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Manual for development of good practice recommendations

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Background information

Good practice recommendations (GPR)

Clinical practice guidelines are defined as "systematically developed statements to assist care providers and patient decisions about appropriate health care for specific clinical circumstances" [4]. A manual for development of ESHRE guidelines has been available since 2010 and was updated in 2017 (www.eshre.eu/guidelines).

Evidence-based guidelines are primarily based on high quality evidence and appropriate for areas where such scientific evidence is available.

In contrast, good practice recommendations are more applicable in areas where there is an opportunity to reduce uncertainty and improve quality of care, but scientific evidence is absent or limited.

Aim and structure of this manual

The aim of this manual is to provide stepwise advice to individual members of ESHRE working groups developing recommendations for good practice. The strategy for developing recommendations for good practice will depend largely on the topic under discussion. For technical recommendations (surgery, ultrasound, certain types of clinical examination), documents may consist of a list of how to apply a certain technique. For clinical/laboratory performance or reference parameters, documents may consist of a table where the recommended parameters are discussed by a panel of experts.

The manual is based on the ESHRE manual for guideline development, on experience with previous consensus-based documents developed by ESHRE, and available scientific publications on development of consensus documents.

The structure of this manual follows the development from its proposal through to publication and beyond.

This ESHRE manual is intended to be a "living" publication and it will be updated regularly based on new developments and experiences in the guideline groups. Comments on either content or presentation are welcome and should be sent to guidelines@eshre.eu.

Previous versions

Manual for development of recommendations for good practice v1.0. 2018

Details on the update 2019

In addition to some minor adaptations and corrections, 2 major adaptations were made in the current manual:

- → Adaptation of the methodology for forming a working group, with more stringent rules and approval by the Executive Committee.
- → Addition of a chapter on translation and adaptation of the ESHRE Recommendations for good practice documents, outlining the different policies

Abbreviations used in this document

ExCo	Executive Committee
GDG	Guideline development group
GPR	Good practice recommendations
Mo	Month
NGT	Nominal group technique
RS	Research Specialist
SIG	Special Interest Group
SIG SQART	SIG Safety and Quality in Assisted Reproductive Techniques
WG	Working Group

ESHRE guidelines and good practice recommendations

The main goal of ESHRE guidelines and good practice recommendations is the provision of both clinical and laboratory recommendations to improve the quality of health care within the European field of human reproduction and embryology.

ESHRE guidelines and good practice recommendations can be adapted and translated by National Societies ensuring more efficient use of resources and improvement of patient outcomes throughout Europe. ESHRE has established a policy for translation of its documents to ensure quality and validity (www.eshre.eu/guidelines).

Medico-legal implications of ESHRE guidelines and good practice recommendations

Potential medico-legal implications of clinical guidelines have been of ongoing concern to medical practitioners [5]. However, clinical guidelines are intended as an aid to clinical judgement, not to replace it. The ultimate decision about a particular clinical procedure or treatment will always depend on each individual patient's condition, circumstances and wishes, and the clinical judgement of the healthcare team as represented within the disclaimer in the

beginning of each guideline. Clinical guidelines are not intended to deprive clinicians of their medical freedom to treat, nor relieve them of their responsibility to make appropriate decisions based on their own knowledge and experience.

To clarify the legal perspective all ESHRE good practice recommendations carry the following statement in the disclaimer:

> *This Good Practice Recommendations (GPR) document represents the views of ESHRE, which are the result of consensus between the relevant ESHRE stakeholders and are based on the scientific evidence available at the time of preparation.*
>
> *ESHREs GPRs should be used for information and educational purposes. They should not be interpreted as setting a standard of care or be deemed inclusive of all proper methods of care, nor exclusive of other methods of care reasonably directed to obtaining the same results. They do not replace the need for application of clinical judgment to each individual presentation, nor variations based on locality and facility type.*
>
> *Furthermore, ESHREs GPRs do not constitute or imply the endorsement, or favouring of any of the included technologies by ESHRE.*

Development of good practice recommendations in 9 steps

Guideline development, implementation, and evaluation is described as a 12–step process (manual 2017).

In the development of good practice recommendations, the emphasis is more on expert opinion based on generalized and established good practice, rather than evidence from large research studies.

The development is described in this manual in a 9–step process, with exclusion of formal evidence synthesis, however this does not imply that if certain scientific evidence is present it will be omitted in the document. Expert opinions are based on both extensive practical expertise and scientific reports, even though they are limited in numbers.

DEVELOPMENT OF GOOD PRACTICE RECOMMENDATIONS: 9 STEPS

1. Topic selection
2. Working Group Composition
3. Scope and Outline
4. Preparing a Draft
5. Discussion & Consensus
6. Stakeholder Consultation
7. Approval
8. Publication and dissemination
9. Updating

Timelines

The time taken to develop an ESHRE GPR document varies according to the topic but will be shorter compared to ESHRE guidelines. It is estimated that the development of a GPR document will be submitted for ExCo approval within 12 months after the first meeting.

Budget

In person meetings should be kept to a minimum but are essential for the working group to reach formal consensus. It is estimated that at least one face-to-face meeting will be required to finalize the draft. To increase efficiency and avoid unnecessary meetings and travel, online meetings or email discussions should be considered to discuss the scope, plan of action, and the outcome of the stakeholder.

A fixed budget is set to cover the costs of meetings of a working group, which include travel (economy class tickets), accommodation, food and meeting facilities. Costs are reimbursed upon request within four weeks, on presentation of original receipts, invoices, bills, tickets etc., together with a provided ESHRE expense claim form.

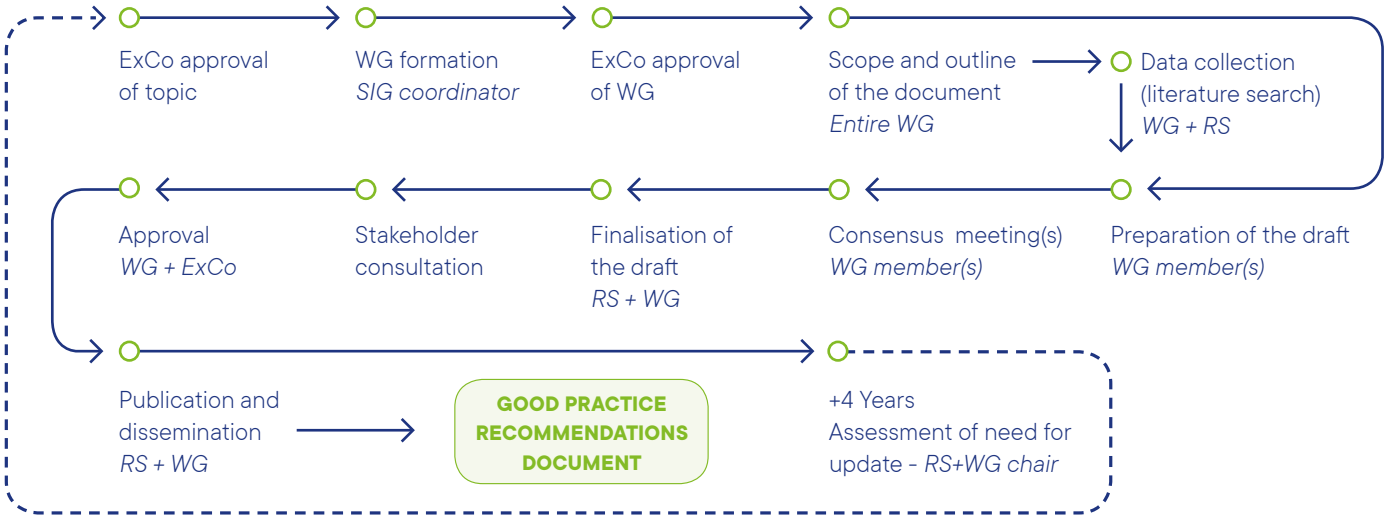
Summary of meetings and timelines

* The development should start as soon as a proposal is approved, but can be postponed due to other projects or workload.

Comparison of the key features of guidelines and good practice recommendations

	GOOD PRACTICE RECOMMENDATIONS	EVIDENCE-BASED GUIDELINES
TOPIC	Clinical / laboratory topics that cannot be addressed as an evidence based guideline, but with significant uncertainty and variation in practice	Clinical / laboratory topics with sufficient evidence based to answer key questions
OUTPUT	One or more papers published in HROpen Implementation tools	Full guideline Summary published in HROpen If relevant: Patient version, tools
SUPPORTING EVIDENCE	Expert opinion Observational data, if available	Systematics reviews, RTCs, or lower quality evidence
RECOMMENDATIONS	Consensus based	Primarily evidence based
DEVELOPMENT GROUP	Working Group	Guideline development group
	8–10 members	10–15 members
	Content experts	Content experts Non-expert clinicians Patient representative Allied health care professionals
TIME FRAME	12 months from the first WG meeting	18 months from the first GDG meeting
EXTERNAL REVIEW	Recommended (can be redundant if a large group of stakeholders was included during the development)	Obligatory

Summary of the steps for development of good practice recommendations



01. Topic selection

Topics should be selected within the field of reproductive medicine and embryology with the aim of assisting physicians and laboratory staff in diagnosis, procedures, and/or clinical management. Good practice recommendations should be developed for areas with significant opportunities for quality improvement despite an insufficient evidence base to support evidence-based guidelines.

Application procedure

The Coordinators of all Special Interest Groups (SIGs) are regularly invited to propose new topics for guideline and good practice recommendations. Proposals are submitted for approval by completing the application form. Individual ESHRE members wanting to present a topic are encouraged to contact the relevant SIG coordinator, who will be responsible for submitting the application form.

The guideline/recommendations application form (Form) can be requested via email (nathalie@eshre.eu). Completed application forms should be sent to the ESHRE research specialist.

Proposals can be added at any time and will generally be evaluated at the next meeting of the Executive Committee.

Selection procedure

The procedure for selection of proposals will be similar to the ESHRE guidelines. In short, all proposals will be checked by the ESHRE research specialist and a representative of the SIG Safety and Quality in Assisted Reproductive Techniques (SQART). If necessary, additional information is requested from the applicant to complete the proposal before submission to the ESHRE Executive Committee.

In a second step, the ESHRE Executive Committee evaluates the application and decides whether the proposal is acceptable. The ESHRE Executive Committee may suggest revisions to the application. If not acceptable, the applicant will be informed of the reason. The decision of the Executive Committee and any comments will be communicated to the applicant by the research specialist.

Good practice recommendations documents can only be developed for guidance on technical aspects of ART, or in areas where evidence is still very limited, but with a large variation in practice or uncertainty. GPR documents should not be developed for topics were evidence-based guidelines are an option.

Summary

Available forms

Application form Ⓐ

02. Working group composition

For development of GPRs, the composition of the working group is crucial. Members of the working group should all be expert on the topic, but preferably with varying expertise and different perspectives.

The idea of a working group, rather than a single person, to develop recommendations, has several advantages, including a broader knowledge and experience. Interaction between group members stimulates the consideration of a wide range of options, eccentricities are filtered out, and the group as a whole may carry more weight than any one individual [3].

WG selection procedure

When a topic is accepted, the applicant/responsible SIG coordinator is invited to propose working group members. First, the applicant/responsible SIG coordinator should consider inviting one representative of each of the relevant ESHRE Special Interest Groups. Experts in the topic of interest can also be invited to join the WG. Finally, an application process ("open call") can be set up by the research specialist where ESHRE members are asked to apply for a position in the WG. All WG members should be members of ESHRE.

Independent of how they were recruited, everyone with an interest of joining the WG will be asked to send a short cv, a motivation on why s/he should be included in the WG and the completed COI form (form). Based on the provided information, the profiles to be included (as above) and considering the balance in gender, geography and expertise, the applicant/responsible SIG coordinator prepares a proposal for the WG composition. This proposal is to be discussed and ratified by ExCo before the WG can be formalized.

Once all members have agreed to participate, the WG can become functional.

Chair of the working group

The chairperson of the WG is either the applicant, the responsible SIG coordinator, or any WG member with appropriate expertise and team-working skills. A chair is appointed for a period of two years. The chairperson of the WG should be a respected content expert, with experience in group facilitation, maintaining constructive dynamics, and identifying and resolving conflicts. Ideally, the chair should be able to remain neutral and objective and have some methodological expertise.

Composition of the working group

The group is composed of experts on the topic and scope of the project. Stakeholders (patient representatives, allied health providers, non-expert clinicians) are generally not involved, but they can be, depending on the topic. Industry representatives and experts with specific conflicts of interest are excluded from membership.

Based on the moderate workload, a working group would be composed of 8 to 10 members, although this can be increased if necessary. Simultaneous membership of more than 2 active[1] guideline development groups or GPR working groups is not allowed.

To ensure recommendations are applicable in different contexts and different regions, the following points should be considered when composing the working group:

- balance in geographical location
- balance in expertise (senior, junior)
- balance in location of employment (university hospital, private clinic)
- (balance in gender)

Depending on the topic, a representative from a related society might be considered for membership of the WG. In the case of a joint development with partner organizations, the Executive Committee must approve the collaboration (preferably at the same time as the application).

Responsibilities of working group members

To ensure that the WG functions effectively and achieves its aims, all WG members should engage to the following responsibilities:

- Attend all meetings [2]
- Sign a statement of confidentiality at the start of the project
- Declare of any conflict of interest
- Actively contribute to the discussions, with acceptance and tolerance of varying viewpoints
- Approve of the final recommendations

[1] Active meaning from the first WG/GDG meeting (scope) to the last WG/GDG meeting (after stakeholder review).
[2] If a member cannot attend two meetings in a row, he/she may be asked to stand down by the chairperson.

New members should usually not be added to the group once the development process has started. Additional needed expertise or the replacement of a member should be discussed within the working group. The research specialist should ensure that new members have all information on the previous steps in the development.

The WG will be supported by an ESHRE research specialist who will be responsible for overall project management and organizing the meetings in collaboration with the chair of the group. In addition, the research specialist will perform a literature search, if needed.

Handling Conflicts of Interest

Because ESHRE aims to ensure objectivity and independence in its European guidelines and recommendations documents, they are developed without external funding. All WG chairpersons and members have to provide disclosure statements of all potential conflicts of interest and sign a statement of confidentiality (see forms and). The disclosure form must be updated if any changes occur during the development process and at the end of the development process.

To ensure objectivity, group members with conflicts of interest in specific topics can be excluded from the discussion on these topics. However, in general, performance documents will be more technical and less prone to financial conflicts of interest.

Tips

- Record the composition of the WG.
- Record competing interests of the WG.
- Request approval of the WG members from ExCO
- Record that the document was developed without external funding.

Available forms:

Disclosure form Ⓑ

Confidentiality form Ⓒ

03. Scope and outline of the document

The aim of the scoping process is to define the overall objectives of the document, the patients and target users to whom the document is meant to apply and its relation to other (ESHRE) documents.

Scope of the document

Rather than a formal scoping with a checklist, the working group should define the content of the recommendations document.

It is recommended to consider the following questions:

- What is/are the overall purpose(s) of the proposed recommendations? (study question)
- What is the proposed target patient population and health care setting?
- Which interventions should be included?
- Who are the target users of the proposed recommendations, and who are the key stakeholders?
- What is the relation to other documents?
- What will be the exact methodology for the document and what is the timeline?

Documenting the replies to these questions will be helpful in a later stage, when composing the paper.

Outline of the document

In addition to defining which interventions/procedures/tests will be included in the document, it is recommended to write the outline of the paper already after the first (online) meeting of the WG. This will aid to define which topics will or will not be included. Furthermore, a clear structure will form the basis of the entire work and avoid misinterpretation.

Both the scope and the outline of the document should be acceptable to the entire working group and approved. During discussion of recommendations, it can be relevant to change the structure slightly, or add additional subsections. However, this should always be discussed within the working group and be acceptable to all members.

At this stage, it should also be discussed and decided how the draft will be written and by who. Furthermore, the need for a formal literature search (on one or more sections) should be discussed. The suggested methodology should be documented.

Tips

- Set deadlines for the whole development process.
- Consult appropriate stakeholders to ensure all relevant topics for the document have been identified and will meet the needs of the target audience(s).
- Record the overall objectives of the document.
- Record the target users of the document.

04. Preparing a draft

In preparation of discussing and reaching consensus on recommendations, all information that can be used to support recommendations should be compiled and summarized, either as a written draft or an oral presentation.

This could include scientific evidence, national data, survey results, other personal data, and experts' opinion (consensus).

Collection of data

Depending on the content of the document, the relevance of a literature search has to be discussed and decided by the working group members. If feasible and relevant, a literature search is recommended. Another option, which could be more appropriate for certain topics, is the collection of data from national/international ART databases, by means of a survey, or by means of Delphi Consensus.

Literature search

In preparation of the literature search, the working group should define the exact questions that will be the focus of the literature search. For questions on comparison of different interventions or tests, questions can be formulated as PICO questions, with clear definition of Patient, Intervention, Comparison and Outcome. These questions can be:

- → *Should [intervention] vs. [comparison] be used for [health problem]/[population]?*
- → *Should [intervention] vs. [comparison] be used to diagnose [target condition] in [health problem/population]?*

For other questions, the PICO format can also be applied, but some components may be irrelevant. This includes questions on etiology, risk factors, prevalence, prognosis, prediction and definition.

For questions on "how to" perform a certain procedure, papers describing this procedure in the methods section or existing guidelines from other professional and scientific societies can be used as a starting point.

The research specialist will perform the requested literature searches and summarize the results. The working group will have access to the raw data, including the full text papers, and will be asked to incorporate the information in the draft of the GPR document. The research specialist will store the search protocol and summarize it for the methods section of the final paper. A list of questions for which a literature search was performed can be added as supplementary information to the paper. For these topics, the working group can decide to formulate recommendations for further research (research agenda).

There will be no selection of study types, no formal data analysis, or grading of the quality of evidence, unless this is relevant for a specific section. More information on developing questions and performing a literature search are available in the manual for ESHRE guideline development [1].

Collection of data on current practice

For certain topics, it is clear that a literature search is not relevant, and collection of data on current practice is preferred. A first step could be a discussion within the working group on how they perform the subject at hand. If there is limited variation in practice, this discussion may be sufficient.

If needed, a formal survey amongst members of both the panel, but also extended through the network of the national representatives of ESHRE, or all ESHRE members, might provide important insights in the current practice. Discussing different practices, analyzing and performing SWOT (strengths, weaknesses, opportunities, and threats) analysis on this practice, can help in building a model for recommendations.

Once the selection and summary of evidence is complete, and/or data are collected on current practice, the information will be combined and condensed into recommendations. Recommendations are statements mostly proposing a course of action (see table p 16).

Preparation of the draft

One of the options used to structure a consensus meeting and enable agreement, is to prepare a written draft, which is then discussed at a working group meeting. This strategy has been used in several ESHRE documents.

In short, the working group members prepare a first draft of recommendations, based on their expert opinion and on current good practice, available (unpublished) data and, if performed, the results of the literature search.

The draft can be prepared by one of the group members (the leading author) or divided between the group members. This should be decided when the outline of the document and the timeline are discussed.

The research specialist will assist the working group members by performing a literature search, collecting full text papers, or summarizing other data. The draft will be written to support the discussion at the meeting.

Alternatively, oral presentations (PowerPoint) can be prepared on each of the topics included in the document, outlining the collected data.

Tips

- Document and store the search strategies used.
- List all questions in the document for which a literature search was performed.
- Record the strengths and limitations of the evidence.
- Record or refer to the methodology used for recommendations' formulation.
  - If no consensus is reached, describe the different views and options
  - Record benefits and harms considerations.
- Recommendations should be specific and unambiguous.

Formulation of recommendations

As users may use both documents with recommendations for good practice and evidence-based guideline, consistency with regard to terminology and formulation of recommendations is recommended.

Recommendations can be formulated as strong recommendations, or conditional recommendations, indicating whether the recommendation is applicable for all situations, or whether there is uncertainty and shared-decision making is recommended.

Although probably not relevant for recommendations documents, research only recommendations can be formulated for tests or interventions that should only be used in the context of research (see table 4.1).

There should not be any label to the recommendations, but consistent language should be used. Standardized wording provides structure for the WG members and aids to ensure clarity and to maintain consistency throughout the document and with other guidelines, avoiding wording that may be vague and nonspecific (see table 4.2).

Recommendations should be unambiguous, clearly defined, actionable, and easy to translate into clinical practice. For some recommendations, it may be helpful to explain the rationale behind the recommendation, which could include:

- Scientific evidence supporting the recommendations
- Benefits or harms
- Values and preferences of patients
- Values and preferences of clinicians

Table 4.1: The implications of the strong, conditional and research only recommendations, adapted from [1]:

TARGET GROUP	STRONG RECOMMENDATIONS*	CONDITIONAL (WEAK) RECOMMENDATIONS	RESEARCH ONLY RECOMMENDATIONS
PATIENTS	Most people in your situation would want the recommended course of action and only a small proportion would not.	The majority of people in your situation would want the recommended course of action, but many would not.	The test or intervention should only be considered by patients and clinicians within the setting of a research trial for which appropriate approvals and safety precautions have been established
CLINICIANS	Most patients should receive the recommended course of action	Recognize that different choices will be appropriate for different patients and that you must make greater effort with helping each patient to arrive at a management decision consistent with his or her values and preferences. Decision aids and shared decision making are particularly useful.	
POLICY MAKERS	The recommendation can be adopted as a policy in most situations.	Policy making will require substantial debate and involvement of many stakeholders.	NA

* Strong recommendations based on high quality evidence will apply to most patients for whom these recommendations are made, but they may not apply to all patients in all conditions; no recommendation can take into account all of the often-compelling unique features of individual patients and clinical circumstances.

Table 4.2: Recommended phrasing for recommendations in the ESHRE documents.

RECOMMENDED PHRASING	
Strong recommendation	— Clinicians should — It is indicated — It is recommended — Do
Conditional / weak recommendation	— It is conditionally recommended — It is suggested — Clinicians might — Clinicians could consider — Clinicians may/might consider

05. Discussion and reaching consensus

Working group consensus meeting(s)

Up to 2 meetings will be organized to discuss all recommendations until consensus is reached within the WG. Ideally, the draft and recommendations are prepared and sent to the research specialist 2 weeks before the meeting, as this would enable the other group members to prepare for discussion which could facilitate reaching agreement.

The leading author of each section will be asked to read through the document, explaining reasoning behind the recommendations and indicating areas of uncertainty. The working group members are asked whether they agree, and if not, how to modify the recommendation. In general, informal methods for consensus are applied, taken into account the possible disadvantages. The chair of the group is asked to ensure every group member has the chance to express their personal judgment, and groups should not be dominated by a single voice. For some recommendations where different views of the members inhibit the group from reaching agreement, formal methods can be applied (see below for more information). A modified Delphi approach is often used: group members are asked to submit their views privately (for instance via email) for the recommendations that did not reach consensus at the meeting. The results of this exercise are summarized, presented to the group and discussed before all members again submit their views privately. The aim is to move towards consensus. In absence of consensus, this should be explicitly stated, with the reasons and how the group was divided.

At the end of the meeting, the recommendations should be collected and sent to the entire working group for written comments. The leading author of the section should review the written comments and address them if relevant.

Finalization of the draft for stakeholder review

The research specialist and/or project leader will collect all information after the consensus meetings and combine this in a single draft.

Writing in committee requires prior agreement about the consistent use of terminology and writing style. If the draft has been written by several authors, consistency should be checked and corrected. Modifications to the text that could impact on the content, rather than pure linguistic improvements, should be checked and agreed upon by the entire working group.

ESHRE documents should be written in English and within a European scope. Furthermore, they should be comprehensive and flexible in order to allow adaptation to diverse settings and circumstances of clinical practice.

The use of paragraphs and headings are recommended to facilitate readers' navigation, and these should be adapted to a style acceptable for Human Reproduction Open. Moreover, the use of tables, illustrations, figures and algorithms is encouraged.

The research specialist is responsible for merging the input of the different WG members and to adapt the content where needed to result in a consistent and well-structured document.

Tips

- Seek approval from all members of the WG for the final document(s).
- Present the different management options clearly.
- Present expected exceptions for recommendation application, if appropriate.
- Facilitate recommendation identification (e.g. bullets, numbering, boxes).
- Discuss potential barriers in applying the recommendations.
- Consider potential cost implications of applying the recommendations.

Table 5.1 Characteristics of informal and formal consensus development methods, adopted from [3]

CONSENSUS DEVELOPMENT METHOD	MAILED QUESTIONNAIRES	PRIVATE DECISIONS ELICITED	FORMAL FEEDBACK OF GROUP CHOICES	FACE-TO-FACE CONTACT	INTERACTION STRUCTURED	AGGREGATION METHOD
INFORMAL	No	No	No	Yes	No	Implicit
DELPHI	Yes	Yes	Yes	No	Yes	Explicit
NGT	No	Yes	Yes	Yes	Yes	Explicit
CONSENSUS DEVELOPMENT CONFERENCE	No	No	No	Yes	No	Implicit

Consensus

Independent of the methodology selected, the WG members will need to make collective decisions throughout the entire development of the document. Such consensus includes the scope and structure of the document, but more importantly, consensus should be reached on the recommendations and the final document. Reaching consensus is an integral part in the development of guidelines and recommendations documents. In development of evidence-based guidelines, decisions ideally depend on high quality evidence, while for recommendations for good practice, evidence is usually absent, and recommendations largely depend on the opinions and experiences of experts.

Several strategies to reach consensus have been used and described, but there is very little information available on how to apply these methods in general, and specifically in healthcare questions.

Consensus can be reached informally or through free discussion, and formally. Informal consensus involves bringing together a group of people to discuss a problem with the aim of reaching agreement. It should be noted that with the informal approach, there may be an influence of the group on individual judgments, perceived social pressure and the focus may be on consensus rather than on the discussion of alternative approaches.
The most commonly used formal methods for consensus development are the Delphi survey, nominal group technique (and RAND/UCLA appropriateness method), and the NIH consensus development conference [3]. The latter is developed predominantly to provide a public forum for the discussion of issues, rather than group decisions of a group of experts. Differences between these methods, and the informal approach, are summarized in table 5.1.

Delphi method

The Delphi method involves an iterative survey of experts seeking their individual views. The factors to be taken into account by the participants can be suggested by the participants in an initial survey. Each participant completes a questionnaire and is then given feedback on the whole set of responses. Participants are given the opportunity to revise their judgment, based on explanations for any views they hold that were significantly divergent from the viewpoints of the other participants or based upon his/her evaluation of new information provided by other participants. This process can be repeated in several rounds, with increasing consensus in each round compared to the former. The result can include a numerical indication of the agreement in the group. Importantly, participants never meet or interact directly, although newer methods of face-to-face Delphi have been developed [2] [3].

Nominal group technique

The aim of the nominal group technique is to structure interaction within a group, and it is often used to generate ideas. Each participant records his or her ideas independently and privately. Each participant is then asked to name one of the ideas, and these are listed in a round-robin format (for instance on a flip board). The process is continued until all ideas have been listed. Each idea is then discussed in turn by the group. Individuals then privately record their judgments or vote for options. Further discussion and voting may take place [3].

06. Stakeholder consultation

To ensure a recommendations document is acceptable for stakeholders, a stakeholder consultation is recommended. In addition to verifying the acceptability and adequacy of the document, stakeholder review can also highlight issues with the methodological quality, the language and whether it is unambiguous, the feasibility of the recommendations, and any conflicts of interest that could have influenced the recommendations.

Procedure

The review phase starts with a review of the draft by several stakeholders. All members of the involved SIGs, patients' representatives (lay reviewers), and representatives of national organizations are invited by email to review the draft. At the same time, the draft is web posted with an invitation to review for all ESHRE members. Interested reviewers must sign a statement of confidentiality and submit their review comments within four weeks. Following this procedure results in an addition to the stakeholder review report that will be published on the ESHRE website (Reviewer comments form Ⓓ).

For adapted (parts of) or updated documents, the draft should be also sent for review to the original developers.

The comments received from reviewers are tabulated and discussed in the stakeholder review report. The WG will respond to each of the comments, but does not commit to altering the recommendations in all instances. If no change is made, the reasons for this will be recorded in the report. Any alterations to the recommendations must be made with the agreement of the whole WG and noted in the review report. The report is published on the ESHRE website alongside the recommendations document.

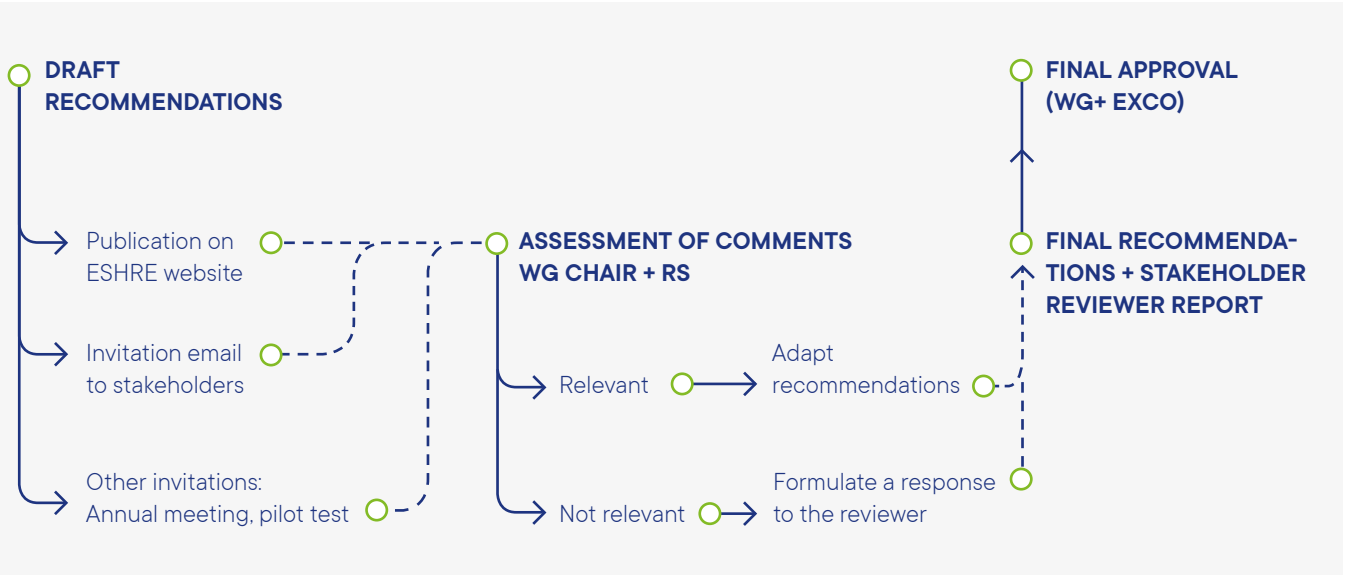
Tips

- Use the reviewing and piloting phase as an opportunity to advertise the existence of a new document.
- Set a policy and process for handling consumer and stakeholder feedback and dealing with different perspectives (e.g. ensure that diverse perspectives are taken into account in making decisions, provide transparent rationale for judgments made, provide an appeal process for stakeholders, publish consultation comments and the WG's responses).
- Record the stakeholder review reporting methodology, document the internal and external peer review process and, if applicable, publish consultation comments and the WG's responses
- Document the enrollment and selection of consumers and stakeholders for the WG and the involvement and consultation with all other consumers and stakeholders to ensure explicit and transparent methods.

Available forms:

Reviewer comments form Ⓓ

Summary



07. Approval

Final version & authorization

After stakeholder consultation, the entire WG should formally approve the final version of the GPR document.

After completion of all revisions, English language reviewers and proofreaders (and possibly lawyers) can be called upon when necessary.

The final step is to submit the document for formal approval by the ESHRE Executive Committee.

08. Publication, dissemination, translation and implementation

Dissemination is considered as a continuation of the work of the WG and involves making guidelines accessible, advertising their availability, and distributing them widely. Guidelines and recommendations documents are (most) effective if their dissemination and implementation are carefully considered and vigorously pursued. The standard dissemination procedure for ESHRE good practice recommendations comprises publishing and announcement.

Publication

As soon as a GPR document is accepted for publication by the ESHRE Executive Committee, it will be submitted for publication at the ESHRE pages of Human Reproduction Open. A link to the document will be added to the website of ESHRE (www.eshre.eu/guidelines) upon online publication in HROpen.

The relevance of a patient version of the document should be assessed by the working group as it will depend largely on the topic. Similarly, the value of additional tools for implementation should be evaluated.

Dissemination

All relevant ESHRE communication channels will be used to announce the release of a new document:

- A newsflash on the ESHRE website's homepage
- A mailing to the members of the relevant SIGs, or all ESHRE members
- An announcement in "Focus on Reproduction", if relevant
- Promotion at the annual ESHRE meeting.
- A mailing to all related National Societies to inform them and ask them to encourage local implementation by, for instance, translations or condensed versions. National societies are also offered a website link to the original document.
- All appropriate remaining stakeholders - for instance, European policy makers, patient societies and industry representatives - will be separately informed.

Translation and endorsement

An important factor facilitating implementation is endorsement by professional groups. Endorsement of ESHRE Guidelines and Good practice recommendations is always sought from relevant National Societies by informing their presidents.

ESHRE and the working group members put significant effort into developing recommendations documents. Furthermore, we try to involve different nationalities in the working groups, and to organize a broad stakeholder review. By doing so, we provide good practice recommendations written to apply to a broad population which ideally should be endorsed by national societies, and if wished upon, translated verbatim.

National Societies and organizations can request permission to translate (verbatim) one of the recommendations documents, or any specific content related to the GPR documents, in their language. For translation of the GPR document, or any material published in the ESHRE journals, formal permission should be requested from Oxford University Press (OUP), by sending an email to journals.permissions@oup.com. For all other documents, ESHRE can give permission according to a straightforward 4–step procedure of approval, translation, validation and publication is outlined in a policy (see p24–25).

For reasons of consistency, only one translation of a certain ESHRE document in any given language is accepted by ESHRE. ESHRE reserves the exclusive right to publish the first edition of all ESHRE documents and post its translation on the ESHRE website. National Societies must secure copyright protection in their own country.

When a verbatim translation of a GPR document is insufficient for national uptake, ESHRE will allow for national societies to use the ESHRE GPR documents as the basis of their national documents. To ensure transparency, the methodology should clearly refer to the ESHRE GPR paper (including the weblink www.eshre.eu/Guidelines and the reference of the paper in HROpen) and state how this document was used, and for which topics the recommendations differ significantly between the documents. The resulting document will be considered a national recommendations document, not an ESHRE GPR document.

Implementation tools

For recommendation documents, development of implementation tools is highly encouraged to aid users in applying the recommendations. Whether implementation tools are developed and in which format is dependent on the topic of the GPR document and should be discussed within the working group. The WG members are expected to actively contribute to the development of implementation tools.

Examples can be:

- A pocket version of the document, online or printed
- An E-campus with presentations focusing on the topic and the recommendations
- A web platform outlining the document with the addition of educational material (videos, pictures, tutorials)
- Flow charts or other graphical representations of the content

Detection of barriers to implementation related to the document can be helpful to develop targeted implementation tools. The different types of barriers to implementation can be detected with the GLIA instrument [6] (http://nutmeg.med.yale.edu/glia/doc/GLIA_v2.pdf) and are divided as:

- internal to the document itself
- factors related to the individual care providers (e.g. attitude and skills)
- factors related to the (social) setting (e.g. patients' and colleagues' characteristics)
- external factors related to the system (e.g. reimbursement).

At an appropriate time after dissemination and implementation an evaluation is necessary for insight into the impact of the recommendations. Such an evaluation consists of several components, namely an assessment of:

- dissemination
- change in practice performance
- change in health outcomes, and
- change in consumer's knowledge and understanding.

More detailed information on guideline implementation and evaluation is available in the ESHRE manual for guideline development [1].

Tips

- Develop or adapt tools, support, and derivative products to provide guidance on how the recommendations can be implemented into practice (e.g. mobile applications, integration with clinical decision support systems, make document adaptable as an educational resource for target audience for education outreach).
- Make considerations for adaptation of the document and provide specific instructions for how target end users who would like to adapt the recommendations to other contexts can do so in a systematic and transparent way (e.g. modifying a recommendation based on local resources and baseline risk, implications that deviate from the judgments made by the WG).
- Conduct an internal evaluation (i.e. self-assessment) of the development process, including the working group meeting(s), by asking working group members for feedback.
- Consider pilot testing the recommendations with the target end users
- Provide criteria and tools for target end users to monitor and audit the implementation and use of the recommendations (e.g. identify outcomes that should change with implementation and suggest methods for measuring the outcomes).
- Provide support and tools for prospective evaluation of the recommendations to determine its effectiveness after implementation (e.g. using randomized evaluations where possible, using before-after evaluations cautiously due to uncertainties regarding the effects of implementation).
- Plan to collect feedback and evaluations from users to identify how to improve the intrinsic implementability of the recommendations in subsequent versions.
- Support the document with application tools and record those within the recommendations document.

Policy for the translation of ESHRE® Documents[1]

Please note that this policy sets out general rules with regard to the translation of ESHRE® Documents (as defined below). Depending on the type of ESHRE® Documents, specific provisions might also be applicable (as is for example the case for the ESHRE® guidelines). In case of a conflict between the provisions of this policy and specific provisions, the latter shall prevail.

Translation of ESHRE® Documents:

In summary, the following four steps must be followed in case of translation of an ESHRE® Document:

1. Request written permission of ESHRE® before endeavouring translation
2. Make an exact translation and ensure that the ESHRE® copyright statement and the ESHRE® disclaimer are foreseen on the document, as well as full reference to the ESHRE® Document
3. Request written validation of the translation from ESHRE®
4. Ensure that the translation is up-to-date and corresponds to the latest version of the ESHRE® Document

1. Prior permission to translate

A National Society shall have the right – at its own cost – to translate ESHRE® Documents and publish the translations thereof in its own country upon (i) prior written approval of ESHRE® and (ii) full endorsement of the corresponding parent ESHRE® Document.

For reasons of consistency, ESHRE® shall accept only one translation per ESHRE® Document in any given language. At all times, ESHRE® retains full (copy)rights whatsoever on every ESHRE® Document and its translations.

2. Obligations for the translators and the National Society

General

All costs and expenses relating to the translation of an ESHRE® Document (including the cost of compensating translators) shall be borne by the National Society exclusively.

The National Society ensures that every translator transfers all rights whatsoever (which the latter might possibly possess with respect to the performed translation) to ESHRE®.

The National Society shall be responsible for the exact translation of the ESHRE® Document by the translator it appeals on. Each translation shall contain all textual, pictorial and diagrammatic material, as foreseen in the ESHRE® Document, without any alterations. Footnotes or annexes may be added to highlight national and/or regional practices. In no event, amendments to the original text shall be allowed.

Further, the National Society (and the translator it appeals on) undertake to:

1. give full credit to ESHRE® for the ESHRE® Document by including on the title page of the translated document:
   - → the ESHRE® copyright statement (as mentioned below),
   - → the ESHRE® logo,
   - → full reference to the original publication of the ESHRE® Document on ESHRE's® website and in ESHRE's® official journals ('Human Reproduction')
2. foresee the appropriate ESHRE® disclaimer, as mentioned below, in the translated document;
3. mention in the title of the translated document the name of each ESHRE® working group member who is (co-) author of the ESHRE® Document; and
4. clarify in the (sub)title of the translated document that it entails a translation from an ESHRE® Document, whereby the full title of the parent ESHRE® Document needs to be mentioned.

Whenever possible, a back-to-back translation is recommended.

The National society that produces a translation of an ESHRE® Document may foresee the translated document of its own logo(s) and additional information about its society. The names of the translators, reviewers and/or other people involved in the translation of the ESHRE® Document, can also be foreseen on the translated document, provided that it has been made clear they were solely involved in the translation of the ESHRE® Document and thus took no part in the production and publication of the ESHRE® Document.

Translation sponsored by companies

In case a National Society obtains sponsoring from commercial organisations in order to finance the translations of ESHRE® Documents, it shall be strictly prohibited to foresee in any kind of product advertising on the translated document.

However, corporate logos of the sponsoring company(ies) in question can be displayed with the following statement: '*The translation of this ESHRE® document was made possible through an educational grant from [name sponsor]. [Name sponsor] acknowledges explicitly that it was not involved in the actual production and publication of the parent ESHRE® document, hence influenced in no way the content thereof.*'

3. Validation of the translation

All documents translated in line with the above can only be published upon prior written validation of ESHRE®. Such validation shall:

1. be organised by the ESHRE® central office;
2. be performed by a native speaker from the ESHRE® working group or the committee of national representatives; and
3. only relate to the translation itself and in no case entail a review of the content, meaning that ESHRE® shall not verify if the scientific value of the parent ESHRE® Document has been preserved in the translated document.

ESHRE® strives to inform the National Society of the outcome of the performed validation within four weeks upon receipt of the translation by ESHRE®.

Validated translations of ESHRE® Documents will be published by ESHRE® on its website, upon prior written approval of the respective National Society.

4. Keep the translation up-to-date

It is the responsibility of a National Society to ensure that the translated document is kept up-to-date and corresponds to the latest version of the parent ESHRE® Document.

ESHRE® strives to inform the National Society of any updates on the parent ESHRE® Document, and this within due time.

ESHRE® copyright statement

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ESHRE® disclaimer

"This publication entails a translation of an original ESHRE® document – as fully referred to on the title page of this document – whereby such translation was performed in line with the provisions of the 'Policy for the translation of ESHRE® Documents', as consultable on the ESHRE® website (www.eshre.eu).

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[1] Any document, produced and published by ESHRE®, to which ESHRE® exclusively possesses all rights of ownership. The English version always entails the original version of the document.

09. Updating

Updating of a GPR document is less dependent on the publication of new scientific data and hence less urgent.

It is recommended to monitor the relevance of the document annually, starting 4 years after publication. For monitoring, the research specialist will contact the chair of the working group and the chair of the SIG SQART to verify whether an update is required of the recommendations document. If an update is required, each section should be evaluated to assess whether it can be endorsed (the recommendations are still current and relevant), updated or archived. If needed, the entire working group can be asked for input.

Complete or partial update

If a need for review is identified for one or more sections (partial review), or the full document (complete review), approval for the update must be requested from the ESHRE Executive Committee by completing the application form, and a report of the assessment for the need of an update. A complete review, approved by the ESHRE Executive Committee will follow the usual process described in this manual, unless emerging evidence has enabled the possibility of an evidence-based guideline on the topic. Updated documents are also subject to consultation and will follow the usual validation process.

Tips

- → Decide who will be responsible for routinely monitoring the literature and assessing whether new significant knowledge/evidence is available (e.g. consider involvement of experts not previously involved in the WG to periodically review the document).
- → Make arrangements for working group membership and participation after completion of the document (e.g. rotating membership every 1–2 years, selection of a new group at time of updating, continuing participation by the chair).
- → Plan the logistics for updating the document in the future.
- → Refer to the procedure for updating.

10. Developing standards

When defining parameters for the lab or clinic, such as performance indicators, or when defining a classification system, it may be relevant to ensure the recommendations are acceptable and agreed upon by a larger group of experts, rather than within the working group.

To achieve the input of a larger group of stakeholders, the working group can prepare an expert panel meeting to which representatives of different countries, (national or international) organizations, and/or disciplines are invited. Alternatively, a Delphi survey can be used to collect input and reach consensus in a larger group of stakeholders.

Topic selection, working group composition, scope and outline

Development of a document defining parameters for the lab or clinic will start with the selection of a topic, and request of approval by the ESHRE Executive Committee, as described in this document. As soon as the scope and outline of the document are defined, the expert panel consultation can be prepared.

Expert panel consultation

In preparation of the expert panel meeting, the working group members are asked to make a presentation on a specific topic, or chair a session. The research specialist supports the presenters by searching and collecting best available evidence, if requested. For more information, check chapter 4.

The working group members are asked to present their findings from the literature and expertise during the expert panel meeting, after which the details are further discussed until consensus within the expert panel. Discussion is facilitated by a chair, who is responsible for ensuring one voice does not dominate, and for ensuring consensus is reached on all topics.

After the meeting, the workshop report is written by the research specialist and/or the working group members. For consistency with previous documents, the resulting manuscript is divided in the workshop report (i.e. a summary of all presentations) and the recommendations of the expert panel (i.e. the full list of all consensus points as discussed at the meeting).

Delphi survey

Another approach to include the input of a larger group of stakeholders, is the development of a Delphi survey, which is an established technique to reach consensus.

The outcome of the Delphi survey will be discussed within the working group, which will be responsible for drafting the document. All participants to the Delphi survey should be listed to the resulting paper as contributors.

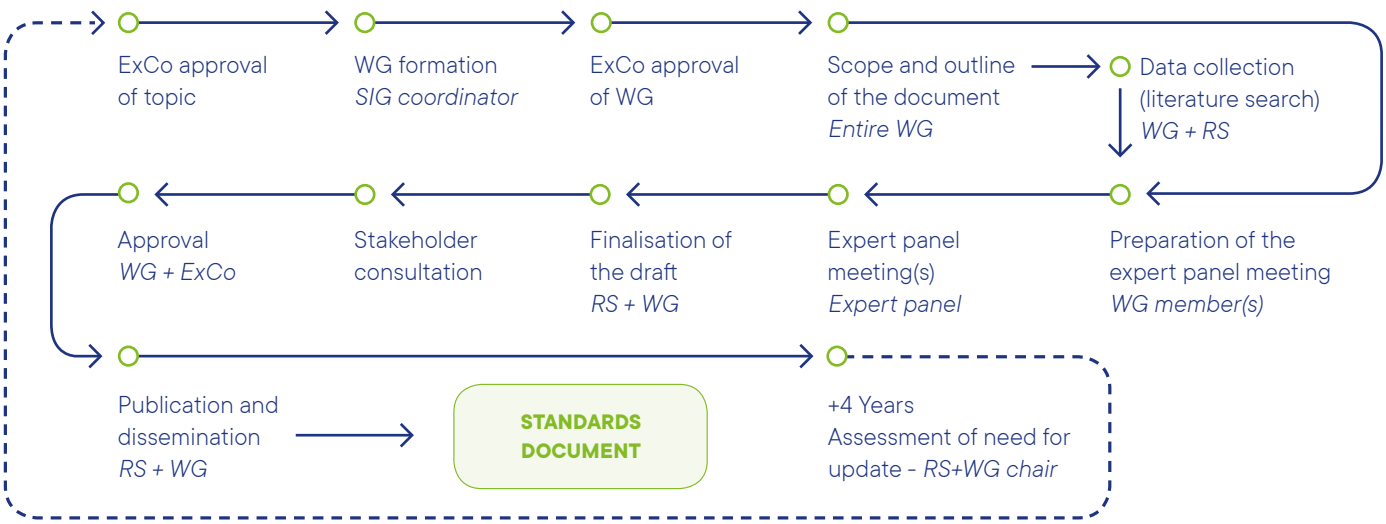
More information on the Delphi method is available in chapter 5.

Stakeholder consultation, approval, publication and updating

For documents where a larger group of stakeholders has been included in the development, separate stakeholder consultation may be redundant.

All other steps should follow the normal procedure as outlined in this document.

Summary



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Forms

Ⓐ Application form

Ⓑ Disclosure form

Ⓒ Confidentiality form

Ⓓ Reviewer comments form

A. Application form

Guideline / Good practice recommendations document

Applicants

CONTACT PERSON(S):

ESHRE SPECIAL INTEREST GROUP(S):

SUGGESTED MEMBERS OF THE WORKING GROUP (EXPERTS AND / OR ESHRE SIG REPRESENTATIVES)[3]

Topic

PROPOSED TITLE:

GUIDELINE OR GOOD PRACTICE RECOMMENDATIONS:

PROPOSED (CLINICAL) PROBLEM:

THE RELEVANCE OF THE PROPOSED CLINICAL PROBLEM (E.G. VOLUME, COSTS AND PATIENT IMPACT):

MAIN OUTCOME(S) TO BE ADDRESSED BY THE PROPOSED GUIDELINE/ GOOD PRACTICE RECOMMENDATIONS:

INDICATION OF ACTUAL PRACTICE VARIATION:

EXPECTED BENEFIT(S) FROM THE PROPOSED GUIDELINE/ GOOD PRACTICE RECOMMENDATIONS DEVELOPMENT AND IMPLEMENTATION:

INDICATION OF THE SIZE AND STRENGTH OF THE EVIDENCE FOR THE PROPOSED TOPIC:

OTHER COMMENTS: (IN CASE OF A GOOD PRACTICE RECOMMENDATIONS DOCUMENT, PLEASE CLARIFY METHODOLOGY, SCHEDULE AND COSTS FOR THE PROJECT)

Other existing guidelines / Good practice recommendations documents

EXISTING GUIDELINES WITHIN THE FIELD OF THE PROPOSED TOPIC:

OVERLAP WITH OTHER ESHRE DOCUMENTS:

THE COMPLETED APPLICATION FORM SHOULD BE SENT TO NATHALIE@ESHRE.EU

[3] If feasible suggest a few names. A final list of WG members will have to be presented to and approved by ExCo before the working group can start.

B. Disclosure form

ESHRE Good practice recommendations document

All ESHRE working group members are expected to provide completed and signed disclosure statements about all financial, personal, or professional relationships with industry, individuals, or organizations to avoid the perception of a conflict of interest. Updates should be made if changes occur during the development process.

Contact information of the working group member

NAME:

INSTITUTION, ADDRESS:

E-MAIL ADDRESS:

Information on potential conflicts of interest from the last 3 years, or anticipated in the next 12 months

- ○ I HAVE NO POTENTIAL CONFLICT OF INTEREST FROM THE LAST 3 YEARS TO REPORT
- ○ I HAVE THE FOLLOWING POTENTIAL CONFLICT(S) OF INTEREST FROM THE LAST 3 YEARS TO REPORT:
  - ○ RESEARCH GRANT(S) FROM ONE OR MORE COMPANIES, FROM
  - ○ CONSULTING FEE(S) FOR E.G. SERVICES ON AN ADVISORY BOARD OR LEGAL TESTIMONY, FROM
  - ○ SPEAKER'S FEE(S) FOR INSTANCE AS COMPENSATION FOR LECTURING AND TRAVEL, FROM
  - ○ SALARY OR POSITION FUNDING, FROM
  - ○ OWNERSHIP INTEREST BY STOCK (OPTIONS) OR PARTNERSHIP OF A HEALTHCARE COMPANY, FROM
  - ○ OTHER (FINANCIAL) BENEFIT E.G. BY INSTITUTIONAL CONFLICTS OF INTEREST IN THE TOPICS OR ISSUES ADDRESSED IN THE DOCUMENT:

SIGNATURE (OR STATE YOUR NAME):

DATE:

C. Confidentiality form

ESHRE Good practice recommendations document

As a writer of an ESHRE document you have been or may be exposed to certain confidential and/or proprietary information, materials or data. It is important to the integrity of the writing process and final work that this information should be kept strictly confidential and not disclosed at any time under any circumstance.

Contact information of the working group member

NAME:

.....

INSTITUTION, ADDRESS:

.....

E-MAIL ADDRESS:

.....

Statement of confidentiality

- → I WILL NOT DISCLOSE ANY CONFIDENTIAL AND/OR PROPRIETARY INFORMATION, MATERIALS OR DATA RELATED TO WORKING GROUP'S WORK TO ANY THIRD PARTY, BUT KEEP THIS INFORMATION STRICTLY CONFIDENTIAL.
- → I WILL KEEP ANY CONFIDENTIAL AND/OR PROPRIETARY INFORMATION, MATERIALS OR DATA IN MY POSSESSION IN A SAFE AND SECURE PLACE TO PROTECT AGAINST INADVERTENT DISCLOSURE.
- → I WILL NOT USE ANY CONFIDENTIAL INFORMATION AND/OR PROPRIETARY INFORMATION, MATERIALS OR DATA FOR ANY PURPOSE OTHER THAN PARTICIPATING IN AN ESHRE GOOD PRACTICE RECOMMENDATIONS DOCUMENT DEVELOPMENT PROCEDURE.

SIGNATURE (OR STATE YOUR NAME):

.....

DATE:

.....

D. Reviewer comments form

Recommendations

Review period

Contact information of the reviewer

NAME:

COUNTRY:

E-MAIL ADDRESS:

I AM PARTICIPATING

- ○ AS AN INDIVIDUAL
- ○ ON BEHALF OF A (INTER)NATIONAL ORGANIZATION, NAMELY

- ○ ON BEHALF OF A COMPANY, NAMELY

Statement of confidentiality

- → AS A REVIEWER OF THIS ESHRE DOCUMENT YOU HAVE BEEN OR MAY BE EXPOSED TO CERTAIN CONFIDENTIAL AND/OR PROPRIETARY INFORMATION, MATERIALS OR DATA. IT IS IMPORTANT TO THE INTEGRITY OF THE WRITING PROCESS AND FINAL WORK THAT THIS INFORMATION SHOULD BE KEPT STRICTLY CONFIDENTIAL AND NOT DISCLOSED AT ANY TIME UNDER ANY CIRCUMSTANCE.
- → I WILL NOT DISCLOSE ANY CONFIDENTIAL AND/OR PROPRIETARY INFORMATION, MATERIALS OR DATA RELATED TO WORKING GROUP'S WORK TO ANY THIRD PARTY, BUT KEEP THIS INFORMATION STRICTLY CONFIDENTIAL.
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- → I WILL NOT USE ANY CONFIDENTIAL INFORMATION AND/OR PROPRIETARY INFORMATION, MATERIALS OR DATA FOR ANY PURPOSE OTHER THAN PARTICIPATING IN THE REVIEW PROCEDURE.

SIGNATURE (OR STATE YOUR NAME):

DATE:

Comments on the document

PAGE	LINE	COMMENT

Please send completed forms (as word-document or pdf) to guidelines@eshre.eu before XX.

All comments will be revised by the working group and assessed. If the comment is accepted by the working group, it will result in a modification of the document. If not, the working group will formulate a reply to the reviewer. The details of the review procedure, the comments, modifications and replies will be summarized in a stakeholder review report which will be available online.

By submitting this form, you will be listed as an expert reviewer of the document. The list of reviewers will be published in the review report and as supplementary data in HROpen.

For more information on the review, you can contact guidelines@eshre.eu.

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