Updating Clinical Practice Guidelines in the Spanish National Health System: Methodology Handbook

CLINICAL PRACTICE GUIDELINES IN THE NATIONAL HEALTH SYSTEM

SPANISH MINISTRY OF HEALTH AND SOCIAL POLICY

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Foreword

To improve the quality of clinical practice we must provide medical professionals with the tools they need to do their job and make the best decisions in each case, and Clinical Practice Guidelines are one of the tools that help to minimize inappropriate variation in clinical practice and to improve the effectiveness, efficiency and safety of clinical decisions.

The launch, in 2006, of the Clinical Practice Guidelines Programme in the National Health System represented a major advance in the development of such guidelines in terms of the number of guidelines developed, their quality and accessibility via the GuíaSalud (www.guiasalud.es) web portal. This methodology handbook for updating clinical practice guidelines is another key component of this programme.

Even after the publication of a methodology handbook for developing clinical practice guidelines (*Manual Metodológico para la Elaboración de Guías Clínicas*) more work was still needed to provide our National Health System with rigorous and transparent methodological instruments that deal with the different lifecycle stages of guidelines. Now that we have developed guidelines for use throughout the National Health System, we are faced with a new challenge in the form of our commitment to updating these guidelines and ensuring their quality. Every effort must be made to minimize the time lag between the emergence of new knowledge and technologies and the transfer of these advances into daily clinical practice.

Since the subject of this handbook has not previously been addressed in depth either internationally or in Spain, the aim was to create an open and widely available document that could be used both by teams actively involved in developing guidelines within the framework of the Clinical Practice Guidelines Programme in the National Health System and also by others working outside that framework who may benefit from the proposed methodology and procedures.

Like the methodology handbook for developing clinical practice guidelines in the National Health System, this new document was compiled by a team of authors who all belong to Spanish teams with experience in scientific research and guideline development. The process began with reviews and analyses after which the authors worked towards a final consensus document.

This initiative once again reflects our desire to encourage inter-regional and inter-institutional cooperation, under the coordination of the Aragon Health Sciences Institute (I+CS), by facilitating communication and collaboration between professionals working in the primary and specialist healthcare sectors and in health technology assessment agencies in the different Spanish Autonomous Communities.

Addressing the question of updating guidelines was a necessary step in consolidating the Clinical Practice Guidelines Programme in the National Health System in order to ensure that guidelines that have been developed are kept up to date in accordance with a common methodological framework.

In conclusion, we hope that all those involved in developing clinical practice guidelines will find this handbook both useful and practical.

Pablo Rivero Corte

Director General

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Contents

1. Introduction

Clinical practice guidelines (CPGs) are a set of "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".[1] CPGs also improve patient care and reduce variability in clinical practice.[2]

In recent years, and particularly since the publication of the AGREE Instrument,[3] CPGs have improved greatly in terms of thoroughness and quality. The 2006 launch of the Spanish National Health System's Clinical Practice Guidelines Programme, coordinated by GuíaSalud, represented a qualitative leap in the development of CPGs in Spain. This programme, the consequence of a ministerial agreement between the National Health System Quality Agency and Spanish health technology assessment agencies and services, undertook to develop a common methodology for developing, implementing and updating CPGs. It is this last aspect which is addressed in comprehensive detail in this handbook.

Because scientific knowledge is continually developing and improving, the emergence of new studies requires ongoing reviews of clinical practice. Updating CPGs is therefore an essential matter to be addressed in order to ensure the validity and quality of CPG recommendations. Nevertheless, only a handful of authors have studied the effects of the passing of time on the validity of CPGs and the need for update arising from changes in the information that formed the basis of the original recommendations.[4,5] Although the main institutions that develop CPGs tend to include basic CPG update guidelines in their methodology manuals,[6-8] few manuals provide this information in detail. This handbook, in addition to serving as a tool to update the CPGs included in the Clinical Practice Guidelines Programme in the National Health Systems, will also be useful for any team or institution wishing to update a CPG.

Updating should be understood as a process which aims to ensure the validity and the quality of a CPG. Although there are few studies on this subject, it is estimated that CPGs become obsolete and need to be updated after an average of three to five years.

This handbook assumes that there are two distinct areas within the updating process:

- Monitoring
- Updating itself.

Monitoring consists of identifying information which might suggest the need to update a CPG even before the estimated expiry date (three to five years after the original search has been concluded).

Updating begins either when monitoring reveals new evidence or when a pre-specified interval has elapsed since the last update. The CPG update takes place in stages covering literature search, critical appraisal, collation of evidence, formulation of recommendations and, finally, publication.

CPGs need to be updated according to a systematic, thorough and detailed methodology. As will be seen in the various chapters of this handbook, the CPG updating process must be based on some of the methodological resources used to develop it originally; this means that the quality and usefulness of the updated version depend on the outcome of the original development process. Since it is difficult for an update to improve the quality of the original CPG, it is unwise to invest time, effort and resources in updating a CPG if the original version is of poor quality.

It is clear that simply publishing a CPG does not guarantee either that it will be used or that it will remain valid over the long term. Therefore, in developing a CPG, issues that might affect implementation processes and future updates need to be taken into account. Clearly defining the scope and purpose of the CPG while it is being developed will make it easier to define and shape new clinical questions during the updating process. Similarly, the design of the evidence search and selection strategies used to develop a CPG will affect the design of these strategies for an updated version. Finally, the continuity of the roles of the original CPG developers, the experts involved in the process and patients and their carers should be reflected in the updating process.

Updating represents an opportunity to improve certain aspects of the original CPG. New clinical questions dictated by new information, new profiles that enrich the multidisciplinary nature of the development team and greater patient participation in the update stage are some of the possibilities to consider.

This handbook also discusses the role of technology in CPG updating processes, particularly interesting in terms of simplifying and making the updating process and the presentation of the final result more flexible. We need to advance towards the principle of 'living guidelines', which are constantly reviewed from their development onwards and which are updated as important new evidence emerges. This inevitably involves the use of technologies that enable updated CPGs to be presented with a minimum delay between the emergence of new knowledge and its incorporation into routine practice.

As will be seen in the remaining chapters of this handbook, the contributions from experts and CPG end users (health professionals, patients and the general public) represent a major source of information. An updated CPG should provide guidelines for implementing its recommendations and should take into account any necessary changes in the original implementation strategies.

Although dealt with at greater length later on in this handbook, at this point it is important to highlight the need for a multidisciplinary professional and technical team as well as sufficient material resources and time.

Updating a CPG requires knowledge of the various development stages of a CPG. Since this handbook is intended to guide teams already experienced in developing CPGs, it is assumed that certain terms and concepts are familiar to its readers.

In short, the ultimate aim of this handbook is to facilitate the planning and implementation of CPG updates. Its contents will complement the CPG development methodology described in the *Manual Metodológico para la Elaboración de Guías Clínicas* (henceforth, *Manual Metodológico*).[9]

This handbook consists of the following chapters, with four chapters covering the different steps of the updating process:

- Chapter 2: Assessing the Need to Update CPGs and Types of Update
- Chapter 3: The CPG Updating Process
- Chapter 5: Publishing the Updated CPG
- Chapter 6: Evaluating the CPG Updating Process.

Chapter 4 —Methodological Tools and Resources for Updating CPGs— pays specific attention to methodological tools and resources that facilitate the task of updating CPGs.

To make this handbook more accessible and easy to use, an electronic version is available from the GuíaSalud website (www.guiasalud.es).[10]

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2. Assessing the Need to Update CPGs and Types of Update

Javier Gracia, Petra Díaz del Campo, Pablo Alonso

This chapter discusses key issues in assessing the need to update a clinical practice guideline and the various possible kinds of update, addressing, in particular, the following questions:

- What aspects should be taken into account when deciding whether to update?
- How often should validity be reviewed?
- What kinds of update are possible?

Introduction

Assessing the need to update a clinical practice guideline (CPG) is an essential part of guaranteeing that CPG recommendations remain valid. An out-of-date CPG will not incorporate newly available information and so may lead to malpractice. An organization which has developed a CPG is also likely to rapidly lose credibility if its CPGs become obsolete.

An assessment of the current validity of a CPG will establish whether or not its recommendations need to be updated. Update assessments should therefore be cyclical and should result in better CPG quality.

This chapter, which describes key issues in determining whether and when a CPG needs to be updated, covers a number of aspects that need to be taken into account in this decision, such as monitoring for new study results and new relevant areas and the issue of timeframes. Finally, it describes types of update and the kind of update required in particular cases.

2.1 Assessing the Need to Update

An assessment of the need to update a CPG is a key element in maintaining and improving its quality and, consequently, the quality of decision making based on its recommendations—whether taken by healthcare professionals or by patients.

Crucial questions in assessing the need to update a CPG include the following:

- Has new evidence emerged since the original CPG was drafted?
- Does this new information significantly affect recommendations?
- Does the strength of the original CPG recommendations remain the same?

Answering these questions requires an analysis of the current validity of CPG recommendations in the light of new results and the current scientific/technical, sociological and cultural context.[1-3] Analysing these issues will enable a reasonable and objective assessment as to whether or not to update a CPG.[4-6]

2.1.1 Issues To Take Into Account in Assessing the Need to Update: Monitoring

An assessment of the need to update a CPG will be affected by certain developments that require systematic monitoring and analysis aimed at determining whether a CPG needs to be updated. Such developments include:

- Identification and assessment of new evidence
- Opinions expressed by experts and by CPG authors
- User perceptions

- Context analysis.

Identification and assessment of new evidence

CPG developers should establish regular monitoring mechanisms aimed at identifying new information which may affect the validity of the CPG. A number of monitoring strategies are possible.

Limited or focused searches

Since repeated systematic reviews of all the literature is often not feasible, a limited or focused review is recommended to highlight new studies which may alter clinical practice and so need to be assessed. This kind of search can be carried out by designated staff in large organizations or by CPG authors or other clinicians. Working groups in scientific societies might also find the information useful for their own documents.[7-10] (See Chapter 4 for further discussion of limited or focused searches and procedures).

Collating evidence from CPG authors, experts and users

Information provided by CPG authors and by experts in the field in question should be collected and assessed,[7-9] and also feedback from the end users of the CPG.

Collating alerts

Strategies to collect alerts issued by regulatory authorities—such as the Spanish Medicines Agency (AEMPS)—should be established. This is necessary to obtain new information on the adverse effects of treatments, so that recommendations on drugs and other healthcare interventions can be removed from the CPG and risk/benefit ratios modified. CPG updates may be necessary as a consequences of the results of new studies (randomized trials, etc), new diagnostic or treatment tools, changes to drug authorizations, warnings by healthcare authorities and important changes to cost structures entailing cost/efficacy ratio changes.[4,5,11] If substantial problems are detected, an earlier update than intended may be necessary. Other approaches are possible, depending on the institution and the subject of the CPG, but, irrespective of the approach used, it is important to plan and implement strategies rigorously.

Opinions of experts and CPG authors

The opinions of the multidisciplinary team which developed the original CPG[12] and of other experts in the field should be taken into account in updates. CPG authors and experts may also contribute with up-to-date information on new concepts, new technologies, issues for which sufficient information was not available when drafting the original CPG and changes to licences for particular drugs and other technologies.[9,13]

User perceptions

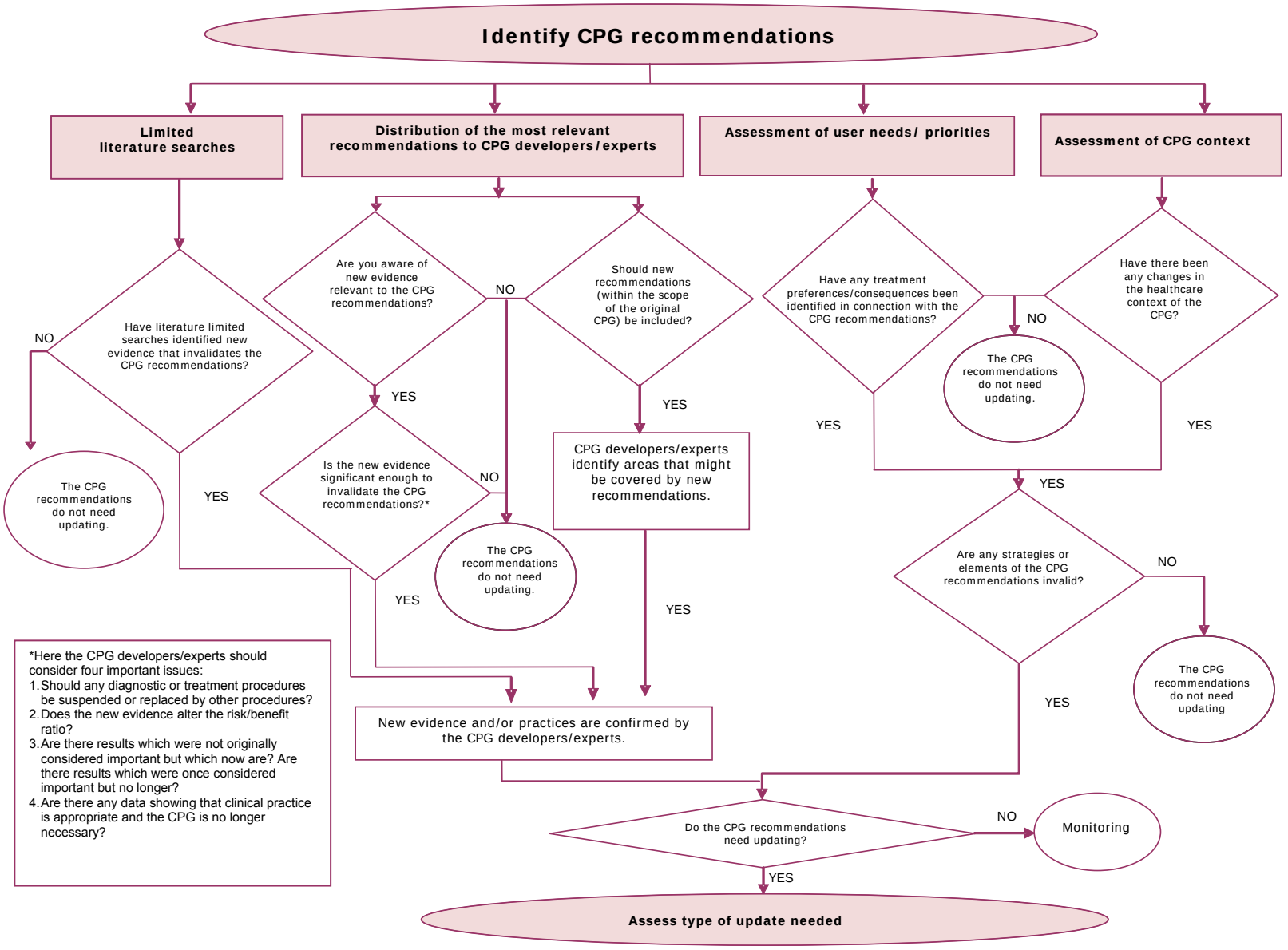
CPG users—whether healthcare professionals, patients or members of the public—also have an important role to play, as they can help identify the changes taking place in daily clinical practice. Within the group of end users, the needs and priorities of patients and the public need to be taken into account in terms both of their opinions after a CPG has been adopted and their preferences concerning recommended treatments and their results. For example, a treatment schedule for a particular disorder prescribed on the basis of CPG recommendations will only be effective if the patient follows the schedule; in other words, faulty compliance may affect the treatment results. It is therefore vital to consider patient values and preferences at an early stage of developing a CPG.[7] One option for collating CPG user perceptions is to make available an e-mail address or provide a platform on the institutional website so that comments and suggestions can be collected (see Appendix 1).

Context analysis

The medical and sociological context in which the CPG is applied should be analysed. The economic and technological dynamics of social processes involving professional groups, scientific associations and members of the public in responses to healthcare problems sometimes make adjustments necessary. This means that some strategies and elements of the recommendations contained in a CPG may be invalidated by a change in context. Finally, it should not be forgotten that the decision regarding CPG update is not necessarily the consequence of any one of the issues outlined above, but may be due to all of them as a whole. Taking the work of Shekelle et al.[8] as a starting

point, the main factors to be taken into account and the procedure for assessing the need to update a CPG are summarized in the algorithm below. The actions outlined should be carried out jointly and in parallel**.**

Figure 2.1. Algorithm for assessing the need to update a CPG



2.1.2 How Often Should CPG Validity be Reviewed?

The effect of the passing of time on the validity of CPGs—and of their essential components, systematic reviews—has been studied by a number of authors.[8,14] Shekelle et al.[8] evaluated information obsolescence in 17 CPGs, revealing that that CPGs quickly became outdated, with approximately half of them obsolete in 5.8 years (CI 95%, 5.0-6.6 years) and with around 10% out of date after 3.6 years (CI 95%, 2.6-4.6 years). Although this timeframe is very approximate, authors and developers of CPGs recommend or carry out updates at least once every three years.[4,5,7,9,11,15,16]

Another way to explore how fast CPG information goes out of date is to assess the need to update the systematic reviews that are the main source of information for formulating recommendations for a CPG. The dates of publication of these systematic reviews indirectly provide information on the validity of a CPG and its recommendations. Shojania et al.[14] evaluated 100 high-quality systematic reviews for their degree of obsolescence, observing that reviews became obsolete in relatively short periods of time. For example, although the mean time after which an update was necessary was 5.5 years (CI 95%, 4.6-7.6 years), 23% and 15% of cases required an update two years and one year, respectively, after publication. More rapid obsolescence was observed for cardiovascular reviews and for reviews with heterogeneous results. Other authors have systematically reviewed potential strategies for deciding when and how to update systematic reviews, observing that there was little information available on the subject and concluding that the feasibility and efficiency of the few methods available were uncertain.[17]

This research indicates that it is difficult to estimate when to update a CPG and schedule future updates. Nonetheless, the results can serve as a reference for deciding optimal frequency for a CPG update, in cooperation with the group that developed the CPG and depending on the subject. For example, very intensive monitoring is less likely to be needed for health problems with a consolidated corpus of information, whereas a relatively new procedure or diagnostic test may require earlier and regular reassessment.

Even assuming that a CPG will be updated at least once every three years and certainly never less than once every five years, there are no golden rules and deciding how often to assess the validity of a CPG requires many factors to be evaluated in conjunction. Indicating an expiry date represents an alarm signal that warns of the need to consider the issues outlined above.

However, this approximate timeframe does not mean that an update cannot be carried out earlier if there happens to be a significant innovation that may alter the course of treatment of an illness[18] (see Section 2.1.1). In fact, CPGs should be reviewed earlier than planned if significant evidence emerges that requires an update of one or several CPG recommendations (new randomized clinical trials, new diagnostic tests, changes in treatment indications, alerts by healthcare authorities or significant changes regarding costs and safety). These updates, which tend to be exceptional from the point of view of the timeframes recommended, are usually due to new evidence requiring changes to recommendations and needing to be published rapidly. Experience shows that an update is rarely needed because errors have been identified in a CPG after publication. Exceptional updates should be made in the same way as partial updates (discussed below).

2.2 Update Types: Criteria for Deciding What Actions to Take

Once an assessment has been made of the issues to be taken into account in assessing whether a CPG needs updating, a decision should be taken as to the next step: whether or not to update and, if an update is considered necessary, what type of update is the most appropriate. Updates fall into the following categories: full update, partial update, update with no changes and withdrawal.[4,5,15] The following table, based on a proposal by the UK's National Institute for Clinical Excellence (NICE),[5] describes the basic factors that guide the decision as to the type of update required.

Table 2.1. Determining factors for different CPG update types

Type of update	Factors to be considered
Full update	➢ Most sections or chapters of the CPG need to be updated. ➢ Many of the recommendations are no longer valid. ➢ Relevant new areas which need to be included have been identified.
Partial update	➢ Only some recommendations need to be updated. ➢ There are relevant new areas which need to be included.
Update with no changes	➢ No information which might change or alter any of the recommendations has been identified.

	➢ No clinical practice information indicates a need to change recommendations or the scope and purpose of the original CPG.
Withdrawal	➢ The CPG recommendations are no longer applicable or are outdated. ➢ The subject of another more recent CPG partly or wholly overlaps with that of the CPG. ➢ There is evidence that the CPG has been fully implemented in the healthcare system and has been accepted as clinical practice. ➢ Discovery of new preventive or treatment measures make the CPG obsolete.

Actions According To Update Type

Each type of update requires certain issues to be taken into account. The following table, based on a proposal by NICE,[5] shows the actions to be considered depending on the type of update required.

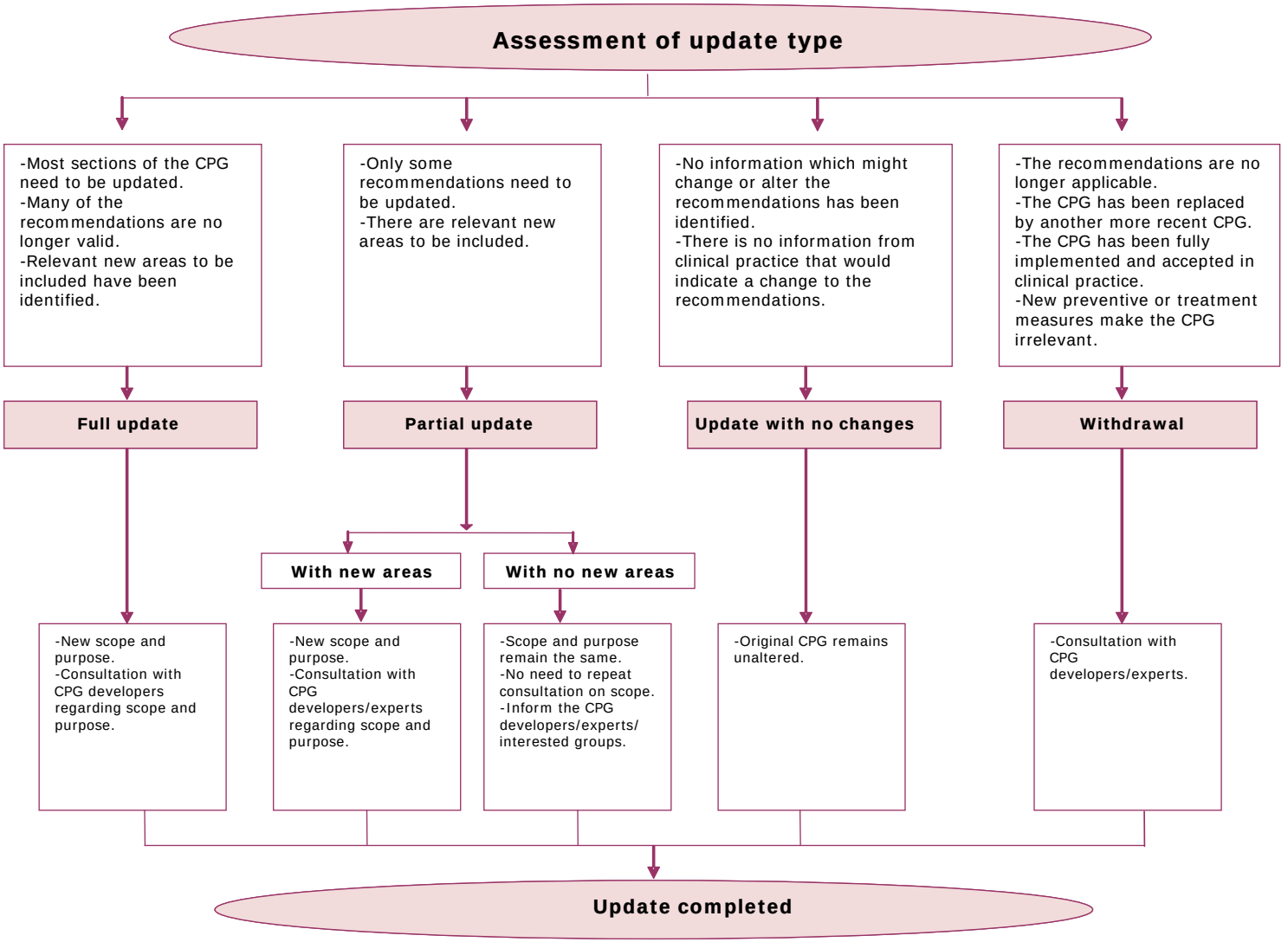
Table 2.2. Actions for different CPG update types

Type of update		Actions
Full update		➢ Prepare new scope and purpose. ➢ Consult scope and purpose with the CPG development team.
Partial update	**With new areas**	➢ Prepare new scope and purpose. ➢ Consult scope and purpose with the CPG development team/experts.
	With no new areas	➢ Use the original scope and purpose. ➢ No need for repeat consultation on scope and purpose. ➢ Inform the CPG development team/experts/interested parties.
Update with no changes		➢ No modification to the original CPG. ➢ Inform the CPG development team/experts/interested parties.
Withdrawal		➢ Consult the CPG development team/experts.

Notes. 1. The *Manual Metodológico*[18] describes CPG scope and purpose aspects. 2. Once a CPG is updated, the need for further updating is regularly monitored but updating is assessed at least once every three years.

An algorithm summarizing the types of update and the actions to be taken is shown in Figure 2.2.

Figure 2.2. Algorithm for CPG update types and actions



KEY POINTS

- Assessing the need to update a CPG implies assessing the validity of its recommendations.
- Key aspects in monitoring to assess whether a CPG needs to be updated:
  - Identify and assess relevant new evidence
  - Obtain the opinions of the CPG development team and experts
  - Analyse user perceptions
  - Analyse context.
- A rule of thumb is to assess the validity of a CPG and the need for an update at least every three years and never later than five years.
- CPG update options are a full update, partial update, update with no changes and withdrawal.

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3. The CPG Updating Process

Pablo Alonso, Javier Gracia, Ivan Solà, Petra Díaz del Campo

This chapter, which discusses key aspects of carrying out a clinical practice guideline update and incorporating the process within an organization, addresses the following questions:

- What issues should be considered when planning an update?
- What stages and actions are necessary for an update?
- Who is involved in an update? What role does the original development team play in an update? How are potential conflicts of interest resolved?

Introduction

Updating is a crucial step in the lifecycle of a clinical practice guideline (CPG).[1,2] Although efforts have been made to adopt a systematic approach,[3-6] CPG updating, like CPG development, is a complex process which consumes substantial resources. Organizations concerned with the quality of their CPGs and whose approach to their development is thorough acknowledge that they have difficulties in ensuring that CPGs stay up to date.[5] Most do not have, in fact, formal procedures for updating their CPGs[7] and those that do often fail to apply them systematically. To date, very little research has been conducted into the CPG updating process and its impact.[8-10]

3.1 Issues to Consider When Planning an Update

From the organization's point of view, the key factors in planning and undertaking a specific update include information obsolescence, the resources required, the time available, staff experience, the possibility of adapting other CPGs and the synergy between different organizations.

3.1.1 Information Obsolescence

The speed with which information becomes outdated is a fundamental problem in developing and updating CPGs. The effect of the passing of time on the validity of both CPGs[10] and their essential components, systematic reviews,[11] has been evaluated in individual studies that serve as guides on the subject. There are no golden rules and the decision regarding updating requires many factors to be assessed as a whole. Depending on the intrinsic nature of the subjects to be addressed, each individual organization needs to consider how many CPGs per year it can feasibly develop and keep fully updated. This issue is discussed in more detail in Chapter 2 (Section 2.1).

3.1.2 Material and Human Resources

Developing and updating CPGs are both costly and time-consuming processes. Each organization needs to be realistic about the number of CPGs it can develop and this decision should also take into account the number of CPGs it can feasibly keep updated.

The various types of updates incur varying costs. At the most costly end of the spectrum are updates which are virtually continuous processes (living guidelines).[4] This kind of update has been the subject of intense debate but, at the time of writing, it is not a generalised practice. At the other extreme are updates made after a number of years, in principle at least every three years.

To maintain a high CPG development rate while also ensuring CPGs updates at least every three years, an organization should have a suitable infrastructure and stable funding. This is often only possible in bodies receiving substantial state funding and established for this very purpose. Two of the most internationally well known such bodies are the Scottish Intercollegiate Guidelines Network (SIGN)[12] and the UK's National Institute for Health and Clinical Excellence (NICE).[13] Similar initiatives are being undertaken in other European countries;[14] in Spain the main drive in recent years has come with the launch of the National Health System Quality Plan.[15]

CPGs developed by organizations with smaller budgets often remain outdated for excessively long periods of time which can negatively affect the credibility of both the CPGs and the developing organizations.

Some suggestions for minimizing the financial repercussions of updating CPGs are as follows:

- Limit the number of new CPGs to those that can be kept updated.
- Establish a systematic process and take advantage of existing critical appraisals and syntheses of the literature (including published quality CPGs).
- Pool efforts with other organizations at home and abroad so as to share the workload and create synergies.
- Train more professionals in CPG updating, ideally in professional societies or on the specialist areas represented by the CPG developers.
- Prioritize the publication of electronic versions over hard-copy versions.

3.1.3 Time Requirements

Developing CPGs takes time and so does updating them. An average update, three or four years after the date of the last search, usually takes three to six months or even a year, depending on the subject matter. Organizations with very limited time available, due to the subjects they deal with or the publication timeframes they require for their documents, should take on fewer CPGs or find ways to overcome these restrictions, as, otherwise, the quality of the CPGs will suffer.

3.1.4 Staff Experience

Another key aspect in planning an updating process is the number of trained, skilled professionals available in an organization to maintain a CPG project. The number will, in fact, determine the number of CPGs which the organization can reasonably develop and maintain. Organizations without staff experienced in CPG development will find it difficult to develop CPGs and keep them updated. In such cases, the best strategy is to think long term and gradually train more professionals to work full-time or sporadically on CPG projects.

3.1.5 Adaptations

CPG adaptation is a practical strategy for both development and updates. Adaptation is defined as a systematic approach to deciding whether or not to use or adapt one or several CPGs issued in other cultural or organizational contexts. Adaptation is an alternative to developing a completely new CPG or an option for making an existing CPG suitable for the local context.

Organizations with fewer resources may be overwhelmed by the huge task of developing and updating CPGs. As an alternative to developing completely new CPGs (ex novo), adaptation encourages the use of quality CPGs; it also reduces redundancy and duplication of effort, increases efficiency and encourages the incorporation of quality recommendations.[16] The adaptation process, which is already applied in Spain,[17] is not excessively complex and does not necessarily compromise quality. Despite the fact that there is little literature available on this subject, a structured methodology has recently been developed (ADAPTE).[16,18]

3.1.6 Synergy Between Institutions

The popularity of CPGs is increasing and the number of institutions developing and updating them independently is growing. For more mainstream subjects, there often are many international CPGs and several others within a particular country or even region. This duplication and waste of resources should be avoided through networking and resource sharing. One approach is to encourage collaboration between institutions developing CPGs on the same subject; they could review and synthesize the literature jointly and, at least, share the synthesis of evidence, as this is the stage that requires the most effort. Such projects are not a chimera but are slowly emerging[19] and the Guidelines International Network (GIN)[20] is investigating and exploring ways to make potential collaboration between institutions more systematic and flexible.

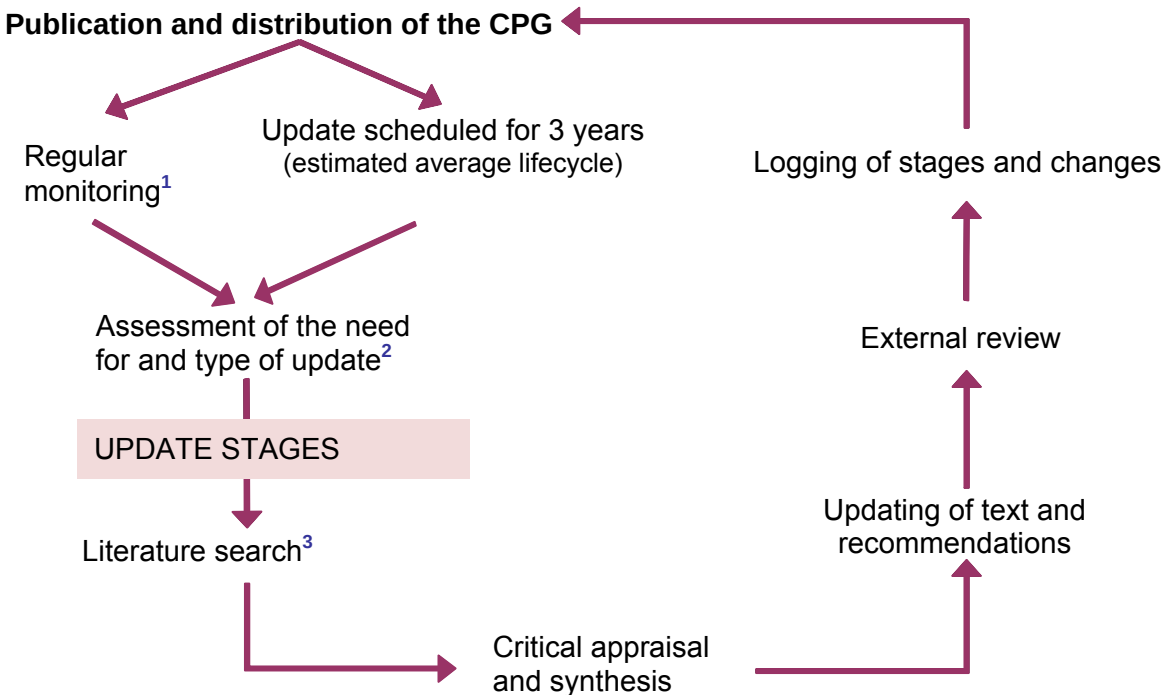
3.2 Update Stages

Any CPG updating policy ought to include a system to monitor the validity of the CPG in question. This monitoring should be a preliminary stage in the updating process rather than part of updating itself, as monitoring indicates whether or not a CPG actually needs to be updated. During the monitoring phase, it is recommended to consider using more inexpensive (in terms of both time and resources) strategies with more than those used for the updating process itself. The task of assessing the need to update a CPG essentially corresponds to experts, either the CPG development

team or external collaborators or reviewers. This pre-update monitoring phase should clearly identify whether or not the CPG needs to be updated (see Chapter 2, Section 2.1).

Once it has been decided that an update is necessary, the updating process itself begins. Figure 3.1 illustrates pre-update monitoring, assessment of the need for and type of update and the various stages of the updating process.

Figure 3.1. CPG update stages



Notes:
1. A more frequent, regular but limited monitoring of CPGs, systematic reviews, clinical trials and alerts from authorities is optional.
2. See Chapter 2 and Figures 2.1 and 2.2.
3. See Chapter 4 and Figure 4.1.

3.2.1 Literature Search

Once the decision to update a CPG has been taken, searching the literature is the first stage of the update itself. Searches at this stage should be more rigorous than those carried out during monitoring. They need to be more focused and initially should focus on secondary sources of information (CPGs and systematic reviews). Strategies to plan literature searches are discussed in more detail in Chapter 4.

Regardless of how an organization develops a CPG, duplication of effort can be avoided by taking advantage of work previously carried out by other organizations that develop CPGs. Similarly, an organization can also share its own information with other organizations. Furthermore, and provided the aims and issues addressed are the same, critical appraisals of the literature performed by other organizations that have developed a CPG for a similar subject can be used.

Only part of an existing CPG may prove useful or it may be necessary to consult several different CPGs. Before using existing CPGs, it should be ensured that the methods are appropriate and that the authors have carried out a comprehensive review of the literature.[16] Ideally, the planned CPG should have used the same grading system to evaluate the quality of the evidence and strength of recommendations as the existing CPG. However, even if a different grading system has been used, the synthesis of information is still useful and its critical appraisal of the quality of studies can very often be used. It is very important, obviously, that this information and the sources used are reflected in the updated CPG.

Once previously published CPGs have been collected, searches should be made for any published systematic reviews and health technology assessment reports. It is important not to overlook such documents as they will be very useful in synthesizing the CPG update and its recommendations.

Update searches may initially be more focused and targeted than the searches originally carried out to develop the CPG, as we are unlikely to fail to locate any relevant studies if we depart from an existing systematic review. However, specific subjects or new issues may require more detailed review. Chapter 4 discusses search tools, resources and strategies in detail and Appendix 2 lists useful resources and information sources.

3.2.2 Critical Appraisal and Synthesis

Critical appraisal of the literature and assessment of the quality of the information available is no different from the appraisal and assessment carried out during CPG development itself. This process is described in detail in Chapter 6 of the *Manual Metodológico*.[15] A critical appraisal or assessment of the quality of information of another reliable CPG can be used, leaving only studies published since the last search to be located. This process is not always straightforward, as it generally requires the two CPGs to have used the same quality assessment system. Nonetheless, even if it a different quality grading system was applied, the synthesis of information can still be used. Quality can be appraised from studies of complete texts; alternatively, the other CPG's appraisal can be used if the questions included in the quality assessment are the same as for our CPG.

Previous tables of evidence should be updated and new information incorporated in the synthesis. An update provides a good opportunity to compile study assessment tables (if none were originally included) and to improve existing tables. Appendix 3 gives an example table from SIGN.

3.2.3 Updating Text and Recommendations

Once information has been appraised and synthesized, a draft that includes the modifications to be made is drawn up, either by a small number of authors or organization staff. When new information is included, the authors will need to evaluate how it affects the assessment of evidence quality and the strength of the recommendations; hence, all the persons involved at this stage should have both a methodological and a clinical background.

3.2.4 External Review

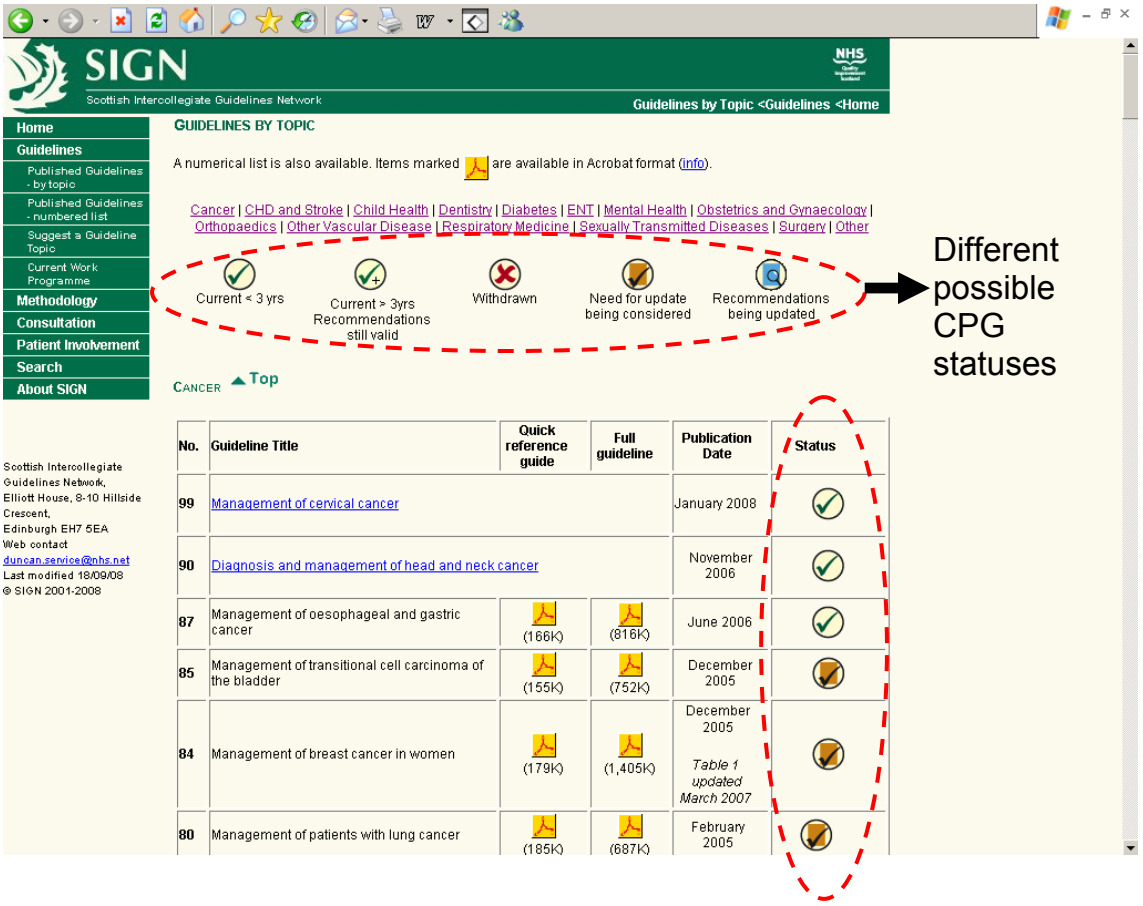
Once an updated version that includes the modifications (or a completely new CPG) has been drafted, a broad-ranging external review should be carried out. This stage, which can enrich a CPG enormously, is fully described in the *Manual Metodológico*.[15] It is important for the consultation to be broad-ranging and multidisciplinary and, ideally, people with different backgrounds from those involved in the process should be consulted.

3.2.5 Monitoring Stages and Changes

Monitoring of stages and changes is a weak point in most organizations, as explicit procedures are often not devised and stages and changes are thus not recorded systematically. Given that it is vital for organizations to become more transparent and thorough in their work, they should be able to provide records to users or other organizations which may be interested in adapting part of their work. Although this transparency is necessary when developing new CPGs, it is perhaps even more important when updating CPGs, as users should be able to easily identify changes and the reasons for them.

A simple way to publish these details is to keep a record of actions, modifications and methodologies in the organization's own website. SIGN, for instance, keeps records indicating the CPGs that have been updated or withdrawn, those being assessed for update and those in the process of updating (Figure 3.2). Chapter 5 describes this procedure in more detail.

Figure 3.2. SIGN's CPG status record[12]



The information made available to users should include the following:

- Names and affiliations of the CPG updating team
- Potential conflicts of interest
- Methodology used (including search strategies and evidence tables)
- Advanced drafts.

It is also useful for the following documents to be made available:

- Preliminary drafts
- Data collection forms
- Evidence quality assessment forms
- Minutes of working group meetings.

3.2.6 Publication

Electronic publication allows CPGs to be published and maintained at a lower cost. The use of this technology is also essential in publicizing new developments, whether via alerts on the organization's website or via distribution lists. Online publication of CPGs also enables significant changes to CPGs to be easily identifiable.

It is crucial to publicize both CPGs and changes as widely as possible via publication in key indexed journals and/or the journals of the associations involved in developing the CPG. In Spain, it is also important to inform GuíaSalud so that a CPG can be included in its catalogue.[21] If a CPG may be of use internationally, an application can be made to index it in the National Guideline Clearinghouse (NGC)[22] of the US Agency for Healthcare Research and Quality (AHRQ).

3.3 Participants

An issue on which there is no clear consensus is who should participate in the CPG updating process. Different organizations use different strategies, according to their size, the number of CPGs in their portfolios and whether they

are public or private. The nature of participants also tends to vary according to whether the update is a partial update or full update (see Table 3.1).

3.3.1 Monitoring

There are generally two stages in monitoring to check the validity of a CPG. On the one hand, documentation and methodology staff update searches, select studies and synthesize information on new developments. On the other hand, the team which developed the CPG or relevant experts assess the new information and the CPG's key recommendations and questions. In large organizations, monitoring is generally carried out by the organization's own staff. In the most important organizations, methodologists with a clinical background coordinate several different projects. Organizations with fewer resources generally share out the work, although searches ideally should be supported by an information specialist.

3.3.2 Update Type

For a partial update, even if there has been a lengthy external review and consultation period, the CPG team can probably communicate via e-mail and teleconferences rather than meet in person.

When a CPG requires a full update or major overhaul, the team will probably need to meet several times, as not only will existing sections of a CPG have to be updated but also whole new sections may have to be written (e.g., when new diagnostic procedures or tests have been developed).

3.3.3 Organization Type

The final decision as to whether or not an update is needed (depending on the type of organization) may be made by the CPG developers or expert collaborators, together with staff in charge of CPG coordination (ideally methodologists with a clinical background). The various possibilities vary from organization to organization but, for simpler updates, staff members may make the decision together with one or two key authors (e.g., the clinical coordinator and the methodology coordinator).

Table 3.1. Participants in monitoring and according to CPG update type

	Methodologist in charge of CPG	Information specialist	Key CPG team authors	Entire CPG team	Expert collaborator	Other individuals
Monitoring	√	√	√	+/-	+/-	+/-
Partial update	√	√	√	+/-	+/-	+/-
Full update	√	√	√	√	√	√

Note. √: required, +/-: optional or additional.

3.3.4 Professional Profiles

The profiles required vary according to the type of update but individuals with a background in methodology and experience in literature searches (ideally, information specialists) are necessary. Author profiles should be similar to those of the authors of the original CPG, provided there have been no major new developments in CPG scope or questions; profiles other than those involved in the development of the original CPG (economists, social workers, etc) may be required.

An update represents an ideal opportunity to enrich the working group if it is considered that more multidisciplinary contributions are required. It also represents an opportunity to create a wholly or partly new team, to overcome deficiencies or problems in working dynamics and to take account of excessively dominant experts or experts with major conflicts of interest. It is not unusual for a CPG development team to have a leader who exerts excessive influence on the team's working dynamics and management, thereby possibly biasing the end result. In

such cases it is necessary to discuss and weigh possible solutions. Individuals with stronger personalities, for instance, are often more useful as external consultants, as this reduces their influence on the decisions of the group.

3.3.5 Authorship and Conflict of Interest Declarations

Authorship will remain the same if the CPG development team also updates the CPG. If new authors or external consultants or reviewers are included, however, both they and the original authors should approve all changes and the text as a whole before the CPG is published.

A more complex situation is when a CPG is fully updated by a different team. The work of the previous team, if it has served as the basis for the updated CPG, should be mentioned in the new list of authors (ideally with details of all the participants). If the team develops a genuinely new CPG, there is no need to cite the original team in full; it is merely necessary to state that this is a new CPG rather than an improved version of the previous CPG.

In some cases, as with publications in certain biomedical journals, details are provided regarding who has done what in the CPG development process (this applies equally to the original and updated versions).[23] Although this procedure reflects the actual level of involvement and work of the team members, it can create mistrust if too much emphasis is placed on particular group members. It may also give rise to the feeling among CPG users that some fields dominated in the development of the CPG, thereby making it less applicable to other, less well-represented fields. Particularly dedicated members of the CPG team can be suitably acknowledged by placing their names in a prominent position in the list of authors when the CPG is published in an indexed journal.

When declaring activities that may represent potential conflicts of interest, it is important to indicate any changes in the original CPG team. New members should also declare any conflicts of interest in full. External reviewers and collaborators (whether new or participants in the original CPG project) should also make (or update, as appropriate) this declaration.[15]

One situation which often arises is a conflict of interest due to participation in clinical trials by members of the CPG development team. It is important to know the trials associated with the CPG topics in which members have participated. Experts who have been involved in large-scale trials, for instance, are usually more likely (whether consciously or unconsciously) to have a more favourable opinion of a intervention in which they have invested time and effort. It is not uncommon for clinicians whose departments have received funding for clinical trials (sometimes via a foundation) to fail to mention these trials when they declare potential conflicts of interest. If it is felt that the conflicts of interest are significant, such individuals can be excluded from particular chapters or even from the whole CPG and may, instead, be appointed as expert collaborators.

KEY POINTS

- The update process begins once it is decided that a CPG needs to be updated, whether as a consequence of new information being identified through monitoring or because the period of time established in the original CPG has elapsed.
- From an organization's point of view, some of the key factors to be considered when planning and undertaking an update are the amount of outdated information, the time and resources available, staff experience and methods used.
- Update stages are as follows:
  - Literature search
  - Critical appraisal and synthesis
  - Updating the text and recommendations
  - External review
  - Monitoring stages and changes
  - Final publication.
- Participants and decision making when updating a CPG vary according to update type and organization type.
- During the update process, it is recommended to review both the authors and their activities to ensure there are no potential conflicts of interest.

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4. Methodological Tools and Resources for Updating CPGs

Ivan Solà, Antoni Parada, Carlos González, Pablo Alonso

This chapter discusses how to identify relevant literature for clinical practice guideline updates and suggests tools which may be useful for this purpose. It addresses the following questions:

- Which resources and sources of information yield the best results when assessing the need to update? When and how can literature for an update be identified?
- How should the original search strategies be revised when updating?
- What role can the new technologies play in identifying new literature for an update?
- What methodological tools and resources can facilitate an update?

Introduction

The scientific literature on updating clinical practice guidelines (CPGs)[1,2] and the main organizations that develop them[3,4] all highlight the fact that a decisive factor affecting the decision to update a CPG is the emergence of new scientific literature that alters previous results. It is important to identify relevant literature both when assessing the need to update a CPG and when carrying out searches to synthesize studies whose results might alter the recommendations of a CPG.

The two aspects forming the core of this chapter are issues relating to identifying studies and tools for controlling the volume of information that authors need to handle.

4.1 Identifying Scientific Literature When Updating a CPG

New scientific information accumulates continually,[5] which means that it is crucial to identify any studies that may lead to significant changes in the recommendations of a CPG. In relation to updates, identification occurs at two specific points: when assessing whether a CPG needs to be updated and when identifying studies which may lead to modifications in recommendations.

4.1.1 Proposals for Identifying Literature When Assessing the Need to Update

The main study assessing when a CPG needs to be updated proposes a limited search of the literature and consultation with field experts;[2] the most relevant studies, with the highest methodological standards or the most significant conclusions, are generally published in a limited number of medical journals and are generally accompanied by editorials and comments or are cited in other high-profile journals. The same authors concluded that combining a limited search with expert consultation was preferable to a comprehensive review of the literature to decide whether or not a CPG needed to be updated. Other studies have confirmed this conclusion,[6,7] suggesting this to be an efficient option when deciding whether or not to update a CPG.

As stated in Chapters 2 and 3, the limited literature review is the framework used by institutions that discuss the CPG update process in more detail. In its developer's handbook, the Scottish Intercollegiate Guidelines Network (SIGN)[4] indicates that the first step should be to search for other CPGs, health technology assessment reports and systematic reviews that have emerged since the CPG to be updated was published. New study information is collated for discussion of the extent to which the results affect the original CPG recommendations. It is also recommended to carry out focused searches for new research areas and interests that may raise important new questions.

The UK's National Institute for Health and Clinical Excellence (NICE) carries out searches that prioritize precision and specificity over sensitivity and sees no need to implement systematic reviews of the scientific literature.[3] As well as referring to the literature indexed in the usual literature databases, NICE also mentions the role played by regulatory authority and other alerts and by experts in the field, physicians and even patients.

Both SIGN and NICE agree on one very important point. All literature updates should be based on the search strategies designed for the original CPG.

According to this limited approach to identifying relevant literature, information on the most relevant new CPGs should first be collected. Alerts regarding new developments in the main CPG databases—the National Guidelines Clearinghouse (NGC) of the US Agency for Healthcare Research and Quality (AHRQ) and the National Library of Guidelines of the UK's National Health Service (NHS)—should be activated in order to identify new CPGs. Spain has the GuíaSalud catalogue of CPGs. Appendix 1 provides more details on databases and the use of alerts.

Focused database searches for systematic reviews and large clinical trials should also be carried out and articles cited by the main studies referred to in the original CPG should also be identified.

4.1.2 Proposals for Searching the Literature When Updating

The *Manual Metodológico*[8] includes a chapter describing how to search and select the literature that will be the reference material for addressing some of the issues discussed below. It should be borne in mind that the suggestions below are based on the idea that the original CPG search strategies are valid for identifying the most relevant literature on the basis of which to formulate recommendations.

There is no empirically tested gold standard for establishing the steps to be taken in identifying the literature for a CPG update; however, any approach prioritizing search precision and specificity will identify the most relevant studies (as occurs when assessing the need for an update). On this basis, consultation of secondary sources of information should be prioritized.

Below are two sections discussing necessary changes to the original search strategy and sources in which to identify literature. Appendix 1 describes both the sources of information mentioned and most of the actions proposed to identify literature in more detail.

Editing Original Search Strategies

As already commented, the original search strategies should be used to identify new literature for a CPG update.[3,4] They should, however, be redesigned, although retaining the terms which yielded the best results in the original search. Using a thesaurus and basic terms from the title and abstract of the main systematic reviews and large trials should be sufficient to formulate new search strategies. These strategies can be combined with validated filters offering the greatest specificity in recovering particular study designs. Ample collections of these methodological filters are available online.[9,10]

To ensure search validity and performance, it is important to ascertain whether controlled vocabulary of interest or methodological filters have been further developed since the CPG was originally published.

Searching should start with the year of publication of the original and should be repeated when the update is almost finished and before the updated CPG is published to see whether any further relevant studies have been published. This procedure is not recommended, however, for new procedures, technologies, diagnostic techniques or clinical questions formulated specifically for the update, as a more comprehensive search based on sensitive search strategies is required in this case, similar to the search strategy for a systematic review.[12]

Literature Sources

To conduct searches that favour precision, searching should begin with secondary sources that index syntheses of the scientific literature. The process should also include consultation of databases of original studies so as to update the studies identified.[11]

Clinical Practice Guidelines

The three main steps in identifying CPGs or CPG updates of interest are the following:

1. Consult the NGC database of the AHRQ and the NLH database of the NHS.
2. Consult the main institutions which develop CPGs: SIGN, NICE, the Australian National Health and Medical Research Council (NHMRC) and the New Zealand Guidelines Group (NZGG).
3. Search using the TRIP Database or Excelencia Clínica clinical search engines.

A search in PubMed may help to identify CPGs published only in medical journals (such as CPGs developed by scientific associations). For a more comprehensive search for CPGs, the websites of the main scientific associations can be consulted; citations of the main CPGs published in medical journals can be tracked down using citation alerts (e-TOCs, CiteTrack Alerts and Google Alerts) or by searching in the ISI Web of Science. The CPGs identified will be useful as a source of studies of relevance to the update.

Systematic Reviews

Identifying the most up-to-date systematic reviews which enable CPG recommendations to be formulated is particularly important when no CPGs contributing new literature have been identified. A search of these studies should start with the UK Centre for Reviews and Dissemination databases: DARE (Database of Abstracts of Reviews of Effects), HTA (Health Technology Assessment) and NHS-EED (National Health Service Economic Evaluation Database). The Cochrane Database of Systematic Reviews in particular should be tracked, as it is possible that an original reviews has been updated or that a protocol has been published as a systematic review. The search for reviews should be rounded off with a focused search in PubMed, as this is one of the most frequently updated databases. A search in TRIP Database or Excelencia Clínica would also be useful to ensure that no important studies are omitted.

Original Studies

The search for original articles should be limited to identifying the most relevant studies that have emerged since the date of the search for systematic reviews. Articles citing the most important studies in the original CPG should be identified in the Web of Science. Whether any of the ongoing studies identified in trial registries have been published in a biomedical journal can be checked by searching for the identification code (e.g., according to the ISRCTN (International Standard Randomized Controlled Trial Number) in PubMed. The PubMed Clinical Queries option can also be used to search, using specific and narrow criteria, for original articles updating studies identified in other sources.

Although the recommended course of action when carrying out a systematic review is to search several different literature databases so as to identify as many studies as possible,[12] when updating a CPG these databases only need to be consulted if their yield was satisfactory in the original search (e.g., CENTRAL or EMBASE) or if recommendations need to be formulated on specific issues (e.g., PsycINFO for mental health issues or CINAHL for nursing-related issues).

Contacting the authors of the main systematic reviews of interest may also furnish details of an original study to be included in the search.

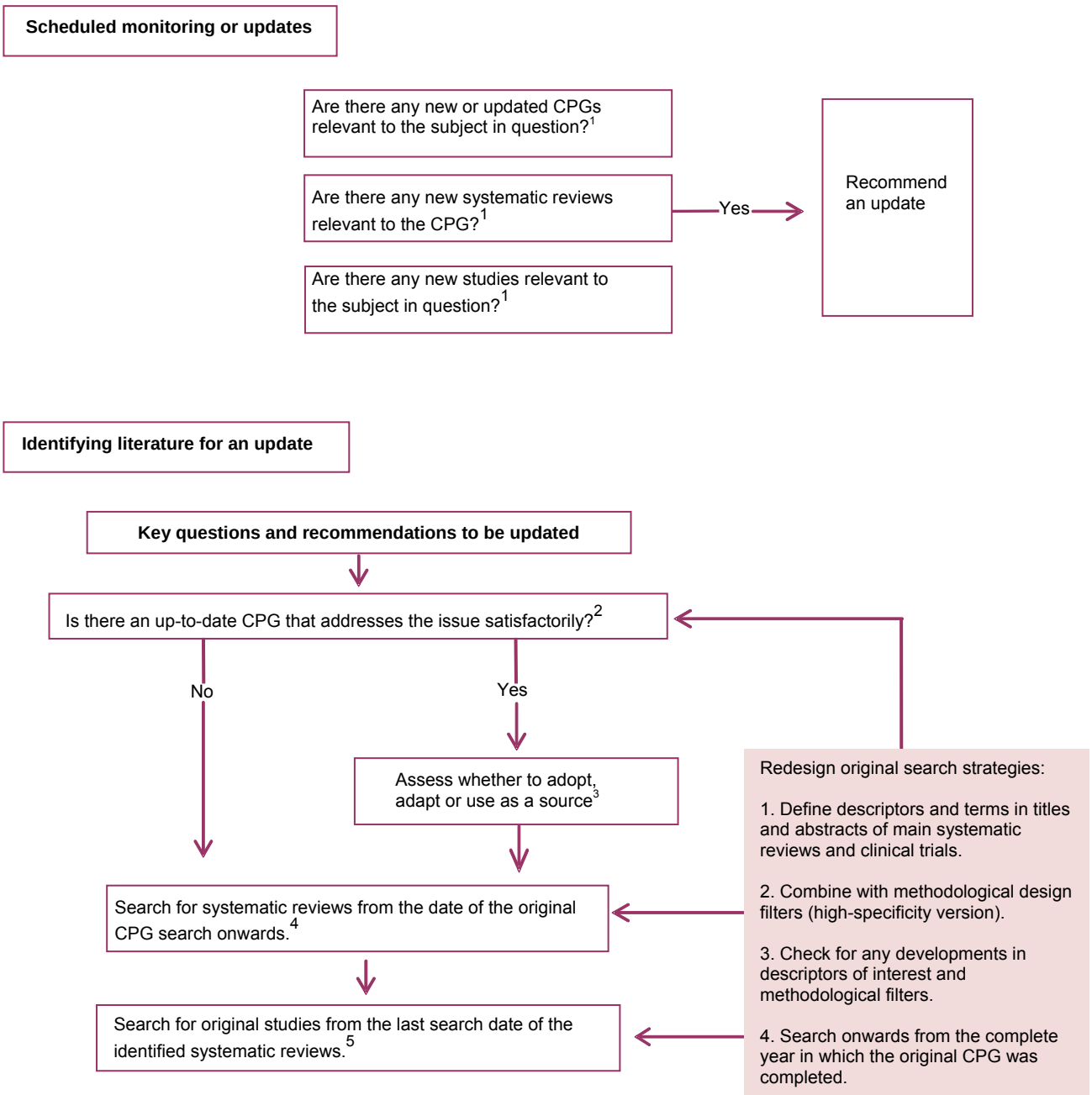
The possibilities offered by Web 2.0 enable additional strategies to be developed that can broaden the focus of the search; this more comprehensive approach can add to, organize and even optimize the literature identification process.[13-15] Electronic alerts and special functions such as Google Alerts[16] and web feeds (RSS) enable newly indexed or published literature to be regularly centralized. Electronic alerts should be used throughout the entire CPG update process in order to identify the most relevant studies as they emerge.

However, the use of these tools has not been standardized, their performance has not been demonstrated empirically and consulting them may be time consuming. Furthermore, since they merely identify the newest developments, they should never replace more focused searches.

The literature identification process will generate a substantial amount of information with a certain degree of overlap so it is recommended to use a bibliographical log software to manage all the collected literature. Information specialists play a major role in this process, not only in consulting sources of scientific literature but also in managing the studies and assisting the CPG team with their work. If the resources of the group developing the CPG do not stretch to a information specialist, there should at least be someone available who is skilled in using these resources.

Figure 4.1 shows a chart indicating how to assess the need to update a CPG and how to identify new literature. Appendix 2 lists the various sources and their websites.

Figure 4.1. Strategy for searching the literature when assessing the need to update a CPG and for identifying literature for a CPG update



Notes
1. **Recommended procedure:** Alerts of new development in the NGC of the AHRQ, the NLH of the NHS and GuíaSalud's Catalogue of CPGs. Focused search for systematic reviews and large-scale clinical trials in PubMed.
2. **Recommended resources:** NGC of the AHRQ, NLH of the NHS, organizations which develop CPGs (SIGN, NICE, NHMRC and NZGG). **Additional resources:** TRIP Database, Excelencia Clínica, scientific association websites, PubMed. Track publications in medical journals via the Web of Science and citation alerts (e-TOCs, CiteTrack Alerts, Google Alerts).
3. If a good quality and updated CPG which properly answers the clinical question is located, to avoid any unnecessary duplicate effort it is recommended to assess adoption or adaptation or, if these options are not feasible, to use the CPG as a source from which to update the literature search.
4. **Recommended resources:** Centre for Reviews and Dissemination of the UK's NHS: DARE, HTS, NHS-EED; Cochrane Database of Systematic Reviews: new reviews, updated original reviews, new protocols, etc; focused searches on PubMed. **Additional resources:** TRIP Database or Excelencia Clínica.
5. **Recommended resources:** ISI Web of Science; high-precision searches in PubMed.
Additional resources: Evidence-based journals, ongoing study databases, contact with experts, web feeds and citation alerts.

4.2 Methodology Resources for Updating CPGs

Updating a CPG requires every effort to ensure that each stage of the process is systematic and contributes to a rigorous update. Certain tools can be used to make the main stages of the process more efficient. The previous section highlighted the tools available for literature searches. This section will provide an outline of useful resources for appraising and collating the scientific literature.

It is important to stress that the resources described below are not in any way mandatory but are included purely because they could be useful for developing or updating a CPG. Their use should be considered in terms of the resources, time and knowledge available to the CPG development team.

4.2.1 Critical Appraisal Forms

In the critical appraisal phase, critical appraisal forms should be used to systematically extract and record data of interest and to assess the quality of studies. The *Manual Metodológico para la Elaboración de Guías Clínicas*[8] contains a full compendium of resources where critical appraisal forms for different study designs can be found.

One of these resources is OstFLCrítica, the open-access IT application for critical appraisal forms of the Basque Health Technology Assessment Office (OSTEBA).[17] It contains seven model forms, classified by type of study design, which can be grouped into tables of evidence. The program has a help module which explains the main criteria for the critical appraisal process, a glossary of the terms used and tools to calculate both absolute effects (absolute risk reduction, number needed to treat) and relative effects (odds ratio, relative risk).

4.2.2 Software to Optimize Literature Synthesis and Analysis

When a CPG is updated, new information usually has to be integrated with the original information. This information may refer to studies which update the results of a systematic review or new studies that have to be integrated into those evaluated initially.

Software to Evaluate and Compare Recommendations

OSTEBA has developed software which allows different CPGs to be compared when recommendations are being evaluated or adapted to a specific context. This freeware, called EGOKi (Evaluation of Guidelines Obsolescence and Kindness) and based on Access 2000 databases, combines the recommendations of different CPGs in a single file so that they can be compared and evaluated.[18]

Meta-Analysis Software

Meta-analysis software enables the results of several studies to be combined, provided that the relevant methodological criteria are met. If a previous systematic review (and meta-analysis) is available for a therapeutic procedure, the results of new studies can be included and a new global estimate can be calculated to improve precision. The additional studies included should, naturally, meet the inclusion criteria of the original systematic review. Depending on the time and resources available, it may be possible to contact the authors of systematic reviews for additional data. When there is no systematic review available, it may be possible to integrate new studies with those of the original CPG, carrying out meta-analyses of their data if this is feasible. There are several freeware programs for carrying out meta-analyses of the data in original studies.

Review Manager (RevMan),[19] the Cochrane Collaboration software for preparing and maintaining systematic reviews, carries out meta-analyses of studies of therapeutic procedures. Other meta-analysis freeware programs are EpiData[20] and Meta-DiSc.[21]

Software for Developing Recommendations

Another important issue in synthesizing information to formulate recommendations is the grading of the quality of evidence in an overall evaluation of the literature. A software called GRADEpro evaluates the quality of information for a set of studies in a structured, explicit way that applies the methodology recommendations of the Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE).[22] It should be used only for CPGs whose recommendations are formulated on the basis of the GRADE methodology.

GRADEpro collates information on the quality of evidence and the magnitude of the effect of specific interventions and classifies the data according to the importance of the outcomes. This free-access software, available

online, is accompanied by a practical, comprehensive help manual.[23] It evaluates quality of evidence for each outcome of interest by evaluating different aspects of a rigorous systematic review.[24,25] Although it requires a significant time investment, it enables ordered and summarized quality evaluation.

If meta-analysis software is used to synthesize original study data and GRADEpro is used to tabulate all the information and classify it by endpoint, it is advisable to also use RevMan. The main reason for this recommendation is that GRADE can export all the meta-analysis information from the RevMan files and automatically generate tables to which only the information required to classify the evidence quality needs to be added.

4.2.3 Virtual Platforms for Networking

Groups that develop CPGs usually include healthcare professionals with various different profiles who are generally decentralized. This means that networking at a distance is usually necessary. The ongoing development of new technologies has made several possibilities available for networking and sharing materials through virtual platforms.

It would be difficult to supply an exhaustive list of the resources that make it possible for a group to work together online; moreover, the constant development of the different tools available makes it hard to recommend any in particular. The needs and knowledge of the group developing the CPG will to a great extent determine the use made of these tools.

One of the most useful tools for online work[26] is Google Docs, which allows documents to be worked on online using file formats similar to those of Microsoft Office (mainly Word, Excel and PowerPoint). Users have a virtual space where they can create, upload or download files and which they can use to share and edit documents created by others or by themselves. Use of this platform requires a registered Google e-mail (Gmail) account.

Using the document types that can be worked on in Google Docs, a group developing a CPG can create its own Gmail account and centralize, for example, all the drafts being developed by the various group members. Google Docs can also be used to create simple spreadsheets to structure and centralize data extraction from studies of interest. Google Calendar can also be used to manage the group's schedule, arrange meetings and set deadlines for the submission of documents.

If, as well as creating and editing documents, a CPG team needs to store and share relevant articles, article databases and other documents of interest, it may be useful to create a space on a virtual platform such as Box.net (www.box.net) for storing and classifying documents. Group member subscribed to a Box.net account can access the space and share all CPG-related content, which is organized in a similar way to Windows Explorer. Another platform where files can be stored temporarily is SpeedyShare. Finally, Zamzar (www.zamzar.com) is a tool that converts documents from one file format to another (e.g., from Word to PDF).

Lastly, depending on the involvement of group members, a common space could be created using any social networking program[26] (e.g., a blog), where forums can be created to resolve queries and discuss issues related to various stages of the CPG.

KEY POINTS

- When assessing the need to update a CPG, a limited search should first be carried out based on alerts of new developments in the main databases that index CPGs, followed by precise searches for systematic reviews and large-scale clinical trials.
- Searching new literature should prioritize the precision of the search, using the terms that yielded the best output in the original phase. Priority should be given to identifying other similar updated CPGs that may serve as a source of literature and secondary literature sources.
- It is advisable to use bibliographical management software to handle all the information collected.
- The active involvement of a information specialist is likely to assist the literature identification and organization process.
- Softwares are available that can implement meta-analysis calculations and synthesize the literature, thereby enabling information to be used more efficiently.

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5. Publishing the Updated CPG

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This chapter, which discusses key issues related to the presentation and publication of the results of the clinical practice guideline updating process, addresses the following questions:

- What experience is there with formats for updates?
- How should updates be presented?
- What are the advantages of an electronic format for updates?

Introduction

As stated in Chapter 2, clinical practice guidelines (CPGs) may require either a partial or a full update, depending on the volume and relevance of the evidence which has emerged since the original CPG was published.[1,2]

The guiding principles for publishing an update should be similar to those for publishing an original CPG. The main aims of the CPG development team, when deciding on format and publication, should be clarity of presentation, transparency, a reader-friendly format and usability. As well as these general attributes, a published update should also enable the most significant modifications made as a result of review to be identified swiftly and clearly. For both original CPGs and updates, it is advisable to compile the following versions: full, summarized, quick reference versions and material for patients.[1]

When a CPG is updated fully, the standard practice has been to present a new document, generally in all the versions listed above, without the reader being able to identify the modifications made. This is the most common practice applied by both Spanish and overseas institutions that issue successive CPGs on a single topic. Examples are the Reports on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure compiled by the Joint National Committee of the US National Heart, Lung and Blood Institute,[3,4] the thrombosis CPGs of the American College of Chest Physicians[5] and the CPGs of the Spanish Cardiology Society.[6]

When new evidence substantially affects one or more sections of a CPG, an update of the section(s) in question can be published. New publications on the efficacy of beta blockers in hypertensive patients, for instance, led to the publication of an update to the drug treatment section of the Hypertension CPG of the UK's National Institute for Health and Clinical Excellence (NICE) in 2006,[7] only two years after the first version.[8]

We have not located any publications regarding the preferences and needs of those who develop or use CPGs or on the most suitable formats for publishing CPG updates, nor are there any evaluations available regarding the impact of the update presentation format on compliance with CPGs or on health outcomes.

5.1 Printed and Electronic Formats and Updates

The use of new technologies for publishing and distributing CPGs has led to a proliferation of documents in electronic format. By electronic CPG we mean a document that can be consulted using information technology devices (computers, CD-ROMs, PDAs, etc).

Although there are various electronic CPG designs, the most common format is reproduction of the hard-copy version in Portable Document Format (PDF).

Other technically more complex designs integrate CPG recommendations in computer programs that manage clinical histories in hospitals[9] or primary care.[10] Many such initiatives are part of research projects on the efficacy of CPG implementation.[11] This chapter will focus on the electronic formats that can be consulted independently of clinical histories.

Electronic CPGs may either coexist with printed versions or form part of a set of CPGs published in electronic format only. The former group includes CPGs recently issued in Spain under the Clinical Practice Guidelines Programme for the National Health System. The Clinical Knowledge Summaries (CKS) published by the UK's National Health Service (NHS)[12] are a good example of CPGs made available exclusively online. A special case is where hard copies of electronic versions of CPGs are offered, such as by the Finnish Medical Society Duodecim,[13] although the electronic versions are better known and more widely used than the printed versions.

As will be seen below, the use of electronic formats simplifies the CPG publication process and makes updates easier.

5.2 CPG Update Publication Recommendations

Publication should make it easy to identify the main changes made in the update:

- New questions and clinical areas
- New evidence considered
- New and significantly modified recommendations.

5.2.1 New Questions and Clinical Areas

Item 2 in the Scope and Purpose section of the AGREE Instrument[14] states that the CPG should provide a detailed description of the clinical questions covered (see example in Table 5.1). This also applies to updates. Ideally, therefore, all CPGs should have a list of 'questions to be answered', in which new questions not included in the original version can be clearly identified. This applies to both full and partial updates.

Table 5.1. Initial list of diagnostic questions in the Basque Health Service (Osakidetza) Hypertension CPG (2007 full update, printed and electronic formats)[15]

Diagnosing hypertension:

1. What figures define someone as having hypertension?
2. How are hypertensive patients at the greatest cardiovascular risk selected?
3. What are the MAPA BP values that define hypertension?
4. What are the AMPA BP values that define hypertension?
5. What are the indications of AMPA and MAPA in primary care?
6. Is AMPA useful in diagnosing isolated clinical hypertension?
7. What is the prognosis for white coat hypertension?
8. Should patients with white coat hypertension receive drug treatment?
9. Does home AMPA improve control of hypertension? *
10. How many measurements should be taken using home AMPA? *
11. What devices can be used for self-monitoring?

*New questions in the 2007 version.

[Translated from Spanish]

Many CPGs do not provide a list of this kind but usually give an overview of the new subjects included either in the introduction or in the description of the methodology (see example in Table 5.2). However, an initial list of the new questions included enhances clarity and transparency.

Table 5.2: Description of new topics included in the British Asthma CPG (2008 full update)[16]

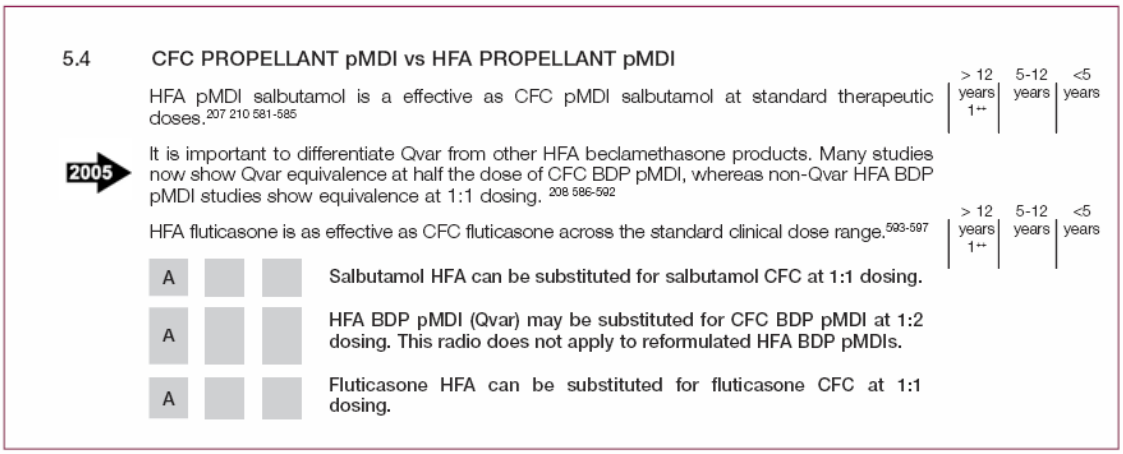
The new 2008 guideline has considered literature published up to March 2007. It contains a completely rewritten section on diagnosis for both adults and children; a section on special situations which includes occupational asthma, asthma in pregnancy and the new topic of difficult asthma; updated sections on pharmacological and non-pharmacological management; and amalgamated sections on patient education and compliance and on organization of care and audit.

5.2.2 New Evidence

The time required to complete and publish a CPG varies but may be several months, so there is usually a time lag between the search completion date and the publication date. It is therefore important to state the end date of the review of the literature, so that readers will know the latest evidence included. Although this date is usually indicated in the methodology section, it is sometimes difficult to find. It is recommended, therefore, to state the end date of the literature review and the date of the most recent update in a prominent place in the CPG.

New evidence identified when updating a CPG may be presented in various different ways. Although it is usually mentioned in the literature review section, it is crucial that new evidence and the associated new recommendations be highlighted in each chapter. The CPG of the Global Initiative for Chronic Obstructive Lung Disease (GOLD)[17] provides only an initial list of new references, stating the pages where they are cited. A more explicit way of presenting new evidence is at the beginning of each chapter and then by referencing it in the evaluation of evidence before providing recommendations (Figure 5.1).

Figure 5.1. New recommendations in the British Asthma CPG (2005 full update, electronic format)[18]



5.4 CFC PROPELLANT pMDI vs HFA PROPELLANT pMDI

HFA pMDI salbutamol is a effective as CFC pMDI salbutamol at standard therapeutic doses.[207 210 581-585] (> 12 years 1++ | 5-12 years | <5 years)

2005 It is important to differentiate Qvar from other HFA beclamethasone products. Many studies now show Qvar equivalence at half the dose of CFC BDP pMDI, whereas non-Qvar HFA BDP pMDI studies show equivalence at 1:1 dosing. [208 586-592]

HFA fluticasone is as effective as CFC fluticasone across the standard clinical dose range.[593-597] (> 12 years 1++ | 5-12 years | <5 years)

A Salbutamol HFA can be substituted for salbutamol CFC at 1:1 dosing.

A HFA BDP pMDI (Qvar) may be substituted for CFC BDP pMDI at 1:2 dosing. This radio does not apply to reformulated HFA BDP pMDIs.

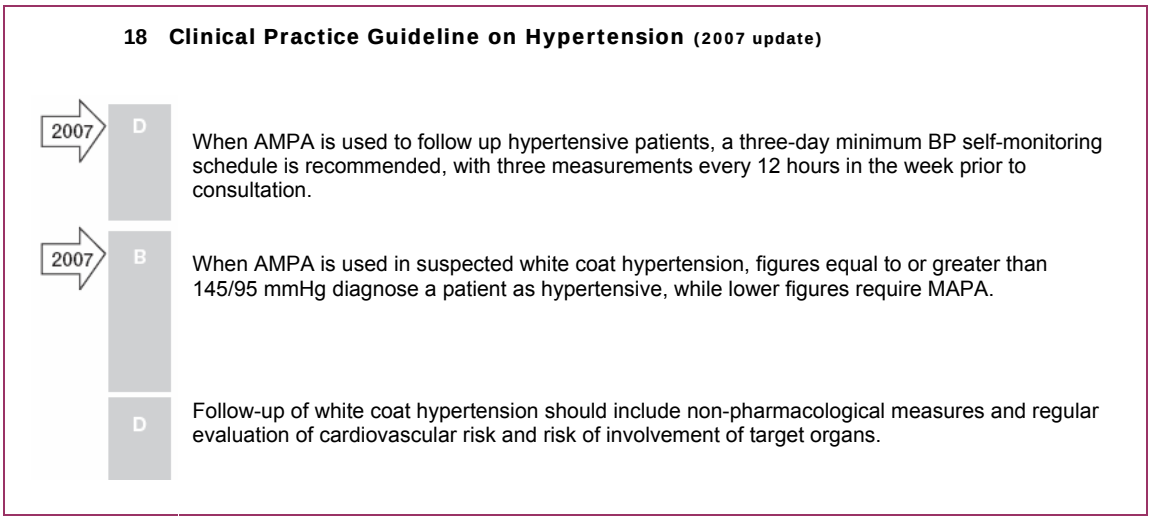
A Fluticasone HFA can be substituted for fluticasone CFC at 1:1 dosing.

5.2.3 New and Modified Recommendations

According to Item 17 of the AGREE Instrument,[14] key recommendations should be easily identifiable and the relationship between evidence and recommendation should be explicit. For a CPG update, this should translate into identifying new recommendations and their relationship to the evidence supporting them.

As with new questions, a list of individual CPG recommendations should be provided that identifies new recommendations (Figure 5.2). New recommendations should also be highlighted in the relevant chapter (Figure 5.3).

Figure 5.2. Initial list of recommendations in the Basque Health Service (Osakidetza) Hypertension CPG (2007 full update, printed and electronic formats)[15]



18 **Clinical Practice Guideline on Hypertension** (2007 update)

2007 D When AMPA is used to follow up hypertensive patients, a three-day minimum BP self-monitoring schedule is recommended, with three measurements every 12 hours in the week prior to consultation.

2007 B When AMPA is used in suspected white coat hypertension, figures equal to or greater than 145/95 mmHg diagnose a patient as hypertensive, while lower figures require MAPA.

D Follow-up of white coat hypertension should include non-pharmacological measures and regular evaluation of cardiovascular risk and risk of involvement of target organs.

[Translated from Spanish]

Figure 5.3. Identification of new evidence linked to recommendations in the Basque Health Service (Osakidetza) Hypertension CPG (2007 full update, printed and electronic formats)[15]

3.2.2 Beta blockers

UPDATE 2007
5 meta-analyses (109; 112-114; 116) and 1 RCT (117) added
Modified Recommendation

	Summary of Evidence
1++	When AMPA is used to follow up hypertensive patients, a three-day minimum BP self-monitoring schedule is recommended, with three measurements every 12 hours in the week prior to consultation.
1+	A meta-analysis based on age showed beta blockers to be better than a placebo at reducing the aggregate variable (death, non-fatal AMI, non-fatal CVA) only in those aged over 60 (113).
1++	Beta blockers did not prove better than other families of anti-hypertensive drugs at preventing cardiovascular morbidity/mortality. Moreover, they are worse than diuretics at preventing coronary disease in patients aged over 65, worse than calcium antagonists at reducing mortality, CVAs and cerebrovascular disease, and worse than ACEIs/AIIRAs at preventing CVAs (116).
	Recommendation
2007 **A**	Beta blockers are not recommended as first-line drugs for initial treatment of non-complicated hypertension.

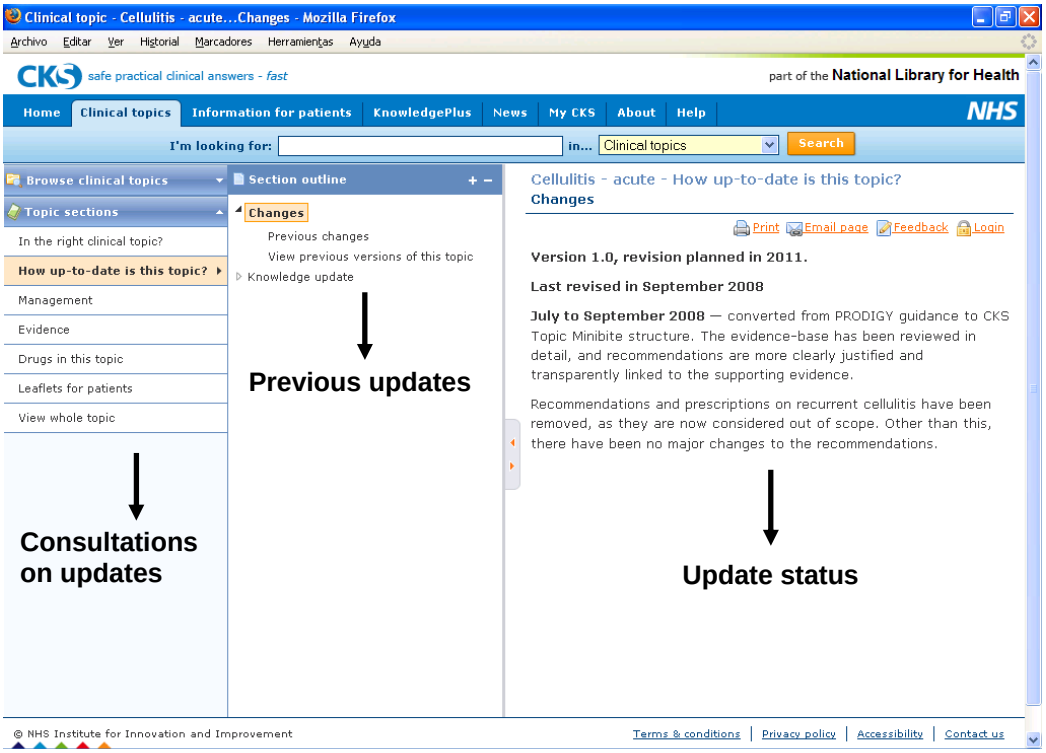
[Translated from Spanish]

5.3 Electronic Formats and GPC Update Publication

In theory, electronic formats should enable more efficient updating. They are almost the only formats capable of incorporating new evidence in a flexible way, providing that updates are managed appropriately. The process for printed formats, on the other hand, is more laborious. Occasionally, modified chapters and sections are published, such as NICE's section on the pharmacological treatment of hypertension[7,8] mentioned above.

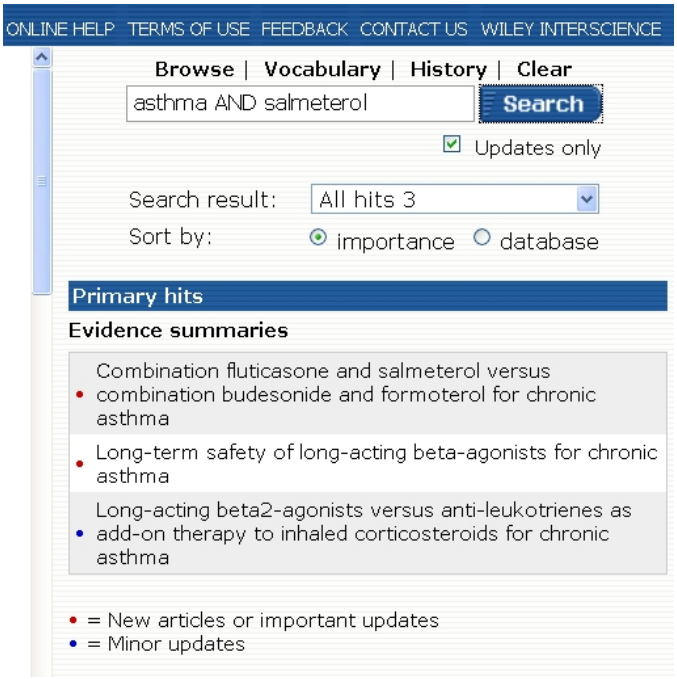
Electronic formats enable modified sections to be identified more easily and rapidly when a CPG is updated. The NHS's electronic CKS permit consultation of earlier versions of updated topics.

Figure 5.4. Updates to the infectious cellulitis CKS for 2008



Other, more sophisticated designs make it possible to carry out specific searches of updated subjects. The Duodecim CPG collection allows the search engine to be restricted to updated topics and results to be classified according to the degree of modification (Figure 5.5).

Figure 5.5. Relevance-classified results for a search restricted to updated subjects in a Duodecim collection of electronic CPGs[13]



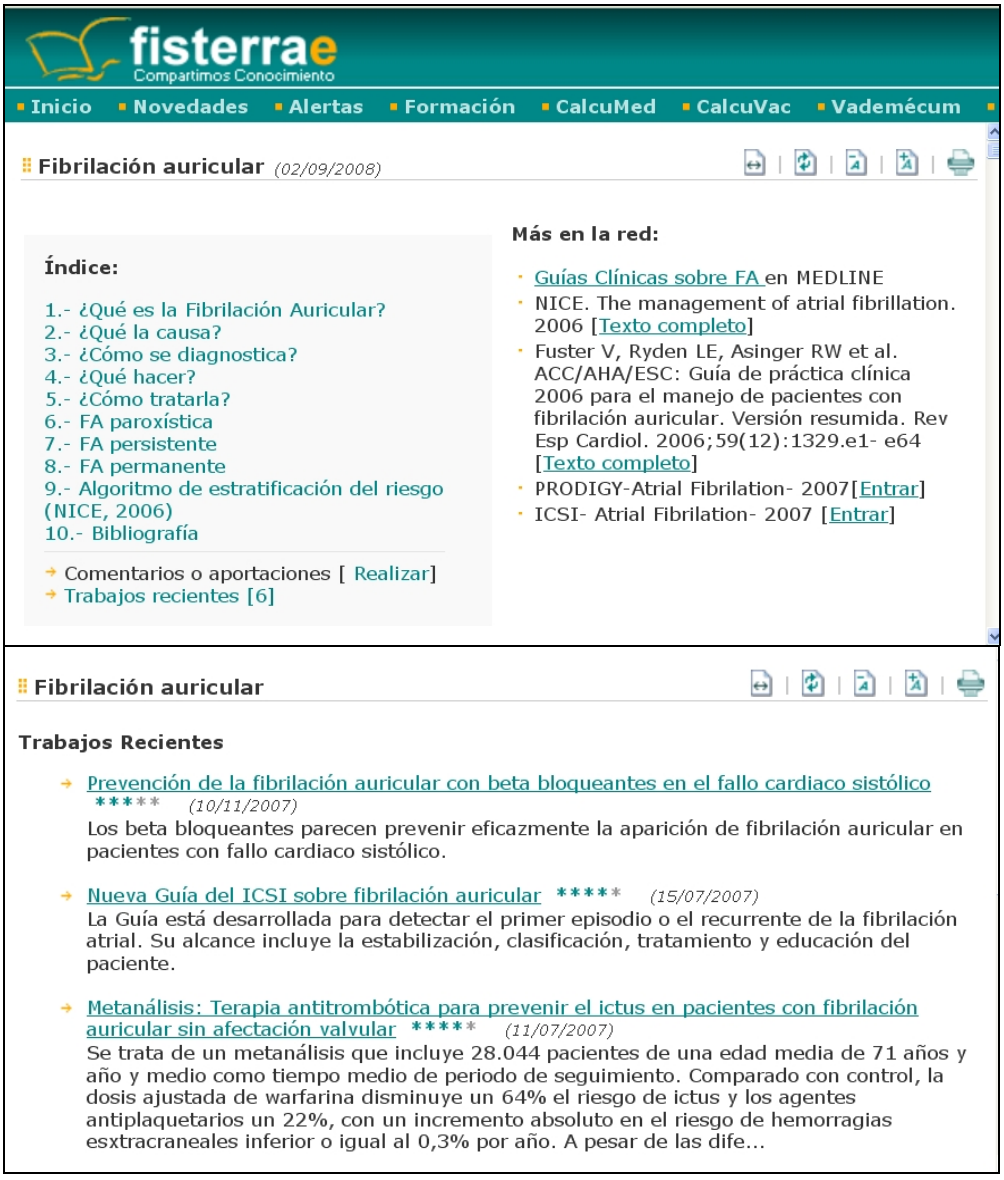
Provided that new evidence is efficiently managed, electronic formats admit the new concept of CPGs as living guidelines, whereby new evidence, almost immediately after its publication, is evaluated and incorporated into a CPG.

Although electronic formats may be very attractive to CPG developers and end users, the mere presentation of a CPG in electronic format does not ensure more thorough development no matter how sophisticated the design is.

Managing an update efficiently requires the appropriate professional and technical staff and sufficient time and resources. These ideal conditions are rarely present, which means it is not always possible to incorporate new evidence into new or modified recommendations as rapidly as would be desirable.

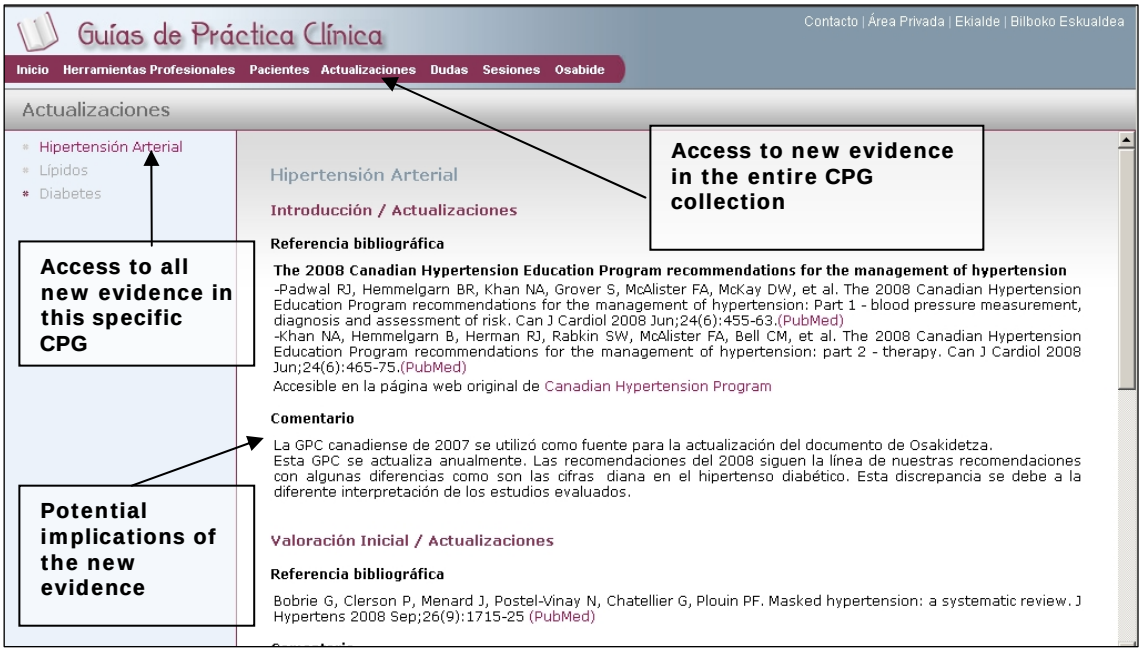
Even if it is not possible to modify recommendations on an ongoing basis as new relevant evidence is published, electronic formats do at least allow new evidence to be posted, leaving it to the user to evaluate it and draw conclusions and implications for clinical practice. The Fisterra website uses this system to add new evidence into its guidelines (documents based on CPGs) and evidence-based summaries[19] (Figure 5.6).

Figure 5.6. New evidence (*'Trabajos Recientes'*) in the Fisterra Atrial Fibrillation CPG 2008 (electronic format)[19]



Electronic formats allow new evidence to be posted immediately, possibly accompanied by conclusions regarding its potential impact on CPG recommendations. Figure 5.7 shows an example of new evidence classified by CPG and subject and with a description of its possible effects on recommendations.

Figure 5.7. Presentation of new evidence in the Basque Health Service (Osakidetza) Hypertension CPG (2007 full update, printed and electronic formats)[15]



5.4 Recommendations Regarding CPG Update Publication

Table 5.3 summarizes the recommendations made in this chapter regarding the publication of CPG updates. The information is presented separately for printed and electronic formats as some issues only refer to the latter.

Table 5.3. Recommendations for CPG updates

Recommendation	Print	Electronic
Indicate date of last CPG update	√	√
Indicate end date of the literature review in a prominent place	√	√
Indicate new questions addressed by the CPG in the list of questions	√	√
Compile an initial list of recommendations that highlights new recommendations	√	√
Identify new or modified recommendations in each chapter	√	√
Identify new evidence at the beginning of each chapter	√	√
Identify new evidence in relation to new or modified recommendations	√	√
Enable electronic searches of chapters and of new or modified recommendations		√
Incorporate new evidence, modifying recommendations as evidence is published		√
Identify new evidence not yet incorporated		√

KEY POINTS

- CPG updates should identify new questions, evidence and recommendations, regardless of the type of update (full or partial) or the format of the CPG (printed or electronic).

- Electronic formats make updating easier, provided that the original CPGs were developed rigorously and that updating is managed with the necessary material and human resources.

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6. Evaluating the CPG Updating Process

Arritxu Etxeberría, Rafael Rotaeche, Rosa Rico

This chapter, which discusses key aspects of evaluating clinical practice guideline updating processes, addresses the following question:

- How is the updating process evaluated?

Introduction

Published experience on evaluating Clinical Practice Guideline (CPG) updates is limited. Some studies concentrate on evaluating obsolescence or the need for an update.[1] Other studies[2] compare a full search with the model proposed by Shekelle,[3] consisting of a limited search and contact with experts, with results measured in terms of the number of relevant studies identified and the effort invested. Browman[4] evaluated the updating protocols for oncology CPGs and measured the results in terms of the number of relevant studies included, the type of study and its source (experts or databases) and the impact of these studies on recommendations (number of new recommendations, number of modified recommendations and impact on the strength of recommendations).

Within the Spanish National Health System, the updating process for the Hypertension CPG of the Basque Health Service (Osakidetza) was recently evaluated,[5] with results also measured according to the relevant studies included and impact on recommendations. As far as we are aware, no tool has been designed specifically to evaluate the CPG updating process.

Most work has measured the impact of an update on recommendations and the time and effort invested. However, evaluation of an update process should cover all the stages of the process, from assessment of the need for an update to format and publication.

This chapter discusses aspects to be considered when a CPG updating process is evaluated.

6.1 Proposal for Evaluating Update Stages

The proposal for evaluating update stages is based on the literature consulted and the recommendations for the various update stages proposed in this handbook. Each of the ten criteria listed below includes an explanation and description of objectives and a description of how to evaluate each criterion. Examples illustrate the evaluation process.

6.1.1 Stage 1: Evaluating the Need for an Update

CRITERION 1: Was the update carried out at the right time or in the recommended circumstances?

Explanation/Objectives

As a general rule, it is recommended that CPGs be updated at least once every three years. However, this is only a rule-of-thumb; the main reasons for updating should be stated explicitly for each individual case (see Chapter 2). Updates made before three years or after five years should be duly explained (see Chapter 2). This criterion ensures that the CPG is updated within a suitable or reasonable period of time (with neither excessive delays nor unnecessary updates) and that the decision to update has been made on the basis of clear criteria.

How to Evaluate

- Check the publication date of the previous version of the CPG and the end date of the literature search.
- Check whether the previous version of the CPG referred to a specific time interval for future updates and whether this has been complied with.
- For CPG programmes, check whether the development manual establishes a particular update frequency or overall criteria for updating CPGs and whether these have been complied with.
- Check whether the reasons for the update are explicitly stated (usually in the purpose or methodology sections).

CRITERION 2: Is the procedure for deciding whether to update and the update type suitable?

Explanation/Objectives

It is important to ensure that the decision as to the need for an update is structured, as, on this basis, it can be decided whether to update a CPG completely or partially, to withdraw it or to transfer it to a static list. It may also be decided to introduce new areas or to make other changes to the scope of the CPG (e.g., to include new target users), in which case the scope and purpose should be rewritten.

How to Evaluate

- Check whether the original CPG describes a procedure for assessing the need for an update or refers to the handbook of the organization promoting the update.
- Consider the type of update required.
- Consider whether newer areas have been introduced and whether the scope of the CPG has been altered.
- Check that the perspective of end users (healthcare staff and patients) has been taken into consideration.

Example: The Spanish Clinical Practice Guidelines on Digestive Illnesses: From Primary to Specialist Care[(6)] has resulted in the publication of two successive documents on rectorrhagia. The first of these[(7)] mentioned that an update would be made after three years. The update itself[(8)] states that the scope of the CPG had not been modified and also states the type of update made and announces the nature of future updates:

> *The update has maintained the original structure of the guideline with more detailed chapters. There are also new algorithms, one on patients with haemorrhoidal symptoms and another on patients with anal fissures. This update of the Rectorrhagia CPG will be reviewed in 2010 or earlier if any new relevant scientific evidence emerges. Any modifications made during this period will be reflected in the electronic version of the guideline.*
> [Translated from Spanish]

CRITERION 3: Are there regular monitoring mechanisms in place to ensure CPG validity?

Explanation/Objectives

All CPGs should have monitoring mechanisms in place that regularly evaluate the need for an update. Monitoring, obviously, should be implemented more frequently than updates (that is, more frequently that the three to five year interval recommended in Chapter 2). If there are changes that may invalidate any significant recommendations of the CPG before its scheduled update, monitoring will ensure that they are detected and taken into account when the CPG is updated. The ultimate aim of monitoring is to avoid erroneous or out-of-date recommendations in CPGs.

How to Evaluate

- Check what monitoring systems, if any, are in place (methodology section of the update).
- If the CPG is part of a CPG programme, check whether there are systems to collect user suggestions.

Example: In relation to annual updates of its Hypertension CPG, the Canadian Hypertension Education Program (CHEP)[(9)] holds meetings with various working groups and has a centralized department of documentalists in charge of annually reviewing the literature.

6.1.2 Stage 2: Update Staff Participation

CRITERION 4: Is information on the institution promoting the update, the professionals involved in the process and the distribution of tasks and responsibilities clearly stated?

Explanation/Objectives

In order for the updating process to function correctly, the responsibilities and actions or tasks of the organizations and individuals involved in the update process should be defined, particularly those of the institution promoting and financing the update and the authors and reviewers collaborating in the update. Other information should be provided on the multidisciplinary nature of the team and collaboration with patients or patient associations. Authorship should be clear, participant interests should be clearly stated and the responsibilities and tasks of individuals and organizations involved should be listed.

How to Evaluate

- Ensure that there is a clear indication of who is promoting and financing the update.

- Ensure that the update team includes the authors of the original version of the CPG or at least that the original authors have been informed of the update.
- Ensure that the update has been carried out with the permission of the authors of the original CPG.
- Ensure that points of view of the main groups involved are represented among the authors or reviewers (multidisciplinary group).
- Ensure that conflicts of interest have been declared.

Example: The criteria listed above are described in the 2007 update of the Guideline on the Management of Asthma of the British Thoracic Society (BTS) and the Scottish Intercollegiate Guidelines (SIGN).

Chapter 1 (Introduction): *Both the BTS and SIGN have recognized the need to update their asthma guidelines, using evidence-based methodology, to cover all aspects of asthma care. It was agreed that the two organizations should jointly produce a comprehensive new guideline, the process being further strengthened by collaboration with Asthma UK, the Royal College of Physicians of London, the Royal College of Paediatrics and Child Health, General Practice Airways Group, and the British Association of Accident and Emergency Medicine. The outcome of these efforts is this new British Guideline on the Management of Asthma.*

Chapter14 (Guideline Development Group): *The development of the original 2003 asthma guideline and the 2004 update involved the work of nine different multidisciplinary Evidence Review Groups, a Steering group and an Executive group. The membership of these groups has evolved since 2003. The two chairmen (Dr Bernard Higgins and Dr Graham Douglas) remain the same. Further details of membership can be obtained from the SIGN Executive (sign@sign.ac.uk). The 2004 revisions were coordinated by Joanne Topalian, Duncan Service and Safia Qureshi at SIGN.*

6.1.3 Stage 3: Updating Procedure and Methodology

CRITERION 5: Has updating followed an explicit procedure?

Explanation/Objectives

Like the development of a new CPG, updating should follow an explicit, systematic procedure, which is usually based on a combination of limited searching and contact with experts.

How to Evaluate

- Search for the description of the method used.

Example: The update of the Basque Health Service (Osakidetza) Hypertension CPG,[5] in its Appendix I (CPG Update Methodology), describes the methodology used for updating, namely, consultation with experts, selection of reference CPGs and specific searches of the literature.

Updating was carried out according to a structured plan based on the Hypertension CPG published by Osakidetza in 2002 and following the same methodological principles as in the original version. A CPG developer team and an expert committee on hypertension were formed and a list of clinical questions was drawn up, based mainly on the questions of the previous version but with the addition, using a pre-designed instrument, of proposals by the team after group discussion and by the expert committee. Beforehand, reference CPGs were selected by applying the AGREE Instrument to several Spanish and overseas hypertension CPGs published between 2002 and 2006. The three CPGs with the best AGREE Instrument scores—the Canadian CPG, the NICE CPG and the BHS CPG—were used in the subsequent stages.

For the questions covered in the previous version, the bibliography supplied by the expert committee and those included in the selected CPGs were used and a systematic search was conducted of the literature for the period 2002-2007.

[Translated from Spanish]

CRITERION 6: Is the literature search adequate?

Explanation/Objectives

Searching for updating purposes is generally limited and more specific than sensitive. However, there should be some guarantee that searching is thorough enough not to omit relevant studies (see Chapters 3 and 4).

How to Evaluate

- Evaluate the data sources used and check whether search strategies are specified.
- Ensure that the most relevant databases have been searched.
- Check that experts have been contacted to locate evidence.

Example: The update of the Basque Health Service (Osakidetza) Hypertension CPG,[5] in its Appendix I (CPG Update Methodology), describes the literature search performed.

For the questions covered in the previous version, the bibliography supplied by the expert committee and those included in the selected CPGs were used and a systematic search was conducted of the literature for the period 2002-2007. A bibliographical alert service was maintained so as to incorporate relevant studies up to the date of publication of the CPG. For all the searches, the sources of information used were Clinical Evidence, Evidence Based Reviews, Cochrane Library, MEDLINE, Embase, the Índice Médico Español, IBECS, UpToDate and the TRIP Database. Publications were prioritized in the following order: systematic reviews, clinical trials, cohort studies, case control studies, descriptive studies and expert opinion.

[Translated from Spanish]

CRITERION 7: How is evidence assessed and synthesized?

Explanation/Objectives

As when developing a new CPG, it is important to assess the quality of the evidence. All evidence relevant to the various questions or areas to be updated should also be synthesized.

How to Evaluate

- Ensure that explicit methods have been used to assess evidence quality and check that this is similar to the evidence used in the original CPG.
- If there is no match with the original evidence, ensure that an equivalence procedure is specified and the reasons for the change in method are explained.
- Check whether there is a summary of the evidence or if the tables of evidence are available or can be obtained.

Example: The update of the Basque Health Service (Osakidetza) Hypertension CPG,[5] in its Appendix I (CPG Update Methodology), explains how evidence was assessed:

The references considered were independently evaluated by at least two reviewers, using explicit NICE criteria for diagnostic issues and SIGN criteria for prognosis, aetiology and treatment issues. Differences were resolved by consensus.

For questions not directly adapted from the original CPG the references evaluated were summarized in tables of evidence, which served as the basis for 'formal evaluation' or 'reasoned judgement' as the grounds for the final recommendations.

[Translated from Spanish]

CRITERION 8: How are recommendations formulated?

Explanation/Objectives

As when developing a new CPG, recommendations should consider the benefit/risk ratio and possible patient discomfort. It is important to ensure that an explicit method is used for this purpose.

How to Evaluate

- Examine the methodology used to formulate recommendations and check whether it matches the methodology of the original CPG. Also ensure that the method used to develop recommendations (SIGN, Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE), etc) is stated.
- If the methodology does not match that of the original CPG, check that an equivalence procedure is specified and that the reasons for the change in method are explained.

Example: The Spanish gastro-oesophageal reflux disease CPG,[10] in its notes for users, describes the methodology for formulating recommendations.

To classify the scientific evidence and strength of the recommendations, the system proposed by the Centre of Evidence-Based Medicine (CEBM) in Oxford has been used again in this update. However, on the basis of previous experience in developing CPGs, we have introduced some of the criteria proposed by the Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE) system.

[Translated from Spanish]

6.1.4 Stage 4: Updated CPG Publication

CRITERION 9: Clarity of presentation: are the main changes to the update clearly presented?

Explanation/Objectives

The format of the update should allow the main changes to the viewed swiftly and clearly.

How to Evaluate

- New questions/areas included in the update are clearly presented.
- New recommendations and recommendations which have been significantly modified are clearly presented.
- New evidence added (new references) are clearly presented.
- There is explicit indication of modifications that may affect implementation of the CPG.

Example: The update of the Basque Health Service (Osakidetza) Hypertension CPG,[5] in its Appendix I (Methodology of the CPG Update), states the following in its section on methodology:

> *This document is an update of the original guideline published in 2002. To simplify reading, the new questions covered are presented at the beginning of each chapter and it is stated whether there are any significant changes (modification, partial modification, addition or no change) to the previous recommendations. When the same evidence is provided again, the previous version of the CPG is cited, except in cases where the authors feel that citing the original study makes the text easier to understand.*
>
> *At the end of each chapter, the evidence is briefly summarized and recommendations are formulated along with the corresponding grades. New recommendations and those significantly modified since the last edition of the guideline are indicated by arrows.*
>
> [Translated from Spanish]

CRITERION 10: Is there a file for all the documents used to develop the initial and subsequent CPG versions?

Explanation/ Objectives

To facilitate CPG updating processes, it is important to maintain a file containing the relevant documents (scope and purpose statement, search strategies, tables of evidence, minutes of meetings, etc).

How to Evaluate

Although all this material is not usually made available in an updated document, it is advisable to refer to it and to make it available on a website or on request.

KEY POINTS

- Evaluation of the CPG updating process should include all stages, from the initial assessment of the need for an update to decisions as to format and publication.
- Evaluation of the results of the update should cover the relevant evidence added, new and significantly modified recommendations and the updating process itself in terms of time and cost.

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7. Appendices

Appendix 1. Issues Regarding the Identification of Scientific Literature for Clinical Practice Guideline Updates

The following section takes a closer look at some of the concepts described in Chapter 4 in relation to identifying scientific literature for clinical practice guideline (CPG) updates and also describes some of the key sources of information.

1.1. Reviewing and Redesigning Original Search Strategies

1.1.1 Search Approach

Whatever approach is adopted in literature searches when updating a clinical practice guideline (CPG), it should always be based on the original search strategies,[1,2] assuming that these were successful in identifying the most relevant literature. Nevertheless, strategies can be modified for the updating process to optimize searches.

As mentioned in Chapter 4, the strategies followed should prioritize specificity over sensitivity. A good option is to use the original search terms to identify the most relevant studies for updating recommendations to review the main terms from the titles and abstracts of the main studies evaluated for the original CPG and the search descriptors used to index them in the main databases. This kind of search incorporating the original search algorithm will offer more precise results.

A precise approach is not recommended for a treatment or technique that has emerged since the publication of the original CPG on the basis of which a recommendation has to be made in the updated guideline. In the case of new technologies a more sensitive approach, as recommended for systematic reviews, is advised as it enables as much information as possible to be identified to assess effectiveness.[3] This approach should also be applied if new clinical questions have been posed for the update.

1.1.2 Validated Descriptors and Filters in Updating

Depending on how long ago the search was carried out, it is worthwhile checking if the descriptors originally used have undergone any changes. For example, during the development of a CPG on the prevention of stroke,[4] the main descriptor for this condition in MEDLINE evolved from ‘cerebrovascular disorder’ to ‘stroke’.

The use of validated methodological filters to identify certain study designs are of particular importance in updating a CPG. Most such filters offer options to optimize sensitivity and precision in identifying studies of treatments, diagnosis and prognosis and even systematic reviews and qualitative studies.[5-9] Users select the filter that best matches their needs depending on the search approach and the database to be searched.[10] Again, it should be checked that the filters used in the original version of the CPG are still valid at the update stage.

In MEDLINE, for instance, some of the MeSH terms related to study design (for example, ‘Randomized Controlled Trial [MeSH]’) have evolved to publication types (‘Randomized Controlled Trial [Publication Type]’). Similarly, some of the best known filters for identifying clinical trials[11] have changed radically to adapt to the changes commented above.[12]

Users can consult websites offering methodological filters: e.g., the Cochrane Collaboration to identify clinical trials in MEDLINE; the McMaster University Health Information Research Unit (HIRU) filters,[10] some of which are integrated in PubMed’s Clinical Queries search engine; and the comprehensive set of methodological filters offered by the InterTASC Information Specialists Group of the University of York.[13]

Furthermore, some topics have more advanced resources that integrate multiple filters for identifying new literature. For example, the palliative care website CareSearch[14]—an Australian government initiative—offers a number of filters to assist searches in MEDLINE regarding palliative care and the organization of palliative care. It also has tools for locating literature that is not published in indexed biomedical journals or is published as 'grey literature'. The US National Library of Medicine also has a resource to carry out searches on specific themes through the PubMed Special Queries function.[15]

1.1.3 Search Strategy Time Limits

Another noteworthy aspect is that of time limits on literature searches for updates. Once the original search strategies have been reviewed it is useful to perform a search of the full year in which the searches for the original CPG were performed, so as to identify studies that were not indexed at the time of the initial searches;[16] note, however, that this strategy is not based on empirical studies demonstrating yield. Good results in identifying relevant studies in systematic updates[17,18] have also been obtained using the 'entry date' field instead of the 'publication date' to identify the publication date for studies when searching MEDLINE via Ovid[19] or by using the field limiter 'added to PubMed in the last …' instead of the 'published in the last …' field when carrying out searches in PubMed.

1.2 Databases and Other Useful Scientific Literature Resources

The *Manual Metodológico para la Elaboración de Guías Clínicas*[20] points to bibliographic databases as sources of scientific information. Some databases and search engines can optimize the effort that goes into designing the search strategy and the time employed in identifying the most relevant studies for a CPG update.

Described below are particularly useful resources for identifying studies to update scientific literature and CPGs and strategies to take maximum advantage of these resources. The resources are presented hierarchically: sources that identify or index CPGs first, followed by sources of systematic reviews and health technology assessment reports. Useful steps for searching databases of original studies are also described.[21,22]

1.2.1 Clinical Practice Guidelines

A study by Fisterra[23] has exhaustively studied all the possibilities of the Internet in terms of identifying CPGs, classifying the different compiling bodies, institutions responsible for preparing CPGs, methodology centres and general databases that can be searched for CPGs.

The literature update phase is worthy of special attention. A search can be carried out for CPGs developed by other teams working in the same health area that have recently been updated (based on search date or update information provided in the websites of developing institutions). The main studies on which recommendations are based can be checked for their relevance to our update. Obviously, the search can be aimed at locating CPGs published after our original guideline was published.

There are several ways to obtain information on CPGs. The first approach should be to consult search engines that index CPGs: the TRIP Database, the National Guidelines Clearinghouse (NGC) of the American Agency for Healthcare Research and Quality (AHRQ) and the websites of CPG developers, namely, the Scottish Intercollegiate Guidelines Network (SIGN), the National Institute for Clinical Excellence (NICE), the Australian National Health and Medical Research Council (ANHMRC) and the New Zealand Guidelines Group (NZGG). The NGC and AHRQ have an updating service for the guidelines indexed in their databases, available through the NGC's weekly newsletter.

The websites of the main scientific associations can be consulted to locate relevant guidelines and consensus documents; for example the American Heart Association (AHA) has a comprehensive compendium of all of its CPGs, classified by clinical category and year of publication. The main source for locating CPGs in Spanish is GuíaSalud.

A query in PubMed may identify CPGs that have only been published in biomedical journals. For instance, scientific associations like the AHA publish their CPGs in journals of relevance in their field.

1.2.2 Systematic Reviews

Systematic reviews are an exhaustive summary of the best scientific literature available on the effects of a health intervention. They are an invaluable tool for healthcare decision makers and for experts required to develop recommendations.

The TRIP Database is a scientific literature metasearch engine which searches according to hierarchical criteria; it first identifies information sources providing the best quality scientific literature and then systematically tracks down resources of increasingly lower quality offering further information.[22] All the sources identified by the TRIP Database fulfil evidence-based medicine criteria.[24] TRIP also simultaneously searches in PubMed using Clinical Queries. TRIP results are automatically classified according to the type of publication. The most useful sections are Guidelines and Systematic Reviews and the index of the main secondary journals (Evidence-Based Synopses). Results can also be classified by year of publication, which facilitates consultations for updates. Several tutorials are available to users.[25,26] Spain has Excelencia Clínica, a metasearch engine that uses the same methodology as the TRIP Database to search for scientific literature in Spanish.

The UK Centre for Reviews and Dissemination and the DARE (Database of Abstracts of Reviews of Effects), HTA (Health Technology Assessment) database and the NHS-EED (National Health Service Economic Evaluation Database) offer the option of limiting searches to systematic reviews and health technology assessment reports. They have the additional advantage that they describe the output and provide critical synopses of methods and results. DARE contains more than 5,000 synopses of systematic reviews of the effect of health interventions, accompanied by critical commentaries, and includes analytical abstracts of Cochrane systematic reviews. The reviews in this very complete database include material from more than 50 leading biomedical journals and include searches in unpublished literature. The HTA database indexes around 7,000 reports of health technologies by members of the International Network of Agencies for Health Technology Assessment (INAHTA) as well as reports by other organizations. Finally, NHS-EED indexes critical comments on economic assessment reports discussing the effects of health interventions and formally analysing their cost. Studies for this database are identified using the same exhaustive process as in DARE.

The Cochrane Database of Systematic Reviews contains reviews on the effect of health interventions, characterized by their quality[27,28] but with some limitations due to the lack of updating.[17,29] The Cochrane reviews fulfil a series of methodological requirements[3] that have important implications for CPG literature updates. The Cochrane Library indexes Cochrane review protocols—a requirement to be met before a systematic review can be published. Hence, if the original CPG included Cochrane reviews, the review protocols should be checked to see whether they have been published as systematic reviews; new protocols for existing reviews should also be checked. The Cochrane Collaboration establishes an explicit policy for updating its reviews which, on occasion, means that some are withdrawn from the Cochrane Library as being outdated. It is thus important to check whether the Cochrane systematic reviews assessed in the original CPG have undergone any significant updates that would dictate a new assessment. Both the Cochrane Library and Biblioteca Cochrane Plus (free access to Cochrane reviews translated into Spanish) allow searches of new or updated reviews.

Clinical Evidence, whose content is updated annually, publishes reviews that synthesize the literature available on the prevention and treatment of clinical conditions in several specialties. It draws on exhaustive critical reviews of systematic reviews, clinical trials and observational studies, and also comments on any identified areas of uncertainty.

UpToDate and Dynamed are similar electronic resources, with experts carrying out updated reviews of the literature to answer clinical questions referring to several clinical specialties. Although these resources are not like the databases mentioned, they may be useful in updating literature as great effort goes into keeping them up to date. Consulting one of the clinical categories or periodic newsletters may identify relevant studies for the CPG update.

1.2.3 Original Studies

Literature searches should not be restricted to identifying systematic reviews responding to the clinical questions posed for the CPG, given that their main limitation is the lack of updating.[17,18] The search date for these reviews should be established so as to identify the main original studies published subsequently. Certain steps should be taken into account regarding the efficient identification of new studies.

Secondary journals are a good source for keeping up to date on the main studies published in the biomedical literature and on specific clinical specialties. These journals monitor the main biomedical journals to select, according to explicit criteria, the most relevant studies of the highest quality. Experts evaluate the relevance of the study for their area and present the main results in a structured manner with comments on their implications for clinical practice. Hence, monitoring the most important secondary journals covering the clinical category of the CPG will identify the most relevant studies. There are a number of secondary journals adopting either a general approach (*Evidence-Based Medicine, ACP Journal Club, Bandolier*) or a specialist approach (*Evidence-Based Nursing, Evidencias en Pediatría, Journal of Epidemiology and Community Health*). Note that both the TRIP and Excelencia Clínica clinical search engines search in many of these journals.[24]

The Web of Science of the ISI Web of Knowledge offers a simple way of checking the list of references for a specific article and, even more useful, for other studies mentioned in the consulted article. It should be checked which studies have cited the main studies on which the CPG recommendations are based. Searching for the main systematic reviews, clinical trials and observational studies of the original CPG will identify the most up-to-date studies covering the same topic as these reference studies. Some authors have pointed to the usefulness of this tool for tracing the citation ratio of Cochrane systematic reviews[30] and for building up specialist clinical trial records.[31] The Web of Science is also recommended for locating other CPGs of interest that have been published in biomedical journals. Resources such as Scopus have similar features, although universal access to the Web of Science is possible in Spain, thanks to an agreement between the Spanish Ministry of Science and Innovation and the Spanish Foundation for Science and Technology.

A further option—one that most biomedical journals include in their electronic version to enable location of articles cited in studies—is citation alerts (e-TOCs, CiteTrack Alerts), which send an email to inform that a study of interest has been cited. This function may be useful for CPGs published in journals and by international scientific associations. Other services permit alerts to be personalized according to their relevance, topic, applicability or periodicity, namely, EvidenceUpdates of the BMJ Publishing Group and the AMEDEO platform.

1.2.4 Study-in-Progress Databases

Initiatives have recently arisen to overcome publication bias, such as that supported by the editors of the main biomedical journals: prospective registration for clinical trials before they are launched and rejection of non-registered trials for publication.[32] Another initiative is the creation of databases of studies in progress. Users can identify the International Standard Randomized Controlled Trial Number (ISRCTN) of studies that are relevant to the clinical questions posed and can follow up on them to see if they are published. For example, during a systematic review of the effect of supplements with folic acid and vitamin B to improve homocystine levels and prevent cardiovascular events,[33] locating trial NCT00354081 enabled a publication on the results of the Western Norway B Vitamin Intervention Trial[35] to be identified. Given that it is recommended that clinical trial structured abstracts include the registration number,[35,36] a simple PubMed search with these numbers should be sufficient to check whether the results of a trial have been published.

Contact with experts is a valuable resource for identifying relevant studies that is recommended for systematic reviews;[3] this approach may also be useful when updating a CPG.

Finally, bibliographic databases of original studies are an ideal tool for identifying literature. Clinical Queries in PubMed and the numerous tools available on the Internet (third-party PubMed tools) make searches in this kind of database easier. PubMed has a useful free tool for periodically updating literature called My NCBI through which periodic updates can be implemented and classified by specific topics for any search executed in PubMed.[37]

1.2.5 Web 2.0 for Literature Updates (blogs, wikis and RSS)

Web 2.0, which refers to an emerging WWW context in which various tools can be used to create, edit and pool knowledge, facilitates the creation of web-based communities and participation in the Internet as an alternative to traditional forms of exchanging information.[38-40] Described below are some of the most popular Web 2.0 utilities offering promise in terms of the production, handling, dissemination and identification of knowledge.[41]

Blogs are a simple and popular social platform that enable the exchange of information. The fact that readers can comment on content and publish their own ideas or knowledge regarding the original posts, makes the blog a useful source of information for identifying emerging trends or debates in different fields of knowledge.

Google Blog Search is a high-performance tool for searching blogs[42] which offers excellent results in identifying blogs which comment on new CPGs or new utility studies for literature updates. Another Google options allows e-mail alerts to be created to track down websites that cite a specific concept.[43] Creating an alert with the title of the original CPG or the main related studies will enable monitoring of material of interest.

Wikis (the best known is Wikipedia) enable ongoing text reviewing and updating. They can be used to obtain and access information and for virtual cooperation through debates with the members of a work group.[44] The health wiki, Ganfyd,[45] is a collaborative electronic encyclopaedia edited by health professionals.

RSS (Really Simple Syndication) subscriptions are a good option for keeping up to date with new information on a specific topic. RSS feeds centralize new content alerts in a website or compile feeds on the content of the medical journals of greatest interest as they are published. RSS subscription means that it is no longer necessary to perform the tedious task of constantly revisiting sources, blogs or journal websites, as all news is sent by the sources of information themselves.

Most of the information resources mentioned allow subscriptions to new content related to queries made. Even PubMed offers the possibility of subscribing to new content for simple searches in MEDLINE.[46] The effectiveness of these tools as an aid to updating literature is clear.

The Internet enables search strategies to be developed that can, if necessary, broaden the search focus to perform more exhaustive searches, thereby further optimizing the process for identifying literature. Electronic alerts and RSS web feeds can periodically centralize newly indexed or published literature for many of the resources previously discussed. Although there is no empirical evidence supporting the use of Web 2.0 tools, the use of feeds and alerts is a good option for regular, organized searches in certain databases. Using Google's special functions to activate alerts on specific topics or searching blogs can complement these tools. However, use of these tools is not standardized and can be time consuming; moreover, the mere fact that these new tools are seen as a novelty should not detract from the specific and precise nature of searches for a CPG update.

1.2.6 The Importance of Software for Managing and Publishing Bibliographies

All the information compiled between the publication of the original CPG and its update needs to be organized and managed using software for managing and publishing bibliographies. These software programmes automatically download bibliographic references, enable the creation of bibliographic databases and generate bibliographies that can be inserted into a text.[47] They are an excellent resource for recording and compiling references for the studies identified when updating a CPG.

The best known tools, EndNote, Pro-Cite, Reference Manager and RefWorks, function in very similar ways (for a comparison of functions, see the Bibliography Management Software website[48]). The subscription offered to the Web of Knowledge by the Spanish Science and Technology Foundation includes the option to use an electronic version of EndNote, accompanied by a user guide.[49]

The CPG updating team should include an expert in scientific literature and documentation to play the role of sentinel and organize the entire updating process. Information and information specialists play a key role, not only in consulting sources of scientific literature but also in compiling study records that facilitate the work of the other members of the CPG team.

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Appendix 2. Resources and Information Sources for Updating Clinical Practice Guidelines

CLINICAL PRACTICE GUIDELINES	
Recommended resources	
Compilers	
AHRQ National Guidelines Clearinghouse	www.guideline.gov
NHS National Library of Guidelines	www.library.nhs.uk/GuidelinesFinder
GuiaSalud	www.guiasalud.es
Institutions that elaborate guidelines	
Scottish Intercollegiate Guidelines Network	www.sign.ac.uk
National Institute for Clinical Excellence	www.nice.org.uk
Australian National Health and Medical Research Council	www.nhmrc.gov.au
New Zealand Guidelines Group	www.nzgg.org.nz
Additional Resources	
Metasearch engines	
TRIP Database	www.tripdatabase.com
Excelencia Clínica	www.excelenciaclinica.net
Others	
MEDLINE via PubMed	www.ncbi.nlm.nih.gov/sites/entrez
Scientific association websites	
Web of Science	http:// isiknowledge.com
Citation alerts for biomedical journals	
SYSTEMATIC REVIEWS AND HEALTH TECHNOLOGY ASSESSMENT REPORTS	
Recommended resources	
Databases	
Centre for Reviews and Dissemination (databases)	www.crd.york.ac.uk/crdweb
Cochrane Database of Systematic Reviews	www.thecochranelibrary.org
Biblioteca Cochrane Plus	www.bibliotecacochrane.net
MEDLINE via PubMed	www.ncbi.nlm.nih.gov/sites/entrez
Additional Resources	
Metasearch engines	
TRIP Database	www.tripdatabase.com
Excelencia Clínica	www.excelenciaclinica.net
Others	
Clinical Evidence	http://clinicalevidence.bmj.com
UpToDate	www.uptodate.com
Dynamed	www.ebscohost.com/dynamed

ORIGINAL STUDIES	
Recommended Resources	
Databases	
Web of Science	http:// isiknowledge.com
MEDLINE via PubMed (Clinical Queries)	www.ncbi.nlm.nih.gov/entrez/query/static/clinical.shtml
Additional resources	
Databases for studies in progress	
ClinicalTrials.gov	http://clinicaltrials.gov
Current Controlled Trials	www.controlled-trials.com
International Clinical Trials Registry Platform	www.who.int/ictrp
Others	
Secondary journals	
Contact with experts	
Electronic alerts (Amedeo, EvidenceUpdates)	www.amedeo.com; http://plus.mcmaster.ca/EvidenceUpdates/
Syndications (web feeds), blogs	

Appendix 3. SIGN Guideline Review Form

SIGN

PROPOSED REVIEW OF SIGN GUIDELINE
CONSULTATION FORM

Title of guideline	SIGN 67: Management of Colorectal Cancer
Date of publication	2003
SIGN scoping search – sources	MeSH headings for the condition specified and any common variations as free text, plus terms for the interventions and care processes discussed in the guideline Sources: **Guidelines:** NICE; National Library for Health guidelines finder; National Guidelines Clearinghouse; GIN Web site. **Technology appraisals:** NICE; UK HTA database (Southampton); INAHTA database. **Cochrane reviews:** Cochrane Library. **Other good quality systematic reviews:** UK HTA database (Southampton); DARE.
SIGN scoping search - summary	**Guidelines** – 28 **HTAs** – 1 **Cochrane reviews** – 14 **Other good quality systematic reviews** – 22
Other guidelines/HTAs	▪ **NICE:** Improving outcomes in colorectal cancer. June 2004 ▪ **New Zealand Guidelines Group (NZGG). Surveillance and management of groups at increased risk of colorectal cancer.** Wellington (NZ): New Zealand Guidelines Group (NZGG); 2004 May. 84 p. [222 references] ▪ **American Gastroenterological Association medical position statement:** hereditary colorectal cancer and genetic testing. Gastroenterology 2001 Jul;121(1):195-7. ▪ **Finnish Medical Society Duodecim**. Prevention and screening of colorectal cancer. In: EBM Guidelines. Evidence-Based Medicine [CD-ROM]. Helsinki, Finland: Duodecim Medical Publications Ltd.; 2005 Feb 23 [Various]. ▪ **U.S. Preventive Services Task Force.** Screening for colorectal cancer: recommendations and rationale. Ann Intern Med 2002 Jul 16;137(2):129-31. PubMed ▪ **Singapore Ministry of Health.** Colorectal cancer. Singapore: Singapore Ministry of Health; 2004 Feb. 85 p. [245 references] ▪ **Figueredo A, Rumble RB, Maroun J, Earle CC, Cummings B, McLeod R, Zuraw L, Zwaal C.** Follow-up of patients with curatively resected colorectal cancer: a practice guideline. BMC Cancer 2003 Oct 6;3(1):26. [62 references] PubMed ▪ Desch CE, Benson AB 3rd, Somerfield MR, Flynn PJ, Krause C, Loprinzi CL, Minsky BD, Pfister DG, Virgo KS, Petrelli NJ. Colorectal cancer surveillance: 2005 update of an **American Society of Clinical Oncology practice guideline**. J Clin Oncol 2005 Nov 20;23(33):8512-9. [35 references] PubMed ▪ Gastrointestinal Cancer Disease Site Group. Kocha W, Maroun J, Jonker D, Rumble RB, Zuraw L. Oral capecitabine (Xeloda) in the first-line treatment of metastatic colorectal cancer [full report]. Toronto (ON): **Cancer Care Ontario (CCO);** 2003 Dec 5. 19 p. (Practice guideline report; no. 2-15). [26 references] ▪ Smith RA, Cokkinides V, Eyre HJ. **American Cancer Society guidelines** for the early detection of cancer, 2003. CA Cancer J Clin 2003 Jan-Feb;53(1):27-43. [57 references] PubMed ▪ **Anthony T, Simmang C, Hyman N, Buie D, Kim D, Cataldo P, Orsay C, Church J, Otchy D, Cohen J, Perry WB, Dunn G, Rafferty J, Ellis CN, Rakinic J, Fleshner P, Stahl T, Gregorcyk S, Ternent C, Kilkenny JW 3rd, Whiteford M**. Practice parameters for the surveillance and follow-up of patients with colon and rectal cancer. Dis Colon Rectum 2004 Jun;47(6):807-17. [54 references] PubMed ▪ Gastrointestinal Cancer Disease Site Group. Figueredo A, Moore M, Germond C, Kocha W, Maroun J, Zwaal C. Use of irinotecan in the second-line treatment of metastatic colorectal carcinoma. Toronto (ON): **Cancer Care Ontario (CCO)**; 2004 Jul. 21 p. (Practice guideline

	report; no. 2-16). [40 references] ▪ Gastrointestinal Disease Site Group. Germond C, Maroun J, Zwaal C, Wong S. Use of raltitrexed (Tomudex) in the management of metastatic colorectal cancer. Toronto (ON): **Cancer Care Ontario (CCO);** 2005 Feb 10. 13 p. (Practice guideline report; no. 2-17). [22 references] ▪ Gastrointestinal Cancer Disease Site Group. Use of irinotecan (camptosar, CPT-11) combined with 5-fluorouracil and leucovorin (5FU/LV) as first-line therapy for metastatic colorectal cancer [full report]. Toronto (ON): **Cancer Care Ontario (CCO);** 2003 Feb [online update]. 20 p. (Practice guideline; no. 2-16b). [17 references] ▪ **Association of Coloproctology of Great Britain and Ireland.** Referral guidelines for bowel cancer. London (UK): Association of Coloproctology of Great Britain and Ireland; 2002 Apr 25. Various p. [356 references] ▪ **Otchy D, Hyman NH, Simmang C, Anthony T, Buie WD, Cataldo P, Church J, Cohen J, Dentsman F, Ellis CN, Kilkenny JW 3rd, Ko C, Moore R, Orsay C, Place R, Rafferty J, Rakinic J, Savoca P, Tjandra J, Whiteford M.** Practice parameters for colon cancer. Dis Colon Rectum 2004 Aug;47(8):1269-84. [152 references] PubMed ▪ **Institute for Clinical Systems Improvement (ICSI).** Colorectal cancer screening. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2006 Jun. 50 p. [71 references] ▪ Welch S, Kocha W, Rumble RB, Spithoff K, Maroun J, Gastrointestinal Cancer Disease Site Group. The role of bevacizumab (Avastin) combined with chemotherapy in the treatment of patients with advanced colorectal cancer. Toronto (ON): **Cancer Care Ontario (CCO)**; 2005 Dec 12. 23 p. (Evidence-based series; no. 2-25). [18 references] ▪ Winawer S, Fletcher R, Rex D, Bond J, Burt R, Ferrucci J, Ganiats T, Levin T, Woolf S, Johnson D, Kirk L, Litin S, Simmang C, **Gastrointestinal Consortium Panel**. Colorectal cancer screening and surveillance: clinical guidelines and rationale. Update based on new evidence. Gastroenterology 2003 Feb;124(2):544-60. [102 references] PubMed ▪ Davila RE, Rajan E, Adler D, Hirota WK, Jacobson BC, Leighton JA, Qureshi W, Zuckerman MJ, Fanelli R, Hambrick D, Baron TH, Faigel DO. **ASGE guideline**: the role of endoscopy in the diagnosis, staging, and management of colorectal cancer. Gastrointest Endosc 2005 Jan;61(1):1-7. [72 references] PubMed ▪ **Figueredo A, Zuraw L, Wong RK, Agboola O, Rumble RB, Tandan V**. The use of preoperative radiotherapy in the management of patients with clinically resectable rectal cancer: a practice guideline. 2003 Nov 24;1(1):1. PubMed ▪ Benson AB 3rd, Schrag D, Somerfield MR, Cohen AM, Figueredo AT, Flynn PJ, Krzyzanowska MK, Maroun J, McAllister P, Van Cutsem E, Brouwers M, Charette M, Haller DG. **American Society of Clinical Oncology** recommendations on adjuvant chemotherapy for stage II colon cancer. J Clin Oncol 2004 Aug 15;22(16):3408-19. [45 references] PubMed ▪ Smith A, Rumble RB, Langer B, Stern H, Schwartz F, Brouwers M, Laparoscopic Colon Cancer Surgery Expert Panel and Program in Evidence-based Care. Laparoscopic surgery for cancer of the colon. Toronto (ON): **Cancer Care Ontario (CCO)**; 2005 Sep. Various p. (Evidence-based series; no. 2-20-2). [13 references] ▪ **American College of Radiology (ACR), Expert Panel on Radiation Oncology-Rectal/Anal Work Group**. Locally unresectable rectal cancer. Reston (VA): American College of Radiology (ACR); 2002. 10 p. (ACR appropriateness criteria). [30 references] ▪ **Place R, Hyman N, Simmang C, Cataldo P, Church J, Cohen J, Denstman F, Kilkenny J, Nogueras J, Orsay C, Otchy D, Rakinic J, Tjandra J.** Practice parameters for ambulatory anorectal surgery. Dis Colon Rectum 2003 May;46(5):573-6. [47 references] PubMed ▪ **Tjandra JJ, Kilkenny JW, Buie WD, Hyman N, Simmang C, Anthony T, Orsay C, Church J, Otchy D, Cohen J, Place R, Denstman F, Rakinic J, Moore R, Whiteford M.** Practice parameters for the management of rectal cancer (revised). Dis Colon Rectum 2005 Mar;48(3):411-23. [143 references] PubMed ▪ Colorectal Cancer Screening: guidance on large bowel surveillance for people with two first degree relatives with colorectal cancer or one first degree relative diagnosed with colorectal cancer under 45 years. **British Society of Gastroenterology.** Oct 2002 ▪ Colorectal Cancer Screening: guidelines for follow-up after resection of colorectal cancer. **British Society of Gastroenterology**. Oct 2002 **NICE**. The clinical effectiveness and cost effectiveness of capecitabine and tegafur uracil for colorectal cancer. May 2003.
Main conclusions from new evidence	▪ Capecitabine or tegafur with uracil (and folinic acid), to be taken by mouth, should be among the first options considered for a person with metastatic colorectal cancer. *Guideline recommends that outside a clinical trial, the choice of an appropriate regimen includes continuous infusional fluorouracil (Lokich), FUFA infusion (de Gramont) or capecitabine (A). Evidence on tegafur/uracil was awaited.* ▪ Two reviews found that there is no conclusive evidence that surveillance colonoscopy prolongs

	survival in patients with extensive colitis. *The guideline recommends that patients with left-sided colitis or pancolitis of 10 years duration should undergo three yearly colonoscopy with mucosal biopsies and biopsy of any suspicious lesions and that the frequency of examination should increase to yearly when the disease has been present for 20 years, or when indeterminate dysplasia has been diagnosed (D).* ▪ One review suggests that if the long-term oncological results of laparoscopic and conventional resection of colonic carcinoma show equivalent results, the laparoscopic approach should be preferred in patients suitable for this approach to colectomy. Another shows that laparoscopic colectomy appears to be more expensive and to take longer than traditional open surgery. *There is a good practice point that says laparoscopic surgery can be considered for colorectal cancer.* ▪ No apparent differences in quality of life are found in rectal cancer patients with a permanent stoma when compared to non-stoma patients*. Guideline says that patients who require stoma formation generally experience more problems than those who do not, without citing evidence. There are no recommendations about stoma and QoL.* ▪ There was evidence from three pooled RCTs that ASA significantly reduces the recurrence of sporadic adenomatous polyps after one to three years. There is evidence from short-term studies to support regression, but not elimination or prevention of CRAs in FAP. *No recommendations made whilst waiting for long-term toxicity data.* ▪ There is an overall survival benefit for intensifying the follow-up of patients after curative surgery for colorectal cancer. It is not possible to infer from the data the best combination and frequency of clinic (or family practice) visits, blood tests, endoscopic procedures and radiological investigations. *There is a good practice point that says colonoscopic follow-up after curative resection for colorectal cancer should be carried out as for adenomatous polyps (ie 3-5 years depending on presence of adenomas).* ▪ There is no convincing evidence that mechanical bowel preparation is associated with reduced rates of anastomotic leakage after elective colorectal surgery. There is evidence that this intervention may be associated with an increased rate of anastomotic leakage and wound complications. The dogma that mechanical bowel preparation is necessary before elective colorectal surgery should be reconsidered. Mechanical bowel preparation before colorectal surgery cannot be recommended as routine. *The guideline acknowledges that there is no evidence that bowel preparation confers benefit, but finds that the quality of evidence suggesting no effect is too weak to make a definitive statement that it is not necessary. There is a good practice point suggesting that the decision to use bowel preparation must be individualized according to the patient's need and the surgeon's experience.* ▪ The optimal VTE prophylaxis in colorectal surgery is the combination of graduated compression stockings and low-dose unfractionated heparin. The unfractionated heparin can be replaced with low molecular weight heparin. *The guideline recommends that patients undergoing surgery for colorectal cancer should have venous thromboembolism prophylaxis (A), but refers readers to the SIGN VTE guideline for details on how.* ▪ CT colonography should only be used in research protocols, or when other accepted screening methods are not appropriate, until heterogeneity is more clearly explained and CT colonography is found to be sensitive. *Guideline recommends a CT pneumocolon as a sensitive test for colorectal cancer, where the radiological expertise and equipment exist (D).*
New areas that could be added to the guideline	▪ Capecitabine or tegafur with uracil (and folinic acid) in metastatic colorectal cancer ▪ Stoma and quality of life ▪ The optimal VTE prophylaxis in colorectal surgery
Summary of the recommendations that could be updated	▪ Effect of surveillance colonoscopy on survival ▪ Role of laparoscopic surgery ▪ Role of NSAIDs and aspirin ▪ Follow-up of patients after curative surgery for colorectal cancer ▪ mechanical bowel preparation

Please answer the following questions as fully as possible:

Name, designation, organization:	Other: 2 Academic: 2 Consultant: 4
1(a)	Is there still a requirement for an evidence-based guideline on this topic?
	Yes = 8
1(b)	If no, should the guideline be withdrawn?
2(a)	Do you agree with the assessment of the impact of the new evidence and its likely effect on recommendations?
	▪ No = 1 ▪ Yes = 7

	▪ I think there is much more evidence that requires review in the field of non-surgical approaches. There have been a number of pivotal phase III trials published which have altered clinical management and they are not listed in the current revision summary ▪ With regard to laparoscopic surgery facts have shown no detriment. NICE have said laparoscopic colonic surgery should be offered where appropriate ▪ While I agree with the assessment of the impact of the new evidence and its likely effect on the recommendations as far as it goes, I believe that there is a substantial body of evidence in both surgical and non-surgical approaches to colorectal cancer. In particular there have been a number of important phase III trials which have altered clinical management and which are not mentioned in this document.	
2(b)	Based on the information given above, and your own clinical judgement, does the guideline require revision in the light of new evidence? *Please give details.*	
	▪ Yes = 7 ▪ No = 1 ▪ New agents, such as monoclonal antibodies merit review, the role of adjuvant chemotherapy for node negative patients, the role of peri-operative chemotherapy for patients with respectable liver metastases, the use of combination chemotherapy as first-line therapy ▪ The chapter on chemotherapy and radiotherapy requires total revision as significant sections do not reflect current evidence and practice. Data from the Mosaic study and NSABP-07 establish the role of oxaliplatin based combination chemo in adjuvant setting. There role of combination chemotherapy in advanced disease is now considerably broader than in the guideline. The are data from multiple sources including the MRC Focus study results. There requires to be a section on the role or otherwise of the newer biological agents such as cetuximab and bevacizumab (irrespective of NICE/SMC advice). MRC trial CR07 on short course preop radiotherapy has been presented and is likely to be published within the time frame of any review of the guideline as well as further data which have been published from the Dutch TME radiotherapy study. Section 7.1 on preop staging does not reflect current practice and any revision needs to include data from the MERCURY study and probably broadened to include an assessment of the data on PET scanning. As mentioned in SIGN conclusions the section on follow up merits review. ▪ Clinically a very high-profile and important area. The guideline must be seen to be contemporary and relevant even if there are only relatively modest changes ▪ Need to review laparoscopic colorectal surgery practice point in light of above ▪ I believe that the guideline does require revision in the light of new evidence, particularly related to radiotherapy for rectal cancer, adjuvant chemotherapy for colorectal cancer, perioperative chemotherapy for patients with liver metastases, the use of new biological agents, new evidence in terms of lifestyle factors and chemoprevention and finally I believe account needs to be taken of the National Screening Programme and more robust guidance is needed in this area.	
3	Please list any additions to the remit of the guideline that you think would be beneficial	
	▪ See above. ▪ As mentioned above I believe that the guideline should be extended to include detailed recommendations on population screening. ▪ Data on newer regimens is available, e.g., XELOX. These data were presented at ASCO 2007 (J Cassidy et al. Journal of Clinical Oncology, 2007 ASCO Annual Meeting Proceedings Part I. Vol 25, No. 18S (June 20 Supplement), 2007: 4030). This is likely to be published soon and will be submitted to SMC in Q1 2008. Consideration should be given to including reference to such newer regimens in the guideline.	
4	Please tick your preferred option for reviewing this guideline	
	a. there is no new evidence that will affect existing recommendations and the guideline should not be reviewed at this time	1
	b. some recommendations will change in the light of the new evidence and selected elements of the guideline should be reviewed	5
	c. the entire guideline should be reviewed	2
	d. the guideline should be withdrawn	

Thank you very much for taking part in this consultation.

Please return to: