



CANEVAS
pour la réalisation
d'une Recommandation
de Bonne Pratique

TABLE DES MATIERES

| | |
|--|----------|
| 1- CHOIX DU THEME..... | 3 |
| 2 - AUTEURS, COMITE SCIENTIFIQUE ET VALIDATION..... | 3 |
| 3 - SUGGESTION DE PLANNING | 3 |
| 4 - RECHERCHE BIBLIOGRAPHIQUE | 3 |
| 4.1 Objectif principal et question cliniques | 4 |
| 4.2 Stratégie de recherche par paliers | 4 |
| 4.3 Evaluation critique et traitement des données | 4 |
| 4.4 Concertation afin d'établir un consensus | 4 |
| 5 - STRUCTURE DES RECOMMANDATIONS DE DOMUS MEDICA ET DE LA SSMG | 5 |
| 6 - REALISATION DU DRAFT..... | 6 |
| 7 - VALIDATION PAR LE COMITE SCIENTIFIQUE..... | 6 |
| 8 - EVALUATION PAR DES EXPERTS EXTERNES | 6 |
| 9 - EVALUATION DANS LES DODECAGROUPES OU GLEMS | 6 |
| 10 - PATIENTS..... | 7 |
| 11 - NOUVELLE CONCERTATION POUR UN CONSENSUS FINAL..... | 7 |
| 12 - VALIDATION..... | 7 |
| 13 - IMPRESSION et DIFFUSION | 7 |

1- CHOIX DU THEME

Les thèmes des Recommandations de Bonne Pratique sont choisis en fonction de différents critères qui sont détaillés dans l'Annexe I.

2 - AUTEURS, COMITE SCIENTIFIQUE ET VALIDATION

Une recommandation de bonne pratique (RBP) est élaborée par un groupe d'auteurs, dont la majorité sont des médecins généralistes en activité, ayant une pratique régulière de la lecture critique de la littérature, particulièrement des études cliniques.

Des intervenants spécialisés dans d'autres disciplines peuvent également faire partie de ce groupe d'auteurs.

Des représentants de tous les groupes professionnels concernés par la RBP doivent être impliqués dans l'élaboration de la RBP.

Dans le groupe d'auteurs, siègera au moins un membre du « comité scientifique du groupe de travail des RBP » (SSMG) ou du « stuurgroep aanbevelingen » (WVVH).

Le « comité scientifique du groupe de travail des RBP » (SSMG) ou le « stuurgroep aanbevelingen » (WVVH) est responsable de l'accompagnement, de l'élaboration et de la rédaction de la RBP.

3 - SUGGESTION DE PLANNING

Le planning suivant est suggéré aux auteurs afin de rédiger la recommandation endéans deux années :

• Année 1:

- Mois 1-3 :
 - formulation de questions cliniques précises, principales ou annexes, pour lesquelles des recommandations doivent être données
 - revue des niveaux de preuve tertiaires et quaternaires: guidelines et systematic reviews en recherchant leurs références secondaires,
- Mois 4-6: compléter par Medline (si possible RCT et méta-analyses). Si guidelines bien faits (méthodologie décrite, mode de recherche décrite, le tout valide) se limiter aux parutions après la date de fin de recherche dans la littérature de ces guidelines
- Mois 7-9: Projet de canevas RBP
- Mois 10: première version imprimée
- Mois 11-12: corrections

• Année 2:

- Mois 1: Version pré-définitive
- Mois 2-5: experts et tests glems / loks
- Mois 6-7: validation 1
- Mois 8-10: finalisation
- Mois 11: validation 2 (CEBAM)
- Version finale

4 - RECHERCHE BIBLIOGRAPHIQUE

! Référence AGREE

Méthodologie (items 8-14) correspond au processus de collecte et d'assemblage de preuves et aux méthodes utilisées en vue de l'élaboration et de la révision de recommandations.

Des méthodes systématiques ont été utilisées pour rechercher les preuves scientifiques.

Les critères de sélection des preuves sont clairement décrits.

Les méthodes utilisées pour formuler les recommandations sont clairement décrites.

Les bénéfices, les effets secondaires et les risques en terme de santé ont été pris en considération dans la formulation des recommandations.

Il y a un lien explicite entre les recommandations et les preuves scientifiques sur lesquelles elles reposent.

La RBP a été revue par des experts externes avant sa publication.

Une procédure d'actualisation de la RBP est décrite.

4.1 Objectif principal et question cliniques

- définir et formuler des questions cliniques précises
- transposer ces questions en termes de recherche corrects
 - termes de recherche précis
 - selon l'avis d'experts, préciser les domaines importants à explorer
 - après le 1er screening général des guides de pratique disponibles concernant le sujet
 - aperçu des sujets pertinents → termes de recherche
 - aide pour déterminer les mots-clés de recherche
 - (première estimation du volume de littérature disponible pour le sujet).

Plus de détails dans l'ANNEXE II.

4.2 Stratégie de recherche par paliers

La recherche pour une nouvelle recommandation sera toujours effectuée suivant la même stratégie méthodologique, décrite en détails dans l'ANNEXE II.

En premier lieu, les auteurs utiliseront les données issues des synthèses méthodiques, des méta-analyses et des études originales, données analysées dans les guidelines et Clinical Evidence.

Dans une deuxième étape, les méta-analyses et synthèses pertinentes seront recherchées. Enfin, dans une troisième étape, les études Randomisées Contrôlées (RCT) seront recherchées.

Pour la recherche des synthèses, méta-analyses et RCTs, il sera fait usage des bases de données électroniques : MEDLINE (PubMed) et The Cochrane Library.

Seuls les articles pouvant donner une réponse aux questions cliniques posées seront sélectionnés. Pour ce faire, des critères de sélection stricts seront utilisés et toute la littérature identifiée ne sera pas retenue.

La recherche pour une mise à jour d'une recommandation de bonne pratique existante se fera selon la méthodologie ADAPTE (voir Enclosure II).

4.3 Evaluation critique et traitement des données

a Evaluation critique

La littérature sélectionnée est analysée de manière critique et sa qualité est évaluée. Pour évaluer les guides de pratiques, les auteurs pourront utiliser la grille AGREE. Pour les autres types d'études, des grilles d'évaluation sont disponibles sur le site www.cochrane.nl (revues systématiques, essais cliniques, méta-analyses). Pour l'évaluation des études sur le diagnostic, la grille d'analyse QUADAS peut également être utilisée.

Plus de détails dans l'Annexe II.

b Résumé des preuves accumulées

Pour les messages importants (réponses aux questions cliniques) un tableau des preuves est établi (Evidence Tabel) avec les niveaux de preuve pour chaque référence + des propositions sont faites pour l'attribution d'un grade de recommandation (GRADE Working Group) pour chaque message, en apportant tous les arguments nécessaires, y compris des considérations économiques (cfr c) (Pour les détails, voir Annexe II)

c Considérations économiques (coûts & bénéfices en matière de santé ⇔ plus-value pour les recommandations dans le guide de pratique).

- Si une analyse économique (minimalisation des coûts, coûts/efficacité, coût/utilité, coût/bénéfice) reprenant des données belges existe, il faut la valider (analyses Dutch Cochrane, KCE) et en mentionner les résultats.
- Le coût comparatif des différentes stratégies diagnostiques et thérapeutiques proposées sera utilement mentionné. Il faut aussi mentionner les conditions de remboursement en Belgique s'il y a lieu

4.4 Concertation afin d'établir un consensus

au niveau du groupe d'auteurs (→ point 3.)

5 - STRUCTURE DES RECOMMANDATIONS DE DOMUS MEDICA ET DE LA SSMG

Les éléments suivants doivent être pris en considération. Certains sont indispensables pour toute RBP, d'autres seront sans objet pour certains thèmes choisis.

1. ABSTRACT
Apports essentiels de la RBP ; recommandations avec leur niveau de preuve et de recommandation.
2. INTRODUCTION
Éléments de MOTIVATION (choix du sujet, exposé du problème, épidémiologie, étiologie, ...).
Objectifs généraux de la RBP (cfr. AGREE item 1 : [L'\(les\) objectif\(s\) de la RBP est \(sont\) décrit\(s\) explicitement ici](#))
population visée (cfr. AGREE item 3 : [Les patients auxquels la RBP doit s'appliquer sont décrits explicitement ici](#))
contexte pour son application (première ligne de soins) (cfr. AGREE item 6 : [Les utilisateurs cibles de la RPC sont clairement définis ici](#))
interventions diagnostiques et thérapeutiques concernées
3. QUESTIONS CLINIQUES (et/ou diagnostiques)
questions cliniques précisant les objectifs (cfr AGREE item 2 : [La \(les\) question\(s\) clinique\(s\) couverte\(s\) par la RBP est\(sont\) décrite\(s\) explicitement ici](#))
intérêt de formuler un PICO
4. AUTEURS ET METHODOLOGIE DE RECHERCHE
 - Donner la liste des chercheurs et auteurs (cfr. AGREE item 4 : [Le groupe ayant élaboré la RBP inclut des représentants de tous les groupes professionnels concernés](#)) et mentionner leur indépendance éditoriale (cfr. AGREE items 22 et 23), entre autres, que la rédaction de la RBP est indépendante des organismes de financement. Les conflits d'intérêts des membres du groupe ayant élaboré la RPC doivent être documentés
 - Décrire la méthodologie de la recherche dans la littérature (cfr AGREE items 8-14 « [Rigueur d'élaboration](#) » décrit le processus de recherche et de synthèse des preuves scientifiques ainsi que les méthodes utilisées pour formuler les recommandations et pour les actualiser).
5. DEFINITIONS ET CONCEPTS
6. RECOMMANDATION
Recommandation proprement dite, avec réponses aux questions cliniques diagnostiques et thérapeutiques.
7. INFORMATION POUR LE PATIENT
8. CONCLUSIONS ET RECOMMANDATIONS
Avec en annexe une fiche récapitulative
9. CONDITIONS DE MISE EN APPLICATION
Avis du terrain, difficultés d'application, résistances, connaissances et habiletés, changements de comportement nécessaires, organisation de la pratique, matériel et équipement, organisation des soins.
10. CONSIDERATIONS ECONOMIQUES
11. PERSPECTIVES
Propositions sans preuves actuelles, axes de recherche
12. ELABORATION DE LA RBP
 - experts
 - comité scientifique
 - GLEMs et LOKs tests
 - validation
 - commanditaire et financement
 - délai de mise à jour.
13. NOTES.
14. GLOSSAIRE
15. TABLE DES MATIERES.

6 - REALISATION DU DRAFT

par les auteurs, en suivant la canevas de structure proposé au point 5.

!Référence AGREE

Clarté et présentation

Les recommandations sont précises et sans ambiguïté.

Les différentes options pour la prise en charge de la situation clinique sont clairement présentées.

Les recommandations clés sont facilement identifiables.

La RBP est accompagnée d'outils permettant son application.

7 - VALIDATION PAR LE COMITE SCIENTIFIQUE

Validation du draft par le « comité scientifique » (SSMG) ou le « stuurgroep aanbevelingen » (Domus Medica).

8 - EVALUATION PAR DES EXPERTS EXTERNES

Le projet est alors soumis à plusieurs experts, soigneusement choisis, non impliqués jusqu'alors dans l'élaboration de la RBP.

C'est le « comité scientifique » (SSMG) ou le « stuurgroep » (Domus Medica) qui dresse, en fonction du sujet de la RBP, une liste d'experts possibles dans laquelle la présence de médecins généralistes est souhaitable.

Les experts peuvent formuler des amendements, s'ils sont étayés par la littérature, ils seront impérativement pris en compte.

Tous les amendements sont ensuite discutés lors d'une réunion de consensus des auteurs qui décident d'apporter les modifications nécessaires dans le texte de la RBP, en accord avec le « stuurgroep » ou le « comité scientifique ».

Un nouveau draft est réalisé.

9 - EVALUATION DANS LES DODECAGROUPES OU GLEMS

Il est important d'évaluer l'applicabilité de la RBP sur le terrain, comme mentionné dans les items 19-21 de l'instrument AGREE :

Les barrières organisationnelles potentielles à l'application des recommandations ont été discutées. L'impact économique de l'application des recommandations a été examiné. La RBP propose des critères permettant le suivi de l'adhésion aux recommandations et/ou la réalisation d'audit.

Le draft de la recommandation est partiellement traduit : traduction des recommandations, des cas cliniques et des documents à projeter décrivant le contenu, utilisés lors de l'évaluation de faisabilité.

Le projet de RBP est ensuite testé « sur le terrain » dans plusieurs GLEMs ou dodécagroupes (au minimum 4 au total dans la propre langue et 2 dans l'autre langue nationale).

Un animateur expérimenté est présent pour cette réunion, ainsi qu'un des auteurs de la RBP. L'auteur fera, en collaboration avec l'animateur, un rapport de réunion portant particulièrement sur l'appréciation des médecins généralistes quant à l'applicabilité des recommandations (les cas tests doivent être construits en fonction des pierres d'achoppement possibles), quant à leurs résistances à l'application des recommandations et quant aux conditions de mise en application encore nécessaires. Tous les participants à la réunion reçoivent le jour même un exemplaire de la RBP avec, comme mission, d'évaluer la faisabilité de certaines questions concrètes dans la pratique et proposer d'éventuelles remarques sur le contenu.

Pour des recommandations sur un sujet très limité ou pour un mise à jour d'une recommandation entraînant une modification de comportement, l'évaluation par les praticiens peut se limiter à une évaluation écrite.

Un formulaire d'évaluation est ensuite renvoyé à la SSMG ou à Domus Medica, ou une deuxième réunion est prévue pour une évaluation. Les évaluateurs voient leur travail honoré.

Les auteurs tiendront compte des remarques formulées. Toutes ces remarques seront examinées et, lors d'une réunion de consensus des auteurs, des amendements du texte de la RBP seront éventuellement réalisés, en accord avec le « comité scientifique » ou le « stuurgroep ».

10 - PATIENTS

Si un feuillet éducatif à l'intention des patients est rédigé, il devra être validé pour sa compréhension et sa lisibilité.

11 - NOUVELLE CONCERTATION POUR UN CONSENSUS FINAL

- consensus final
- formulation des Recommandations avec des Niveaux de preuve et de Recommandations selon GRADE
- fixer le délai de révision nécessaire et le processus de mise à jour (auteur responsable).

12 - VALIDATION

Le texte modifié sera en premier lieu remis au « comité scientifique » ou au « stuurgroep » et sera ensuite adressé au CEBAM pour validation.

13 - IMPRESSION et DIFFUSION

Le texte définitif validé par le CEBAM et sa traduction sont relus par les deux sociétés scientifiques. Ils sont ensuite adressés à l'imprimeur (SSMG) ou à la rédaction de Huisarts Nu (Domus Medica) pour publication (sur document papier et sur site web). Les messages-clés sont traduits dans l'autre langue nationale et en anglais et placés sur le site web. Un lien avec le site web GIN est établi.

Criteria for selecting topics for guidelines in family practice

*Dominique Paulus (SSMG)
An De Sutter (Domus Medica)*

The objective of this document is to highlight the criteria which should guide the Belgian scientific societies of family practice for choosing new topics of guidelines.

Guidelines are designed to improve the quality of health care, to reduce the number of unnecessary interventions and to optimise the treatment of the patients at an acceptable cost (NHMRC 1999). Moreover, the topic must answer to a public health concern, i.e. either in terms of the importance of the disease or in terms of the costs for the society. The judicious choice of topics will contribute to the interest of the physician for the guideline.

Some authors have already described desirable attributes of clinical guidelines (Lohr 1994, Grimshaw 1993), i.e.:

- ❖ Validity (based on the evidence, evaluation of health outcomes)
- ❖ Reliability/reproducibility (between experts and between GPs)
- ❖ Clinical applicability
- ❖ Clinical flexibility
- ❖ Clarity
- ❖ Multidisciplinary process
- ❖ Scheduled review
- ❖ Documentation

However, the literature about criteria for choosing topics is scarce. The current paper is based on two sources of information, e.g. a literature search and information collected from organisations which are known to produce guidelines. This second source of information was quite disappointing. Some organisations who publish guidelines often depend of authorities or other payers for the choice of the topic (e.g. ANAES, Canadian guidelines). The criteria used for the choice of their topics remain unclear. Other organisations have defined criteria for the selection of their topics (e.g. AETMIS (Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé), AHCPR (Agency for Health Care Policy and Research)).

The priority setting for guidelines' development should consider the following points (AETMIS 2001, AHCPR 1998, Baker 1997, Beaulieu 1999, Greenhalgh 2000, Grol 1993, Grol 1995, Grol 1998, NHMRC 1999, Shekelle 1999, Oxman 2006).

1. Relevance of the topic :

Developing guidelines is time and money consuming and the available means should be reserved primarily for the most relevant topics, namely the major causes of morbidity and mortality in the population. Relevant topics are important health problems as well as problems with a high incidence or prevalence. Since the guide-lines in this project are primarily meant to assist general practitioners, topics should be relevant in primary care.

- Important health problem :

Important problems are problems that lead to substantial (physical or psycho-social) morbidity or mortality. The more important the problem, the greater the possible gain as consequence of improvement of care.

- High incidence/prevalence :

A guideline will be of more use if it can be applied to more patients in the daily practice of the general practitioner. Upper respiratory infections are for example among the commonest reasons for encounter in primary care.

- Health problem is (or should be) mainly managed in primary care :

A guideline can only be beneficial to primary care if it concerns diagnostic procedures and/or treatments that are applicable in primary care. However, the guideline will include clear criteria for referring a patient to a specialist when needed.

2. Problem area

- Substantial practice variation

Practice variations have many sources, including health care system features (e.g. reimbursement system), differences in access to care and patient preferences. In particular, they reflect also an uncertainty regarding the most appropriate medical decision for a given medical problem. Antibiotics prescription in case of acute sore throat illustrates the large practice variations for the same condition. New guidelines will possibly render many old processes obsolete and propose new decision models based on the available evidence. The initial analysis of the problem should therefore also take account of the potential barriers of the general practitioners to use the best available evidence.

- Suboptimal outcome for patients

The problem should have a high prevalence/incidence in the population as explained above. Moreover, the current solutions (therapeutics, follow-up) applied to solve this problem should not lead to optimal results for the patient. A good example is the management of diabetic patients in any level of care. All physicians know that an appropriate follow up of the patient decreases the complication rate. However, this follow up is difficult to organise in daily practice. The guidelines developed on this topic are an instrument for daily practice to help the general practitioner to enhance the quality of care of his diabetic patients and therefore decrease undesirable outcomes.

- Under/over consumption (investigations, prescribing, referrals)

There is an increased interest in the evaluation and appropriate use medical services. It appears that patients who should benefit from services do not use them whereas other ones use them too frequently. An example is the use of mammography. Women outside the recommended age group have regular controls whereas a large proportion of 50-69 year-olds have never access to this screening procedure. Decisions based on guidelines should increase the judicious use of medical products/services and decrease the useless prescriptions.

3. Potential benefit

- Possibility for improving outcome

Data from the literature inform about the potential benefits for the patient. These benefits might relate to health indicators, morbidity or mortality data. However, other aspects are also worthy as the well-being, satisfaction or quality of life of the patient. An illustration is the control of pain in chronic patients. Better decision-making between general practitioner and patient will enhance the quality of care through better processes and outcomes.

- Possibility for cost saving (for patients, society)

Changes of practices following new guidelines lead to a more rational use of drugs and investigations. This consequence might involve greater costs for the society and the patient. The treatment of all patients eligible for statin treatment is an illustration. However, guidelines will generally lead to a more rationalised prescription with cost savings for the patient and for the society. The limited use of radiography in case of lower back pain is an example.

- Public Health benefit

Changes in practices might also be beneficial for public health as a whole. The case is obvious for antibiotics prescription where unrestricted use entails resistances and the need for larger spectrums in case of serious conditions. The optimal treatment of any communicable disease will be beneficial to the health of the whole community.

4. Feasibility

- availability of evidence of effective treatment on the topic :

Guidelines on effective treatment are preferable based on research evidence about the topic concerned. Inevitable, the recommendations of guidelines will always be an interpretation of available research evidence. However, guidelines must enable the user to distinguish recommendations based largely on evidence from those based largely on opinion. An explicit link between each recommendation and the justification for it is important for improving adherence of the users.

- potential for reaching consensus :

As mentioned above, current practice can show great variations and this often reflects uncertainty regarding the most appropriate medical decision for a given medical problem. In some cases this cannot be solved by the development of a guideline, because existing research evidence is contradictory, inconclusive or rapidly changing and expert opinions are too divergent. These topics should not be chosen as formulating clear univocal recommendations will not be possible.

- potential for effective implementation and evaluation

Grol et al. showed that guide-lines will be more easily implemented if they are compatible with existing values among the target group and are not too controversial. Neither should guide-lines demand too much change to existing routines. If compliance to a guideline affects too much the organisation of the practices, adherence is less. Although "difficult" guidelines (which demand drastic changes of current practice) should not be entirely avoided if the topic is sufficiently relevant, the likelihood of actual implementation is best also considered in the choice of a topic. Also, it should be taken into account if the actual care provided by general practitioners in the chosen health problem can be evaluated and in what way.

References

- AETMIS (Agence d'Evaluation des Technologies et des Modes d'Intervention en Santé) : http://www.aetmis.gouv.qc.ca/fr/01_manda/index.htm
- AHCPH (Agency for Health Care Policy and Research) : <http://www.ahcpr.gov>
- Baker R, Feder G. Clinical guidelines: where next? Int J Qual Health Care 1997;9:399-404.
- Beaulieu MD. Les guides de pratique clinique : valides et valables à quelles conditions ? Louvain Med 1999 ;118 :527-34.
- Greenhalgh T. Savoir lire un article médical pour décider. BMJ Editions Rand 2000.
- Grimshaw J, Russell I. Achieving Health Gain through clinical guidelines. I: developing scientifically valid guidelines. Qual Health Care 1993;2:243-248.

- Grol R. Development of guidelines for general practice care. *Br J Gen Pract* 1993;43:146-151.
- Grol R, Dalhuijsen J, Thomas S, in't Veld G, Rutten G, Mokkink H. Attributes of clinical guidelines that influence use of guidelines in general practice: observational study. *BMJ* 1998;317:858-861.
- Grol R, Thomas S, Roberts R. Development and implementation of guidelines for family practice: lessons from the Netherlands. *J Fam Pract* 1995;40:435-439.
- Hutchinson A, Baker R. Chap 1. What are clinical Practice guidelines? In: *Guidelines in clinical practice*. Radcliff Med Press, Oxford 1999:1-13.
- Lohr K. Guidelines for clinical practice: applications for primary care. *Int J Qual Health Care* 1994;6:17-25.
- NHMRC (National Health and Medical Research Council). *A guide to the development, implementation and evaluation of clinical practice guidelines*. Commonwealth of Australia; 1999.
- Shekelle P, Woolf S, Eccles M, Grimshaw J. Developing guidelines. *BMJ* 1999;318:593-596.
- Oxman AD, Schüneman HJ, Fretheim A. Improving the use of research evidence in guideline development: 2. priority setting. *Health Research Policy and Systems* 2006, 4:14-20.

METHODOLOGY LITERATURE SEARCH

DE NOVO GUIDELINES

1. From aim to clinical question(s)

To describe the **overall aim** of the guideline, one can use the “PIPOH” method (Burgers J, Guideline Adaptation: a New Approach to Guideline Development, G.I.N. conference Budapest 2006). PIPOH is short for :

- P: patient population / disease characteristics
- I: intervention(s) of interest
- P: professionals targeted by the guideline
- O: outcomes and endpoints to be taken into consideration
- H: healthcare setting and context

thereby offering a framework to clarify the overall aim.

The overall aim is often translated into specific **goals** and subsequently into practical **clinical questions**. These are to be formulated and agreed upon by a multidisciplinary group of authors. To define them, one can use –if and whenever appropriate- the PICO method (Van den Bruel et al., 2003). PICO is short for:

- P: population or patient
- I: intervention or indicator
- C: comparison or control
- O: outcomes

offering a framework to translate a certain problem or practical question into a manageable research question.

2. Search criteria

Based on the above proposed clinical questions, search criteria should be defined. Criteria might differ, depending on which source is being searching for evidence (guidelines or publications).

The 2 sets of criteria below (1 set for guidelines, 1 for publications) should be described explicitly and if applicable, appropriately stored for future use (e.g. search re-runs in view of an updating or reviewing process).

These sets of criteria are to be seen as the minimal data set to be discussed and agreed upon by the group of authors before a literature search can commence. This also implies that the below listed criteria are not limited: if required, additional criteria may be added.

2.1. Criteria for guidelines

1. Guideline finders

The following sources should be searched (well known and major guideline finders):

- G.I.N. guideline resources: www.g-i-n.net

- NEHL guidelinefinder: <http://www.library.nhs.uk/guidelinesFinder/>
- National Guideline Clearinghouse: www.guideline.gov

... as combining the results of these 3 guideline finders yields a very high percentage of all online available international guidelines.

Other sources can be searched in the presence of an (argued) indication of the multidisciplinary group of authors. The reason why should always be documented.

2. Entries

The goals and clinical questions normally already contain the most relevant search terms. A first screening of the guideline(s) found based on these terms, also often yields relevant entry terms. Additional search terms can also be looked up in the MeSH- medical subject heading- database: typing in one of the search terms in the MeSH search engine will produce a list of possible and/or related terms.

The multidisciplinary group of authors is responsible for the approval of the final list of search terms. If necessary or appropriate, they will report on the terms that are excluded from the final list, also stating the reason why they were not included.

When listing terms, attention should be paid to possible synonyms and translations.

Resulting list of search terms:

| |
|-----------|
| Entry 1 |
| Entry 2 |
| Entry 3 |
| Entry ... |

3. Time span

- Most available guidelines are being updated within 5 years. Therefore guidelines will be searched for within the time span of the last 5 years, unless explicitly stated otherwise by the group of authors.
- The date of the last search performed, the so-called end date, should be explicitly reported.

4. Languages

Unless explicitly stated otherwise by the multidisciplinary group of authors, searches will be restricted to the languages mastered by at least one of the authors.
Standard:

- Dutch
- English
- French
- German

5. Population

Description of the patient population under study, e.g. human, age, sex, ...

6. Setting / context of the health care system (WHO reference, Llevel)

- Preferably search within settings / contexts of health care systems closely related to the Belgian health care system
- Depending on the question(s) at hand, exceptions can be allowed (but explicitly state why)

Criteria for publications

1. Sources

The multidisciplinary group of authors will decide upon which databases will be searched (preferably at least 2). If less / more databases need to be searched, the group will explicitly report which and if required also why.

As most databases contain their own search strategy or engine, whenever appropriate these will be used (described in short if necessary).

The criteria described below should thereby always be taken into account.

Possible databases (list not limited):

1.1 Clinical Evidence

1.2 For systematic reviews and meta-analyses

1.2.1 Main sources

- Cochrane Database of Systematic Reviews
- Medion
- Medline
- Embase
- Other databases as appropriate (report)

1.2.2 Additional sources

- Centre for Reviews and Dissemination (CRD) website
- Database of Abstracts of Reviews of Effects (DARE) online database
- Health Technology Assessment (HTA) online database : databases: may be useful to analyse the utility of a treatment of diagnostic techniques via the CRD database
<http://www.york.ac.uk/inst/crd/crddatabases.htm> which gives access to the NHS Economic Evaluation Database (NHS EED) and the Health Technology Assessment (HTA) Database or the Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
<http://www.cadth.ca>

1.3 For research articles

- Medline
- Embase more European and non-Anglo-Saxon articles; more about pharmacotherapy, psychiatry
- Cochrane Central Register of Controlled Trials
- Other databases as appropriate, e.g.:
 - PsychINFO: psychological aspects
 - CINAHL: nursing and paramedical professions
 - Pedro : physiotherapy
 - International Pharmaceutical Abstracts : drugs

- International Society of Drug Bulletins (Revue Prescrire, Drug and Therapeutics Bulletin, Geneesmiddelen Bulletin, etc...)

For areas where there are few or no good systematic reviews or randomised controlled trials, the search may be extended towards observational studies (recommended databases: Medline and Embase databases). This also applies when it is necessary to retrieve studies on adverse effects.

2. Entries

The goals and clinical questions normally already contain the most relevant search terms. Depending on the databases consulted, these terms have to be “translated” into the appropriate entries used by the particular database(s). The latter often contain proper search methods to define these term (e.g. the MeSH database).

When listing terms, attention should be paid to possible synonyms and translations.

Resulting list:

| |
|-----------|
| Entry a |
| Entry b |
| Entry c |
| Entry ... |

3. Time span

- Define the time span within which will be searched for publications.
- The date of the last search performed, the so-called end date, should be explicitly reported.

4. Language

Unless explicitly stated otherwise by the multidisciplinary group of authors, searches will be restricted to the languages mastered by at least one of the authors

Standard:

- Dutch
- English
- French
- German

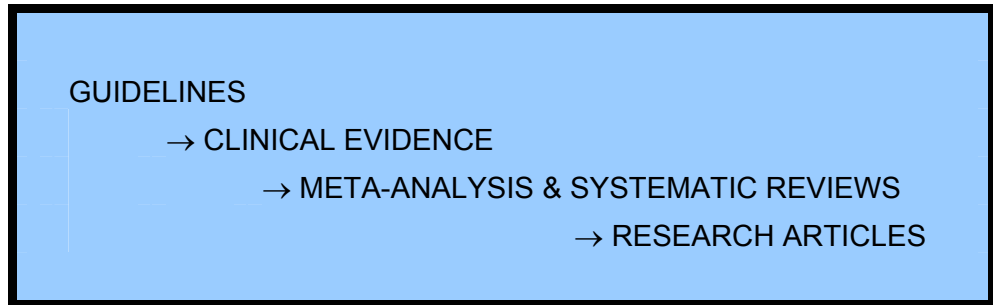
5. Population

Description of the patient population under study, e.g. human, age, sex, ...

6. Setting / context of the health care system

- Preferably search within settings / contexts of health care systems closely related to the Belgian health care system
- Depending on the question(s) at hand, deviations can be allowed (but explicitly stated why)

3. Search strategy (step-by-step approach)



3.1. Strategy for guidelines

1. Guideline search according to the above defined criteria
2. Inventarisation of the found guidelines
 - E.g. in an excel file, with the following structure
 - # GL: autonumbering guidelines
 - GL name: specific name guideline
 - GL origin: guideline developers (scientific organisation, government, industry... +/- name)
 - Country: country of guideline origin / country where GL applies; use ISO 3166 country codes: <http://www.iso.org/iso/en/prods-services/iso3166ma/>
 - GL-publi: most recent date of publication
 - GL-language: published in which language
 - GL-www: direct link to website
 - GL-remarks: e.g. first publication year (original guideline), publication status
3. Screening / selection method
 - a. **STEP 1: Reassess** if the found guidelines indeed answer to the above pre-defined criteria.
 - i. If the title / summary indicates that a guideline definitely does not match one of the above criteria it is excluded.
 - ii. When in doubt and/or unable to definitely exclude a guideline using the information in the title / summary, it is included.
 - b. **STEP 2: Does the guideline, based on title and/or summary, potentially answers (a part of) the proposed clinical questions?**
 - i. Three investigators will independently assess this, by scoring yes (+) or no (-). If no (-), the reason why should be documented.
 - ii. Guidelines that score (+) at least twice, should be kept for further assessment.

4. Critical appraisal

a. STEP 1: Quality

To evaluate the methodological quality of the above selected guidelines the AGREE instrument will be used. (ref)
With this instrument 6 different domains are scored independently.

- **Scope and purpose** (items 1-3): concerned with the overall aim of the guideline, the specific clinical questions and the target patient population.
- **Stakeholder involvement** (items 4-7): the extent to which the guideline represents the views of its intended users.
- **Rigour of development** (items 8-14): the process used to gather and synthesise the evidence, the methods to formulate the recommendations and to update them.
- **Clarity and presentation** (items 15-18): the language and format of the guideline.
- **Applicability** (items 19-21): the likely organisational, behavioural and costs implications of applying the guideline.
- **Editorial independence** (items 22-23): the independence of the recommendations and acknowledgement of possible conflict of interest from the guideline development group.

Three investigators will independently score the different domains for each selected guideline. These scores will be discussed after which final scores will be assigned (consensus).

The most qualitative guidelines will be kept (after consensus agreement within the group of authors).
The group of authors can thereby or therefore decide to attach more/less value to certain AGREE domains.
If required, the reason why for the latter should be stated explicitly.

b. STEP 2: Content

From the selected qualitative guidelines a matrix with recommendations from these guidelines should be made.

Whenever available, the level of evidence (LeO) from each recommendation should be recorded as well.
The description of the (different) LeO system(s) used in the selected guidelines should be documented (but not necessarily in the draft of the guideline).

Example of a matrix of recommendations.

| Clinical question | Guideline 1 | | Guideline 2 | | Guideline 3 | | Guideline ... | |
|-------------------|---------------|------------|---------------|------------|---------------|------------|---------------|-----|
| | Recomm. | LoE | Recomm. | LoE | Recomm. | LoE | Recomm. | LoE |
| Question 1 | Recomm 1.1 | LoE 1.1 | Recomm 1.2 | LoE 1.2 | Recomm 1.3 | LoE 1.3 | | |

| | | | | | | | | |
|--------------|---------------|------------|---------------|------------|-------------------|----------------|------------------|---------------|
| Question 2 | | | Recomm 2.2 | LoE 2.2 | | | | |
| Question 3 | Recomm 3.1 | LoE 3.1 | | | | | Recomm 3. ... | LoE 3. ... |
| Question ... | | | | | Recomm 3 | LoE 3 | | |

STOP

ASSESS the MATRIX with RECOMMENDATIONS
“Is there a guideline that answers all the clinical questions asked?”

YES → Follow the final adaptation step below

NO → Is there one (or more) guideline(s) answering **some** of the clinical questions asked?

YES → Follow the final adaptation step below for these clinical questions
+ continue with the following search strategy for the remaining questions

NO → Continue with the following search strategy (= de novo development)

5. Final adaptation step

- Literature update.
Whenever required, an additional search should be performed for relevant publications published **after** the publication of the guideline where the recommendation is taken from and **before** the date of the last search performed for this guideline-in-development.
 - Follow the methodology as described in this document
 - If present,
 - consider the new evidence together with the existing evidence of the recommendation and agree, based on consensus within the group of authors, whether or not the original assigned level of evidence for that recommendation should be changed
 - or newly assign a GRADE level (based on consensus) if no LoE was present.
- Levels for quality of evidence.
 - To allow a uniform system to be used, the different levels of

evidence (LoE) of the above recommendations should be “translated” into the appropriate levels for quality of evidence of the GRADE system (adapted according to (authors Chest article; (<http://www.gradeworkinggroup.org/index.htm>))), resulting in either a HIGH, MODERATE or (very) LOW level of quality of evidence per recommendation.

- If no LoE was/were present, assign a GRADE level (based on consensus).

Example of recommendations with translated LoE’s.

| Clinical question | Guideline 1 | | |
|-----------------------|-------------|---------|-------|
| | Recomm. | LoE | GRADE |
| Question 1 | Recomm 1.1 | LoE 1.1 | HIGH |
| Question 2 | | | |
| Question 3 | Recomm 3.1 | LoE 3.1 | LOW |

- Strength of a recommendation.
In order to assign the strength of a recommendation according to the GRADE system, resulting in a WEAK or a STRONG recommendation, some considerations should be made and/or answered before consenting on the strength of each of the recommendations:
 - Availability of the necessary expertise
 - Capability to overcome organisational barriers, if presenting
 - Necessary conditions to be met
 - Economical considerations
 - ≠ health economical analysis
 - = advantages / disadvantages / possible costs / ...
 - Ability to extrapolate the recommendation to the population under study, if necessary

Example of completely GRADE’d recommendations.

| Clinical question | Guideline 1 | | | |
|-----------------------|-------------|---------|-----------------------------|------------------------|
| | Recomm. | LoE | GRADE | |
| | | | (final) Quality of Evidence | Strength of Recommend. |
| Question 1 | Recomm 1.1 | LoE 1.1 | HIGH | WEAK |
| Question 2 | | | | |
| Question 3 | Recomm 3.1 | LoE 3.1 | LOW | STRONG |

3.2. Strategy for Clinical Evidence

1. Search the Clinical Evidence database according to the above defined criteria
2. Inventarisation
3. Screening / selection
 - a. **STEP 1: Reassess** if the found evidence indeed answer to the above pre-defined criteria.
 - i. If the title / summary indicates that the evidence definitely does not match one of the above criteria it is excluded.
 - ii. When in doubt and/or unable to definitely exclude evidence using the information in the title / summary, it is included.
 - b. **STEP 2: Does the evidence, based on title and/or summary, potentially answers (a part of) the proposed clinical questions?**
 - i. Three investigators will independently assess this, by scoring yes (+) or no (-). If no (-), the reason should will be documented.
 - ii. Evidence that scores (+) at least twice, should be kept for further assessment.
4. Critical appraisal
 - a. The method by which the topics in the Clinical Evidence database have been assessed and appraised, is extensively described on the Clinical Evidence website (www.clinicalevidence.org: "How *BMJ Clinical Evidence* is put together"). As this method closely relates to the own methodology, the group of authors
 - i. decided to adopt this method, implying that no additional critical appraisal will be done for the selected clinical evidence topics
 - ii. unless specifically stated otherwise by the authors (with documentation of the reason why).
 - b. From the selected clinical evidence topics, a matrix with keymessages answering the above (remaining, unanswered) clinical questions should be made.

STOP

ASSESS the MATRIX with KEYMESSAGES from Clinical Evidence

"Have all the proposed clinical questions been answered?"

YES → Follow the final adaptation step below

NO → Continue with the following search strategy (= de novo development)

5. Final adaptation step

- Literature update.
Whenever required, an additional search should be performed for relevant publications published **after** the publication of the clinical evidence topic where the keymessage is taken from and **before** the date of the last search performed for this guideline-in-development.
 - Follow the methodology as described within this document
 - If present,
 - consider the new evidence together with the existing evidence of the keymessage and agree, based on consensus within the group of authors, whether or not the original assigned level of evidence for that keymessage should be changed
 - or newly assign a GRADE level (based on consensus) if no LoE was present.

- Levels for quality of evidence.
 - If necessary “translate” the original LoE into the appropriate levels for quality of evidence of the GRADE system, resulting in either a HIGH, MODERATE or (very) LOW level of quality of evidence per recommendation
 - If no LoE was/were present, assign a GRADE level (based on consensus).

- Strength of a recommendation.
In order to assign the strength of a recommendation according to the GRADE system, resulting in a WEAK or a STRONG recommendation, some considerations should be made and/or answered before consenting on the strength of each of the keymessages:
 - Availability of the necessary expertise
 - Capability to overcome organisational barriers, if presenting
 - Necessary conditions to be met
 - Economical considerations
 - ≠ health economical analysis
 - = advantages / disadvantages / possible costs / ...
 - Ability to extrapolate the keymessage to the population under study, if necessary

3.3. Strategy for Meta-analyses & Systematic Reviews

1. Search according to the above defined criteria
2. Inventarisation
Use e.g. Endnote library or RefMan
3. Screening / selection
 - a. **STEP 1: Reassess** if the found publications indeed answer to the above pre-defined criteria.
 - i. If the title / summary indicates that a publication definitely does not match one of the above criteria it is excluded.

- ii. When in doubt and/or unable to definitely exclude a publication using the information in the title / summary, it is included.
 - b. **STEP 2: Does the publication, based on title and/or summary, potentially answers (a part of) the proposed clinical questions?**
 - i. Three investigators will independently assess this, by scoring yes (+) or no (-). If no (-), the reason why should be documented.
 - ii. Publications that score (+) at least twice, should be kept for further assessment.
4. Critical appraisal

To further assess the selected publications the appropriate Cochrane checklists (available at <http://www.cochrane.nl/index.html>) should be used .

5. Summary of findings: evidence table(s)
 - a. Evidence tables should be constructed based on the above Cochrane checklists or –if accessible– by using the GRADE Working Group software (<http://www.gradeworkinggroup.org/index.htm>)
 - b. Next step:
 - i. Categorize the conclusions per clinical question answered
 - ii. Record the different levels of evidence (LoE) of these conclusions / recommendations (if present)

STOP

ASSESS the EVIDENCE TABLE(s) of the MA & SR

“Have all the proposed clinical questions been answered?”

YES → Follow the final adaptation step below

NO → Continue with the following search strategy
(= complete de novo development)

6. Final adaptation step
 - Literature update.
Whenever required, an additional search should be performed for relevant publications published **after** the publication of the meta-analysis / systematic review where the recommendation is taken from and **before** the date of the last search performed for this guideline-in-development.
 - Follow the methodology as described within this document

- If present,
 - consider the new evidence together with the existing evidence of the recommendation and agree, based on consensus within the group of authors, whether or not the original assigned level of evidence for that recommendation should be changed
 - or newly assign a GRADE level (based on consensus) if no LoE was present.
- Levels for quality of evidence.
 - If necessary “translate” the original LoE into the appropriate levels for quality of evidence of the GRADE system, resulting in either a HIGH, MODERATE or (very) LOW level of quality of evidence per recommendation
 - If no LoE was/were present, assign a GRADE level (based on consensus).
- Strength of a recommendation.

In order to assign the strength of a recommendation according to the GRADE system, resulting in a WEAK or a STRONG recommendation, some considerations should be made and/or answered before consenting on the strength of each of the recommendations:

 - Availability of the necessary expertise
 - Capability to overcome organisational barriers, if presenting
 - Necessary conditions to be met
 - Economical considerations
 - ≠ health economical analysis
 - = advantages / disadvantages / possible costs / ...
 - Ability to extrapolate the recommendation to the population under study, if necessary

3.4. Strategy for Research articles

1. Search according to the above defined criteria
2. Inventarisation
 - Use e.g. Endnote library / RefMan
3. Screening / selection
 - a. Does the evidence, based on title and/or content, potentially answers (a part of) the proposed clinical questions?
 - b. Three investigators will independently assess this, by scoring yes (+) or no (-). If no (-), the reason why will be documented.
 - c. Evidence that scores (+) at least twice, will be kept for further assessment.
4. Critical appraisal

To further assess the selected publications the appropriate Cochrane checklists (available at <http://www.cochrane.nl/index.html>) should be used .

5. Summary of findings: evidence table(s)

- a. Evidence tables should be constructed based on the above Cochrane checklists or –if accessible– by using the GRADE Working Group software (<http://www.gradeworkinggroup.org/index.htm>)
- b. Next step:
 1. Categorize the conclusions per clinical question answered
 2. Formulate recommendations

6. Final adaptation step

- a. Levels for quality of evidence.

Assign an appropriate level per recommendation according to the GRADE system (HIGH, MODERATE or (very) LOW level of evidence per recommendation), based on consensus by the group of authors.
- b. Strength of a recommendation.

In order to assign the strength of a recommendation according to the GRADE system, resulting in a WEAK or a STRONG recommendation, some considerations should be made and/or answered before consenting on the strength of each of the recommendations:

 - Availability of the necessary expertise
 - Capability to overcome organisational barriers, if presenting
 - Necessary conditions to be met
 - Economical considerations
 - ≠ health economical analysis
 - = advantages / disadvantages / possible costs / ...
 - Ability to extrapolate the recommendation to the population under study, if necessary

UPDATING of GUIDELINES

Process

- Updating should be performed yearly, unless otherwise stated by the authors
- The above described methodology for literature search (search criteria and strategy) should be followed.
 - BEWARE: Time span of the update literature search: one year after the end date of the literature search of the previous version / update and the start of the new update.

REVIEWING of GUIDELINES

Process

- Reviewing should be performed every 3 – 5 years, unless otherwise stated by the authors
- Reviewing includes the critical assessment of the goals and clinical questions, if necessary these should be adjusted and/ or relevant topics should be added
- The above described methodology for literature search (search criteria and strategy) should be followed.
 - BEWARE: Time span of the review literature search: between the end date of the literature search of the previous publication of the guideline and the start of the review.

REFERENCES

- Burgers J, Guideline Adaptation: a New Approach to Guideline Development, G.I.N. conference Budapest 2006)
- Grading Strength of Recommendations and Quality of Evidence in Clinical Guidelines. Report from an American College of Chest Physicians Task Force. Chest 2006; 129: 174-181
- Van den Bruel A, Chevalier P, Vermeire E, Aertgeerts B, Buntinx F. EBM : otitis media in children : how to formulate a PICO question. Huisarts Nu 2003; 32(7): 331-35).
- Van den Bruel A, Chevalier P, Vermeire E, Aertgeerts B, Buntinx F. EBM : otitis media in children : how to formulate a PICO question. Rev Med Liège 2004; 59: 671-5

- AANVULLEN / AANPASSEN