learned from the process, which was generally positive. Some described the ability to talk with colleagues about their practice, to consider evidence and how they learnt from this and from reading through other guidelines. There was a sense of learning by doing, and doing something practical and useful.

**Small country dilemma**

There was a continued and almost universal anxiety about the country being small, and that it was not feasible to carry out guidelines in all areas. One respondent said, "There are perfectly good guidelines from the European Heart Association. Why do we need our own?" While this came up repeatedly when we talked with almost everyone, including specialists who saw their reference group to be at a European rather than an Estonian level, the need for local input became clear.

Part of the dilemma seemed to be the enormity of the task. Almost all interviewees agreed on the need for a process of examining guidelines from international sources. Agreement was almost universal that even if guidelines existed from other countries, there was a need for dialogue and formal consideration for adopting external guidelines at national or local level, deciding whether it was right for the country, and modifying it in the context of the health system or the hospital in which they were working.

**Specialist engagement**

As has been the case in most countries introducing evidence-based guideline development, senior specialists often see this as a threat. They describe this as unnecessary as they know what to do. According to the teams involved in guideline development, the experience in Estonia has been exactly the same. Some senior specialist groups, such as psychiatrists involved in alcohol guidelines, were fully engaged in the process; others, such as pulmonologists involved in asthma guidelines, were relatively disengaged, seeing it as not relevant to them, although anecdotal reports suggest some regretted not participating later.

**Implementation**

Those involved with guideline development were concerned about whether and how the guidelines were used, if they are mandatory or optional, and what mechanisms should be used to ensure their use. There was agreement at all levels that somehow the standards established in guidelines should link to quality of care and audit.

**Speed of guideline development**

Some people involved in guideline development commented that efficiencies could be improved; in particular, panels should read materials before meetings. A few people wanted the guidelines process to be faster, but this was not common, particularly in those who had participated. "It took us five meetings to
reach agreement on one recommendation,” one panellist noted, “but it was worth it. We all agreed by the end.”

**Disappointment when topics not selected**

Some individuals reported their disappointment when their topics submitted to the Guideline Advisory Board were not approved, and the GAC themselves indicated their concern that they were squashing enthusiasm. Currently, decisions seem to be based on the committee’s opinions on the day: one alternative approach would be to consider short-listed questions more carefully; seek existing systematic reviews and guidelines internationally (from Cochrane, a guidelines website, and from the Guidelines International Network database, for example); compile this as a short report and send it back to the person submitted, as well as publishing it on a website for others to view.

**Usefulness for various stakeholders**

The intended use of guidelines influences how they are developed and implemented. Stakeholders include insurers, specialist and general clinicians, public health doctors and the public. If the intention is for doctors’ continued medical education, then guideline development is best focused at universities as part of health professional development; for cost-containment, it is best linked closely to health insurance and for quality of care, it should be linked to quality assurance and audit at a local level. If a policy direction links guideline development to improved health outcomes, the process needs embedding in the system at all levels, from national policy through to public health programmes, hospital and primary care implementation.

Three guidelines were published at the time of the evaluation. Although the guidelines were generally seen as helpful, reviews were mixed about the usefulness for specific situations.

Perceived facilitators of guideline implementation included:

- short summaries;
- Estonian and Russian versions (since several interviewees suggested translating the guidelines either in their entirety or the executive summary to Russian, as the system provides care to primarily Russian-speaking patients and care providers);
- versions for handheld devices; and
- plain language versions for both patients and care providers.

However, it was not clear that guideline users are familiar with the current approach to the use of guidelines that focuses on providing resources for shared, problem-based decision-making as opposed to a rule-based, read-it-all type of approach. This also prompted comments about the provision of simple algorithms on how to care for a patient.

An additional issue is the understanding of the link between guidelines and guideline *products*. A clinical guideline development process can lead to several different outputs, including patient pathways, patient information guides or clinical pathways, for example. However, these need to be derived from the clinical guideline recommendations. In some cases, issues such as which health care providers – e.g. clinical nurse specialist or family physicians or specialists – should offer particular services recommended in a guideline will need to be resolved through a consultation and consensus process after the guideline recommendation is complete.

A website was seen as a helpful place to look for all guidelines although it was noted that old, out-of-date guidelines were posted. It was agreed that guidelines should be labelled as out of date and have expiry dates. Hospital managers saw guidelines as a necessary instrument, but need more support with implementing the guidelines.
RECOMMENDATIONS

Institutional structure

We recommend certain actions with regard to institutional structure.

- Maintain and enhance the commitment to guideline processes, through provision of resources for staff.
- Urgently re-establish core staff and increase capacity at the EHIF to coordinate the guideline process, maintain established networks’ expertise, provide technical support to guideline panels and coordinate implementation.
- Maintain coordinating functions at the EHIF and use external technical capacity (for example, at the University of Tartu or the NIHD) to provide the necessary support to guideline panels.
- Consider establishing, in the longer term, a separate permanent unit for ensuring quality of care, with roles and functions that include the guideline development process, providing technical support and linking guidelines with implementation and monitoring activities.

We consider that over the last five years, increases in the human resources available in Estonia for guideline development have been substantial. To take this forward, the core system requirements for guideline development are:

- identification of topics through analysis of health services data for prioritization according to health outcomes;
- co-ordination of the process of guideline development;
- carrying out evidence synthesis and providing this material to guideline panels;
- production and dissemination of guideline products; and
- oversight of implementation strategies.

The resources to undertake these functions in Estonia already exist for the most part, as a result of the work over the last 4–5 years, but they are spread throughout different organizations and centres. If the guideline process is to continue, commitment is needed now to ensure a core of at least 2–3 FTE staff for the coordination role, five FTEs to provide technical material and possibly another 2–3 FTEs for production, dissemination and implementation. These functions could be located in the EHIF, the Ministry of Social Affairs, the University of Tartu or the NIHD, but an effective coordinating mechanism is required if they are not in one place.

The location of the unit or units is a political and managerial decision, depending on budget, flexibility and existing staff. The additional investment of resources required is likely to be small, especially compared to the potential impact on quality of care and health outcomes. We note that there are plans for the development of an overall quality of care strategy, and clearly, the guideline development process and the guidelines will need to be embedded as a core part of that initiative.

Given the current situation, we consider it unrealistic to assume that the current process can immediately move completely out of the EHIF. However, in the medium term, it may be reasonable for the Ministry of Social Affairs to play a more active role in both funding and supporting guideline development through a quality centre.

Currently, the EHIF has provided the majority of funding for guideline development, and as noted previously, this is consistent with its mandate in relation to delivering high-quality health care. We recommend that this is a reasonable model to continue but if possible, it should be supplemented with support from the Ministry of Social Affairs. One example is support for public health guidelines, as was done for the guideline on alcohol dependence. The methods used for guideline development should be the same, re-
 Regardless of the funding sources. Given the importance of independent guideline development, funding should not be accepted from commercial sources.

As noted previously, the current system is relatively efficient in terms of cost and guideline output. A model for maintaining efficiency without compromising quality would be to contract the technical work on evidence synthesis and document presentation to an institution with the academic capacity to undertake this work. Similar models are used by countries such as Australia (the academic contracts that support the Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee evaluation process), the Canadian Task Force on Preventive Health Care (through evidence practice centres), the United Kingdom (through the National Institute for Health and Care Excellence collaborating centres), and the United States Preventive Services Task Force (contracting evidence practice centres). Current options in Estonia would be contracting the University of Tartu, the NIHD or international research synthesis groups. International experience suggests the usefulness of having more than one contracted group if possible.

As also noted previously, urgent attention should be paid to the practical management of the handover between staff leaving the EHIF and ongoing management of the guideline process. We note that a new focal person was identified in the EHIF to take this forward. A high priority should be to reassure the existing networks of collaborators and clinicians about plans for managing each guideline currently under development as the coordination of this has relied very heavily on the two previous staff.

**Guideline development**

We made five recommendations for improving guideline development.

- Develop a more strategic approach to guideline topic selection, and constrain the scope to more manageable topics.
- Focus the decision-making process in guidelines around fewer prioritized questions.
- Implement fully aspects of the handbook such as updates from 2015, including grade assessment of the quality of the evidence and evidence to decision frameworks.
- Implement fully the option in the handbook for adopting/adapting international guidelines.
- Report on conflicts of interest in the main guidelines of the panel, in line with international recommendations.

Given the relatively limited resources for guideline development, we suggest significant changes to the process used for topic selection. It has to date relied on mostly a bottom-up approach, based on proposals from specialist societies. While this has been useful for engaging health professionals, we strongly recommend an additional step, which is selection of topics based on priority areas for the EHIF and Ministry of Social Affairs. This selection should be based on factors including burden of disease, known effective interventions, and utilization review of services to identify variation in practice and opportunities to manage expenditure. An advisory committee on utilization review may be useful to engage stakeholders in the process. One example of such a committee is the Drug Utilisation Subcommittee of the PBAC Australia (10).

Identifying areas where change in health care practices is needed to improve health outcomes should also help focus guidelines on questions most relevant to health professionals. This in turn should facilitate the development of derivative products, such as care pathways, which have to be based on guideline recommendations, followed by negotiation about delivery of care.

As noted previously, using international guidelines rather than developing Estonian national guidelines was repeatedly raised in discussion with stakeholders. We agree that especially for topics that are highly specialized and directed at few patients, local guideline development may not need to be a priority. We also recommend that international guidelines can and should be used as a starting point, provided the
Developing and implementing guidelines for health policy and clinical practice in Estonia

Basis for these recommendations can be clearly identified. Methods for using international guidelines for national recommendations have been further developed over the last five years and can be included in the handbook revision. However, the localization process will necessarily involve local clinicians in decisions about how to implement guidelines in the Estonian context.

We strongly recommend that personnel working on guideline development in Estonia should develop links with international groups with expertise in both evidence synthesis and guideline development, including the Cochrane Collaboration, the Guidelines International Network and the GRADE working group.

Implementation process

We made three recommendations on the implementation process.

- Articulate the value of the clinical guideline process in Estonian health policy as a core component for improving quality of care.
- Focus on systematic implementation strategies.
- Link current work and processes on developing clinical indicators, audit and feedback explicitly to clinical guideline development; consider combining the guideline advisory board and the clinical indicator advisory board into one.

Each completed guideline has had an implementation plan developed, but to date, the focus has mostly been on education and training strategies. Although these are clearly necessary, there is an opportunity to enhance the implementation process by linking a number of existing processes related to quality improvement that are under development by the EHIF.

Firstly, the development process for clinical guidelines should be recognized and promoted as the core component in improving quality of care. Clinical indicators should be derived from guideline recommendations, so potential advantages exist in combing the two advisory boards that currently oversee the process for guideline development and clinical indicator development.

Secondly, audit processes used by hospitals in Estonia could be linked to guidelines. This would increase uptake of the guidelines and also provide hospital managers with useful tools to promote implementation.

Thirdly, ensuring that appropriate derivative products are made available, using standard templates from guidelines would enhance their uptake. Derivative products could include care pathways, treatment algorithms, and electronic applications for decision support for doctors and health professionals and patient information. Different groups, both internal and external to the EHIF, are already investing resources in all these products, but the linkage across them or with the guidelines is not yet sufficient.

Finally, further explicit consideration of how the guideline recommendations link with reimbursement decisions is needed. The medicines reimbursement list is a key example; stakeholders repeatedly identified that recommending expensive medicines in guidelines would be a problem both for the guideline process and the reimbursement decision-making process. We recommend an explicit policy be developed on this issue, noting that the team in the EHIF who assesses the cost-effectiveness of medicines for the positive list have well developed methodological skills and have already been contributing to some of the technical work for the clinical guidelines.
Methods of updating clinical guidelines

Updating or considering the update of guidelines becomes a priority in the context of an increasing number of existing guidelines. This will require taking several steps.

- Set a policy, procedure and timeline for routinely monitoring and reviewing whether the guideline needs to be updated (e.g. Update a systematic review or search for new systematic reviews every three years to determine if any new evidence is available).
- Decide who will be responsible for routinely monitoring the literature and assessing whether new significant evidence is available (e.g. Consider including experts not previously involved in the guideline development group to periodically review the guideline).
- Set conditions that determine when a partial or a full update of the guideline is required (e.g. If only certain recommendations need to be updated, whether many recommendations are out of date making the entire guideline invalid, or when recommendations are necessary for newly available treatments).
- Plan the funding and logistics for future guideline updates (e.g. Secure ongoing funding, add a standing oversight committee – possibly a role for the guideline advisory board – to oversee the updating process).
- Document the plan and proposed methods for updating the guideline to ensure they are followed, and set expiration or review dates for continued endorsement of existing guidelines.

Updating the Estonian handbook for guideline development

We note the need for a clear agreement on the ownership of the process for the handbook update, as well as timelines. Chapter-by-chapter recommendations are in Annex 6.

We made general recommendations for updating the handbook.

- Build on international standards, approaches templates for guideline development and, while branding appropriately, do not reinvent new formats (e.g. Saudi Arabian example in Annex 7).
- Use methods of adoption, adaptation and development of guidelines.
- Provide examples of well-prepared guidelines in the handbook (e.g. online appendix).
- Revise the prioritization process for topics and questions.
- Link the handbook to the Guidelines International Network–McMaster guideline development checklist (11).
- Tailor the checklist for all guidelines in Estonia that involved input from the core team in Estonia (5).
- Use electronic tools to develop the guidelines (e.g. GRADEpro (12)) to facilitate standardization and development of implementation tools such as applications.
- Provide training material (and links to it) (13).
- Remove color-coding and provide clear information about whether a recommendation is strong or conditional and its underlying quality (colour coding is not visible in printed black and white versions).
- Implement fully GRADE for recommendations.
- Identify key international collaborators for guideline development and adaptation.
- Add a chapter on process evaluation (e.g. PANELVIEW instrument (14)).
REFERENCES


Annex 1. Terms of Reference

1. Background

In 2010 Estonia started revising its national clinical guideline development process as part of an overall programme of quality improvement in health care. A comprehensive assessment of guideline development in Estonia was made by WHO, the EHIF, the Medical Faculty at the University of Tartu, and selected national and international experts in an effort to streamline and harmonize the principles and processes of guideline development in Estonia. As an outcome of a two-year preparation process an “Estonian Handbook for Guidelines Development” was developed. The handbook aimed to bring together the experience and internationally accepted methods for developing guidelines covering all aspects of guideline development. An updated process, described in the new handbook supports a consistent approach to guideline development. This process was tested through a pilot project consisting of development of a new guideline during 2010–2011 on the management of hypertension in primary care.

In April 2015 the new process of guideline development is implemented in full speed. Altogether 15 guidelines are in different stages of development and three of them have been approved so far. The completion of the development cycle provides a good opportunity to review how the process has been implemented and whether it delivers guidelines of improved quality and according to evidence-based medicine standards and has resulted in the improved uptake of guidelines in the everyday practice of health professionals. During the first five years of implementation few challenges, concerns, questions and development areas have emerged that require attention and guidance on how to further support and develop the system. Among the challenges are the following: (a) the process to develop a guideline is considered by the developers too long and burdensome as well as viewpoint why not simply translating internationally available guidelines is persisting; (b) with the low turnover of guidelines and in general resource intense process there are sustainability concerns as well as question whether the use of existing (human and financial) resources and capacities (including secretariat skills) is optimal as well as whether guidelines are developed to most relevant health issues providing the best potential value; (c) the uptake of guidelines is still perceived low and use of guidelines not well integrated into clinical practice and decision-making process, there is lack of stimuli and support to use the guidelines; (d) capacity building proves to be an issue, how ensure that all involved experts and appointed persons have required capacities and understand and accept the methodology; (e) achieving the balanced and equal participation of different health professional groups (including nurses and other auxiliary staff) and patient representatives proves to be difficult. The areas that need further development are the processes to adapting and updating guidelines as well as approving guidelines at the panel, and the development of non-conventional guidelines (for instance patient pathways). Taking stock on the current developments in the area of guidelines development methodology and other country experiences the planned appraisal aims to provide feedback and recommendations on the process, outcomes and impact including addressing above highlighted perceived challenges and development areas.
2. Objectives of the appraisal

The aim of the appraisal is to review the progress made with clinical guideline development in relation to the process, the outcomes, and gain an understanding of potential or actual impact on improvements in quality of care and the health care system as a whole. The appraisal is expected to provide recommendations for updating the guideline development and implementation process, including changes if needed to the handbook and other institutional arrangements to support the development and usage of clinical guidelines.

Research questions:

- Are the guidelines reaching international standards?
- In what ways can the guidelines be further improved?
- How to handle the development of non-conventional guidelines such as patient pathways etc., updating and adaptation of existing guidelines within the process of guideline development?
- How could production and use of the guidelines be further improved and institutionalized in the health system?
- What are the barriers to use, and what is best to improve uptake in health staff?
- Have the guidelines impacted on integration and patient flow between levels of care?
- What has been the process of implementation of clinical guidelines into the clinical practice and what options are there to further support the usage of clinical guidelines (including potential of e-tools, patient management guidelines, training)?

3. Activities

The interim evaluation will consist of several elements:

A. **Describe the process and implementation of developing guidelines.** This includes assessing the implementation of the guidance in the handbook, and the outcome of the guideline development process, (including number of guidelines produced, how much resources and time spent, cost per guideline), analysis of obstacles and opportunities, sustainability assessment.
   a. Collecting relevant information
   b. Developing a structure and drafting a report

B. **Assess the guideline relevance and quality.**
   a. Selecting guidelines for review (include other needed documents)
   b. Consider their relevance to current equipoise and debates in health care
   c. Assess the quality of the guidelines using AGREE
   d. Translating the guidelines and other supporting materials

C. **Assessing the experience and reflections of the guideline developers**
   a. Developing a short questionnaire
   b. Conducting the survey, collecting information
   c. Interviewing selected stakeholders who have been involved in guideline development (include secretariat, panel and advisory group members)

D. **Assess the usefulness of the product for the various stakeholders (insurers, specialist and general clinicians, public health doctors, the public)**
   a. Reviewing and updating the questionnaire of the previous study
   b. Getting ethical committee’s approval
   c. Conducting online
   d. In depth interviews with key informants by the review panel
   e. Analysing results
E. Completion of an agreed evaluation report of the findings and options for strengthening the guideline programme and guideline uptake
   a. Recommendations to updating the “Estonian Handbook for Guidelines Development”
   b. Recommendations on policy option for improving guideline development and implementation process and institutional structure, as well as on the methods of updating clinical guidelines.

4. Team

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Holger Schünemann, consultant, McMaster University
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Anna Vesper, Estonian Health Insurance Fund
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Marge Reinap, WHO Country Office in Estonia
Evelin Peil, intern at WHO Country Office in Estonia, University of Southern Denmark

5. Timeline

Preparatory work: January to August (see annex: Timeline)
Mission: 24–28 August 2015
Evaluation report: 1 draft – 1 November, 2 draft – 1 December 2015

6. Deliverables

- Implementation process overview and analysis (including cost assessment)
- Study report on the feedback from guideline developers
- Study report on health professionals’ attitudes
- Evaluation report, including recommendations and policy options
ANNEX 2. SITE VISIT PROGRAMME

APPRAISAL OF THE CLINICAL GUIDELINE DEVELOPMENT PROCESS IN ESTONIA
24–28 AUGUST 2015

Sunday, 23 August

18:30/19.00 – 21:00 Brief and discussion with the team

Monday, 24 August

Estonian Health Insurance Fund (EHIF)

- Introduction and overview of the evaluation and the team and summary of GL developers’ feedback
- Development and use of guidelines from the viewpoint of EHIF, challenges and opportunities and expectations – EHIF management board

EHIF – clarifying focus for interviews

- Overview of barrier analysis
- Review of handbook for developing of clinical guidelines and forms, etc.

Ministry of Social Affairs

- Steward and regulator perspective to usefulness of guidelines
- Improving the integration into clinical practice and into other health care decision-making processes
- Institutional arrangements and sustainability
- Selection of guidelines for development (relevance)

Tuesday, 25 August, Tallinn

National Institute for Health Development (NIHD)

- Public health perspective
- Potential to join capacities (including for secretariat)
- Selection of guidelines for development

EHIF

Review of handbook for developing of clinical guidelines and forms, etc

Society of Family Medicine

Estonian Society of Cardiology

Association of Surgeons and Anaesthesiologist

Summary of day
Wednesday, 26 August, TARTU

**University of Tartu (UT)**
- General awareness on evidence-based medicine
- Barriers and opportunities in uptake and integration of clinical guidelines into clinical practice, including into medical education
- Capacities for developing the guidelines

**Guideline Advisory Board, followed by discussion**
- Challenges and opportunities for further improvement of the process

**Briefing the Minister of Health and Labour**

**Focus group of heads of secretariat**
(including working on the updating the handbook and its templates)

Thursday, 27 August

**Estonian Hospitals Association**

**Medicines Department, Ministry of Social Affairs**
Interaction with mechanisms of the drug reimbursement decision

**Estonian eHealth Foundation (EeHF)**
Potential to integrate guidelines into the eHealth system

**Focus group of heads of secretariat**
(including working on the updating the handbook and its templates)

**Preparation for the draft report**

Friday, 28 August

**Preparation for the draft report and debrief**
Debrief for EHIF management board
Agreement on next steps and report writing time
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<td>Name and Email address</td>
<td>Job title</td>
<td>Organization</td>
</tr>
<tr>
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</tr>
<tr>
<td>Lidia Rändvee</td>
<td>Head Physician/Medicum</td>
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<tr>
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<td>University of Tartu</td>
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<tr>
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<td>Member of the Board</td>
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<tr>
<td><a href="mailto:alar.irs@ravimiamet.ee">alar.irs@ravimiamet.ee</a></td>
<td>Member of the Board</td>
<td>Guideline Advisory Board</td>
</tr>
<tr>
<td><a href="mailto:liis.roovali@sm.ee">liis.roovali@sm.ee</a></td>
<td>Member of the Board</td>
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<td><a href="mailto:kristi.toode@regionaalhaigla.ee">kristi.toode@regionaalhaigla.ee</a></td>
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<td>Guideline Advisory Board</td>
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<tr>
<td><a href="mailto:anneli.usukula@ut.ee">anneli.usukula@ut.ee</a></td>
<td>Member of the Board</td>
<td>Guideline Advisory Board</td>
</tr>
<tr>
<td><a href="mailto:jane.alop@tai.ee">jane.alop@tai.ee</a></td>
<td>Member of the panel “The management of a bariatric patient before and after surgery”</td>
<td>Guideline panel</td>
</tr>
<tr>
<td><a href="mailto:pille.tabaks@klinikum.ee">pille.tabaks@klinikum.ee</a></td>
<td>Member of the panel</td>
<td>Guideline panel</td>
</tr>
<tr>
<td><a href="mailto:tiina.uuetoa@itk.ee">tiina.uuetoa@itk.ee</a></td>
<td>Member of the panel “Management of Hypertension in adults in primary care”</td>
<td>Guideline panel</td>
</tr>
<tr>
<td><a href="mailto:piret.viiklepp@tai.ee">piret.viiklepp@tai.ee</a></td>
<td>Member of the panel “Diagnoses of tuberculosis (including early diagnosis) and treatment”</td>
<td>Guideline panel</td>
</tr>
<tr>
<td><a href="mailto:ylle.vohma@regionaalhaigla.ee">ylle.vohma@regionaalhaigla.ee</a></td>
<td>Head of the panel “The management of generalised anxiety disorder and panic disorder (with or without agoraphobia)”</td>
<td>Guideline panel</td>
</tr>
<tr>
<td><a href="mailto:teelia.rokko@klinikum.ee">teelia.rokko@klinikum.ee</a></td>
<td>Head of Secretariat “The management of patients with alcohol abuse disorders”</td>
<td>Guideline Secretariat</td>
</tr>
<tr>
<td><a href="mailto:kadri.suija@ut.ee">kadri.suija@ut.ee</a></td>
<td>Head of Secretariat “The management of generalised anxiety disorder and panic disorder (with or without agoraphobia)”</td>
<td>Guideline Secretariat</td>
</tr>
<tr>
<td><a href="mailto:marje.oona@ut.ee">marje.oona@ut.ee</a></td>
<td>Head of Secretariat “The management of asthma in adults in primary care”</td>
<td>Guideline Secretariat</td>
</tr>
<tr>
<td><a href="mailto:isi.kriipsalu@tai.ee">isi.kriipsalu@tai.ee</a></td>
<td>Member in the “The management of patients with alcohol abuse disorders” secretariat</td>
<td>Guideline Secretariat</td>
</tr>
</tbody>
</table>
ANNEX 4. SURVEY OF CLINICAL GUIDELINE DEVELOPERS

By: Evelin Peil, intern at WHO Country Office in Estonia; University of Southern Denmark

The aim of the survey was to collect feedback from Estonian clinical guideline developers on the process of developing guidelines according to the new methodology. The survey is part of the appraisal of the clinical guideline development process in Estonia that aims to review the progress made with clinical guideline development in relation to the process and outcomes, and to gain an understanding of potential or actual impact on improvements in quality of care and the health care system as a whole.

Data and methods

Feedback data were collected using an online survey from 16 July 2016 to 13 August 2015. Ninety-eight specialists took part in developing six clinical guidelines, and some guideline developers participated in multiple development processes. The guidelines were:

- The management of a bariatric patient before and after surgery
- Perioperative management of patients with acute pain
- The management of patients with alcohol abuse disorders
- The management of asthma in adults in primary care
- The use of a surgical safety checklist in operating rooms
- Prevention and management of pressure ulcers – clinical questions of conservative treatment

In addition, specialists who developed the guideline *The management of generalised anxiety disorder and panic disorder (with or without agoraphobia)* participated in an open discussion where they answered the same questions asked of other respondents via the online survey. But since the answers from that discussion (8 participants) are synthesised, their responses are mentioned separately.

The final number of respondents was 30 (see Table A4.1).

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In addition, two responses were not included, because those respondents filled out the survey twice with the exact same answers. The response rate was 30.6%. The survey was anonymous; therefore, the name, workplace and speciality of the respondents are not known.

The survey had two parts. The first part included general background information, e.g. to identify in which clinical guideline development process respondents participated and their role. In the second part, guideline developers provided feedback on what was positive, the areas needing improvement and could make suggestions. The second part was analysed qualitatively, because these were open-ended questions meaning respondents could provide their own answers. Qualitative analysis is important because feedback from clinical guidelines developers is valuable, and requires in-depth and detailed analysis.

Results

In this section, we present results by question topic. Because respondents could choose not to provide feedback on what worked or what needed improvement, the number of respondents for these sections differ (Table A4.2).

Table A4.2. Number of respondents per question topic

<table>
<thead>
<tr>
<th>Question topic</th>
<th>Positive feedback</th>
<th>Needs improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26</td>
<td>22</td>
</tr>
<tr>
<td>2</td>
<td>26</td>
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<td>4</td>
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<td>22</td>
</tr>
<tr>
<td>5</td>
<td>26</td>
<td>24</td>
</tr>
</tbody>
</table>
Topic 1. Training and methodological support during the guideline developing process

Positive feedback

Most (25) respondents agreed that the training was necessary and relevant. Positive feedback included that training sessions had a comprehensible structure, were well-considered, helped them understand the process of developing guidelines, and that training was organized regularly throughout the process of drafting the guideline. Thereby eight respondents mentioned that in quite a few situations, methodological support was available and sufficient, and helped to better understand and follow the entire process. A member of the secretariat of the guideline Perioperative management of patients with acute pain said, “The training was well-considered and the topics discussed contributed to the preparation of the guideline. The methodological support was excellent and it was always possible to ask for the advice and discuss how one or another thing could be done better/more comprehensibly.” A methodologist who participated in two guideline preparation processes noted that in the preparation process of one guideline, he/she had to advise the secretariat outside the meetings more frequently than in the case of the other guideline.

Specialists who prepared the guideline The management of generalised anxiety disorder and panic disorder (with or without agoraphobia) pointed out in a discussion that using the Estonian handbook for guidelines development helped them find answers.

Needs improvement

Four respondents agreed that basic training in the process of preparing a clinical guideline should be required, because quite a few people have no experience with guideline development. They suggested two kinds of trainings: a general one on the process of preparing clinical guidelines, and a specific one covering all stages of the preparation step by step. Three respondents pointed out that training should be in Estonian, because a lot of information is lost due to the language barrier when training and materials are in English. Some respondents said that the training was too detailed; and the secretariat and panels should have separate training, because their tasks are different.

Two respondents provided contradictory feedback about the training provided by the Medical Information Centre of Tartu University Hospital. While one thought that “…it should have been mandatory to complete the Medical Information Centre’s course on searching for information…”, the other one differed

Training in searching for information should be carried out by someone other than the Tartu Medical Information Centre. The information that they gave was very technical. This training should be carried out by a person who works in a foreign medical information centre and truly practices the activities. The Medical Information Centre was later of great help in obtaining articles and full texts. I can only praise this part.

In addition, professionals who prepared the guideline The management of generalised anxiety disorder and panic disorder (with or without agoraphobia) pointed out in a discussion the risk of learned helplessness due to methodological support.

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6 As a result, training has been revised and now begins with the introduction of the guideline preparation process and further preparatory trainings take place step by step.

7 Since 2014, basic trainings are held in Estonian.
Topic 2. Members of groups and their roles and commitment (leadership)

Positive feedback

The topic is analysed based on the roles of the respondents, because depending on which team they were part of, their tasks and responsibilities were different.

Most (11) responses indicated satisfaction with the contribution of the secretariat and pointed out the good cooperation among its members. Moreover, good leadership was mentioned several times. An example response on the secretariat’s good work was, “The secretariat worked as a team and there was a discussion that quickly led to a result at the meetings.” Three panel members were also very pleased with the secretariat’s work, adding that the topics were well prepared in a timely manner, which ensured adherence to the timetable.

As for the contribution and work of the panel, responses were more mixed. Five respondents praised the participation of specialists of different specialties, as it gives a good overview of the practices and helps to focus critically on the topic. One respondent said, “It is good to listen to discussions between colleagues from different institutions over the current practices and to hear their criticism and desire to reach a better result in the management of patients.” It was mentioned twice that cooperation among the panel members improved over time.

Needs improvement

Two members of the secretariat felt that the tasks of the secretariat were not very clear and that caused some confusion. One wanted the head of the secretariat to give clearer instructions; as a result, the leader had to do a lot of work, because members did not have a clear understanding of what was expected from them and by what time. To solve this issue, they suggested that separate training be carried out or a meeting be held for secretariat members before commencing work (see topic question 1). In addition, one secretariat member found that performing this work in addition to one’s primary job was not sustainable in the long term. As an exception, one panel member who participated in the preparation process of the guidelines The management of a bariatric patient before and after surgery and The management of asthma in adults in primary care found that, at times, participants seemed passive, especially members of the secretariat whose contribution remained questionable.

A negative aspect most frequently mentioned (seven responses) in the panels was that panel members often failed to do their preparatory work and review the materials. This was also mentioned by one methodologist who said, “As for contribution, it seems that the panel does not do much homework, but the process is based on the assumption that the panel does the homework.” A panel member who participated in the preparation process of two clinical guidelines pointed out the difference between the contributions of panel leaders. In one panel, the leader’s contribution was minor, and the member who joined the panel later did not even understand at first who the leader was. However, the panel leader of the other clinical guideline left an entirely different and positive impression. Including patient representatives in the composition of the panel is considered essential (three respondents).

One panel member added that in order to motivate the secretariat and panel members more, participation in the guideline preparation process should be paid.

Topic 3. New methodology and systematic working process

Positive feedback

Nineteen respondents found the new methodology and systematic work process to be suitable, well-structured and logical; the existence of a specific work plan, and professional associations’ linkages with
research and scientific literature were considered praiseworthy. For instance, one panel member noted, “I like the new methodology, because the main questions of the guideline are focused on the basis of the new methodology, and people look for evidence only with these topics in mind and with a specific aim.”

Needs improvement

Nevertheless, nine respondents found the work process and methodology complicated and too time-consuming. One bottleneck identified was that doctors and nurses lack the skill of carrying out searches and assessing research articles. And, for this reason, more training is needed. In addition, guidance should be provided when no systematic literature overviews exist, if little evidence-based information is available or where practices differ in countries. Two respondents mentioned that the cost–effectiveness and budget impact analysis skills should be developed further.

Two respondents indicated that panel members should be better at assessing aspects of the GRADE form indicating, “The reasons given by the panel of formulating the recommendations need proper refinement and should be more matter-of-fact.” However, it was mentioned that once one has become familiar with the guideline work process, further work would be a lot easier and faster. Two respondents indicated the introduction of GRADE tables should be considered as well. One respondent said, “The systematic work process is great, but it can probably be fully enjoyed only upon preparing further guidelines. If you participate in the process for the first time, learning the methodology is a serious effort in itself.”

One recommendation was to educate doctors about the importance of new methodology in clinical guidelines. Subsequently, a panel member of the guideline _The management of a bariatric patient before and after surgery_ said:

Too many time resources were spent … the current choice of the topic may not ensure that the topics selected out are optimal in completing this labour-intensive process and there are no more cost-effective alternatives. The process is so long that it requires very strong institutional support to complete it … which at the moment may not have reached such a stage and jeopardises the entire guideline preparation system on the whole.

**Topic 4. Evidence summaries and reaching recommendations**

Positive feedback

Agreeing on recommendations from evidence summaries was found to be systematic, well-functioning and easier (nine responses), especially when the evidence was of a high-level and easily obtainable, and the panel members were prepared. One indicated, “Reaching consensus recommendations via panel discussions was actually a positive surprise.” In addition, respondents pointed out benefits such as getting an overview of previous materials, and gaining new knowledge on the topics and the collection of evidence-based literature. Three respondents added that recommendations were agreed upon thanks to the good work performed by the secretariat.

Needs improvement

In the (three) cases with little evidence, disputes arose and agreeing on recommendations was more difficult. One response was, “Making practical recommendations based on weak evidence is questionable. In such a case, the guideline will contain recommendations based on a lack of knowledge or poor knowledge.” Five respondents emphasized the need for panel members to do their homework before each meeting, so the discussions would not start from scratch (see question topic 2). Two respondents felt that personal judgements were dominant and that the decision was based more on gut feelings than objective evidence. To quote one respondent, “I would have liked to see that the panel, not the secretariat, makes a summary based on the evidence summaries.”
Those who prepared the guideline *The management of generalised anxiety disorder and panic disorder (with or without agoraphobia)* discussed that to linguistically differentiate between a weak and a strong recommendation was not always possible in Estonian.

One respondent indicated that, "The Estonian habits (work culture and possibilities) should have been investigated more beforehand, and these should have been more integrated into the guidelines."

One member of the "The management of asthma in adults in primary care” panel and one member of the “The management of a bariatric patient before and after surgery” panel suggested that it should be possible to revise clinical questions in the course of preparing the guideline.

**Topic 5. Organizing and administering meetings**

**Positive feedback**

Twenty-two respondents found that the organization and overall administration of the meetings were good and well run; other positive feedback included the possibility to participate in meetings via Skype or by teleconference, the sufficient advance notice given prior to meetings, the fixed schedule of meetings and spacious meeting rooms. Having the meetings in Paide was appreciated as Paide, located in the middle of Estonia, allows participants to travel the same distance to attend the meetings. As one respondent indicated, "In my opinion, the meetings were very well organized. The discussions were usually concrete and the plan was carefully followed."

In the discussion held among the authors of the guideline *The management of generalised anxiety disorder and panic disorder (with or without agoraphobia)*, they noted that everyone’s roles and expectations were discussed at the meetings.

**Needs improvement**

Two respondents noted the difficulty in bringing the panel together at the same time. One said, “It is difficult to bring a large company together at the same time. ... If you skip a meeting, next time you will have questions that the others have already discussed – you lose time again.” Efforts should be made to ensure a quorum (three respondents) and the attendance of one or more persons who gives permanent methodical advice at the panel meetings (one respondent).

In the discussion held among the authors of the guideline *The management of generalised anxiety disorder and panic disorder (with or without agoraphobia)*, it was suggested that all major research, meta- and systematic analyses should be available to all members of the secretariat and the panel.

Additional feedback included that the meetings should take place during the day (two respondents) and that organized transport should be provided.

Some respondents raised crosscutting issues. Four respondents thought that a guideline published earlier in another country should be adapted to Estonia.

Given the labour-intensity and the existing manpower that is able and wants to participate in drawing up a clinical guideline, we should undertake the translation of (an) existing modern clinical guideline(s) prepared by a renowned organization. The translation and national adaptation of existing clinical guidelines is used by far larger and wealthier countries than us, thus valuing the work of their colleagues and saving the time resources of the local colleagues for performing substantive work.

Three respondents suggested that the secretariat should be a permanent entity (or, at least, the head of the secretariat), because the experience and skills gained in assessing, analysing and gathering evidence would be retained. The methodologist who participated in the preparation of guidelines *The management of asthma in adults in primary care* and *Perioperative management of patients with acute pain* suggested that an experienced mentor should be appointed as head of a starting secretariat.
One respondent suggested, “The methodology of preparing a clinical guideline + participating in the secretariat of a clinical guideline ([and earning university course] credits) should be included in the studies of medical science as a compulsory course and the role of the University of Tartu Medical Faculty should be greater and more visible.”
ANNEX 5. A CROSS-SECTIONAL SURVEY AMONG HEALTH CARE WORKERS IN ESTONIA: BARRIERS AND FACILITATORS TO THE USE OF CLINICAL PRACTICE GUIDELINES

By: Ivar-Endrik Eiche, intern at EHIF; Medical Faculty, University of Tartu, Estonia

Barriers and facilitators to the use of clinical practice guidelines: a cross-sectional survey of health care workers in Estonia

Introduction

In 2011, the Estonian Health Insurance Fund, in collaboration with the University of Tartu, the World Health Organization and the Ministry of Social Affairs of Estonia, published the Estonian handbook for guidelines development (1). Since then, much progress has been made in standardizing the process of developing clinical guidelines and increasing the level of evidence-based health care. However, the outcome of these efforts is not known, as there has been no investigation of the implementation, dissemination and adoption of the guidelines. This study aimed to assess attitudes towards the clinical practice guidelines, and the barriers to, and facilitators of, implementation of clinical guidelines among Estonian health care workers. A secondary objective was to gather suggestions for alternative methods of dissemination and more effective implementation of clinical guidelines.

Methods

Subjects

The target group of the study was health care workers in Estonia, including family doctors, specialists, nurses, midwives and resident physicians. Subjects were reached through the email lists of 22 hospitals and 45 professional societies. It was assumed that all practising physicians, nurses and midwives are on one of these email lists, and thus that all active health care workers in Estonia were contacted, i.e. about 4500 doctors and 8700 nurses and midwives (2, 3).

Questionnaire

The study's methodological frame and questionnaire were based on a study by Taba et al. published in 2012 (4). Data were collected using self-reported online questionnaires. A first set of invitations was sent out in June 2015, and all received two additional invitations in July. The survey contained 18 questions related to individual characteristics (occupation, workplace, experience), opinions and perceived barriers to the implementation of clinical guidelines in Estonia, and suggestions for improving the quality of the guidelines. Individual characteristics (dependent variables) were classified as follows: occupation: family doctor, specialist, nurse/midwife; workplace location: Tallinn, Tartu, other; work experience: less than 10 years, 10–25 years, 25 years or more. Nurses and midwives were classified as one group because of their similar professional background; resident physicians were included in the group (specialists, family physicians or nurses/midwives) most closely related to their specialization. Independent variables were categorized using either a five-level Likert scale (strongly disagree, disagree, no opinion, agree, strongly agree) or binominal scale (yes/no). Other variables were classified using a nominal scale.
Three open-ended questions were asked.

1. What is your opinion of Estonian clinical guidelines? (question 11)
2. Please describe other methods for introducing clinical guidelines. (question 15)
3. How can the use of clinical guidelines in everyday practice be improved or the guidelines made more user-friendly? (question 18)

Negative or constructive answers to the first question were categorized as: system censures (outdated guidelines, more frequent updates); content censures (too complicated, structural inadequacies); attitudinal barriers (international guidelines preferred to Estonian guidelines, Estonian guideline development is impractical); or other. Comments were analysed according to occupational group. A comment that contained multiple components was placed in two or more categories.

Data analysis

We hypothesized that attitudes towards the guidelines would differ by occupation, workplace location and work experience. The differences between groups were analysed using the Kruskal-Wallis non-parametric test with a $P$ value for significance of 0.05, followed by a post-hoc analysis with an adjusted $P$ value for significance of 0.00833 for comparison between single group pairs by occupation, workplace location and years of work experience. Empirical data were analysed using the statistical package Stata 13. Open-ended questions were analysed by descriptive statistics and interpretation.

This study was evaluated by the Ethics Committee of the University of Tartu and classified as exempt from ethical review.

Results

Characteristics of participants

A total of 586 health care providers responded to the survey, of whom 520 (88.7%) were female and 66 (11.3%) male. As most nurses/midwives are female, removing these professions from the sample raised the proportion of males to 15.8%. For comparison, 40% of Estonian physicians are male. A total of 198 respondents (33.8%) worked in Tallinn, 131 (22.3%) in Tartu and 257 (43.9%) elsewhere (“other”). Of the respondents, 267 (45.5%) were specialists, 151 (25.8%) were family doctors, 168 (28.7%) were nurses or midwives. Some 141 (24.0%) respondents had less than 10 years’ work experience, 274 (46.8%) between 10 and 25 years, and 171 (29.2%) more than 25 years.

In all, 135 participants (23.0%) claimed that they used clinical guidelines daily, 240 (41.0%) often, 122 (20.8%) sometimes, 72 (12.3%) rarely and 17 (2.9%) never. As the use of guidelines is strongly recommended in clinical work, the respondents who answered “never” were referred to an additional question to obtain more information on the reason for their answer. Of these, 14 respondents said that there were no Estonian clinical guidelines available for their speciality, or that they followed international guidelines. Only 3 respondents (2 nurses and one specialist) admitted that they did not follow any clinical guidelines. All respondents said that they were familiar with, or had heard of, the Estonian guidelines.

There was no statistically significant difference in frequency of use of guidelines in relation to occupation, work location or experience.
Attitudes towards Estonian clinical guidelines

The respondents who said that they followed treatment guidelines were asked their opinion of guidelines. There was general agreement (82.2–82.8%) that guidelines are evidence-based, improve the quality of care, and sufficiently address different aspects of diseases (Table 1). A less positive result was found regarding the convenience of the guidelines (70.4%). There was a significant difference in mean ratings between groups with different work experience ($P = 0.0053$). Respondents with the longest work experience (25 years and more) had a more positive opinion of the convenience of clinical guidelines than those with 10–25 years’ experience.

Table A5.1. Opinion of Estonian health care workers on clinical guidelines

<table>
<thead>
<tr>
<th>Survey question ($n$ = 569)</th>
<th>Strongly agree (%)</th>
<th>Agree (%)</th>
<th>No opinion (%)</th>
<th>Disagree (%)</th>
<th>Strongly disagree (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonian clinical guidelines are evidence-based</td>
<td>196 (34.5%)</td>
<td>271 (47.6%)</td>
<td>95 (16.7%)</td>
<td>6 (1.0%)</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Estonian clinical guidelines improve the quality of care</td>
<td>196 (34.4%)</td>
<td>275 (48.3%)</td>
<td>82 (14.4%)</td>
<td>14 (2.5%)</td>
<td>2 (0.4%)</td>
</tr>
<tr>
<td>Estonian clinical guidelines address different aspects of diseases sufficiently</td>
<td>102 (17.9%)</td>
<td>351 (61.7%)</td>
<td>80 (14.0%)</td>
<td>34 (6.0%)</td>
<td>2 (0.4%)</td>
</tr>
<tr>
<td>Estonian clinical guidelines are convenient to use (provided information can be easily interpreted)</td>
<td>105 (18.5%)</td>
<td>298 (52.4%)</td>
<td>99 (17.4%)</td>
<td>60 (10.5%)</td>
<td>7 (1.2%)</td>
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</tbody>
</table>

Barriers to use of clinical guidelines

In comparison with the questions about attitudes towards clinical guidelines, those about perceived barriers elicited a somewhat wider range of responses (Table 2). The biggest obstacles to implementation of clinical guidelines were considered to be resource barriers (lack of time (43.9%) and medical resources (29.2%)). Accessibility and existence of care routine were considered the least important barriers (11.1% and 4.7%). In contrast to other queries, about a quarter of the respondents (23.0%) had no opinion on patient barriers. Overall, resource barriers were perceived as the most significant barriers and patient barriers as the least.

There were no significant differences among the work locations.

Table A5.2. Perceived barriers to use of guidelines

<table>
<thead>
<tr>
<th>Survey question ($n$ = 586)</th>
<th>Strongly agree (%)</th>
<th>Agree (%)</th>
<th>No opinion (%)</th>
<th>Disagree (%)</th>
<th>Strongly disagree (%)</th>
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</thead>
<tbody>
<tr>
<td>Resource barriers</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Clinical guidelines are hard to implement in daily practice because of a lack of medical resources (investigational abilities, etc.)</td>
<td>32 (5.5%)</td>
<td>139 (23.7%)</td>
<td>95 (16.2%)</td>
<td>264 (45.0%)</td>
<td>56 (9.6%)</td>
</tr>
<tr>
<td>There is no time to search for information</td>
<td>42 (7.2%)</td>
<td>215 (36.7%)</td>
<td>51 (8.7%)</td>
<td>186 (31.7%)</td>
<td>92 (15.7%)</td>
</tr>
<tr>
<td>System barriers</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Clinical guidelines are not accessible</td>
<td>10 (1.7%)</td>
<td>55 (9.4%)</td>
<td>53 (9.0%)</td>
<td>281 (48.0%)</td>
<td>187 (31.9%)</td>
</tr>
<tr>
<td>Clinical guidelines are too complicated and it is difficult to find information</td>
<td>17 (2.9%)</td>
<td>94 (16.0%)</td>
<td>75 (12.8%)</td>
<td>311 (53.1%)</td>
<td>89 (15.2%)</td>
</tr>
</tbody>
</table>
Survey question (n= 586) Strongly agree Agree No opinion Disagree Strongly disagree

**Attitudinal barriers**

| Clinical guidelines limit care options | 9 (1.5%) | 58 (9.9%) | 107 (18.3%) | 301 (51.4%) | 111 (18.9%) |
| Clinical guidelines limit flexibility and individual approach | 18 (3.1%) | 122 (20.8%) | 87 (14.8%) | 287 (49.0%) | 72 (12.3%) |
| There is no need for clinical guidelines as care routines exist | 5 (0.9%) | 22 (3.8%) | 53 (9.0%) | 234 (39.9%) | 272 (46.4%) |

**Patient barriers**

| Clinical guidelines are hard to implement in daily practice because of discontent of patients | 2 (0.3%) | 73 (12.5%) | 135 (23.0%) | 290 (49.5%) | 86 (14.7%) |

There were a number of differences in the responses of the various subgroups. Family doctors perceived fewer barriers to accessibility of guidelines than specialists (P = 0.0047). All the responses about attitudinal barriers differed according to work experience. The health care workers with the least experience found that clinical guidelines limited care options less than more experienced workers. There were significant differences between the group with less than 10 years’ experience and both those with 10–25 years (P = 0.0000) and those with more than 25 years (P = 0.0033). The least experienced health care workers rated the barrier to individuality and flexibility lower than respondents with 10–25 years’ experience. The least experienced respondents also rated the existence of a care routine as a less important barrier than the most experienced participants (P = 0.0008). Respondents with 10–25 years’ experience considered patient barriers more important than the least experienced health care workers (P = 0.0028). Specialists rated patient barriers as less important than did nurses/midwives (P = 0.0003).

**Comments on improving guidelines**

In total, 332 participants (57%) made suggestions on improving guidelines; they comprised 114 family doctors, 127 specialists, 53 nurses, 15 midwives and 23 resident physicians.

**Family doctors.** Most family doctors (85 of 114, 75%) considered that clinical guidelines were useful tools in clinical practice and were easy to follow. However, several respondents voiced concerns about the content and implementation of guidelines. There were 29 critical replies (25%). Six replies were classified as system censures, 16 as content censures, one as attitudinal censure and six as “other”. Most of the criticism related to the perceptions that the guidelines quickly become outdated, that the text is overwhelming with hard-to-read information, or that the structure is illogical. One doctor stated that family doctors lacked the time to read comprehensively the clinical guidelines. Several physicians considered that clinical guidelines were too general and did not take into consideration the medical history of individual patients. Thus, the guidelines were not applicable in daily clinical practice but should be taken only as indicative. Furthermore, some family doctors pointed out that the development of clinical guidelines is done on a voluntary basis and panel members do not receive financial support, so that the doctors participating in this work might lack motivation, which could result in poor quality.

**Specialists.** The responses of 83 specialists (64%) were positive and supportive of clinical guidelines; 44 comments (36%) were negative or critical. Constructive responses included 11 system censures, 18 content censures, 15 attitudinal censures and 10 other censures.

The group of specialists had the most negative perspective on the guidelines. Many stated that the clinical guidelines were outdated and needed to be updated more frequently, or that no clinical guidelines were available. One rhinologist mentioned that he was obliged to follow international guidelines, as only a limited number of Estonian clinical guidelines were available in his speciality. Several respondents said
that the guidelines were too complicated and needed to be simplified. Like family doctors, specialists
stressed that not all situations can be covered in guidelines, which should be used simply as a helpful
tool. Several specialists mentioned that there is no need for guidelines in institutional care. Estonian clini-
cal guidelines are beneficial in primary health care, where the demand for, and benefit of, a standardized
approach are more pronounced. Several specialists mentioned that doctors should be educated enough
to understand clinical guidelines written in a foreign language. One intriguing comment came from a
doctor who was working shifts in the emergency medicine department of a small hospital. He mentioned
that, in many cases, he could not follow guidelines as the necessary information was hard to find. The
doctor was using a Finnish electronic guideline system, Terveysportti, and mentioned electronic dissemi-
nation as a way of improving the quality of the Estonian system.

Nurses/midwives. Nurses and midwives generally agreed that guidelines are easy to read, logically struc-
tured, and essential in daily practice (positive responses 52 of 68, 76%). Of the 17 constructive respons-
es, three were classified as system censure, ten as content censure, two as attitudinal censure and five
as “other”.

Unlike family doctors and specialists, none of the nurses or midwives mentioned that Estonia should stop
developing local guidelines or that international guidelines should be preferred. Some nurses pointed out
the absence of clinical guidelines on specific topics (e.g. haemodialysis, weight loss) and that they are
obliged to follow international clinical guidelines. Four people mentioned that they were following the
same guidelines as doctors, but that they were structured from the doctors’ perspective. They suggested
that clinical guidelines for nurses should focus more on action rather than on different aspects of disease.
Several midwives mentioned that they were satisfied with the obstetrics, gynaecology and other profes-
sional clinical guidelines. One midwife emphasized that clinical guidelines should be stored systematically
in one place.

A large proportion of resident physicians’ replies were negative or constructive (16 of 23 or 70%); seven
(30%) were positive. Seven replies were categorized as system censure, four as content censure, nine as
attitudinal censure and three as “other”.

Resident physicians. Resident physicians were concerned that the number of guidelines covering different
diseases is inadequate and suggested that guidelines should be updated more frequently. Also, there is
too much “noise” or unimportant information in the guidelines. Several respondents were accustomed to
using international guidelines and were not familiar with Estonian guidelines. One resident physician
mentioned that doctors follow guidelines on different levels and there is a need for a more consistent
approach to the use of guidelines.

Comments on introducing guidelines

In all, 194 (33%) health care workers made suggestions on how to introduce guidelines among health
care workers. The main suggestions were:

- presentations at society meetings;
- training in hospitals or health centres;
- pocket guidelines and mobile apps;
- annual updates and modifications;
- email announcements to all the target audience when new guidelines are published;
- advertisements or articles in journals, such as Eesti Arst, Perearst and Meditsiniuudised;
- integration of guidelines in Perearst2 software or physicians’ computerized work desk;
- national campaign;
- cooperation with quality managers in hospitals.
Comments on implementing guidelines

A total of 118 (20%) physicians, nurses and midwives made suggestions on how to improve the implementation of clinical guidelines. The suggestions are summarized below.

Many respondents suggested the guidelines should be published in new formats. In addition to the existing version, there should be a pocket version containing the most relevant information. Practical recommendations should be highlighted in a different font style (e.g. in bold or colour). Clinical guidelines should be integrated in the patient information system, digital receipt software, physicians’ computerized work desk, and other programs used by health care workers. Software-based solutions should include a search tool that accepts synonyms as well as the official disease name. Computerized clinical guidelines were considered the most important for physicians working in emergency medicine, as fast access to the relevant information is essential in this field.

Some participants considered that there was no need for Estonian health care specialists to develop clinical guidelines from scratch. Clinical guidelines should be based on international guidelines, adjusted to local needs. If international guidelines are outdated shortly after publication and need frequent updates, so too are Estonian guidelines. The number of published Estonian clinical guidelines is limited and they are seldom updated. Specific clinical guidelines, which take into account local peculiarities, are however needed for some locally relevant diseases (infections, and genetic and endemic diseases) and primary health care.

Other queries

Estonian clinical guidelines website. All Estonian clinical guidelines are available on a website (www.ravijuhend.ee) and can be downloaded. A total of 468 (80%) participants were aware of the site; 118 (20%) were not (Table 3). Specialists, health care workers with less than 10 years of experience and those working in Tallinn were least aware of the website.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Aware of site?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Yes (%)</td>
<td>No (%)</td>
</tr>
<tr>
<td>Occupation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specialists</td>
<td>197 (74%)</td>
<td>70 (26%)</td>
</tr>
<tr>
<td>Family doctors</td>
<td>145 (96%)</td>
<td>6 (4%)</td>
</tr>
<tr>
<td>Nurses/midwives</td>
<td>126 (75%)</td>
<td>42 (25%)</td>
</tr>
<tr>
<td>Work experience</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;10 years</td>
<td>99 (70%)</td>
<td>42 (30%)</td>
</tr>
<tr>
<td>10-25 years</td>
<td>218 (80%)</td>
<td>56 (20%)</td>
</tr>
<tr>
<td>&gt;25 years</td>
<td>151 (88%)</td>
<td>20 (12%)</td>
</tr>
<tr>
<td>Workplace location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tallinn</td>
<td>145 (73%)</td>
<td>53 (27%)</td>
</tr>
<tr>
<td>Tartu</td>
<td>101 (77%)</td>
<td>30 (23%)</td>
</tr>
<tr>
<td>Other</td>
<td>222 (86%)</td>
<td>35 (14%)</td>
</tr>
</tbody>
</table>

Use of specific guidelines. Most family physicians (93.8%) were following the guidelines on hypertension among adults in primary care. Slightly fewer (81.5%) were using the guidelines on asthma among adults in primary care, while only 76% were using the guidelines on generalized anxiety disorder and panic disorder.
Discussion

Clinical guidelines are an essential part of clinical practice, as they help improve both the quality of health care and the use of resources. This study found that the majority of health care workers in Estonia use clinical guidelines often, and that they are considered an important source of information (Table 1). The main obstacles to the use of clinical guidelines are lack of time and medical resources (Table 2). Exhaustive and constructive feedback from participants enabled us to understand problems with the use and dissemination of clinical guidelines. Many participants were not aware of the website that holds all Estonian clinical guidelines (Table 3). In addition some participants suggested that a user-friendly computerized system of clinical guidelines that allows fast access to the necessary information should be developed.

Although a large proportion of the health care providers participating in the survey used clinical guidelines often, only about a quarter (23%) did so on a daily basis. Poor compliance rates with clinical guidelines could result in suboptimal clinical outcomes and increase the risk of overinvestigation and overtreatment (5). A previous study of paediatricians in Australia found similar results, in that only 22% of physicians were following clinical guidelines frequently when managing patients (6). The authors recommended the introduction of stricter implementation strategies, as physicians were sometimes not aware of available clinical guidelines (6).

The low compliance rate in Estonia may be at least partly due to local disparities. Numerous respondents mentioned the limited number of clinical guidelines available in Estonian and the fact that they are often out of date. Many Estonian health care workers use international clinical guidelines. Shekelle et al. recommended that clinical guidelines should be updated whenever new information becomes available (7). In a separate study, the same group proposed that, as a general rule, clinical guidelines should be reviewed every three years (8).

Length of work experience affects the perceived attitudinal barriers. Participants with longer experience of clinical practice considered that clinical guidelines limit care options, make an individual approach difficult and there is no need for clinical guidelines as clinical experience is enough. There are several explanations for this difference. Clinical guidelines should not be overloaded with treatment suggestions for every aspect of the disease (9). As one older specialist said: “Clinical guidelines are meant for health care workers with little/limited/outdated knowledge to facilitate the decisions for diagnostics and care.” Older physicians make care decisions based on their knowledge and experience; a patient with several diagnoses may need a different approach than that suggested in the respective clinical guidelines. Less experienced health care providers found the guidelines to be more efficient, as they lack professional experience. However, behavioural factors cannot be excluded. Health care providers graduating from medical school may find it easier to use clinical guidelines, since they are familiar with them from the curriculum.

Specialists used the website containing the clinical guidelines less often than the family doctors. Many respondents were not aware of the site that contains all Estonian clinical guidelines (www.ravijuhend.ee) (Table 3). The awareness was lowest among specialists and highest among family physicians. Many participants accessed guidelines through the website of their professional society. National campaigns and other measures should be employed to increase physicians’ awareness of the website. Since most clinical guidelines targeted at specialists are outdated, many of them follow international clinical guidelines with computerized features. Those who consider that Estonian guidelines are not easily accessible may be referring to the absence of electronic versions with a search tool and other features that improve accessibility. Although this opinion was not widely held, the developers of Estonian clinical guidelines should construct a computerized system to allow better access to the information (10).

The methods and questionnaire of the study were based on a survey by Taba et al., which analysed a population similar to the one in this study (4). Taba et al. also found that physicians had a positive view on clinical guidelines. The perceived barriers were also similar, except for the patient barriers. Our study
found a 10% higher rate for perceived discontent of patients when implementing recommendations in clinical guidelines. Another study, conducted in Germany, found that 34% of doctors considered inability to reconcile patient preferences with guideline recommendations as a problem (11). A literature review on compliance of psoriasis patients estimated that only 50–60% of patients were compliant with the prescribed therapy (12). However, these estimates apply only to the particular clinical guidelines, as different diseases are associated with different levels of psychological burden. More research is needed to identify the reasons for the increasing rate of perceived patient barriers.

This study had some limitations, which should be mentioned. First, we had expected a higher response rate. Subjects were drawn from the email lists of professional societies and hospitals. It is difficult to assess the number of members in the professional societies or how many people received the invitation. The survey was conducted in summer, when many people are on vacation. In addition, the number of male participants was low in relation to the overall proportion among Estonian health care workers. However, Taba et al. (4) found that attitudes and perceived barriers towards guidelines were not affected by the sex of the respondent.

One of the study’s strengths is the high response rate to the open-ended questions. Most of the participants commented on at least one question. Their suggestions provided additional valuable information on strategies for improving adoption and implementation of guidelines. We assessed the use of specific clinical guidelines by family doctors. Although this information cannot be generalized to all family doctors, it provides additional information about adoption and dissemination of the documents.

**Conclusion**

Estonian health care providers feel that clinical guidelines are evidence-based, improve the quality of care and sufficiently address different aspects of diseases. Most of the respondents use clinical guidelines; however, only one-quarter followed clinical guidance daily. Lack of time and medical resources were reported as the biggest barriers to implementation of clinical guidelines. Less experienced health care workers found attitudinal barriers less important than more experienced respondents. A computerized clinical guidelines system, integrated with the health care providers’ digital work desk, was considered a beneficial tool, which would increase the usage rate and convenience of clinical guidelines. Most family physicians were aware of the new clinical guidelines published since 2011; however, more attention should be given to their dissemination. In order to improve the quality of the health care services provided by doctors and other health care workers, even greater attention must be paid to the development, dissemination, use and evaluation of clinical guidelines.
References

### Clinical guidelines survey

1. **Sex**
   - Male
   - Female

2. **Occupation**
   - Specialist (doctor)
   - General practitioner
   - Nurse
   - Midwife
   - Family doctor
   - Resident physician
   - Other (specify)

3. **Please select your (main) speciality**
   - Anaesthesiology
   - Dermatovenereology
   - Endocrinology
   - Emergency medicine
   - Gastroenterology
   - Haematology
   - Infectious diseases
   - Independent inpatient nursing
   - Cardiology
   - Ambulance
   - Surgery
   - Laboratory medicine
   - Nephrology
   - Neurology
   - Ophthalmology
   - Oncology
   - Otorhinolaryngology
   - Paediatrics
   - Family medicine
   - Family nursing
   - Psychiatry
   - Pulmonology
   - Internal diseases
   - Midwifery and gynaecology
   - Rehabilitation
   - Midwifery
   - Nursing (other)
   - Physician (other)
4. Where is your workplace located?

- Tallinn
- Tartu
- Harju county
- Pärnu county
- Ida-Viru county
- Tartu county
- Lääne-Viru county
- Viljandi county
- Rapla county
- Võru county
- Saare county
- Jõgeva county
- Järva county
- Valga county
- Põlva county
- Lääne county
- Hiiumaa county

5. Length of service (full years)

6. How often do you follow guideline recommendations in clinical practice?

- Every day
- Often
- Sometimes
- Rarely
- Never

7. If you answered “never” to question 6, please explain your answer.

- There are no guidelines for my profession in Estonian
- I have not heard about Estonian clinical guidelines
- I do not use guidelines
- Other (please specify)

8. I am familiar with the following Estonian clinical guidelines (these guidelines are based on the new method provided in clinical guidelines handbook and have been written since 2012):

- Hypertension among adults in primary care
- Asthma among adults in primary care
- Surgical safety checklist for use in operating theatre
- Generalized anxiety disorder and panic disorder (with or without agoraphobia) in family medicine
9. I am using the following clinical guidelines:

- Hypertension among adults in primary care
- Asthma among adults in primary care
- Surgical safety checklist for use in operating theatre
- Generalized anxiety disorder and panic disorder (with or without agoraphobia) in family medicine

10. The following clinical guidelines are associated with my profession:

- Hypertension among adults in primary care
- Asthma among adults in primary care
- Surgical safety checklist for use in operating theatre
- Generalized anxiety disorder and panic disorder (with or without agoraphobia) in family medicine

11. What is your opinion about Estonian clinical guidelines in general? You may describe problems that have occurred while using the guidelines, make suggestions, etc.

12. Opinion about guidelines

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>No opinion</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estonian clinical guidelines improve the quality of care</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Estonian clinical guidelines sufficiently address different aspects of diseases</td>
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<tr>
<td>Estonian clinical guidelines are evidence-based</td>
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<tr>
<td>Estonian clinical guidelines are convenient to use (provided information is easily interpreted)</td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

13. Perceived barriers to guideline use

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>No opinion</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical guidelines are hard to implement in daily practice because of a lack of medical resources (investigational abilities, etc.)</td>
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<tr>
<td>Clinical guidelines are hard to implement in daily practice because of discontent of patients</td>
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<tr>
<td>Clinical guidelines are too complicated and it is difficult to find information</td>
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<tr>
<td>Clinical guidelines limit care options</td>
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<tr>
<td>Clinical guidelines limit flexibility and individual approach</td>
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<tr>
<td>There is no need for clinical guidelines as care routines exist</td>
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<tr>
<td>Clinical guidelines are not accessible</td>
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<tr>
<td>There is no time to search for information</td>
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</tbody>
</table>
14. Please rank the following suggestions to increase the use of clinical guidelines according to your personal preference.

- An easy-to-find online database
- Special training courses
- Published materials
- Video tutorials

15. Please mention other methods for introducing clinical guidelines

_____________________________________________________________________________________

16. Connection with clinical guidelines

- I have participated in the process of developing Estonian guidelines
- I have participated in the guideline development training?

17. Have you heard about the website www.ravijuend.ee?

- Yes
- No

18. Below you can make suggestions, e.g. on how to improve the use of clinical guidelines in everyday practice, how to make guidelines more user-friendly, etc.

_____________________________________________________________________________________

_____________________________________________________________________________________
ANNEX 6. DETAILED RECOMMENDATIONS FOR UPDATING THE HANDBOOK

Chapter-by-chapter recommendations for the handbook

Chapter 1

1. Revise definition of guideline to include WHO’s definition.
2. Link to planning the guideline with the guideline development checklist.
3. Describe guideline development process (perhaps tailor) using the process diagram shown in Fig. 5.1.

Fig. A6.1. Overall guideline development process

Legend: flow diagram of the guideline development process. The steps and involvement of various members of the guideline development group are interrelated and not necessarily sequential. The guideline panel and supporting groups (e.g. methodologist, health economist, systematic review team, a secretariat for administrative support) work collaboratively, informed through consumer and stakeholder involvement. They report to the oversight committee. While deciding how to involve stakeholders early for priority setting and topic selection, the guideline group must also consider how developing formal relationships with the stakeholders will enable effective dissemination and implementation to support uptake of the guideline. Furthermore, considerations for organization, planning and training encompass the entire guideline development project, and steps such as documenting the methodology used and decisions made, as well as considering conflict-of-interest occur throughout the entire process.
Annex 6. Detailed recommendations for updating the handbook

Chapter 2
4. Revise composition following restructuring of GAB?
5. Implement GRADE (required per handbook but not done).
6. Panel chair (section 2.3.4) should use the panel chair’s checklist (appendix 1).
7. Secretariat and the Global Advisory Board training material needs to be made available.

Chapter 3
No specific suggestions were made.

Chapter 4
8. Topic selection needs a more deliberate process including consideration of needs of different stakeholders, availability of existing systematic reviews and guidelines that could be used to adopt, adapt or develop guidelines.
9. Use a form to suggest topics (see appendix 2 for an example).

Chapter 5
10. Needs complete revision of the part about foreground and background questions, their importance and what to answer. Much of it is incorrect in this section (e.g. values and preferences or baseline risk is not background information but information directly needed to answer the foreground question; also separate out recommendations).
11. Include examples of more questions (e.g. diagnosis and screening).

Chapter 6
12. Eliminate the phrase “hierarchy of sources” (page 31) – first, this hierarchy is certainly wrong (source 3 and 4), and, second, there probably is no existing hierarchy at all.
13. Add (section 6.4) Guideline International Network as source to search for guidelines.
14. Prioritize sources that have GRADE evidence profiles or summary of findings tables.
15. Prioritize sources that have GRADE evidence to decision frameworks.
16. Change reference to AMSTAR to ROBIS, the new and updated tool (section 6.5.3).

Chapter 7
17. Change reference to GRADE to www.gradepro.org (also includes full GRADE Guideline development tool).
18. Revise description of GRADE and update (section 7.1).
19. GP reimbursement should be reviewed (currently reimbursed for certain quality indicators)
20. Adhere to the definitions in the actual guidelines.
21. Insert evidence summaries in GRADE evidence to decision frameworks (EtD).

Chapter 8
22. Complete resource section in Evidence to Decision frameworks.

Chapter 9
23. Use Evidence to Decision frameworks.
Change the order in section 9.2; first introduce the question, then review the evidence tables, then present the draft recommendations.

24. Use consistent language across recommendations.

Chapter 10

25. The implementation plan is currently focused on measuring impact without concrete activities that describe the implementation. Provide for implementation through other means, such as lectures etc.

26. Use electronic tools for implementation (e.g. apps – see example from Ministry of Health of Saudi Arabia).

Chapter 11

27. Focus description on updating of existing evidence tables and EtDs.
ANNEX 7. RECOMMENDED TEMPLATES AND CHECKLISTS

A7.1 Checklist for Guideline Panel Chairs

Checklist for Guideline Panel Chairs©8
v.1.5.2 | 20150510

Name of meeting

Before the meeting

- Ensure involvement of panel members in the question (PICO) development process
- Familiarize yourself:
  - with all material
  - with the strategies for declaring and managing COI
  - with panelists and their declared COI
  - with controversial issues
- Ensure background material (i.e., particularly, systematic reviews and evidence profiles) is disseminated to panel members ahead of time
- Ensure meeting worksheets (i.e., evidence to recommendation/decision frameworks, including neutral recommendations) are ready for the meeting
- Allow for sufficient face-to-face meeting time with the technical team (systematic reviewers and guideline methodologists) before the meeting starts

At the beginning of the meeting

- Introductions
- Make appropriate acknowledgments
- As people introduce themselves, note names and seating of panelists
- Solicit any new COI since they were last declared
- Remind panelists about the confidentiality of discussions
- Clarify ground rules (rules of process)
- Stress importance of adhering to methodology and that “this is not the time to discuss its value”
- Clarify who is a voting panelist and who is not
- Review goals and agenda and stress importance of adhering to schedule
- Check if panel members are representing organizations

Throughout the meeting

- Structure the discussion around the decision tables (and the factors that affect the final recommendation)

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Please contact Elie Akl & Holger Schünemann with any suggestions for improvement or copy emails: ea32@aub.edu.lb; schuneh@mcmaster.ca
• As panelists raise points that are relevant but not directly related to factors that not directly affect the recommendation, attempt to classify them as: conditions/key remarks to go underneath the recommendation statement; implementation considerations; monitoring considerations; implications for future research

• Offer a neutral recommendation as a starting point for discussing the recommendation statement

• Discuss first the direction of the recommendation (for vs. against) then its strength (strong vs. conditional)

• In trying to achieve consensus among panelists:
  - Check first whether there is agreement.
  - If not, label the disagreement; clarify what people are agreeing on and what they are disagreeing on; and check whether those disagreeing would be willing to accept the majority’s opinion.
  - If not, ask whether a modification or addition would make them agreeable.
  - If not, resort to voting.

• Enforce time, assign someone to help with time keeping if needed
• Enforce the COI management strategy
• Stay alert to, and manage strong advocacy
• Note to minute taker important points to go in the meeting report or guideline document; this is particularly relevant when you need to ensure transparency
• Clarify conceptual issues as needed
• Ensure everyone has the chance to participate, particularly community/patient representative
• Allow for time to debrief with the technical team during the meeting at regular intervals and as needed

At the end of the meeting
• Summarize what has been achieved
• Agree on what needs to be achieved after the meeting
• Clarify communication plan
• Make appropriate acknowledgments
### A7.2. Submission of topic and scope

<table>
<thead>
<tr>
<th>Domain</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Describe the general topic:</td>
<td></td>
</tr>
<tr>
<td>Does the potential guideline complement other programmes or interventions in the particular therapeutic area?</td>
<td></td>
</tr>
<tr>
<td>Population to be included or excluded (e.g., specific age groups or people with certain types of disease):</td>
<td></td>
</tr>
<tr>
<td>Health care settings (e.g. primary or specialized care):</td>
<td></td>
</tr>
<tr>
<td>The different types of interventions and treatments to be included or excluded (diagnostic tests, surgery, rehabilitation, lifestyle advice).</td>
<td></td>
</tr>
<tr>
<td>Information and support for patients and carers to be provided:</td>
<td></td>
</tr>
<tr>
<td>The preliminary outcomes that will be considered (benefits and potential harms to patients, impact on health insurance, society perspective)</td>
<td></td>
</tr>
<tr>
<td>Links with other relevant guidance. Are there any similar guidelines available in Saudi Arabia in this particular therapeutic area? If so, will the new guideline replace or supplement the existing one(s)?</td>
<td></td>
</tr>
<tr>
<td>Provide an overview of what the clinical guideline will include and what will not be covered:</td>
<td></td>
</tr>
<tr>
<td>Identify some of the key questions (clinical, as well as organizational, regulatory, etc.) following PICO format:</td>
<td></td>
</tr>
<tr>
<td>Describe the up-to-date evidence that is available on the topic (see list of preferred topics)?</td>
<td></td>
</tr>
<tr>
<td>Who are the key stakeholders for implementation and for further consultation on the scope, if they have not already been involved in preparing it.</td>
<td></td>
</tr>
</tbody>
</table>

A7.3 Example of evidence to decision framework (from Saudi Arabian Handbook for Healthcare Guideline Development)

Question 3. Should sublingual specific immunotherapy be used for treatment of allergic rhinitis in adults without concomitant asthma?

Background: Allergic rhinitis (AR) is defined clinically by nasal hypersensitivity symptoms induced by an immunologically mediated (most often IgE-dependent) inflammation after the exposure of the nasal mucous membranes to an offending allergen. Symptoms of rhinitis include rhinorrhea, nasal obstruction or blockage, nasal itching, sneezing, and postnasal drip that are reversible spontaneously or under treatment. Allergic conjunctivitis often accompanies allergic rhinitis.

Allergic rhinitis has been traditionally subdivided into seasonal, perennial, and occupational rhinitis. Perennial allergic rhinitis is most frequently, although not necessarily, caused by indoor allergens such as house dust mites, moulds, cockroaches, and animal dander. Seasonal allergic rhinitis is most often caused by outdoor allergens such as pollens or moulds. As in a 2010 edition of ARIA guideline in this document we retained the terms "seasonal" and "perennial" to enable the interpretation of published studies, and we also include the terms used to classify AR according to the duration of symptoms as "intermittent" rhinitis (symptoms are present less than 4 days a week or for less than 4 weeks) or "persistent" (symptoms are present at least 4 days a week and for at least 4 weeks).

These guidelines do not address the issues related to diagnosis of allergic rhinitis and it is assumed that the correct diagnosis had been established before commencing treatment.
## Seasonal/Intermittent Allergic Rhinitis

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Judgements</th>
<th>Research evidence</th>
<th>Additional considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Is the problem a priority?</td>
<td>1. Overall risk of AR in adults Saudi Arabia is 90 per 1000 (79% SAR)</td>
<td>- The guideline panel estimates a prevalence of 20% to 40% of AR in KSA. They consider that due to the lack of an appropriate data base with this data, the self-reporting studies could underestimate the prevalence (for not recognize the symptoms or not having a medical diagnosis) or overestimate (for considering any kind of rhinitis not only the allergic one).</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>Overall in the Middle East:</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probable No</td>
<td>Runny nose, nasal and throat itching, postnasal drip, and nasal congestion or stuffed up nose were the most common and bothersome symptoms of AR.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
<td>58% of participants with AR reported that the condition had an impact on their daily private and professional life.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably Yes</td>
<td>72% reported that limitations on their work/school activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>35% reported that interfered with and caused them to miss work or</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varies</td>
<td>Sleep disturbances were shown in this survey to be extremely troubling in 15% of AR patients.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Abdulrahman H, 2012. Survey conducted in Middle East including KSA)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. A high percentage of patients with AR surveyed missed work or had their work performance affected by allergies: work productivity decreasing by 23% in AIA, 24% in AIAP, 33% in AILA and 30% in Middle East when allergy symptoms were at their worst.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nasal allergies also interfered with many patients’ sleep, and were associated with feelings of depression, anxiety, irritability and tiredness.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>(Blaiss 2012, America, Asia pacific, Latin America, and Middle East)</td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Judgements</td>
<td>Research evidence</td>
<td>Additional considerations</td>
</tr>
<tr>
<td>----------</td>
<td>------------</td>
<td>-------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>What is the overall certainty of this evidence?</td>
<td>No included studies</td>
<td>Nasal symptoms</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>Very low</td>
<td>Low</td>
<td>Moderate</td>
</tr>
<tr>
<td></td>
<td>Moderate</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Is there important uncertainty about how much people value the main outcomes?</td>
<td>Important uncertainty or variability</td>
<td>Symptom-medication score</td>
<td>Important</td>
</tr>
<tr>
<td></td>
<td>Possibly important uncertainty or variability</td>
<td>Quality of life</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>Probably no important uncertainty or variability</td>
<td>Serious adverse effects</td>
<td>Important</td>
</tr>
<tr>
<td></td>
<td>No important uncertainty or variability</td>
<td>Withdrawal due to adverse effect</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>No known undesirable outcomes</td>
<td>Oral pruritus or burning</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td>Varies</td>
<td>Oral oedema</td>
<td>Critical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gastrointestinal adverse effects</td>
<td>Critical</td>
</tr>
<tr>
<td>Are the desirable anticipated effects large?</td>
<td>No</td>
<td>Summary of the evidence for patients’ values and preferences: This recommendation places a relatively high value on alleviating the symptoms of rhinitis, and relatively low value on avoiding adverse effects and resource expenditure.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably No</td>
<td>Local adverse effects are relatively frequent (~35%). An alternative choice may be equally reasonable, if patients’ values or preferences differ from those described here.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
<td>Summary of findings: see evidence table and reference list</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varies</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Are the undesirable anticipated effects small?</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Annex 7. Recommended templates and checklists

### Criteria

<table>
<thead>
<tr>
<th>Judgements</th>
<th>Research evidence</th>
<th>Additional considerations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the desirable effects large relative to undesirable effects?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probably No</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Uncertain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Probably Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Varies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1. SLIT was compared with standard therapy. It was (just) more effective or, in some cases, both more effective and cost-effective
   - SLIT is likely to be cost-effective at thresholds of £20,000; (Meadows A, 2013. SR)
   - These studies did not, however, report all of the utility data in a disaggregated form and all were funded by a manufacturer of SIT products (Meadows A, 2013. SR)

- Average annual cost per patient: around 35 K SAR
- Average cost per treatment (3 years) and patient: around 100K SAR

Average maintenance vial/ allergen/ month = 707 SAR.
Average 4 allergens/patient: Annual cost = 707 X 4 X 12 = 33,936 SAR

### RESOURCE USE

<table>
<thead>
<tr>
<th>Judgements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Are the resources required small?</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>X</td>
</tr>
<tr>
<td>Probably No</td>
<td></td>
</tr>
<tr>
<td>Uncertain</td>
<td></td>
</tr>
<tr>
<td>Probably Yes</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Varies</td>
<td></td>
</tr>
</tbody>
</table>

- Average annual cost per patient: around 35 K SAR
- Average cost per treatment (3 years) and patient: around 100K SAR

Average maintenance vial/ allergen/ month = 707 SAR.
Average 4 allergens/patient: Annual cost = 707 X 4 X 12 = 33,936 SAR

### Is the incremental cost small relative to the net benefits?

<table>
<thead>
<tr>
<th>Judgements</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>X</td>
</tr>
<tr>
<td>Probably No</td>
<td></td>
</tr>
<tr>
<td>Uncertain</td>
<td></td>
</tr>
<tr>
<td>Probably Yes</td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Varies</td>
<td></td>
</tr>
<tr>
<td>Criteria</td>
<td>Judgements</td>
</tr>
<tr>
<td>------------</td>
<td>------------------</td>
</tr>
<tr>
<td>EQUITY</td>
<td></td>
</tr>
<tr>
<td>What would be the impact on health inequities?</td>
<td>Increased</td>
</tr>
<tr>
<td></td>
<td>Probably increased</td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
</tr>
<tr>
<td></td>
<td>Probably reduced</td>
</tr>
<tr>
<td></td>
<td>Reduced</td>
</tr>
<tr>
<td></td>
<td>Varies</td>
</tr>
</tbody>
</table>

Comments from the panel members:
1. If sublingual immunotherapy use were to be recommended, the health inequity will increase so the indications and the applications of SLIT should be determined: The SLIT should be used only when all other regular options do not work.
2. Impact: Few patients will be affected.

<table>
<thead>
<tr>
<th>ACCEPTABILITY</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the option acceptable to key stakeholders?</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• Uncertain acceptance from patients and likely not for health care system because of cost consideration reasons.

<table>
<thead>
<tr>
<th>FEASIBILITY</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Is the option feasible to implement?</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably No</td>
<td>×</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Uncertain</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Probably Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Varies</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

• Implementation would require expertise and resources (i.e. skin tests, relevant allergen) not readily available in most areas.
### Balance of consequences

<table>
<thead>
<tr>
<th>Undesirable consequences</th>
<th>Undesirable consequences clearly outweigh desirable consequences in most settings</th>
<th>The balance between desirable and undesirable consequences is closely balanced or uncertain</th>
<th>Desirable consequences probably outweigh undesirable consequences in most settings</th>
<th>Desirable consequences clearly outweigh undesirable consequences in most settings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance of consequences</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

### Type of recommendation

<table>
<thead>
<tr>
<th>We recommend against offering this option</th>
<th>We suggest not offering this option</th>
<th>We suggest offering this option</th>
<th>We recommend offering this option</th>
</tr>
</thead>
<tbody>
<tr>
<td>✗</td>
<td>✗</td>
<td>✗</td>
<td>✗</td>
</tr>
</tbody>
</table>

### Recommendation (text)

The KSA MoH panel suggests sublingual immunotherapy for treatment of adults with seasonal or intermittent allergic rhinitis (conditional recommendation; Moderate-quality evidence).

### Justification

The evidence, with an overall moderate certainty, shows that the desirable effects probably are not large relative to undesirable effects. Furthermore, possibly there is an important variability about how much people value its effectiveness because there is a concern that some patients in KSA would not accept SLIT with some allergens of animal origin, however others would accept it as the last option when the symptoms do not decrease with all other regular options. On the other hand the incremental cost is not small relative to the net benefits, and the implementation would require personnel experts and resources (i.e. skin tests, specific allergen) which are not readily available in most areas. Reasons to formulate a conditional rather than a strong recommendation. It is considered that the lack of adherence with the medication use is not related with its adverse effects but with the long duration of treatment. For this reason in the cases when the SLIT would be the treatment of choice clinicians should provide an adequate educational instruction to the patient.

### Subgroup considerations

The SLIT should be used only when all other regular options do not work: It is more appropriate for those with moderate to severe AR who does not respond to first line therapy. The SLIT should not be started during pregnancy, but could be continued if the woman has already started the treatment.

### Implementation considerations

SLIT should only be prescribed by allergy specialists who have expertise in diagnosis of AR, proper identification of the allergens, providing immunotherapy and treatment of potentially serious adverse effects.

### Monitoring and evaluation

If patients receiving SLIT do not respond within 6–12 m consider discontinuation SLIT.

### Research priorities

Nationwide population-based community prevalence studies are needed to correctly estimate the AR rates. Patient values and preferences and cost effectiveness studies are also needed in the context of KSA to inform future guidelines and stakeholders.
The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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