

Guidelines Office Development Handbook

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1. What is the aim of this handbook

The purpose of this handbook is to provide advice on developing an EAU guideline and the methods used. It aims to provide a clear path through the process and seeks to ensure that the resulting guidelines have credibility and meet the EAU's criteria for content, methods and presentation.

2. Background

Clinical Practice Guidelines (CPGs) are a highly influential tool for the improvement of clinical care, the harmonisation of healthcare provision as well as the management of healthcare associated resources. Therefore, clinical guidelines must be free of bias, presenting a balanced view of risks and benefits, in which the preferences of patients, best clinical practice and healthcare policy needs are underpinned by the best available scientific evidence. Ultimately, promoting effective therapy and discouraging/avoiding ineffective or potentially harmful interventions.

3. Structure of the EAU Guidelines Office

Within the EAU CPG production is co-ordinated by the EAU Guidelines Office. The EAU Guidelines Office (GO) consists of;

1. The EAU Guidelines Central Office

Roles and responsibilities

- Support the EAU Guidelines Office Board
- Project management
 - Coordinate all organisational aspects of the development of the EAU Guidelines and associated projects (meetings, conference calls, training, agendas, reports, traditional and electronic delivery of manuscripts and files, update schedules, and review and scientific paper submission)
 - Overview of time lines and ensure adherence to deadlines.
- Interact with other organisations e.g., guidelines producers, national associations, members, journals, and companies.
- Liaise with other EAU offices (Scientific Congress Office (SCO), European School of Urology (ESU), Section Offices, Young Urologists Office to facilitate interaction, collaboration and promotion of all guidelines activities.
- Coordinate in-office activities related to the guidelines e.g. social media, web-based guidelines material, EUT, press releases, etc.

2. The EAU Guidelines Office Board

Roles and responsibilities:

- Guide, support and facilitate all aspects relating to guidelines development (e.g. methodology, dissemination and implementation).
- Actively promote continuous quality improvement.
- Set future goals and establish priorities for the strategic development of the guidelines project.
- Development of a robust conflict of interest (COI) policy and overall responsibility for the appraisal of COI information provided by all those involved in the production of EAU guidelines.

3. The EAU Guidelines Office Methods Committee

Roles and responsibilities:

- Development and implementation of methodological standards across all EAU guidelines.
 - Provision of methodological support and comprehensive training.
 - Overall quality control relating to all systematic reviews produced by the EAU Guidelines Panels.
 - Continual assessment of new developments in Guidelines methodology and adapt of EAU Guidelines protocols to reflect this e.g., how to incorporate real-world evidence alongside traditional evidence based medicine into the guidelines.
4. The EAU Guidelines Office Associates Committee
- Roles and responsibilities:
- Development and co-ordination of the EAU Guidelines Office Associates programme;
5. The EAU Guidelines Office Dissemination Committee
- Roles and responsibilities;
- Active engagement with National Societies and Medical Professional Societies to garner endorsement of the EAU Guidelines;
 - Effective dissemination of EAU Guidelines and EAU Guidelines Office projects;
 - Promotion of discussion and triggering of feedback from guidelines users via Facebook, Twitter and any other Social Media channels;
 - Co-ordination of all social media activities of the guidelines panels.
6. The EAU Guidelines Office IMAGINE Group (Impact Assessment of Guidelines Implementation and Education)
- Roles and responsibilities:
- Quantify the adherence to recommendations from CPGs among different healthcare systems and physicians;
 - Identify existing obstacles and facilitators to adoption of CPG recommendations;
 - Identify interventions to facilitate adoption of recommendations from CPGs in different European healthcare systems;
 - Evaluate and quantify the effectiveness of the interventions applied to facilitate guideline adoption and adherence to recommendations.

Figure 1. EAU Guidelines Office at a glance

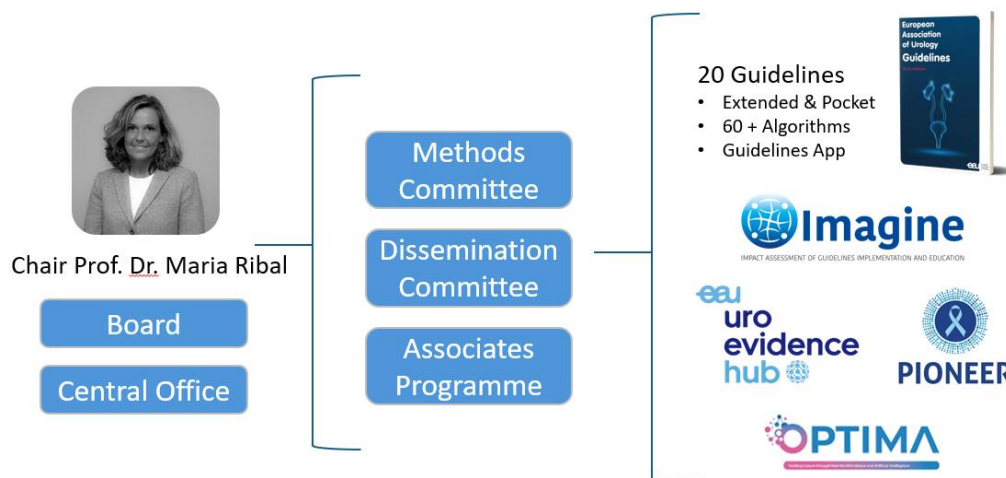


Table 1. Who is who in the EAU Guidelines Office

Guidelines Office Committee	Members	
EAU Guidelines Board	Prof.Dr. Maria J. Ribal (Chair) Prof. Dr. Anders Bjartell Prof. Dr. Steven Canfield Prof. Dr. Philip Cornford Prof. Dr. Caroline Moore	Prof. Monique Roobol Dr. Gianluca Giannarini Dr. Nuno Pereira-Azevedo Prof. Dr. Mauro Gacci Prof. Dr. James N'Dow (ex-officio)
EAU Methods Committee	Prof.Dr. Steven Canfield (chair) Dr. Imran Omar (vice-chair) Dr. Steven MacLennan Dr. Lorenzo Marconi Prof. Catrin Tudur Smith	Dr. Cathy Yuhong Yuan Dr. Arjun Nambiar Dr. Bhavan Rai Dr. Vasileios Sakalis Prof.Dr. Maria J. Ribal (ex-officio)
EAU Associates Programme	Dr. Gianluca Giannarini GO Central Office staff	
EAU IMAGINE Group	Prof. Monique Roobol Prof. Dr. Maria Ribal Dr. Steven MacLennan	Dr. Nuno Pereira-Azevedo GO Central Office staff
EAU Dissemination Committee	Dr. Gianluca Giannarini (Chair) Dr. Nikita Bhatt Dr. Vito Cucchiara Dr. Esther Garcia Rojo Dr. Jeremy Teoh	Dr. Claudia Mercader Barrull Dr. Vineet Gauhar Prof. Dr. Maria J. Ribal (ex-officio) GO Central Office staff
EAU Guidelines Central Office	Dr. Emma Jane Smith Ms. Julie Darraugh Mr. Robert Sheperd Ms. Natasha Schouten	Ms. Carla Bezuidenhout Ms. Hala Ali Mr. Gene Madlon Ms. Maresa Botha

4. EAU Guideline Panels

The EAU GO oversees the activity of seventeen EAU Guidelines panels and one EAU Ad-hoc Guideline panel (producing 21 guidelines), a full list of all panels and panel members is available online at www.uroweb.org/guidelines. Panels are generally comprised of a Chair and Vice-Chair, Panel members (both urologists and clinicians from other specialisms), associates and patient representatives.

4.1. Panel participation

Guidelines panel participation, for which no financial remuneration is provided, involves a significant commitment and investment of time. The result of the work done by the EAU Guidelines expert panels is generally well received by the members of the organisation and clinicians worldwide, and most panel members consider their participation in the EAU Guidelines rewarding.

All panel members are required to submit potential COI information and sign a Non-disclosure Statement as well as a Copyright Transfer Form. Panel members COIs will be assessed and managed according to the GO's COI policy which can be requested from the GO.

A policy of confidentiality regarding any guideline document applies until final publication of all related material. It is expected that details of panel discussions will always remain confidential.

The standard term of office for guidelines panel members is 4 years (assuming satisfactory annual assessment up to the end of the first 2 years), which can be renewed once at the sole discretion of the GO Board (giving a maximum of 8 years). All physicians involved in the EAU Guidelines should be members of the EAU. Membership fees for non-urologists and patient representatives are waived.

A group size of 10 to 15 members encourages diversity and efficiency yet is small enough to avoid delays and redundancy. The standard term of office for guidelines panel members is 4 years (assuming satisfactory annual assessment up to the end of the first 2 years), which can be renewed once at the sole discretion of the GO Board (giving a maximum of 8 years).

4.2. Identification of new Panel Members

1. Profile of new EAU Guideline Panel members

The quality and impact of a Guideline is dependent on the quality and breadth of expertise of the panel members and the recognition of panel members as international opinion leaders. In identifying new panel members therefore, the GO will seek candidates with a track record in high quality evidence synthesis (e.g. systematic review) methodology. The GO will also seek potential candidates who have demonstrated an ability to lead opinion in urological practice at international level and as a result are well respected in the urological community. All potential candidates will demonstrate an ability to deliver tasks on time of the highest quality and be team players. All panel members will commit to the principle of Guideline production as outlined by the GO Methods Committee.

2. Proposals by current members of guidelines panels

The GO will seek the input of panel members in identifying potential candidates to join their panels either as replacements or as new additions to the panel. Such candidates are to supply a letter of motivation, potential COI information as well as a recent CV including a list of their publications. This information is to be sent to the GO Central Office for review after which interviews are held. Declaration of a potential COI does not preclude a potential candidate from joining the Guideline panel; however, failure to declare a significant COI may lead to removal from a Guideline Panel at the discretion of the GO.

3. Public call for new panel members

A public call, inviting experts in a particular field of urology, may be done. All candidates applying are to supply a letter of motivation, potential COI information as well as a CV and a list of publications. For a public call, various EAU communication avenues may be used: association website and/or newsletter(s). Open call applicants are then invited to interview with the respective panel Chair and a subset of the GO Board.

4. Identification of potential candidates by Board members of the Guidelines Office

The EAU Guidelines Office may directly approach potential candidates, inviting them to join one of their Panels. In this instance candidates are still expected to provide a letter of motivation, potential COI information as well as a CV and a list of publications prior to any decision making.

5. Identification of panel members for Ad-hoc topics and panels will follow the above procedure. Membership of such panels will be limited to the duration of the projects undertaken.
6. Involvement of other stakeholders/patients
Most EAU Guidelines panels include clinicians from related specialties. Structured involvement of patients or representatives of a patient advocacy groups is an ongoing project of the EAU GO. The GO are currently developing a policy for meaningful patient involvement in the production of the EAU Guidelines. As a minimum, all guidelines development processes will include comments from patient(s) on the development of clinical questions and the outcomes of most relevance to patients, as well as involvement of patients in review of guidelines prior to their publication, and/or public review. For further information on patient involvement can be found in the EAU Guidelines Patient Handbook: https://d56bochluxqnz.cloudfront.net/media/Guidelines_Office_Patient_Representative_Handbook_website.pdf.

4.3. Appointment of new panel members

A candidate's scientific expertise and provided potential COIs will be assessed. For the appointment of panel members, assessment and final approval will be made by both by the GO as well as the panel Chair, taking into consideration the balance of expertise in the panel and the need to avoid over representation of panel members from one country/institution. Appropriate international representation has a significant impact on dissemination and implementation. However, expertise always takes precedence over geographical distribution. Panel members do not need to be urologists. 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, will be considered in this process. Initial appointment will be for 2 years, which, after satisfactory performance (assessed by the panel Chair and the GO on an annual basis) will be extended until a full 4 year term.

4.4. Appointment of panel Chair

For the appointment of a new panel Chair, assessment and final selection will be by the GO Board. Initial selection is based on proven excellence in a particular area, as well as organisational and leadership skills. Candidates are requested to submit a CV, and project plan for the panel as well as potential COI information. An interview with 3 members of the GO Board (the Chair and 2 Board members) is part of the selection procedure. Taking on this position involves a substantial commitment of time. It is of the upmost importance that if either the Chair or Vice-Chair has a significant COI the other doesn't. Ideally, neither the chair nor the Vice-Chair of a panel will have significant COIs.

4.5. Appointment of panel Vice-Chair

For established panels the panel Chair, together with the panel members, can propose a vice-chair whom the GO Board must ratify. An interview with the GO Board Chair (as a minimum) is part of the selection procedure. Newly formed guidelines panels generally do not have a Vice-Chair until they have been in office for a minimum of one year. However, the GO board has the option to appoint a Vice-Chair directly, in collaboration with the panel Chair, upon formation of the panel.

Even though the EAU Guidelines are widely used by non-urological medical professionals, their focus is first and foremost on clinicians working in the field of urology. Panel Chairs are, therefore, always specialists working full time in the urological field. For Vice-Chairs, this requirement does not apply.

4.6 Appointment of patient representatives

A patient representative maybe “an individual living with or recovered from the condition or a lay advocate representing a group of individuals who have a health condition and their caregivers.”

Patient Members, where representing a patient organisation, are asked to submit a supporting letter from the patient association they are representing, endorsing their involvement on the Panel.

The EAU is committed to appointing people from all backgrounds as patient representatives to its Panels. Reasonable steps are taken to ensure that lay Panel members get any practical support they need when applying for or taking part in the Panels.

4.7. Appointment of Guidelines Associates

Guidelines Associates are junior clinicians that are involved in the production of EAU clinical guidelines systematic reviews. Any activities undertaken by them are carried out under the direct supervision of a senior (experienced) panel member, ensuring adherence to established quality standards. A minimum level of expertise is expected. Training in evidence synthesis and guideline production methodology is provided.

Panel members can propose candidates for consideration for an associate position. The GO Board, in collaboration with other EAU offices may also identify and appoint Guidelines Associates. Furthermore, candidates for Associate positions may also apply directly to the GO Central Office to join the GO Associates Programme. Guidelines Associates will be credited for their contributions and listed as co-authors on publications resulting from systematic review activities and, as appropriate, on individual guidelines. Newly appointed associates will receive a copy of the Guidelines Office Authorship Policy.

4.8. Roles and responsibilities

4.8.1. Panel Chair

- Overall responsibility for the guidelines.
- Maintain overview of project and provide the primary direction for the work of the group.
- Adhere to and implement the agreed-upon production methodology (responsible for the evidence base and literature identification).
- Maintain effective communication with panel members, GO Board and office staff.
- Assessment of the functioning of panel members.
- Chair panel meetings and approve and sign off minutes resulting from meetings.
- Liaise with other guideline groups and external advisors.
- Keep an overview of any potential conflicts of interest and ensure that these cannot (be perceived of) interfere(ring) with any decisions made by the expert panel.
- Maintain confidentiality.

In the absence of the Chair the Vice-Chair will assume these roles and responsibilities. The role of the Vice-Chair is to support the Chair in the effective running of the panel.

4.8.2. Panel Members

- Effectively communicate with the Chair and office staff.
- Participate in meetings and conference calls.
- Follow instructions given by the panel Chair and adhere to the time lines set
- Actively collaborate and perform assigned tasks (e.g., contribute constructively to discussion at meetings, evidence acquisition, drafting recommendations, and reviewing the manuscript);
- Maintain confidentiality.
- Support the Guidelines Associates in completion of systematic reviews undertaken by the panel.

4.8.3. Patient Representatives

All roles and responsibilities (outline above) assigned to Panels Members and additionally:

- Offer guidance so that the views, experiences and interests of all patients or people who use health services are considered by the Panel.
- Identify areas of concern to patients and review topic information and the guidelines from patient or caregiver perspective.
- Take part in any special projects set up by the Guidelines Office (f.i. consensus meetings, big data projects, regulatory and European Union-directed activities, etc).
- Participate in induction training and other training which may be offered.
- Actively engage with their relevant patient associations and networks to survey wider patient views and preferences to inform guideline development and to disseminate guidelines.

Please see the Role Description for Patient Representative Members for more information on tasks.

4.8.4.Guidelines Associates

- Assist with all tasks as determined by the Panel Chair.
- Core activities include, but are not limited to, systematic review activities and processing of annual horizon scope searches.
- Participate in meetings and conference calls.
- Follow Chair and supervising panel member's instructions and adhere to the time lines set.
- Contribute to training and mentoring of newly appointed Guideline Associates.
- Maintain confidentiality.

Guideline development requires the full and active participation of all panel members; producing a guideline requires substantial time and effort, which often tends to be underestimated by group members when they sign on. All members have a responsibility to other participants to behave with integrity, commitment, and with a fully professional demeanour.

4.9. Conflict of interest

Conflict of interest may be defined as a “set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest.” Conflict of interest is an important potential source of bias when developing guidelines as it frequently results in overestimating benefit and underestimating harm. It is not appropriate for

individual panel members to self-judge if a particular relationship causes conflict; their role is to declare, not interpret. The panel Chair, in consultation with the panel as a whole, must ultimately determine if a conflict may result in bias and whether or not the degree of conflict excludes the individual from participating in the entire guideline or selected sections. Panel members COI disclosure forms should be reviewed and updated prior to each panel meeting and prior to publication. The EAU COI policy is laid down in a formal document, which is available online: https://d56bochluxqnz.cloudfront.net/media/Guidelines_COI_Policy_website.pdf.

5. Principals of Guidelines Development

As defined by the Institute of Medicine (IOM) [1], 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.’ Guidelines can never replace clinical expertise when making treatment decisions for individual patients, but rather help to focus decisions - also taking personal values and preferences/individual circumstances of patients into account. Guidelines are not mandates and do not purport to be the legal standard of care.

Quality guidelines are characterised by [2];

1. Explicit scope and purpose: Specific descriptions are given of the overall guideline objective(s), the health question(s) covered, and the population to whom the guideline is meant to apply.
2. Stakeholder involvement: The guidelines panel includes individuals from all relevant professional groups, patients’ views and preferences are actively sought and target users are clearly defined.
3. Rigor of development: Systematic methods are used to search for evidence; methods for formulating recommendations are clearly described; strengths and limitations of the body of evidence are clearly described; methods for formulating the recommendations are clearly described; recommendations take into account health benefits, side effects, and risks; recommendations are linked explicitly to supporting evidence; the guideline is externally reviewed by experts prior to publication; and a procedure for updating the guideline is provided.
4. Clarity of presentation: Recommendations are specific and unambiguous, different options for management of the condition or health issue are clearly presented, and key recommendations are easily identifiable.
5. Applicability: The guideline provides advice and/or tools on how the recommendations can be put into practice, the guideline describes facilitators and barriers to its application, potential resource implications are considered, and the guideline presents key monitoring and/or auditing criteria.
6. Editorial independence: The views of the funding body have not influenced content; competing interests of guideline development group members have been recorded and addressed.

5.1. Five Key Steps in the Development of an Evidenced-based Guideline

1. Identify and refine the subject area.
2. Convene and effectively manage the guideline development panel.
3. Structured assessment of the literature – Systematic reviews / Horizon scoping search.
4. Translate evidence into recommendations in a transparent fashion.
5. Subject the guideline to independent peer review.

Evidence-based CPGs rely on unbiased and structured literature reviews. The main objective of systematically reviewing the literature is to identify all relevant evidence sources, producing a comprehensive body of evidence that will allow clinical questions to be answered whilst highlighting gaps in the evidence base where formal consensus methods may be needed. The EAU CPGs development model is driven by continuous quality improvement using the literature search as one of many factors that help translate evidence into practice. The ratio of benefits to harms, patient and stakeholder preferences and costs (whenever possible) are also considered in formulating recommendations.

Expert opinion or consensus finding outcomes may be used to make recommendations in topics with gaps in the evidence, however the strength of the recommendation will be limited. Discussing topics with limited evidence allows guideline developers to highlight future research needs and suggest how to best fill existing gaps. The guideline as a whole, however, must avoid over-reliance on expert opinion or clinical consensus as a primary decision making strategy.

5.2. Guidelines Production Process

It is important to be clear how the guideline is 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 strength ratings for recommendations aims to provide transparency between the underlying evidence and the recommendations made, so that the clinician can assess how much confidence they can place in a given recommendation.

5.2.1. Definition of the subject/disease/condition of the guideline

The content of the guideline should be explicit from its title, however, any limitations should be stated and if necessary explained. The introductory section should explain the purpose and scope of the guideline as well as the methodology used. All introductory sections must comply with the standardised format which was introduced in 2016 [2]. Standard requirements for all introductory sections are listed in table 2.

5.2.2. List of subtopics to be included

These form the chapters of the guideline. The exact outline is dependent on the guideline subject; however, all guidelines must make the utmost effort to conform to either the oncology or non-oncology template. Both templates are summarised in table 3; for extended versions please see appendix 2.

Table 2. Standard requirements for all introductory guidelines sections

Introduction Sub-headings	Description of content
Aim and scope	Overall scope and purpose of the guideline (clinical, healthcare or social questions covered by the guideline). Also mention what has not been addressed and explain why.
Population to whom the guidelines apply	Population and/or target audience to whom the guideline applies (if this is not directly apparent from the title).
Panel Composition	Multidisciplinary panel, stakeholder involvement. Also rational for not including obvious groups.
Available publications	Brief description of all available scientific publications related to the guideline.

Publication history	Brief history on the guideline when it was first published and last updated.
Methods	Description of methodology used in which the level of evidence and grade of recommendation are addressed.
Review	Description of the guidelines peer review process.
Future Goals	If relevant, comment on the continual work within the panel and the when this be presented in the guideline

Table 3. Oncology and non-oncology templates

Template	Chapters
Oncology	<ol style="list-style-type: none"> 1. Introduction 2. Methods 3. The Epidemiology, Aetiology and Pathophysiology 4. Staging and classification systems 5. Diagnostic evaluation 6. Prognosis 7. Disease management 8. Follow-up 9. References 10. Conflict of interest
Non-oncology	<ol style="list-style-type: none"> 1. Introduction 2. Methods 3. Guideline <ol style="list-style-type: none"> 3.1 Condition A <ol style="list-style-type: none"> 3.1.1 Epidemiology, Aetiology and Pathophysiology 3.1.2 Classification system 3.1.3 Diagnostic evaluation 3.1.4 Disease management <ol style="list-style-type: none"> 3.1.4.1 Conservative management 3.1.4.2 Pharmacological management 3.1.4.3 Surgical management 3.1.5 Follow-up 3.2 Condition B (if applicable) 4. References 5. Conflicts of interest

5.2.3. Data identification

5.2.3.1. Horizon scoping search

All panels are expected to perform an annual horizon scoping search covering their entire guideline. The results of this search will result in one of three scenarios;

1. Signing off the guidelines as still current for the upcoming edition i.e. no changes will be made to the text following assessment of the search.
2. Minor adaptations to the upcoming edition for example identification of higher quality studies, which may be used to replace current references. These data do not, or will only marginally, affect recommendations.
3. Updating of the upcoming edition due to identification of practice-changing research.

All search stages must be documented for transparency and reproducibility. Specific considerations include databases, time periods, keywords, subject headings, language restrictions, use of grey literature (e.g. conference abstracts not published in an indexed journal), and selection criteria. The various search strategies can be found online in the folder 'Scientific publications and appendices' for each individual guideline. Further information regarding the use of Mesh terms and search design may be found at <https://www.nlm.nih.gov/mesh/meshhome.html>. Scientific searches are conducted by a professional librarian.

Update scoping searches should be limited strictly to the time frame covering the cut-off date of the latest scope search and today. Initially, scoping searches should focus on the identification of publications that may change the recommendations (scientific papers matching the evidence level of those publications currently supporting the recommendations).

All abstracts should be screened with reference to the panels predefined inclusion/exclusion criteria as outlined in their study eligibility form. The Methods Committee have produced two template study eligibility forms, one for adaption by panels whose guideline topics have an abundance of high level evidence and the other for panels where high level evidence is limited or lacking altogether. Please see appendix 3 for both forms.

During full text screening each panel member must record why the text is either included or excluded from the guideline. These reasons must be returned to the GO where they will be compiled into a spread sheet and be used as supporting documentation. Upon completion of the scope search the GO will produce a "Scope Management Flow Chart" for each panel which will be part of the supporting documentation.

5.2.3.2. Systematic reviews

The GO has systematically introduced Cochrane review methodology across all Guidelines Panels, ensuring that high quality systematic reviews underpin key recommendations. The responsibility for completion of systematic reviews rests with the Associates together with the senior panel leads, who are supported by methodologists and statisticians.

Systematic reviews are based on clinical questions prioritised by the Guideline Panel responsible for each topic, and their findings are incorporated into the EAU guidelines as they become available.

Benefits and harms of interventions are addressed in detail, both in the development stage of the clinical question and when review findings are being incorporated and treatment recommendations formulated. Whenever possible, patient input is sought at both the development stage of the SR questions as well as when guidelines recommendations are being drafted.

All SRs are performed using standard Cochrane SR methodology:
(<http://www.cochranelibrary.com/about/about-cochrane-systematic-reviews.html>).

Two independent reviewers screen abstracts and full texts, carry out data abstraction, assess risk of bias and do an evidence confidence rating exercise. The results are presented in tables showing baseline characteristics and summaries of findings. Meta-analyses are performed only as part of a SR when several randomised controlled trials have addressed the same question and outcomes reported homogeneously. For lower level data, narrative syntheses of the evidence are provided. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidance is followed.

The GO has produced a step-by-step handbook the "EAU Guidelines Systematic Reviews Methods and Processes Handbook" which must be followed when undertaking SR work for the EAU guidelines,

this handbook is available online:

https://d56bochluxqnz.cloudfront.net/media/Guidelines_Systematic_review_handbook_website.pdf

5.2.4. Text presentation

Each chapter/subchapter should be concluded by a summary of evidence table and a summary of boxed, strength rated recommendations. Summaries and recommendations must be clearly distinguished.

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 algorithms is encouraged for presenting important information whilst helping to keep texts concise. Texts submitted for publication are edited by at least two native English speakers and reformatted, if needed, to comply with the standard publication format. All amendments resulting from the editing process are initially sent to the panel Chair for review. Accuracy of the contents of the Guidelines is the responsibility of the guidelines panel. All Guidelines texts include the following disclaimer:

“It must be emphasised that clinical guidelines present the best evidence available to the experts. However, following guideline recommendations will not necessarily result in the best outcome. Guidelines can never replace clinical expertise when making treatment decisions for individual patients, but rather help to focus decisions - also taking personal values and preferences/individual circumstances of patients into account. Guidelines are not mandates and do not purport to be the legal standard of care.”

5.2.5. Recommendations

Recommendations should be quality driven and propose actions that will improve quality of care. These actions include, but are not limited to:

- Promoting appropriate care.
- Improving diagnosis/recognition.
- Avoiding unnecessary tests or interventions.
- Improved coordination of care.
- Improved patient safety.
- Reducing variations in care.

The aim of recommendations is to influence the behaviour of a clinician in a given situation; recommendations should be actionable and use clear language.

An ideal recommendation describes:

- When → under what specific conditions should the recommendation be implemented
- Level of obligation → this is linked to the strength of the recommendation
- Do what → precisely what action/s should be implemented
- To whom → specifically who the recommendation should be implemented on

Recommendations should be precise. The supporting text, which precedes the recommendations should amplify why the recommendation is important and how it is to be carried out (present a summary of all supporting data). Furthermore, the recommendation should reflect the degree of obligation linked to the intervention. In cases where multiple treatments are equally effective, identical phrasing must be used.

5.2.5.1. Levels of evidence and strength of recommendation

Levels of evidence and strength of recommendations are included in the guidelines in order to provide clinicians with a clear frame of reference by which to rate the statements and recommendations made. Levels of evidence are derived from study type, and do not directly reflect study quality. Strength of recommendations are derived from multiple factors including evidence quality. A comprehensive assessment of evidence quality is not always available; therefore providing transparency between the underlying level of 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.

Currently, the EAU GO uses a modified level of evidence/strength of recommendation table from the Oxford Centre for Evidence-based Medicine Levels of Evidence (modified March 2009).

Table 4. EAU Guideline's levels 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

Each recommendation should be rated as either “strong” or “weak” and largely justified by using the strongest clinically relevant data. It is important to point out any flaws in the evidence used to support any given recommendation. The panel can also make a recommendation AGAINST performing a certain action.

It should be noted, however, that when recommendations are rated, the link between the level of evidence and strength of recommendation is not always immediately apparent. Availability of RCTs may not necessarily translate into a “strong” recommendation where there are methodological limitations or disparity in published results.

Alternatively, absence of high-level evidence does not necessarily preclude a “strong” recommendation (although this should be the norm), if there is overwhelming clinical experience and expert consensus. Also in case the benefit/harms balance is strongly in favour of a given intervention. 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 strength rating is assigned.

The strength of each recommendation is determined by the balance between desirable and undesirable consequences of alternative management strategies, the certainty of the evidence (which includes quality and many other factors), and the nature and variability of patient values and preferences. This decision process, which can be reviewed in the strength rating forms (see appendix 4) which accompany each guideline statement, addresses a number of key elements:

1. The overall quality of the evidence which exists for the recommendation,

2. The magnitude of the effect (individual or combined effects),
3. The certainty of the results (precision, consistency, heterogeneity and other statistical or study related factors),
4. The balance between desirable and undesirable outcomes,
5. The impact of patient values and preferences on the intervention, and
6. The certainty of those patient values and preferences.

These key elements in the SOE tables are the basis which panels use to define the strength of each recommendation. Panels can provide both 'strong' and 'weak' recommendations 'for' or 'against' recommending an action based on the information found in the SOE tables. The strength of each recommendation is determined by the balance between desirable and undesirable consequences of alternative management strategies, the quality of the evidence (including certainty of estimates), and nature and variability of patient values and preferences.

5.2.5.2. Summary of key points to remember/consider when formulating recommendations

- Recommendations must be actionable.
- The total evidence base, quality of the studies, certainty of evidence, and level of evidence when all else is lacking, effect the strength rating.
- Are the findings from the scientific data relevant for the population for whom the recommendation is made (generalisability)?
- Is there a logical link between the supporting text, evidence summary statement and the recommendation?
- The health benefits for each statement must be clear.
- Potential harms and side-effects need to be addressed (potential for overtreatment as well as efficacy and effectiveness of the treatment modality).
- Patient views and preferences.

6. Review

The aim is to ensure double-blinded peer review of all guidelines material produced prior to publication. This applies to the extended documents as well as scientific papers published in either the association's journals, "European Urology, European Urology Oncology, European Urology Focus and European Urology Open Science", or other peer reviewed journals.

The EAU GO are responsible for review of all extended guidelines (or updated sections). A minimum of 3-4 international expert reviewers are invited to review each document. Furthermore, where applicable, a representative from patient advocacy groups will be included as a lay reviewer.

7. Authorship

All full panel members who have contributed to a published Guidelines text (update) will be listed as authors on the title page of the document. Unless otherwise decided, standard listing is, Chair, followed by all other authors in alphabetical order. Experts are credited in the methodology section and/or with a footnote in the document itself. Associates who have directly contributed to the guidelines text will also be listed, in alphabetical order, as associate members on the title page of the document. In case of any disputes, the GO Board can be called upon to referee.

Authorship of scientific publications may vary, depending on the type of publication. In case of a systematic review publication, the lead Associate should be listed as first author (or in case of

multiple leads, co-joint first author). For all authors, to be eligible for authorship, a meaningful contribution to the review is expected.

8. Logistics and other practical matters

8.1. Panel meetings

The number of panel meetings required may vary, but is ultimately decided by the Chair of a panel, in collaboration with the GO central office staff. All panels should schedule a meeting at least once each year. Panel members are expected to attend all panel meetings. In case members are unable to participate, notification of the panel Chair/GO staff is expected. The panel 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 hybrid online meeting format allowing the absent panel member to contribute. It is the responsibility of the Chair to decide whether frequent failure to attend scheduled panel meetings is reason to re-discuss panel participation.

8.2. Logistical support

Logistical support will be provided by the GO in conjunction with the EAU Central Office, this includes:

- Hotel and meeting room bookings (IT requirements)
- Flight arrangements
- Any meals – the GO will arrange for drinks, snacks, lunch and dinners during meetings

The Central 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 panel member by the hotel directly (credit card deposit).

Flights will be booked based on economy fare, reimbursement of costs in case a panel member arranges their own travels will also be based on economy fare. A standard EAU reimbursement form is to be used. Train tickets will be reimbursed based on first class fare. Car travel will be reimbursed at Euro 0.23 per km.

All other reimbursable expenses when traveling for the EAU GO must be listed on the standard EAU reimbursement form. Panel members may submit electronic copies of their receipts along with their individual reimbursement forms, however, the all original receipts must be kept and can be request by the EAU Central Office, if deemed necessary.

8.3 Training

All Panel members will be expected to take part in the EAU GO systematic review training course (or on-line modules). Patient representatives will be offered a tailored programme of training and support.

9. Honoraria

Panel membership does not involve any remuneration, aside from reimbursement of panel meeting expenses. In case a panel wishes to contract assistance elsewhere for any activity e.g. literature, writing or statistical support a prior request must submitted to the GO along with an approximate estimate of the costs involved.

10. Copyright

The EAU Guidelines meet the requirements for copyright protection, as they exhibit a sufficient degree of originality and creative choices made by the authors, making them eligible for copyright protection. There is a broad scope of protection for copyrighted works if the content is considered an 'intellectual creation'. Copyright protects originality. The originality should be apparent from the content itself. There is no 'lower limit' for the length of a text to be protectable. The current online disclaimer of EAU establishes clear limitations on use and prohibits commercial exploitation without explicit permission. The EU DSM Directive and Dutch Copyright Act contain a statutory exception for text and data mining, allowing making a reproduction for text and data mining purposes, unless such use has been expressly reserved in an appropriate manner, such as by using a machine-readable disclaimer. It is defensible that EAU's disclaimer is a sufficient disclaimer as an appropriate 'reservation of rights'. EAU has broad authority to allow or prevent the use of their content, including both direct copies and altered versions. Even if parts of the work are modified or rewritten, EAU's rights still apply as long as the original content remains recognisable in the new version.

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11. References

1. Consensus report, Institute of Medicine. Clinical practice guidelines we can trust. March 23, 2011. <http://www.iom.edu/Reports/2011/Clinical-Practice-Guidelines-We-Can-Trust.aspx>
2. Brouwers et. al. The AGREE Next Steps Consortium, AGREE II Update: September 2013. http://www.agreetrust.org/wp-content/uploads/2013/10/AGREE-II-Users-Manual-and-23-item-Instrument_2009_UPDATE_2013.pdf

Appendix 1 – Activities and time-lines: guidelines yearly update cycle

Time frame	Activity	Who is involved
Mid-Oct	Submission of finalised guidelines manuscripts	Guidelines Panel
Oct-Dec	<ol style="list-style-type: none"> Text editing <ul style="list-style-type: none"> Proofreading and reformatting to comply with the standardised GO layout (where applicable). Reference updating and management. Reformatting of all diagrams and algorithms to match the GO standardised layout. Insertion and updating of all hyperlinks. Review <ul style="list-style-type: none"> Identify texts or subsections of texts requiring external peer review in advance. Identify a shortlist of at least 6 possible reviewers in advance. Once the text has been submitted by the panel contact reviewers asking for their participation in the peer review process. Inform them of a strict three week turn around policy. Review is double blinded. Prepare text for review and send to reviewers who have accepted the invitation to review. Also send reviewers the: <ul style="list-style-type: none"> ➤ Common extended methods section of the guideline; ➤ EAU Guidelines Review Score Sheet Return reviewers comments to the panel Chair, the Chair must address all comments in a timely fashion maximum turn around 2 weeks. Return the Chair's responses to reviewer's comments and the amended document to the reviewers for their final approval, maximum turn around 1 week. Close the review process thanking all reviewers for their time. Signing off of edited Guidelines <ul style="list-style-type: none"> Presentation of the edited manuscript to the panel Chair for final approval prior to typesetting. Allow the chair 1 week for this task. Should the Chair wish to have the entire panel comment impose a very strict deadline of 1 week for receipt of all comments. Make final edits based on panel comments. 	GO staff
Dec - onwards	<ol style="list-style-type: none"> Production of the corresponding pocket guideline or each finalised large text. Finalised full guideline texts and pockets sent to the typesetter as they become available. Production and typesetting of the general introductory sections of the large text. 	

	<ol style="list-style-type: none"> 4. Production and sign-off on the front and back covers of both the full text and the pocket. 5. Proofreading and correction of typeset guidelines and pockets. 6. Each text must be proofed by at least 2 native speakers. 	
Early Jan	<p>Contact printers to arrange print run</p> <p>Standard print run numbers are determined by:</p> <ul style="list-style-type: none"> • Full EAU members eligible for print copies • EUREP participants • Special arrangements with f.i. national societies (like the ICS) • Additional sales (in collaboration with Sales & Marketing Dept) 	GO staff
Jan	Guidelines and pockets to Chair and/or Vice-Chair for final sign off.	
Mid Feb	<p>Final submission to printer of all material.</p> <p>Initiate update of Uroweb and the Guidelines App</p>	
Feb-March	Circulate final full text and pocket pdf files to all panel members.	
Mid-March	EAU Annual Congress – launch of Guidelines for that year.	
April-June	<ol style="list-style-type: none"> 1. Conversion of all final print pdfs back into word documents. 2. Initiate horizon scoping search for the new update cycle <ul style="list-style-type: none"> • Review previous years search strategy and adjust if necessary in consultation with the panel. • Submit the search strategy . • Implement agreed upon screening strategy. • Agree time lines for completion of the screening. 3. Compile final screening results and retrieve selected full texts. 4. Return full text pdfs to panel for screening. 	Panel Research scientist GO staff
June-August	<p>Facilitate panel meetings to discuss the results of the scoping search and updating of the guidelines. Panels should:</p> <ul style="list-style-type: none"> • Discuss the scope results in relation to the current recommendations. • Determine gaps in the literature that need addressing. • Assign panel members to specific sub-topics for updating. • Update guidelines text. 	Panel GO staff
Sept	<ol style="list-style-type: none"> 1. Submit individual guidelines sections to the GO, responsible GO staff member will then produce a draft guidelines master document for the panel. 2. Circulation of draft master document to entire panel for review and comment. Key aim is to refine and unify recommendations (LE and GR). 3. Editing of draft master document to reflect panel's comments. 4. Presentation of the edited manuscript to the panel for sign-off. 	
Mid Oct	Submission of finalised guidelines manuscripts.	

Appendix 2 – Oncology and non-oncology guideline templates

Template for EAU Oncology Guidelines

1. INTRODUCTION

- Need for the guideline, its aims and scope.
- Short guideline history with a mention of previous versions and a summary of what has been updated in the current version.
- Current documents (Pocket Version, Full Version, most recent Scientific Publication).
- Panel composition (Areas of clinical expertise, methodologists, information specialists) and any conflicts of interest that are specifically related to the current guideline.

Note: all references should be included at the end of the guideline.

2. METHODOLOGY SECTION

2.1 The clinical practice guideline is based on a systematic review of evidence as demonstrated by the documentation of the following aspects in the either the guideline itself or its supporting documents.

Note: the PRISMA Flow Diagram and the PRISMA Checklist should be used as an aide in the conduct and the reporting of the results of a systematic review and meta-analysis.

- The guideline has been developed, reviewed, or revised within the past X years, as evidenced by appropriate documentation (systematic review or detailed description of methodology) which has been archived in an online repository. This should include an explicit statement that (or which parts of) the clinical practice guideline was based on a systematic review.
- For each PICO, a description of the PICO, a summary of the study inclusion and exclusion criteria, and the search strategy that includes;
 - a listing of databases 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)
 - the date when the literature search was done.

Links can be provided to an online document where this information has been stored.

- A description of the number of studies identified and the number of studies included. (Links can be provided to an online document).
- A description of data extraction procedures and a reference to data extraction forms (Links can be provided to an online document).
- A description of the data analysis procedures (Links can be provided to an online document).
- Systematic review team composition, their responsibilities for each of the tasks involved and their interaction with the guidelines panel (Links can be provided to an online document).
- A description of the external peer review of the guidelines document prior to its release.

2.2 Information to be provided in supporting online documents for each PICO and guideline:

- Literature search/Systematic Review request form
- Systematic Review/meta-analysis protocol
- Systematic Review team composition and their responsibilities
- List of PICO questions
- Study selection/eligibility criteria

- Search strategy
- Number of studies identified and number of studies included
- Data extraction forms and procedures
- Data analysis procedures
- Results of the Systematic Review to include
- Risk of bias assessment
- Full Summary of Findings Tables (SoF)
- Meta-analysis (if carried out)
- Impact on guideline update
- Reference to the publication of the Systematic Review/Meta-analysis (if published)
- Description of the external peer review of the guidelines document prior to its release

Note: For sections 3, 4, 5 and 6 below, the information may be based on previously published data that are available in the literature.

3. EPIDEMIOLOGY, AETIOLOGY AND PATHOLOGY

Review of data to include disease risk factors and histological subtypes that are pertinent to the understanding of the guideline along with disease

- incidence
- prevalence
- mortality

according to the extent of disease as given below.

4. STAGING AND CLASSIFICATION SYSTEMS

Include classifications and other staging and/or (pathological) grading systems where appropriate.

Note: Where possible, sections 5, 6, 7 and 8 should follow a similar structure based, for example, on the extent of disease.

5. DIAGNOSTIC EVALUATION

Specify screening procedures and investigations undertaken (such as the role of blood tests, imaging, and biopsy) to establish the diagnosis and the clinical stage. This may vary according to the extent of disease as given below.

6. PROGNOSIS

Include prognostic factors, risk stratifications and/or nomograms that are relevant in guiding the choice of treatment.

Provide separate sections, as appropriate, for:

- Localized Disease
- Locally Advanced Disease
- Advanced/Metastatic Disease
- Recurrent Disease

along with any prognostic factors that may be treatment specific within these groupings.

7. DISEASE MANAGEMENT

This part will include a review of the clinical evidence, with an emphasis on systematic reviews and meta-analyses when available. Treatment recommendations should be provided based on the currently used 2009 CEBM LE and a strength rating. In making recommendations, trade-offs between treatment benefits, QoL and harms should be considered for each type of treatment and whether the patient is newly diagnosed or recurrent. Unanswered questions and research recommendations should also be indicated.

Provide separate sections, as appropriate, for:

- Localized Disease
- Locally Advanced Disease
- Advanced/Metastatic Disease
- Recurrent Disease

8. FOLLOW-UP

Based on the available clinical evidence, provide the general principles for follow up, frequency of follow up and the exams to be carried out with separate sections, as appropriate, for:

- Localized Disease
- Locally Advanced Disease
- Advanced/Metastatic Disease

along with any follow up recommendations that may be treatment specific within these groupings.

9. REFERENCES

10. CONFLICTS OF INTEREST

Link to EAU website for the conflicts of interest of panel members.

Template for EAU Non-oncology Guidelines

I. INTRODUCTION

- Need for the guideline, its aims and scope.
- Guideline history with a mention of previous versions and a summary of what has been updated in the current version.
- Current documents (Pocket Version, Full Version, most recent Scientific Publication).
- Panel composition (Areas of clinical expertise, methodologists, information specialists) and any conflicts of interest that are specifically related to the current guideline.
- **SPECIFIC CONDITIONS DISCUSSED IN THE GUIDELINE (if applicable).**

2. METHODS

2.1 The clinical practice guideline is based on a systematic review of evidence as demonstrated by the documentation of the following aspects in the either the guideline itself or **its supporting documents**.

Note: the PRISMA Flow Diagram and the PRISMA Checklist should be used as an aide in the conduct and the reporting of the results of a systematic review and meta-analysis.

- The guideline has been developed, reviewed, or revised within the past X years, as evidenced by appropriate documentation (systematic review or detailed description of methodology). This should include an explicit statement that (or which parts of) the clinical practice guideline was based on a systematic review.
- For each PICO, a description of the PICO, a summary of the study inclusion and exclusion criteria, and the search strategy that includes:
 - a listing of databases 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)
 - the date when the literature search was done.Links can be provided to an online document.
- A description of the number of studies identified and the number of studies included. (Links can be provided to an online document).
- A description of data extraction procedures and a reference to data extraction forms (Links can be provided to an online document).
- A description of the data analysis procedures (Links can be provided to an online document).
- Systematic review team composition, their responsibilities for each of the tasks involved and their interaction with the guidelines panel (Links can be provided to an online document).
- A description of the external peer review of the guidelines document prior to its release.

2.2 Information to be provided in supporting online documents for each PICO included in the guideline:

- Literature search/Systematic Review request form
- Systematic Review/meta-analysis protocol
- Systematic Review team composition and their responsibilities
- List of PICO questions
- Study selection/eligibility criteria
- Search strategy

- Number of studies identified and number of studies included
- Data extraction forms and procedures
- Data analysis procedures
- Results of the Systematic Review to include
 - Risk of bias assessment
 - Full Summary of Findings Tables (SoF)
 - Meta-analysis (if carried out)
- Reference to the publication of the Systematic Review/Meta-analysis (if published)
- Description of the external peer review of the guidelines document prior to its release.

3. GUIDELINES

3.1 “CONDITION A”

3.1.1 EPIDEMIOLOGY, AETIOLOGY AND PATHOPHYSIOLOGY

- Definition and impact of the disease:
 - Incidence
 - Prevalence
 - influence in QoL
- Risk factors and underlying causes
- Specific aetiologies or specific populations or specific condition subtype that will be independently discussed within each section(classification system; diagnostic evaluation and disease management)(if applicable)

3.1.2. CLASSIFICATION SYSTEMS

Classification systems and natural history of the disease

3.1.3. DIAGNOSTIC EVALUATION

- General Evaluation
- Supplemental evaluation
- Diagnostic evaluation algorithms

3.1.4. DISEASE MANAGEMENT

- Management rational
- Global management strategies
- **Specific aetiologies, specific subpopulations, or specific subtypes that will be discussed under conservative management, pharmacological management and surgical management (if applicable)**
- Specific management strategies (for specific aetiologies)

ETIOLOGY/SUBPOPULATION/SUBTYPE A (if applicable)

3.1.4.1 CONSERVATIVE MANAGEMENT

- Watchful waiting=no treatment at all

- Behavioural and dietary modifications (ex: “lifestyle advice” in patients with LUTS= reduction fluid intake at specific times; avoidance of caffeine or alcohol, relaxed/double-voiding techniques...)
- Physiotherapy (ex: pelvic floor muscle training in SUI)

3.1.4.2 PHARMACOLOGICAL MANAGEMENT

- Pharmacological group and mechanism of action
- Comparisons within and between groups in terms of EFFICACY and SAFETY
- Combination therapies

3.1.4.3 SURGICAL MANAGEMENT

ETIOLOGY/SUB POPULATION/SUBTYPE B (if applicable)

3.1.5 FOLLOW-UP













3.2. GUIDELINE ON “CONDITION B” (if applicable – refer to Guideline Conditions List)













4. REFERENCES

5. COI

Link to the EAU website for the conflicts of interest of panel members.

Appendix 3 – Horizon scoping search

Study eligibility form high level evidence topics		
Guideline Panel:		Year of update:
Q1	<p>Type of study is the study design one of the following?</p> <ul style="list-style-type: none"> • Systematic review with or without meta-analysis? • For interventions: Randomised or quasi-randomised trial (quasi-randomised = alternate allocation)? • For diagnostic studies: Cross-sectional study designed to assess diagnostic accuracy of a test using an appropriate reference standard? • For prognostic studies: Cohort studies with appropriately defined baseline/pre-treatment characteristics in assessing prognostic value of a variable, nomogram or classification system. <p>Additional criteria:</p>	<p>Yes Unclear No</p> <p>  </p> <p>Go to next question Exclude</p>
Q2	<p>Participants in the study</p> <ul style="list-style-type: none"> • Are some (i.e. ≥90%) or all of the participants in the study relevant to the Guideline? <p>Additional criteria</p>	<p>Yes Unclear No</p> <p>  </p> <p>Go to next question Exclude</p>
Q3	<p>Interventions and Comparisons or Tests in the study</p> <ul style="list-style-type: none"> • For interventions: Are the interventions and comparisons being assessed in the study relevant to the Guideline? • For diagnostic studies: Are the diagnostic tests being assessed in the study relevant to the Guideline? • For prognostic studies: Are the variables, nomogram or are classification system being addressed in the study relevant to the Guideline? <p>Additional criteria:</p>	<p>Yes Unclear No</p> <p>  </p> <p>Go to next question Exclude</p>
Q4	<p>Outcomes in the study</p> <ul style="list-style-type: none"> • Are the outcomes being reported in the study relevant to the Guideline? <p>Additional criteria:</p>	<p>Yes Unclear No</p> <p>  </p> <p>Include Exclude</p>
	Final decision (subject to clarification of 'unclear' points)	Include Unclear Exclude

Study eligibility form low level evidence topics		
Guideline Panel:		Year of update:
Q1	<p>Type of study is the study design one of the following?</p> <ul style="list-style-type: none"> • Systematic review with or without meta-analysis? • For interventions: Comparative studies with n>XX patients in each arm? (can be prospective or retrospective) • For diagnostic studies: Cross-sectional study designed to assess diagnostic accuracy of a test using an appropriate reference standard? • For prognostic studies: Cohort studies with appropriately defined baseline/pre-treatment characteristics in assessing prognostic value of a variable, nomogram or classification system. <p>Additional criteria:</p> <ul style="list-style-type: none"> • Single-arm case series with n>100 patients 	<p>Yes Unclear No</p> <p>  </p> <p>Go to next question Exclude</p>
Q2	<p>Participants in the study</p> <ul style="list-style-type: none"> • Are some (i.e. ≥90%) or all of the participants in the study relevant to the Guideline? <p>Additional criteria</p>	<p>Yes Unclear No</p> <p>  </p> <p>Go to next question Exclude</p>
Q3	<p>Interventions and Comparisons or Tests in the study</p> <ul style="list-style-type: none"> • For interventions: Are the interventions and comparisons being assessed in the study relevant to the Guideline? • For diagnostic studies: Are the diagnostic tests being assessed in the study relevant to the Guideline? • For prognostic studies: Are the variables, nomogram or are classification system being addressed in the study relevant to the Guideline? <p>Additional criteria:</p>	<p>Yes Unclear No</p> <p>  </p> <p>Go to next question Exclude</p>
Q4	<p>Outcomes in the study</p> <ul style="list-style-type: none"> • Are the outcomes being reported in the study relevant to the Guideline? <p>Additional criteria:</p>	<p>Yes Unclear No</p> <p>  </p> <p>Include Exclude</p>
	Final decision (subject to clarification of 'unclear' points)	Include Unclear Exclude

Appendix 4 – Recommendation worksheet

Guideline:

Section:	
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Recommendation			
Strength rating	Select	Certainty of evidence	Select
Benefits to harms assessment		Select	
Patient values/preference assessment		Select	

Reasoning	
<p>Please provide brief comments and reasons for the certainty of evidence and strength ratings given above, particularly for recommendations that have been upgraded or downgraded.</p> <p>Certainty criteria:</p> <p>High – further evidence is unlikely to affect the recommendation</p> <p>Moderate – further evidence from high quality studies may affect the recommendation if effect is high</p> <p>Low – further evidence from high quality studies is likely to change the recommendation</p> <p>Very low – the recommendation is largely based on panel consensus and other considerations such as patient values/preferences or benefit/harm balance</p>	
Evidence gaps	
Change to recommendation/strength rating/certainty in this update cycle? Tick if yes <input type="checkbox"/>	