EAUN Guidelines Manual

V. Geng , H. Lurvink, K. Plass, S. Vahr

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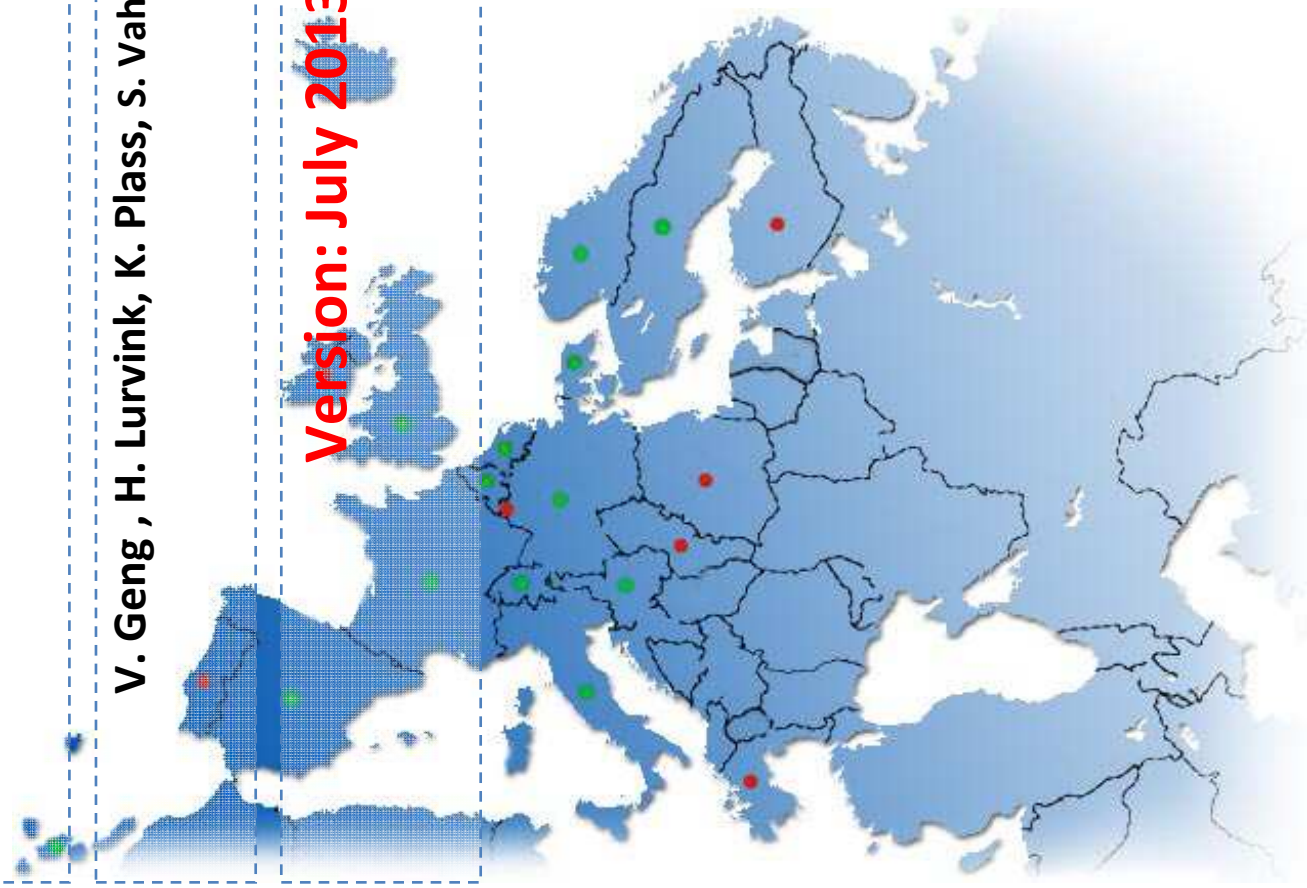

European Association of Urology Nurses
www.eaun.uroweb.org
eaun@uroweb.org
+31 26 38 90 680

"Knowing is not enough; we must apply.
Willing is not enough; we must do."

Goethe

European
Association
of Urology
Nurses

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1. Introduction

1.1 History

The European Association of Urology Nurses (EAUN) declared their aim to produce guidelines for the field of urology nurses in 2004. The first guideline was published in 2005 – Good Practice in Health Care – Urethral Catheterization – male. Since then every year a new guideline was produced. The guidelines are guidelines for nurses but the guidelines in 2011 are guidelines for health care professionals. In 2009 the decision was made that future guidelines should be evidence-based. So the name of the series changed from Good Practice in Health Care to Evidence-based Guidelines for Best Practice in Urological Health Care.

1.2 Clinical guidelines development

The aim of nursing guidelines is to help nurses and health care professionals to make informed decisions about their patients, keeping in mind that guidelines present data that generalise and may not be applicable to individual patient situations. Guidelines are not intended to supersede professional judgment, and adherence to a guideline does not guarantee outcome. Ultimately, healthcare professionals must make their own decisions about care on a case-by-case basis, using their clinical judgement, knowledge and expertise, and after consultation with their patients. Guidelines translate best evidence into practice, aiming to promote quality healthcare and discourage potentially harmful or ineffective interventions.

Clinical practice guidelines are statements that include recommendations intended to optimise patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. To be trustworthy, guidelines should

- be based on a systematic review of the existing evidence;
- be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups;
- consider important patient subgroups and patient preferences, as appropriate;
- be based on an explicit and transparent process that minimises distortions, biases, and conflicts of interest;
- provide a clear explanation of the logical relationships between alternative care options and health outcomes;
- provide ratings of both the quality of evidence and the strength of the recommendations; and
- be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations (National Academy of Sciences)

1.3 How to use this manual

The aim of this document is to describe the guidelines production process and clarify what may be the roles and expectations of all those involved in this process, and provide a basic explanation of the production process. It should be a practical resource promoting a systematic approach to guidelines development. When this manual is used for the production

on a guideline the Agree II standards will be followed. Also the guideline will meet the NGC inclusion criteria dated June 2013 (see appendix 5).

1.4 Updating of this manual

This publication will be subject to continuous revision and should be considered an evolving project. We welcome comments on its content, which can be directed to:
EAUN coordination: eaun@uroweb.org

2. Roles and responsibilities of all involved in the production of EAUN Guidelines

2.1. Responsibility in the EAUN Board for Guidelines

The board of the EAUN appoints one or more board members who are responsible for the guidelines development within in the EAUN Board. That means, that this (these) person(s) should be involved in the process and they should monitor the process of development of the evidence-based guidelines and adjust if necessary.
The EAUN Board decides which topics are chosen for future guidelines. The Special Interest Groups (SIG) can give input into this process.

Patient involvement in the guideline
The views and preferences of the target population (patients, public, etc.) will be sought, but depending on the target user of a particular guideline they may be involved in de guidelines working group or in the reviewer group. (Agree II)

2.2 Chair, Vice-Chair and guideline group members

2.2.1 Chair of a guideline group

The Board of the EAUN decides who should be the Chair of the guideline group. Initial selection is based on proven excellence in writing evidence-based guidelines, experience in the field of the guideline, as well as organisational and leadership skills. Taking on this position involves a substantial commitment of time.

2.2.2 Vice-Chair

The guideline group Chair, together with the guideline group members, can propose a Vice-Chair. The EAUN board ratifies this appointment.

A Vice-Chair is appointed to:

1. Assist the Chair with all his/her tasks
2. To replace the Chair in case of sickness
3. Facilitate ongoing leadership development and succession planning
4. Vice-Chair could be a chance to promote persons for further chair activity

2.2.3 Guideline group members

Nurse specialists, nurse scientists, urologists, and other stakeholders

The EAUN Board, as well as partner organisations such as national urology nurses societies (when applicable), individual members and office staff can propose potential panel members.

Guideline group members are selected first and foremost based on their scientific and clinical expertise, and their willingness to invest considerable time and effort in the production of clinical guidelines.

They are selected by the chair and the responsible board member(s) from members who applied via the application form after a call for application, the membership database and that were proposed by the above mentioned parties. Selection is not definite until the COI is evaluated.

No strict rules apply for the total number of panel members involved in the production of a single guideline. For narrower focus topics, a minimum number of five expert panel members seems reasonable, so that a balanced input can be maintained. To work with more than 9 people would be difficult. If there is a large interest in working in a guideline group for a specific topic it could be an alternative to send the people who are not involved in the writing process the draft for a review.

An additional consideration is that a representative geographical distribution should be maintained. EAUN Guidelines are European guidelines and presenting a well-balanced coverage of the topic discussed is a crucial quality parameter. Appropriate international representation also has a significant impact on implementation and acceptance. However, expertise takes precedence over geography.

Guideline group members do not need to be nurse specialists. For each subject area, decisions are made on a case-by-case basis as to which expertise is needed to address a given topic most effectively. All relevant specialties, other than urology, should be considered in this process.

Guideline group participation, for which no financial compensation is provided, involves a significant commitment and investment of time. The result of the work done by the expert panels is well-received by the members of the organisation, and most guideline group members consider their participation in the EAUN guidelines rewarding.

All Guideline group members are required to submit potential *Conflict of Interest* (COI) information. A policy of confidentiality regarding any guideline document or guideline group discussion applies until final publication of all documents. All guideline group members should be members of the EAUN or EAU.

The guideline development group includes individuals from all relevant professional groups. (Agree II)

2.3 Roles and responsibilities

2.3.1 Responsible Guideline Person from the EAUN Board

Roles and responsibilities:

1. Guide, support and facilitate all aspects relating to guidelines development (e.g., methodology, implementation and promotion)
2. Promote quality improvement
3. Set future goals and establish priorities for the strategic development of the guidelines project
4. Overall responsibility for the appraisal of potential Conflicts of Interest information provided by all those involved in the production of EAUN guidelines.
5. The Responsible guideline person from the EAUN Board may seek external specialist support when needed.

2.3.2 Chair of the guideline group / Vice-Chair

Role and responsibilities:

1. Overall responsibility for the guidelines manuscript
2. Decide, together with the experts, when to update (please consult section 9.3 on literature handling for updates)
3. Maintain overview of project and provide the primary direction for the work of the group
4. Adhere and implement the agreed-upon production methodology (responsible for the evidence base and literature identification)
5. Draft the scope of the guideline to define exactly what will and will not be covered and refine scope after consultation
6. Data handling (e.g., extraction and production of overviews/charts, and update reviews)
7. Maintain effective communication with guideline group members, EAUN board and office staff
8. Oversee and monitor the production process, time lines and quality and, together with office staff, decide on timing of meetings
9. Make sure that all meeting and deadline dates are in principle set before the first meeting takes place.
10. Chair meetings and ensure that agendas are completed
11. Approve and sign off minutes resulting from meetings
12. Liaise with other guideline groups and external advisors
13. Set an example by completing all assigned work on time
14. Maintain confidentiality
15. Interface with media and assist by assessing press releases
16. Try to get support (Sponsors) for developing guidelines in coordination with the EAUN office and financial support for the EAUN

The Vice-Chair, or in a guideline group where no Vice-Chair has been appointed, a guideline group member, can assist the Chair and/or represent the guideline group at meetings in case the Chair is not available.

2.3.3 Guideline group members

Roles and responsibilities:

1. Effectively communicate with the Chair and office staff (respond to emails in a timely fashion)
2. Participate in meetings and conference calls

3. Follow instructions by Chair and adhere to the time lines set
4. Actively collaborate and perform the tasks assigned (e.g., contribute constructively to discussion at meetings, evidence acquisition, grading articles, drafting recommendations, and reviewing the manuscript)
5. Make themselves available within a reasonable time frame for meetings and video-conferences
6. Write the assigned part of the guidelines text within the set timeline and within the set topics
7. Maintain confidentiality
8. Assist with all tasks as determined by the Chair/Vice-Chair
9. Address competing interests of guideline development group members in the meetings (and make sure they are recorded in the minutes if deemed necessary)
10. The guideline group are to provide timely comments to the reviewers
11. Guideline group members can only publish articles about the guideline after the official publication by the EAUN and after approval by the Chair of the guidelines group. The central office should always receive a copy on submission

2.3.4 Patients

Roles and responsibilities:

1. Have relevant experience of the condition and the issues that matter to people with that condition
2. Have the willingness to reflect the experiences of a wide group of people with a condition relevant to the guideline topic through patient organisations or self-help groups and to share this knowledge with the guideline group
3. Have the time and commitment to attend the meetings
4. Actively collaborate and perform the tasks assigned (e.g., contribute constructively to discussion at meetings, do background reading and reviewing the manuscript, but not judging literature or making recommendations)
5. Maintain confidentiality

2.3.5 EAUN Coordinator / Office staff

Roles and responsibilities:

1. Invite members to apply for a new guideline topic
2. Send application forms and COI invitations to interested persons
3. Make COI information available for the Chair and EAUN Board member for appraisal
4. Inform accepted and rejected candidates
5. Request Guideline group members to sign a copyright transfer agreement (see Appendix 6) and a non-disclosure statement (see Appendix 7) at the first meeting.
6. Coordinate all organisational aspects (meetings, conference calls, agendas, reports, create letters for sponsoring companies, traditional and electronic delivery of manuscripts and files, update schedules and finance overviews, and review and scientific paper submission)
7. Liaise with Marketing & Sales department EAU, the EAUN Board member responsible for sponsoring and the Chair of the guidelines group on educational grants
8. Time line management (overview of the various projects)
9. Assistance with reference management (coordinate literature searches, and liaise with research specialist)
10. Interact with other organisations: e.g., guidelines producers, national associations, members, journals, and companies

11. Attend meetings
12. Liaise with guideline groups
13. Contribute to the editing of guideline documents, liaise with medical writers
14. Maintain standardised format for guidelines
15. Management of the document share system (Claromentis)
16. Support the technical needs of the guideline group members
17. Check on issues such as illustration quality, source, courtesy, copyright and licenses
18. Create flowcharts, diagrams and care plans in various formats
19. Coordinate typesetting, printing and shipping process
20. Coordinate in-office activities related to the guidelines efforts (e.g., media, IT and web-based versions)
21. Special project management (e.g., annual meeting activities, and post-congress logistics)
22. Promotion of guideline by distributing it amongst authors, reviewers, sponsors, EAU executive, members, delegates, journals
23. Maintain confidentiality
24. EAUN Coordinator is responsible for all logistics linked to review

3. Declaration of potential COI (see Appendix 5)

All those involved in EAUN scientific activities are obligated to disclose potential COI information. This can be done online through the society website (www.uroweb.org). The EAUN office staff are responsible for the appraisal of all potential COI information. Initial assessment of COI information provided by guideline group members is the responsibility of the guideline group chair. For scientific publications, this COI information is provided to the publisher

4. Independency of the content

The views of the funding bodies have not influenced the content of the guideline. (Agree II)

5. Copyright

The EAUN holds the copyright for all EAUN guidelines. The EAUN allows free once-only re-publication by national urological societies. Commercial re-publication is not allowed. For more information on copyright and usage restrictions, see: http://www.uroweb.org/fileadmin/user_upload/EAUN/EAUN_Guidelines/Guidelines_for_translations_of_EAUN.doc.pdf

6. Guidelines production process

It is important for all involved to have a clear understanding of why and how the guidelines are produced. The purpose of clinical guidelines is to enhance clinical decision making, therefore, the emphasis is on the development of recommendations. The inclusion of levels of

evidence and grades of recommendation aims to provide transparency between the underlying evidence and the recommendations made, so that nurses can assess how much confidence he/she can place in such a recommendation.

6.1 Definition of the subject (disease/condition/procedure)

The content of a guideline should be explicit from its title. However, any limitations should be stated and, if necessary, explained.

An introductory section should explain the purpose and scope of the guideline as well as the methodology used. The chair could get some assistance in providing this information from the EAUN office. A list of standard requirements is available (see Appendix 4).

1. The overall objective(s) of the guideline is (are) specifically described.
2. The health question(s) covered by the guideline is (are) specifically described.
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.
4. Cost-effectiveness in studies across Europe are not comparable and will not be addressed in the guideline.

(From: Agree II)

6.2 List the sub-topics to be included

These usually form the subheadings (chapters) of the guideline. The exact outline is dependent on the guideline subject. A general outline may be:

1. Introduction
2. Role of the nurse
3. Methodology
4. Terminology / definitions
5. Principles of Management
6. Indication / contraindication including epidemiology and complications (short- and long-term).
7. Clinical assessment
8. Interventions
9. Patient Information / education
10. Documentation
11. If relevant: quality of life
12. Research and future directions: this may be a discussion section, or a list of recommendations for future research based on gaps in the existing literature, identified during the guidelines production process.
13. For every section throughout the document, the target population will be clearly identifiable. Also, care is taken that the conclusion and recommendation sections are entirely unambiguous in this respect.
14. Appendices with checklists, procedures, flowcharts, forms, product examples
15. Abbreviations
16. About the authors
17. Reference lists (figures and articles)

A care pathway exercise can be helpful in defining the scope of the guidelines. Basic information on this process is available.

6.3 Methodology

1. Systematic methods were used to search for evidence.
2. The criteria for selecting the evidence are clearly described.
3. The strengths and limitations of the body of evidence are clearly described.
4. The methods for formulating the recommendations are clearly described.
5. The health benefits, side effects, and risks have been considered in formulating the recommendations.
6. There is an explicit link between the recommendations and the supporting evidence.

(From: Agree II)

Requirements – limitations and considerations:

1. Searches focus on English language papers (original or translated) from peer-reviewed journals. (If guideline group members speak French or Spanish well these languages are also relevant)
2. Main databases to consult are:
   MedLine (PubMed)
   Embase
   CINAHL and the
   Cochrane library of randomised controlled trials (RCTs).
   Google Scholar to verify the search
3. Searches are built based on clinical questions (e.g. PICO), care pathways and keywords and Mesh terms (Appendix 2).
4. The use of abstract-only publications as references is discouraged.
   Graded recommendations cannot be supported by abstracts only, although abstracts can be part of the supporting body of text (alongside higher level evidence).
5. Identification of all available level 1 papers (RCTs and meta-analyses of RCTs) is required.
6. For RCTs and other high-level papers, rejection/inclusion criteria are to be recorded.
7. When sufficient level 1 papers are found to answer the clinical questions, no lower-level publications need to be looked for.
8. It is unlikely that point 7 will be fulfilled for a considerable portion of the topics discussed within the EAUN Guidelines; therefore, lower-level evidence will need to be identified.
9. The choice of literature is guided by the expertise and knowledge of the Guidelines Chair and Guidelines Board member.
10. Guideline Chairs can contract the expertise of a research librarian from their own or an institution or a guideline group member if this is helpful. The EAUN will reimburse any costs following prior discussion and approval.

11. Search strategies should be included in the guidelines (as an addendum/or on line). When searches have been carried out by a research scientist, he/she will make those available for this purpose. All search histories are retained on file as the basis for future updates. Also, in cases where support from local information scientists has been contracted, or searches have been carried out by guideline group members, search information should be made available.
    Search information should include: databases consulted, time periods, key words, subject headings, any restrictions (e.g., patient groups and sex), number of papers identified, filters, algorithms and inclusion/exclusion criteria.
12. It should be clear that search strategies for completely new topics may be very complex and need to address all clinical questions covered by the guideline topic.
13. Search strategies available through other guidelines producers or other scientific organisations may be helpful (e.g., Cochrane, NICE, etc.).
14. Cost assessments: Formal cost assessments, considering the geographical area covered by the EAUN Guidelines, are currently beyond the means of the EAUN. Where information exists, it should be included in the guidelines documents. Where two treatment modalities of similar efficacy exist, but costs differ, this can be pointed out.

PICO: The Four-Part Clinical Question

Directly relevant to the care of the patient and our knowledge deficit.

Contains the following elements:

- PATIENT or PROBLEM being addressed
- INTERVENTION or exposure being considered
- COMPARISON intervention or exposure, when relevant
- OUTCOME of (patient important) interest.

A structured and unbiased literature search, based on key words and PICO's aiming to identify the best evidence available, is a crucial step in the production process. A research scientist is available to assist in identifying relevant literature.

Background information
For general or background information, check out useful URLs, general information online, almanacs or encyclopaedias online such as Britannica, or Encarta, etc. Use Search Engines and other search tools as a starting point.
Pay attention to domain name extensions, e.g., .edu (educational institution), .gov (government), or .org (non-profit organisation). These sites represent institutions and tend to be more reliable, but be watchful of possible political bias in some government sites. Be selective of .com (commercial) sites. Many .com sites are excellent; however, a large number of them contain advertisements for products and nothing else. Be wary of the millions of personal home pages on the Net. The quality of these personal homepages vary greatly.

Printed material
Depending on the information you are searching, the Internet is not always the easiest nor the first place you should try. Often the traditional printed resource, such as an encyclopaedia, a dictionary, an almanac, or a directory, can provide you with the needed information much faster. This situation may change, however, as libraries provide more free Internet access, subscribe more to online resources and buy fewer printed materials.
Check out other print materials available in the library:

- Almanacs, atlases, AV Catalogues
- Encyclopaedias and dictionaries
- Vertical files
- Government publications, guides, reports
- Magazines, newspapers

Evidence hierarchy

The highest standard of studies is a meta-analysis of several randomised controlled trials. It is a statistical technique combining the results from studies which are comparable.
The next step is the randomised controlled study with a good quality of study design. The systematic reviews are not included as a reference – for this we have to go to the original texts and studies (RCTs). The evidence hierarchy is shown in the table of evidence level. See page 15.

6.4 Data handling

1. When assessing results of data searches, a record should be kept of inclusion and exclusion criteria and numbers of included and excluded studies.
2. Initial selection is based on the abstract only. When in doubt, the scientific paper is included and the full paper consulted.
3. The decision on which papers to include is taken by the chair and other selected group members
4. The full texts are retrieved for all selected publications and made available to the guideline group.
5. Panel members are assigned papers related to the subtopic(s) they will address and asked to assess the papers and record their assessment in an excel file (the EAUN Guidelines Reference Evaluations file)
6. Dual review is advised
7. Requirements regarding data recording:
8. Assess methodological quality (1–4).
   Assessment of methodological quality differs according to types of studies. Please note that even though the findings presented in a paper may look good, serious methodological flaws may preclude inclusion in the guidelines manuscript.
9. Clinical data. Extraction should focus on the clinical question addressed to ensure standardisation of key findings within one topic.
10. Before any data recording, the expert panel should discuss and decide on key findings looked for.
11. For each paper a summary of findings, comprising of a methodological assessment and clinical data is to be produced. These summaries form the basis of the recommendations made by the guideline group members.

12. The Reference Evaluations file for recording is on the Claromentis management system

6.4.1 High quality data from other sources

A number of organisations post quality evidence summaries on line:

- Cochrane: http://www.cochrane.org/cochrane-reviews
- National Institute for Health and Clinical Excellence (NICE): http://guidance.nice.org.uk/Topic
- US Agency for Healthcare Research and Quality (AHRQ): http://www.ahrq.gov/clinic/epcindex.htm
- Review data produced by the Aberdeen Cochrane Centre (through their charity UCAN) on a number of oncological topics will be shared with the relevant guidelines panels.
- American Urological Association http://www.auanet.org/content/clinical-practice-guidelines/clinical-guidelines.cfm
- German National Guidelines Clearinghouse (German)
- http://www.leitlinien.de/leitlinien-finden
- Guidelines International Network (G-I-N) http://www.g-i-n.net/ (full text document, membership required).

If these sources are used, original articles must be the reference unless a meta-analysis has been made.

6.5 Text presentation

The recommendations are specific and unambiguous.
The different options for management of the condition or health issue are clearly presented.

Each chapter/subchapter should be concluded by a summary of boxed, graded recommendations. Key statements/evidence summaries can be listed, including a level of evidence.

Uniformity is strived for; care should be taken to avoid expanding on guidelines documents indefinitely, where a textbook format is created. Use of tables and flowcharts is helpful in presenting information and keeping texts more concise.

Texts submitted for publication are edited ~~by a UK medical writer~~ and reformatted, if needed, to comply with the standard publication format. All queries flowing from the editing process are initially sent to the Chair of the Guideline group. Accuracy of the contents of the Guidelines is the responsibility of the Guideline group.

Text presentation – key points

1. Avoid lengthy discussions
2. If possible, use tables to present data; certainly when presenting data from multiple studies
3. The use of flow charts is helpful for readers
4. Distinguish clearly between summaries and recommendations
5. Summaries should have a level of evidence included and can be a statement of findings/facts considered of relevance

6. Recommendations should be action based, prompting the readers to take action
7. Recommendations should be graded

Flow charts – key points

1. Clearly label the flowchart – the title should inform about the process
2. Strive for uniformity of flowcharts within one guideline
3. Logical direction of a flowchart is top to bottom, left to right
4. Avoid excessive details
5. Use active verbs where action is to be taken
6. Flowcharts should be a logical extension of the text
7. Flow charts present an additional/visual tool for the readers (not present new information)
8. Do not allow for different scenarios (show the big picture, otherwise produce a second chart)
9. Credit your readership with some intelligence, but avoid ambiguity!

6.6 Authorship

All full guideline group members who have contributed to a published text (update) will be listed as authors on the title page of the document. Unless otherwise decided, standard listing is, Chair first, followed by authors in alphabetical order. Experts are credited in the methodology section and/or with a footnote in the document itself.

Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data. Here meaning grading articles 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors should meet conditions 1, 2, and 3. (www.icmje.org)

In case of any disputes, the EAUN Board can be called upon to referee.

7. Levels of evidence and grades of recommendations

Including levels of evidence and grades of recommendations in the guidelines aims at providing clinicians with a clear frame of reference by which to rate the statements and recommendations made. Providing transparency between the underlying evidence and a recommendation made, allows users to judge the validity of the statement made, which should enhance confidence in the quality of the guidelines.

The EAUN has decided to use modified level of evidence/grade of recommendation tables from the Oxford Centre for Evidence-based Medicine Levels of Evidence (modified March 2009) (1) according to the EAU Guideline Office

Level of evidence

Level	Type of evidence
1a	Evidence obtained from meta-analysis of randomised trials

1b	Evidence obtained from at least one randomised trial
2a	Evidence obtained from one well-designed controlled study without randomisation
2b	Evidence obtained from at least one other type of well-designed quasi-experimental study
3	Evidence obtained from well-designed non-experimental studies, such as comparative studies, correlation studies and case reports
4	Evidence obtained from expert committee reports or opinions or clinical experience of respected authorities

Grade of recommendation

Grade	Nature of recommendations
A	Based on clinical studies of good quality and consistency addressing the specific recommendations and including at least one randomised trial
B	Based on well-conducted clinical studies, but without randomised clinical trials
C	Made despite the absence of directly applicable clinical studies of good quality

Each recommendation should be graded A–C.
As much as possible, justify each recommendation using the strongest, clinically relevant data. It is important to point out any flaws in the evidence used to support particular advice. It is also an option to make a recommendation AGAINST performing a certain action.

It should be noted, however, that when recommendations are graded, the link between the level of evidence and grade of recommendation is not always immediately apparent. Availability of RCTs may not necessarily translate into a grade A recommendation where there are methodological limitations or disparity in published results.
Alternatively, absence of high-level evidence does not necessarily preclude a grade A recommendation, if there is overwhelming clinical experience and expert consensus. In addition, there may be exceptional situations where corroborating studies cannot be performed, perhaps for ethical or other reasons, and in this case, unequivocal recommendations are considered helpful for the reader. The quality of the underlying scientific evidence – although an important factor – has to be balanced against benefits and burdens, values and preferences, and cost when a grade is assigned (2–4).

The literature used in the guidelines includes qualitative research, but because there is no systematic ranking for these types of studies, the qualitative studies are all graded level 4.

Dual review may make it easier to decide on levels of evidence of papers included in guidelines.

Summary key points

1. When phrasing a recommendation: what action do you expect from the nurse? A

recommendation can be made AGAINST an action.

2. The total evidence base, level of evidence (quality of the studies) as well as the number of studies affect the grade of recommendation
3. As does the uniformity of study findings
4. Take into consideration the potential clinical impact of the recommendation made
5. Are the findings from the scientific data relevant for the population for whom the recommendation is made (generalisability)
6. It is possible to give a strong recommendation based on weak evidence (e.g., accepted practice with no evidence, extrapolation of management from other situations, common sense, and laws of nature)
7. Recommendations have to be recognisable as such; avoid hiding recommendations in the supportive text
8. It is possible to make statements and link an evidence level to those statements (in summary overviews f.i.)
9. Statements and recommendations must have a logical link to the supporting text

7.1 Phrasing of recommendations (5)

Since the aim of recommendations is to influence the behaviour of a clinician in a given situation, recommendations should be actionable (inform readers what to do) using clear language.

Be explicit about:

WHEN	i.e. under what specific conditions/circumstances
TO WHOM	specifically
Urgency	A verb expressing the level of obligation (this is linked to the GR) (do NOT use consider; a consideration cannot be graded!)
DO WHAT	precisely what action

Aim for consistency throughout the document to:

- Promote understanding
- Recognition
- Clarity

and thereby increase the likelihood of compliance.

The wording of the recommendation should reflect the grade of recommendation. For example; a grade A recommendation should use phrases such as ‘standard of care . . .’, ‘first line treatment ’, ‘is indicated’.

Correctness and completeness of recommendations are checked using the AGREE II tool.

7.2 Implementation

- The guideline describes facilitators and barriers to its application.
- The guideline provides advice and/or tools on how the recommendations can be put into practice.
- The guideline presents monitoring and/or auditing criteria.

8. Review

The aim is to ensure peer review of all guidelines material produced prior to publication.

A minimum of 6 external reviewers are invited to review each document. The review is double-blinded. For these reviews international experts will be invited by EAUN office staff. Also a representative from patient advocacy groups will be included as reviewer.

The guideline group members are to provide timely comments to the reviewers. The EAUN Coordinator is responsible for all logistics linked to review.

9. After completion of the guideline

9.1 Scientific paper production

Upon completion of the review process, a scientific paper will be produced by a panel member and submitted for publication. Submission of the scientific publication is the responsibility of the Central Office staff

9.2. National Guideline Clearinghouse

Require the National Guideline Clearinghouse (NGC) to provide a clear indication of the extent to which clinical practice guidelines (CPGs) submitted to it adhere to the standards described.

The guideline will be submitted to the National Guideline Clearinghouse after publication by the Central Office.

9.3 Updating guidelines

As a rule, updating should take place no less frequently than every 3 to 4 years.
As experts in their field, guideline group members will be aware of all significant new publications warranting updates. Significant new publications are those that:

- Cover a new topic that has not been discussed before, is pertinent to the guidelines topic, and which will directly affect patient care
- Provides information that changes existing insights and recommendations; this could relate to content or the grade assigned to it.

Care must be taken to avoid only updating existing topics, and focus solely on the structure of the latest version of the document, where new developments may not be considered.
Validation of the guidelines is determined based on an annual scoping search. After panel assessment, guidelines texts not subject to changes should include a notice stating currency and validity of the data presented.
Stakeholders' feedback can also prompt updating the EAUN Guidelines.

9.3.1 Data Identification for guidelines updates

1. Update searches should be limited strictly to the time frame covering the cut-off date of the latest guidelines publication search and today.
2. Expert panel assistance is crucial in focusing searches to assess relevance of existing strategies (EAUN and other organisations).
3. Initially, searches should focus on identification of all level 1 papers (RCTs, meta-analyses of RCTs).
4. If sufficient level 1 papers are found to answer the clinical questions, no lower-level publications need to be consulted.
5. If this is not the case, lower-level evidence should be identified but limited to prospective studies. Retrospective studies should be excluded.

10. Logistics and other practical matters

10.1 Guideline meetings (logistics)

10.1.1 Scheduling of meetings

Guidelines Working groups are encouraged to schedule their meetings to coincide with other (large) urological events where most panel members will already be present (f.i. EAUN annual meetings) or possibly during specialty section meetings. For such meetings reimbursement of travel costs will not apply (see below). For room bookings and other logistical requirements office staff is to be consulted.

10.1.2 Frequency

The number of Guideline meetings required may vary, but is ultimately decided by the chair of the guideline group in collaboration with the EAUN Coordinator.

Standard meeting schedule for groups in the process of writing a guideline would be three meetings. The agenda for the various meetings will also depend on scope and extent of an guideline; for an average complete guideline, 3 meetings would then needed:

- One initial meeting to discuss division of labour and any other relevant topics (provide instructions to the research scientist to develop search strategies)
- Second meeting to discuss results and findings and develop recommendations
- A third meeting to discuss and finalise material prior to print. (see table Appendix 1).

10.1.3 Attendance

Guideline group members are expected to attend all the guideline group meetings. In case he/she is unable to participate, notification of the guideline group chair/staff is expected. The chair can request that any assigned activities are made available in a timely fashion. In case of non-availability there is the option to schedule a telephone/video conference allowing the missing guideline group member to contribute.

It is the responsibility of the chairman to decide whether frequent failure to attend scheduled guideline group meetings is reason to re-discuss guideline group participation.

10.2 Logistical support

Logistical support (if required) will be provided by the EAUN Office. This relates to:

1. Hotel and meeting room logistics (IT requirements)
2. Flight arrangements
3. Any meals

10.2.1 Hotel bookings

The EAUN Office will confirm any hotel bookings in a timely fashion ahead of the meeting. Incidentals such as minibar, telephone calls and other personal expenses are not reimbursed and will be charged to the Guideline group member by the hotel directly (credit card deposit). Special circumstances may apply which will involve prior consent of the EAUN Board/office staff.

10.2.2 Travel arrangements

Flights will be booked based on economy fare, reimbursement of costs in case a guideline group member arranges his/her own travels will also be based on economy fare. A standard EAUN reimbursement form is to be used.

Train tickets will be reimbursed based on economy 2. class fare. Car travel will be reimbursed Euro 0.19 km (Euro 0.31/mile).

10.2.3 Lunches/meals

The EAUN will arrange for drinks, snacks, lunch and dinners during meetings.
All other reimbursable expenses (travel costs) when traveling for the EAUN must be listed on your reimbursement form. Sustenance during travel is not reimbursed. Original receipts are to be sent along when the reimbursement form is submitted to the EAUN Coordinator. Scans of the receipts are also possible.

10.3 Honoraria

No honoraria or reimbursements are provided related to guideline group membership (but for meeting attendance reimbursement)

In case a Chair/panel wish(es) to contract assistance elsewhere (for any activity - literature support, writing support, etc.) a prior request is to be sent to the EAUN Office also providing a rough estimate of the costs involved.

10.4 Web platforms

10.4.1 Panel interaction

A Web platform has been set up to facilitate panel interaction (EAU Document Management System - Claromentis). Access is governed by login. Username and password are provided by

the EAUN coordinator. Additional information on this feature is available on line (user's guides).

10.4.2 Data extraction platform

A Web platform has been set up to facilitate data extraction.

10.4.3 Review platform

A Web platform has been set up to facilitate reviews with Agree questions.

Contact address:

Mailing address:	Street address	Phone: +31 26 3890 680
EAUN Coordinator	[courier shipments]:	Fax: +31 26 3890 674
P.O. Box 30016	Mr. E.N. van Kleffensstraat 5,	
6803 AA Arnhem	6842 CV Arnhem,	
The Netherlands	The Netherlands	

Email: h.lurvink@uroweb.org; EAU Guideline Office: k.plass@uroweb.org

11. References

1. Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2009). Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998. Updated by Jeremy Howick March 2009. http://www.cebm.net/index.aspx?o=1025 [Access date June 2011]
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Appendices

1. Example Activities and time-lines guidelines development

Time frame (indication)	Activity	Who is involved
1 month	Guidelines topic determined Selection guideline group chair and members	EAUN office & Board
1 month	Collect and assess potential COI & Non-disclosure Assess potential COI	Chair & staff
1 month	Information on procedures	Chair & Guideline responsible person from the EAUN Board
	• Define scope of guidelines and produce/review clinical questions to guide identification of data. • Formulate Question for the systematic review	Chair & Guideline responsible person from the EAUN Board
2 month	Search for relevant articles (ideal: 2 people doing the same search with the same keywords)	Chair and a selected person or librarian and chair
	The abstracts are read by the two people to find out which articles should be ordered or organised a full text articles.	Chair and a selected person
	The full text articles are graded by the two persons who have done the search	Chair and a selected person
	The articles are brought into a systematic excel file with the short description	Chair and a selected person
	The literature is listed – which clinical question is mentioned by which article, so that the articles for the guideline group will be selected before the first meeting	Chair and a selected person
3 months	1st guideline group meeting ▪ Assess first literature results (in case data is available) & decide if other sources may need consulting ▪ Discuss potential COI ▪ Assign tasks ▪ Discuss time lines (delivery material and meeting schedule) ▪ Discuss searching and handling illustrations	Chair Expert guideline group Staff
	Guideline group (associates) are to assess data and produce data summaries and draft	Expert guideline group

	recommendations for discussion at a second meeting	
	2nd Guideline group meeting ▪ Discussion of results and recommendations ▪ Determine gaps in the literature that need addressing ▪ Re-assign tasks if needed ▪ Assignment of supporting text for Panel summaries and recommendations sections ▪ Look for additional texts and illustrations for the appendices	Expert guideline group & staff
	Ahead of finalisation meeting: Circulation draft/first manuscript for comments	Expert guideline group & staff
	3rd Guideline group meeting: ▪ Discussion of the entire document ▪ Refine and unify statements and recommendations (LE and GR)	Expert guideline group & staff
2/3 weeks	Amendments & completion of a draft manuscript	Expert guideline group & Staff
1 month	Text editing	Medical writer/editor/staff
2 weeks	Presentation of the edited manuscript to the guideline group for comments	Expert guideline group & staff
6-8 weeks	After guideline group approval and informing EAUN board, review of the full text manuscript	Reviewers & staff
3 months	Discuss reviewers comments in video meetings Final approval of the full text manuscript Simultaneous production of an ultra-short document (or update) (pocket version)	Expert guideline group Expert panel & EAUN board & EAU representative
2/3 weeks	Typesetting and publication in print and online (society website)	Staff
	Production of a scientific publication	Expert guideline group, medical writer & staff
	Annual review of the literature to assess text validity Update search results to be made available at a workgroup meeting.	Expert guideline group

2. PICO(S) – Care Pathways and Mesh terms (1,6) (data identification)

The 'clinical question' should specify the types of population (participants), types of interventions (and comparisons), and the types of outcomes that are of interest. The acronym PICO (Participants, Interventions, Comparisons and Outcomes). Sometimes, S = study quality or T = type of study is included) helps to serve as a reminder of these. Equal emphasis in addressing each PICO component is not necessary. For example, a review might concentrate on competing interventions for a particular stage of breast cancer, with stage and severity of the disease being defined very precisely; or alternately focus on a particular drug for any stage of breast cancer, with the treatment formulation being defined very precisely.

Examples of PICO questions:

- In patients with indwelling catheter do cranberry products reduce symptomatic UTI compared with placebo
- In men who report LUTS, what is the effect of bladder training versus any other conservative therapy or no treatment on patient related and biometric outcomes and adverse events?
- In men and women with urinary incontinence, does physical exercise improve patient outcomes regarding either urinary symptoms, leakage or quality of life, compared to no physical exercise ?

Underlined are the main concepts represented in the PICO questions above. Concepts are the different ideas which make up each unique search topic. Most topics can be broken down into two, three or more main concepts.

Topic	
Population *Condition, disease severity and stage, comorbidities & patient demographics*	Men and women (alternative term = adults) with urinary incontinence
Intervention *Dosage, frequency and method of administration*	Physical exercise
Comparator *Placebo, usual care or active control*	No physical exercise
Outcome *Health outcomes: morbidity, mortality, quality*	Urinary symptoms / quality of life / pad test

of life.	
Question	In men and women with urinary incontinence, does physical exercise improve patient outcomes regarding urinary symptoms, leakage or quality of life, compared to no physical exercise?
Alternative terms	Sport training, physical fitness training

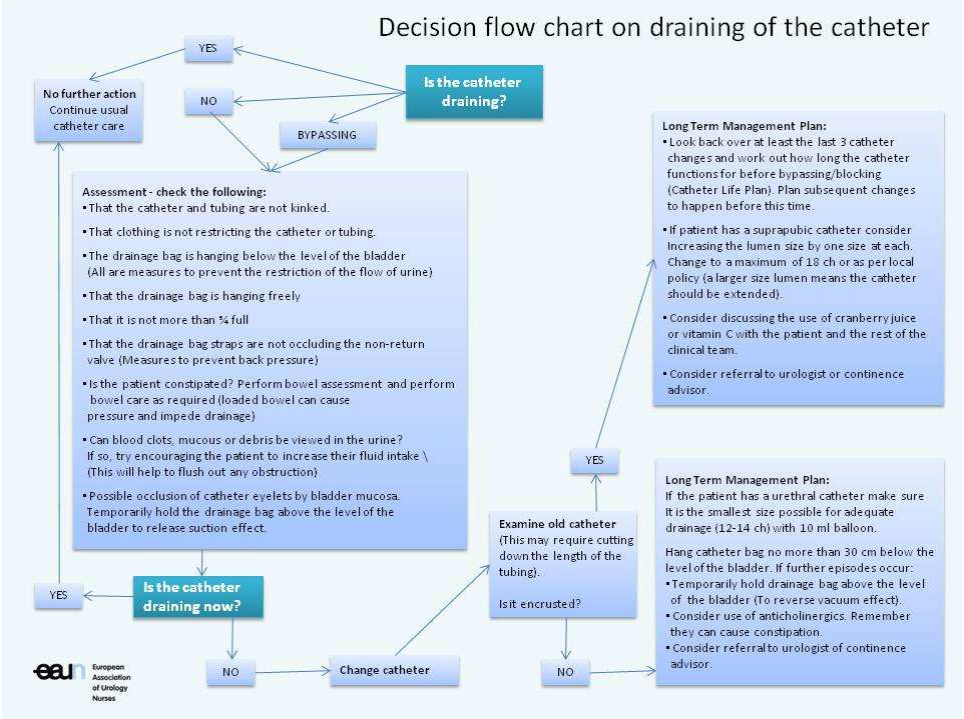
Care Pathways

Alternatively, Care pathway development has the same function (focus of topics and identifying interventions and patient groups).

Care pathways map out the delivery of care to patients with a specific condition
Relevance for guidelines process:

- Ensures comprehensiveness
- Begins standardisation of terminology process
- An opportunity to standardise definition of terminology including outcomes
- Informs the search strategy for the review process
- Helps define scope of the review and guideline

Example:



Helpful resources: http://www.cebm.net/index.aspx?o=1900

◊ MeSH database Medline: http://www.ncbi.nlm.nih.gov/mesh

◊ NICE Guidelines manual (ch. "Developing review questions and planning the systematic search")
http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp

◊ McMaster/Hiru hedges: http://hiru.mcmaster.ca/hiru/hedges/indexHIRU.htm
(Search Strategies for MEDLINE in Ovid Syntax and the PubMed translation)

3. Assignment list (example)

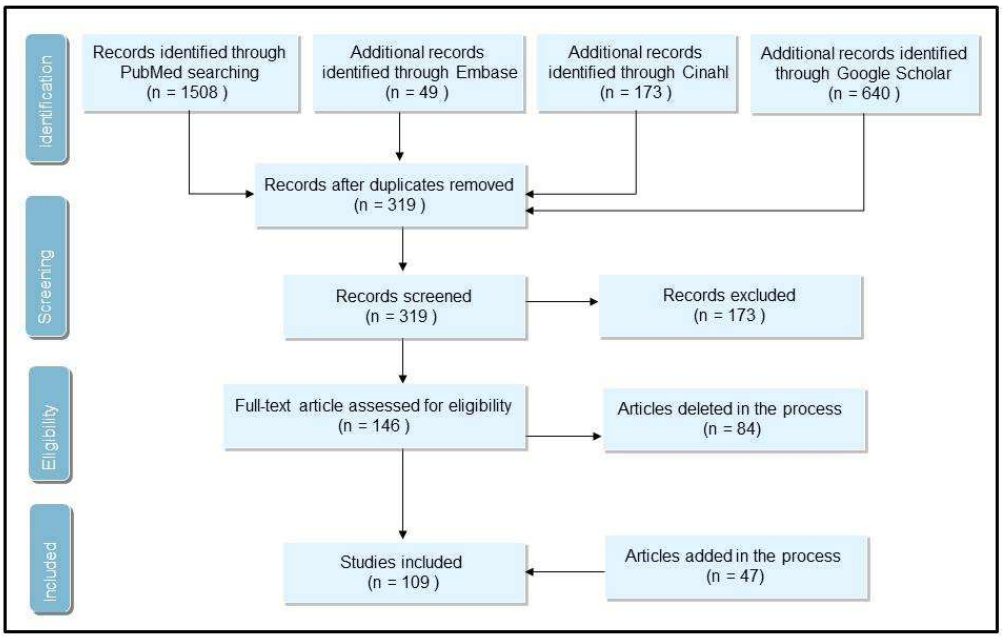
Topic list	Primary author	reviewer
Epidemiology	Panel member A	Panel member I
Risk factors	Panel member B	Panel member C
Screening and early detection	Panel member C	Panel member A
Diagnosis	Panel member D	Panel member F
Staging	Panel member E	Panel member B
Treatment A	Panel member F	Panel member H
Treatment B	Panel member G	Panel member C
Follow-up	Panel member H	Panel member D
Quality of life	Panel member I	Panel member E

N.B. Working with a secondary author is an option, or list associated for specific tasks. Also the topic list can be more detailed/or less detailed, depending on the scope of the guideline and the size of the guidelines group.

4. What should be included in every guidelines introduction?

1.	Overall scope and purpose of the guideline (clinical, healthcare or social questions covered by the guidance). Also mention what has not been addressed and explain why.
2.	Population and/or target audience to whom the guidelines applies (if this is not directly apparent from the title).
3.	Panel composition (multidisciplinary panel, stakeholder involvement. Also rationale for not including obvious groups)
4.	Cost assessments [caution, available data should be included. The EAUN Guideline Office does not have the resources to carry out cost assessments addressing the entirety of healthcare systems the guideline may be applied in]
5.	Description of methodology used
	- Literature identification: databases consulted, search terms [key words/PICOs] time frames, numbers of papers identified, numbers of papers included/excluded. Inclusion/ exclusion criteria.
	- Possibly include a chart or have details published in an addendum.
	- Any other sources of data (proposed by expert panel, books reviews etc.)
	- Discuss specific limitations
	- Address level of evidence, grade of recommendation
	- How the process of consensus finding works
	- Review, conflict of interest
	- Publication history (in case of an update) & dissemination strategies
	- List which information has changed (in case of an update)
All of this information should be fairly brief. A larger, comprehensive document can be available as a reference document for consultation. Such a document may be posted on line.	

Example data handling chart, see page 28



From: S. Vahr, H. Cobussen-Boekhorst, J. Eikenboom, V. Geng, S. Holroyd, M. Lester, I. Pearce, C. Vandewinkel; members of the European Association of Urology Nurses Guidelines Office. Catheterisation, Urethral intermittent in adults – Evidence-based Guidelines for Best Practice in Urological Health Care. Edition presented at the 14th International EAUN meeting, Milan 2013. ISBN 978-90-79754-59-5.

Design: **PRISMA 2009 Flow Diagram**

5. National Guideline Clearinghouse (NGC) inclusion criteria - June 2013

From: http://guideline.gov/about/inclusion-criteria.aspx

Inclusion Criteria

Effective June 2014, NGC will employ the 2011 definition of clinical practice guideline developed by the Institute of Medicine (IOM).[1]

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

For more information, please refer to the Frequently Asked Questions. We invite you to send your comments to info@guideline.gov.

Revised Criteria for Inclusion of Clinical Practice Guidelines in NGC

Effective June 2014: In order for NGC to accept a submitted clinical practice guideline, the guideline must meet all the criteria below. In addition to the guideline, developers must provide NGC with documentation of the underlying systematic review*.

1. The clinical practice guideline contains systematically developed statements including recommendations intended to optimize patient care and assist physicians and/or other health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances.
2. The clinical practice guideline was produced under the auspices of a medical specialty association; relevant professional society; public or private organization; government agency at the Federal, State, or local level; or health care organization or plan. A clinical practice guideline developed and issued by an individual(s) not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
3. The clinical practice guideline is based on a systematic review of evidence as demonstrated by documentation of each of the following features in the clinical practice guideline or its supporting documents.
   a. An explicit statement that the clinical practice guideline was based on a systematic review.
   b. A description of the search strategy that includes a listing of database(s) searched, a summary of search terms used, the specific time period covered by the literature search including the beginning date (month/year) and end date (month/year), and the date(s) when the literature search was done.
   c. A description of study selection that includes the number of studies identified, the number of studies included, and a summary of inclusion and exclusion criteria.
   d. A synthesis of evidence from the selected studies, e.g., a detailed description or evidence tables.

e. A summary of the evidence synthesis (see 3d above) included in the guideline that relates the evidence to the recommendations, e.g., a descriptive summary or summary tables.

NB: A guideline is not excluded from NGC if a systematic review was conducted that identifies specific gaps in the evidence base for some of the guideline's recommendations.

4. The clinical practice guideline or its supporting documents contain an assessment of the benefits and harms of recommended care and alternative care options.
5. The full text guideline is available in English to the public upon request (for free or for a fee). Upon submission of the guideline to NGC, it also must be noted whether the systematic review or other supporting documents are available in English to the public upon request (for free or for a fee).
6. The guideline must have been developed, reviewed, or revised within the past five years, as evidenced by appropriate documentation (e.g., the systematic review or detailed description of methodology).

*Systematic reviews are literature reviews that summarize evidence by identifying, selecting, assessing, and synthesizing the findings of similar but separate studies. They can help clarify what is known and not known about the potential benefits and harms of drugs, devices, and other healthcare services.[2]

For more information, please refer to the Frequently Asked Questions. We invite you to send your comments to info@guideline.gov.

Current Criteria for Inclusion of Clinical Practice Guidelines in NGC (in effect through May 2014)

NGC employs the definition of clinical practice guideline developed by the IOM in 1990.[3] All of the criteria below must be met for a clinical practice guideline to be included in NGC.

1. The clinical practice guideline contains systematically developed statements that include recommendations, strategies, or information that assists physicians and/or other health care practitioners and patients to make decisions about appropriate health care for specific clinical circumstances.
2. The clinical practice guideline was produced under the auspices of medical specialty associations; relevant professional societies, public or private organizations, government agencies at the Federal, State, or local level; or health care organizations or plans. A clinical practice guideline developed and issued by an individual not officially sponsored or supported by one of the above types of organizations does not meet the inclusion criteria for NGC.
3. Corroborating documentation can be produced and verified that a systematic literature search and review of existing scientific evidence published in peer reviewed journals was performed during the guideline development. A guideline is not excluded from NGC if corroborating documentation can be produced and verified detailing specific gaps in scientific evidence for some of the guideline's recommendations.

4. The full text guideline is available upon request in print or electronic format (for free or for a fee), in the English language. The guideline is current and the most recent version produced. Documented evidence can be produced or verified that the guideline was developed, reviewed, or revised within the last five years.

References

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2. Institute of Medicine. Committee on Standards for Systematic Reviews. Eden J, Levit L, Berg A, Morton S, editor(s). Finding what works in health care: standards for systematic reviews. Washington (DC): National Academies Press; 2011 Mar 23. Also available: http://www.iom.edu/Reports/2011/Finding-What-Works-in-Health-Care-Standards-for-Systematic-Reviews.aspx.
3. Institute of Medicine. (1990). Clinical Practice Guidelines: Directions for a New Program, M.J. Field and K.N. Lohr (eds.) Washington, DC: National Academy Press. page 38.

6. Potential Conflict of Interest Form

(online submission through: www.uroweb.org, select "my EAU" – Conflict of Interest)

Conflict of Information (COI)

The EAUN wishes to promote independence, objectivity, scientific rigor and a fair balance of representation, in all its activities.

In order to ensure this, individuals participating in these activities are expected to disclose their financial or in-kind relationships both with health industry that develop, manufacture, distribute or sell health care materials or services, or other organisations that could represent a potential conflict of interest. Such relationships exclude personal or family medical care.

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Disclosure of these relationships is necessary for others to make an informed decision about the impact of the disclosed relationship. For instance, this may be relevant in the context of educational activities of the EAUN or review of material for EAUN publications. Recognition of potential COI will allow the office in question to take this into account in the decision making process.

Each EAUN author, reviewer and editor and office member of the EAUN is requested to complete this form. All relationships over the previous two calendar years and the current year (including future commitments which are foreseen over the coming year) must be disclosed.

The information related to COI will be available on request and relevant COI will be cited at EAUN related presentations and in publications.

Use the following list to declare your existing or known future financial relationships or commercial affiliations. Indicate the name of the company by entering the name in one of the six fields per category.

If you do not have any conflicts of interest to disclose please check the appropriate box.

	Company Name	**Company Name**	**Company Name**
1. Equity interests			
2. Director or employee			
3. Owner enterprise			
4. Ownership of patent(s)			
5. Royalties			
6. Company consultant			
7. Company speaker honorarium			
8. Trial participation			
9. Fellowship, travel grants			

10. Research grants

11. Other – please indicate (see next page) **Company** **Conflict Type**

☐ I do not have any existing or known future financial relationships or commercial affiliations to disclose

1. Equity interests (or entitlement to same) of stocks, stock options, royalties, etc, including income from patents or copyrights
2. Service as a director or employment by a commercial organisation, whether or not remuneration is provided for such service
3. Sole ownership, partnership, or principal of a commercial enterprise
4. Ownership of patent(s)
5. Receipt of royalties
6. Consultant to company including positions on medical or scientific advisory boards
7. Honoraria for speaking at company sponsored meetings or events.
8. Participation in clinical trials
9. Support in the form of fellowships, travel grants, gifts, in-kind donations, etc.
10. Research grants, partial or full salary support from a commercial organisation for self or employees for whom you are managerially responsible (i.e. laboratory technical/research fellow for whom you are managerially responsible).
11. Any other type of financial or other relationship

7. Copyright Transfer Agreement

Copyright Transfer Agreement

European Association of Urology Nurses
Mr. E.N. van Kleffensstraat 5
6842 CV Arnhem, The Netherlands
Fax: +31 26 3890 674

Date:

Manuscript entitled: EAUN Guidelines on …….

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Author signature:

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European Association of Urology Nurses

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