Manual for the development of Good Practice Recommendations documents

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Background information

Recommendations for good practice

Evidence-based guidelines are systematically developed statements, based on the best available scientific research and developed with transparent methodology, to assist care providers and patients' decisions about appropriate care for specific circumstances (Institute of Medicine Committee on Clinical Practice Guidelines, 1992). A manual for development of ESHRE guidelines has been available since 2010 and was updated regularly (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, Recommendations for Good Practice 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 (WG) 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

→ Manual for development of Recommendations for Good Practice v2.0. 2019

Details on the update 2026

In addition to some minor adaptations and corrections, 4 major adaptations were made in the current manual:

→ Adaptation of the methodology for the application procedure for new Recommendations for Good Practice and the update of existing Recommendations for Good Practice, which is now reviewed by the Guidelines Committee before approval by the Executive Committee (ExCO).

→ Adaptation of the methodology for forming a WG, with all members and chairs selected via an application procedure and with more stringent rules on conflict of interest (COI). The composition of the WG with review of the applications and COI is now handled by the Guidelines Committee before approval by the Executive Committee.

→ The scope and key questions will be made public for stakeholder comments for 2-4 weeks.

→ Stakeholders will need to pre-register to be able to submit comments during the stakeholder review period at the end of the Recommendations for Good Practice development process.

ESHRE guidelines and Recommendations for Good Practice

The main goal of ESHRE guidelines and Recommendations for Good Practice 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 Recommendations for Good Practice 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 recommendations for good practice

Potential medico-legal implications of clinical guidelines have been of ongoing concern to medical practitioners (Moses and Feld, 2008). 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 guidelines carry the following statement in the disclaimer:

The aim of practice guidelines is to aid healthcare professionals in everyday decision about appropriate and effective care of their patients. However, adherence to these practice guidelines does not guarantee a successful or specific outcome, nor does it establish a standard of care. Practice guidelines do not override the healthcare professional's clinical judgment in diagnosis and treatment of particular patients. Ultimately, healthcare professionals must make their own clinical decisions on a case-by-case basis, using their clinical judgment, knowledge and expertise, and taking into account the condition, circumstances, and wishes of the individual patient, in consultation with that patient and/or the guardian or caretaker.

Development of recommendations for good practice in 9 steps

Guideline development, implementation, and evaluation is described as a 12-step process (manual 2026).

In the development of Recommendations for Good Practice, the emphasis is more on expert opinion based on generalised 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 Recommendations for Good Practice: 9 steps

① TOPIC SELECTION
② WORKING GROUP COMPOSITION
③ SCOPE AND OUTLINE
④ PREPARING A DRAFT
⑤ DISCUSSION & CONSENSUS
⑥STAKEHOLDER CONSULTATION
⑦ APPROVAL
⑧ PUBLICATION AND DISSEMINATION
⑨ UPDATING

Timelines

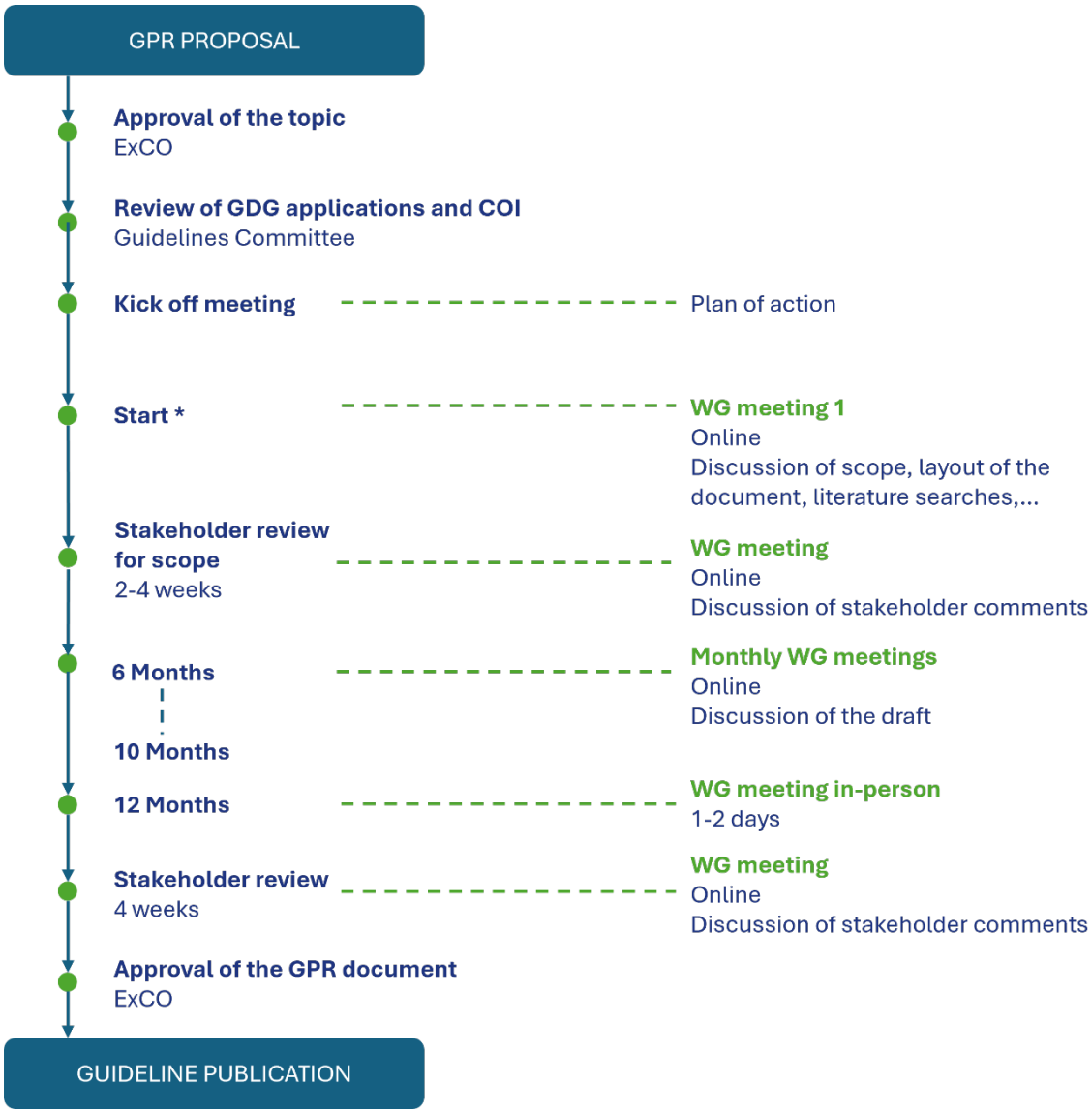
The time taken to develop an ESHRE Recommendations for Good Practice document varies according to the topic but will be shorter compared to ESHRE guidelines. It is estimated that the development of a Recommendations for Good Practice document will be finalised within 12-18 months after the first meeting.

Budget

Most of the meetings of the WG are virtual, with the exception of an in-person meeting during the ESHRE Annual meeting (if needed), and one in-person meeting at the end of the discussion &consensus phase.

A fixed budget is set to cover the costs of meetings of a WG, 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.*

Table 1.1. Comparison of the key features of guidelines and recommendations for good practice.

	RECOMMENDATIONS FOR GOOD PRACTICE	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 Human Reproduction Implementation tools	Full guideline Summary published in Human Reproduction If relevant: Patient version, tools
Supporting evidence	Expert opinion Observational data, if available	Systematics reviews, RCTs, or lower quality evidence
Recommendations	Consensus based	Primarily evidence based
Development group	Working group 8-10 members Content experts	Guideline development group 10-15 members 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 development)*	Obligatory

Abbreviations used in this document

COI	Conflict of interest
ExCO	Executive Committee
GC	Guidelines Committee
GDG	Guideline development group
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

1. 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. Recommendations for Good Practice 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 Recommendations for Good Practice. Proposals are submitted for approval by completing the application form (form Ⓐ). Individual ESHRE members wanting to present a topic are encouraged to complete the application form and send it to the ESHRE research specialists (by emailing guidelines@eshre.eu). The research specialists will contact the relevant SIG coordinator for advice on the relevance of the topic for an ESHRE guideline.

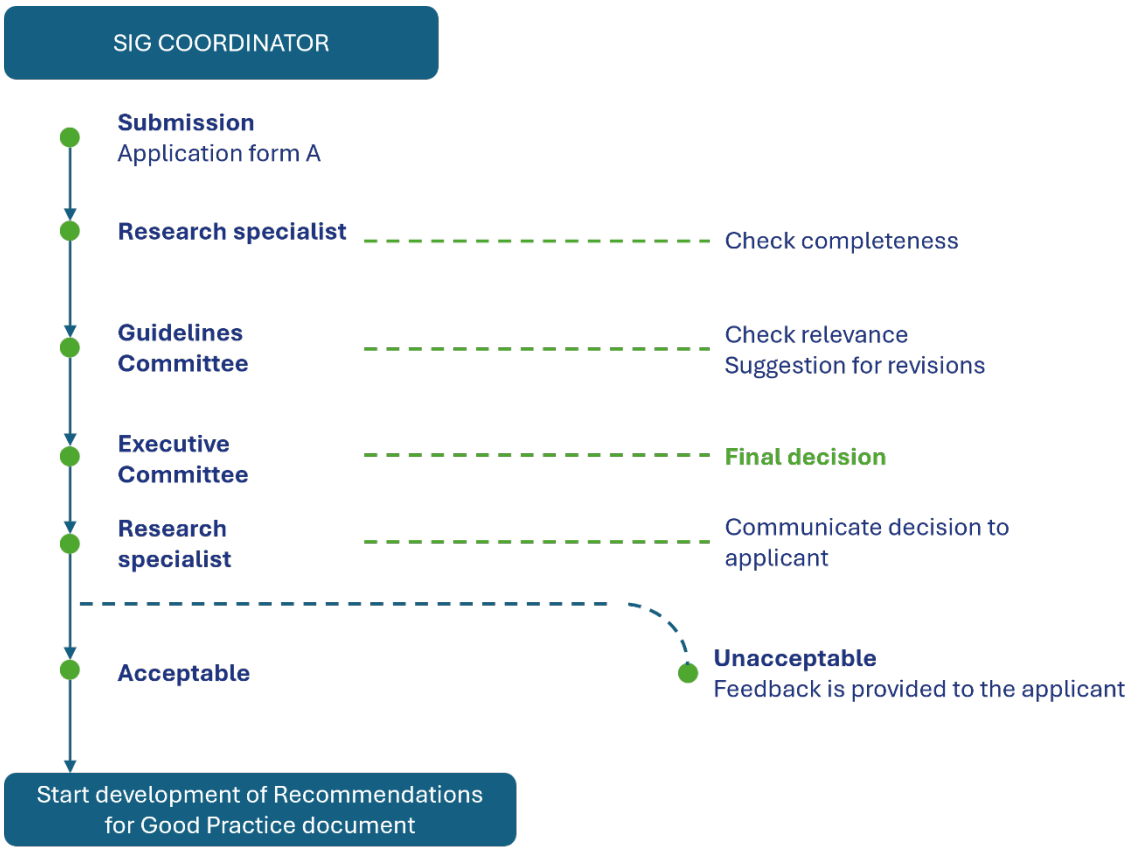
Proposals can be added at any time and will generally be evaluated at the next meeting of the Guidelines Committee.

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 specialists. If necessary, additional information is requested from the applicant to complete the proposal before submission to the ESHRE Guidelines Committee. In a second step, the ESHRE Guidelines Committee evaluates the application and formulates an advice whether the proposal is acceptable for a Recommendations for Good Practice document. The ESHRE Guidelines Committee may suggest revisions to the application or may suggest postponing guidance development on the topic because of important ongoing research studies. The ESHRE Executive Committee revises the advice of the Guidelines Committee and decides if the proposal is acceptable for the development of a Recommendations for good practice document. 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.

> Recommendations for good practice 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. Recommendations for good practice should not be developed for topics where evidence-based guidelines are an option.

Summary



Available forms/checklists:

Ⓐ Application form

2. WORKING GROUP COMPOSITION

For development of "Recommendations for Good Practice", the composition of the WG is crucial. Members of the WG should all be expert on the topic, but preferably with varying expertise and different perspectives.

The idea of a WG, 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 (Murphy et al., 1998).

WG selection procedure

When a topic is accepted, an open call for WG members should be organised. All candidates should submit a short CV, a motivation statement on why they should be included and a completed ESHRE COI disclosure form (form Ⓑ) and indicate whether they would like to be considered for a chair/co-chair position. The Guidelines Committee reviews the applications and selects the WG members, including the nomination of the chair/co-chairs, considering a balance in gender, geography, and expertise. The proposed composition is reviewed and approved by the ExCO before the WG can be formalised.

At the start of the Recommendations for Good Practice development, all WG members, except for patient representatives and invited experts, should be members of ESHRE.

Following ExCO ratification of the WG composition, a formal invitation should be issued to each proposed WG nominee. Once all invited nominees have agreed to participate, the WG can become functional.

New members should usually not be added to the WG once the development process has started. Additional needed expertise or the replacement of a WG member should be discussed within the WG and approved by the Guidelines Committee. The research specialist should ensure that new WG members have all information on the previous steps in the Recommendations for Good Practice document development.

Leadership of the working group

The WG is led by two co-chairs, at least one of whom must be free of any direct COI and have no more than minor-level indirect interests, as defined in **Table 2.1**. This requirement does not exclude clinicians who have a general interest in the topic through the provision of routine clinical care, nor individuals employed within publicly funded health or social care services. The co-chairs of the WG are nominated by the Guidelines Committee after the application procedure described above.

The co-chairs should be WG members with appropriate expertise, team-working skills, and should be respected content experts, preferably with experience in guideline development. They should also be experienced in group facilitation, maintaining constructive dynamics, identifying and resolving conflicts, remaining neutral and objective.

The co-chairs, together with the research specialist, serve as the primary point of contact for the Guidelines Committee and are responsible for overseeing the development of the content and the timely production of the Recommendations for Good Practice document.

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 COI are excluded from membership.

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

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

- balance in geographical location; the group should reflect broad representation across Europe, including Northern, Eastern, Southern, Western, and Central regions.
- balance in gender; efforts should be made to ensure a reasonable and appropriate balance of gender within the group.
- balance in expertise; the group should include a mix of academic and non-academic members, as well as a range of seniority levels (seniors and juniors).

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 organisations, 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 COI (update in case of changes, and at least annually)
- Actively contribute to the discussions, with acceptance and tolerance of varying viewpoints
- Approve of the final recommendations
- Support the dissemination of the Recommendations for Good Practice

The WG will be supported by an ESHRE research specialist who will be responsible for overall project managementand organising 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

Definition of a COI

A COI exists when a secondary interest – financial, professional, institutional, personal, or related to family or close associates – could reasonably be perceived to influence an individual's judgement or actions in the guideline development process.

Types of interests

ESHRE distinguishes two main types of interests: i) Direct interests which are interests personally held by the individual that are directly related to the topic of the Recommendations for Good Practice document. These may be direct financial interests that can be measured by monetary units (e.g., salary, consultancy fees, honoraria, advisory roles, stock ownership, patents, royalties, personal research funding, or institutional grants on which the member is explicitly named as recipient or investigator, etc.), and direct non-financial interests that cannot be measured by monetary units (e.g., leadership roles, advocacy, authorship of topic related opinions, or strong intellectual positions, etc.). ii) Indirect interests which are not personally held by the individual and/or not directly related to the topic of the Recommendations of Good Practice document but could be perceived as influencing judgement. These include indirect financial interests (e.g., institutional grants, funding received by the employer, or family- or close relatives- related financial interests, etc.) and indirect non-financial interests (e.g., institutional affiliations, professional networks, family relationships, etc.).

[1] Active meaning from the first WG meeting (scope) to the last WG 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 co-chairs.

Disclosure

Because ESHRE aims to ensure objectivity, credibility and independence in its European guidelines and Recommendations for Good Practice, they are developed without external funding. All applicants must provide disclosure statements of all potential direct and indirect COI (form ®) on behalf of themselves and their first-degree relatives. Disclosure would rely on self-reporting, accompanied by a CV and a formal "declaration of honour". No routine external verification is proposed, but spot checks are conducted to identify potential inconsistencies and, where necessary, seek clarification (e.g., recent publications, trial registries, other publicly available sources, etc.). The Guidelines Committee reviews the forms prior to the applicant being accepted as a nominated WG member. The co-chairs and the majority of the WG must be free from direct financial COI. In exceptional circumstances, participation of individuals with topic-relevant COI may be permitted following explicit assessment by the Guidelines Committee and approval by the ESHRE Executive Committee, with appropriate management measures in place.

The look-back period for reporting potential COI is 36 months for direct financial interests, 12 months for direct non-financial and indirect interests, prior to assuming WG membership. Any known upcoming COI during the Recommendations for Good Practice document development process must also be disclosed. An exception is made for publications related to the topic of the Recommendations for Good Practice document, for which there is no time limit. Any interests arising during the development period, or becoming relevant during this time, must be declared promptly and will be reassessed by the Guidelines Committee.

Monetary thresholds

Rather than focusing exclusively on the interests' monetary values, ESHRE follows an approach similar to that used by the American Thoracic Society (ATS) which prioritises the nature, scope and relevance of disclosed relationships to the topic of the guideline (e.g., topic of the lecture, consulting, research funding) (Schünemann et al., 2009). The Guidelines Committee assesses the weight of the COI by combining the type of the activity, its relevance to the guideline topic, the individual's role within the WG (co-chair, member, advisor/reviewer). When appropriate, the magnitude of financial relationship is considered as a complementary factor. The assessment of the COI severity is based on a structured scale categorising interests as minor, moderate or severe. This assessment may be informed by indicative value categories (e.g., ≤€1000; €1001-€5000; €5001-€10000; etc.), together with relevance to the topic of the Recommendations for Good Practice document and role-based considerations. In general, lower value ranges (≤€1000) are more likely to be associated with minor interests, mid-range values (€1001-€10000) with moderate interests, and higher value ranges (≥€10000) with more significant (potentially severe) interests; however, the final classification depends on the overall context, particularly the relevance of the relationship to the topic of the Recommendations for Good Practice document (e.g., a €500 payment could still be classified as more than minor if it is directly linked to the intervention under Recommendations for Good Practice document evaluation or if it reflects a pattern of repeated interactions with the same company). This approach supports a proportionate evaluation of direct financial, direct non-financial, and indirect COI recognising that these types of COI may differ in their potential to introduce bias.

Management plan

The Guidelines Committee reviews all COI declarations at the application stage to identify any potential COI relevant to the topic Recommendations for Good Practice document. Disclosed interests are then categorised according to their likely impact on the development of the Recommendations for Good Practice document typically as minor, moderate and major. All assessments and decisions are documented to ensure transparency and consistency.

Based on this assessment, the Guidelines Committee determines the appropriate management measures. These measures are defined before key methodological steps, such as nomination, finalising the scope, preparing the draft and formulating recommendations, and should be revisited throughout the development process as new interests arise or roles evolve. Management actions may include full participation, recusal from

recommendations formulation, restricted participation in specific discussions, or, in case of major COI, exclusion from the nomination process.

Major COI generally leads to exclusion from the nomination process. Individuals with direct financial COI relevant to the topic of the Recommendations for Good Practice document (e.g., marketing-related interests) should be excluded from authorship or leadership positions. They may instead serve in an advisory capacity in case their expertise would otherwise not be available to the group. Where feasible, divestment or resignation from conflicted roles could be requested. Members with direct non-financial COI related to a substantial proportion (>50%) of the evidence base for a specific topic in a Recommendations for Good Practice document can participate in the discussion of the evidence, however, they should be recused from the formulation of final recommendations and from voting on those recommendations. Indirect interests must also be declared for proper assessment. Where such interests are not posing a significant risk of bias, the WG member concerned can engage in all aspects of the development process of the Recommendations for Good Practice document.

Failure to disclose a relevant COI may result in exclusion from the WG. Furthermore, industry interactions during the development process are strictly prohibited, and a confidentiality form (form ©) should be signed before appointment. Failure to sign this form could render an individual ineligible to participate.

Table 2.1. Structured COI severity assessment scale (ATS- aligned approach).

COI SEVERITY LEVEL	NATURE, SCOPE, ROLE	FINANCIAL MAGNITUDE	EXAMPLES	TYPICAL MANAGEMENT ACTIONS
Minor (Low risk of bias)	Indirect interests that are not personally held and/or not directly related to the topic of the Recommendations for Good Practice document. Limited involvement (occasional, peripheral or unrelated activities) No leadership or decision-making role linked to the interest; no reasonable perception of influence on judgement.	Financial magnitude considered of limited relevance.	Occasional lectures or honoraria unrelated to the topic of the Recommendations for Good Practice document; institutional grants not linked to the topic of the Recommendations for Good Practice document and not involving the member personally; general academic publications without advocacy; institutional affiliations without direct stake in the recommendations; Indirect non-financial interests of a family member not relevant to the topic of the Recommendations for Good Practice document.	Full participation in all WG activities; disclosure recorded and monitored; no restrictions unless new interests arise.
Moderate (Potential risk of bias)	Direct non-financial interests personally held and directly related to the topic of the Recommendations for Good Practice document and/or	Financial magnitude considered alongside relevance, scope,	Leadership roles in professional societies linked to the topic; principal investigator of multiple included	Participation permitted with restrictions; recusal from specific discussions where

	indirect institutional or family-related interest relevant to the topic of the Recommendations for Good Practice document. Ongoing roles with partial relevance to the topic of the Recommendations for Good Practice document, or involvement in substantial proportion of the evidence base. Professional or academic roles that could reasonably be perceived as influencing judgement	and role rather than in isolation.	studies; strong publicly stated positions on the topic; institutional funding relevant to the topic of the Recommendations for Good Practice document and known to the member (without personal financial benefit); research funding received by a close relative from entities operating in the same clinical area; employment of a spouse/first-degree relative in a company or organisation with interests related to the topic of the Recommendations for Good Practice document.	the interest is directly relevant; recusal from recommendation formulation and/or voting on affected topics; ongoing monitoring by the Guidelines Committee.
Major (High risk of bias)	Direct financial interests personally held and relevant to the topic of the Recommendations for Good Practice document, strong direct non-financial interests and/or highly relevant indirect interests (institutional, employer, or family-related). Ongoing relationships with entities directly affected by the recommendations of the Recommendations for Good Practice document. Leadership or highly influential role (e.g., co-chairs) with interests that could substantially influence judgement or recommendations.	Financial magnitude considered as an aggravating contextual factor when relevance is high.	Consultancy fees, speaker honoraria, or research funding from industry directly linked to the topic; patents, royalties, or stock ownership related to evaluated interventions/ tests; marketing-related or advisory roles; extensive authorship or intellectual leadership dominating a substantial proportion of the evidence base; spouse or first-degree relative employed by, holding shares in, or receiving consultancy fees from a company directly affected by the recommendations of the Recommendations for Good Practice document; family ownership or financial stake in a commercial entity operating in the field of the	Exclusion from WG membership or leadership positions; advisory role only (non-voting) if expertise is indispensable; mandatory recusal from recommendation formulation and voting; consideration of divestment or resignation from conflicted roles where feasible.

	Recommendations for Good Practice document.

In line with the ATS-informed approach, the assessment of COI severity prioritises the nature, scope, and relevance of the interest to the topic of the Recommendations for Good Practice document, as well as the individual's role within the WG. Financial magnitude and indicative value ranges may be considered as contextual factors to support consistency but are not used as the sole determinant of COI severity.

Operationalisation

The research specialist, in consultation with the co-chairs, operationalises the post-appointment management actions decided by the Guidelines Committee and informs the individual concerned. In case of uncertainty or disagreement between the co-chairs and the research specialist regarding the appropriate management of a declared interest, the matter is referred to the Guidelines Committee for further consideration and decision.

The management actions should be formally presented to the group. The disclosure forms must be reviewed and validated prior to each in-person meeting and updated whenever any individual changes occur during the development process. In addition, the disclosure forms should be updated annually. It is the WG members responsibility to declare any relevant interests at the earliest opportunity and ensure that their declaration remains accurate and up to date throughout their involvement. A final checklist (ICMJE form) should be completed at project completion before submission of the guideline summary paper.

Transparency

The disclosed COI, and the management decisions should be published alongside the Recommendations for Good Practice document, with a summary presented in the methods section and a detailed version provided as supplementary material. Records should be retained long-term according to ESHRE policies.

Training

The research specialist should provide a training on COI for the WG members during the first online WG meeting. The training should cover the types of COI that should be disclosed, how COIs are assessed and managed by the Guidelines Committee, why COI disclosure is essential for guideline activity and what a COI management plan is and how it will be executed.

Tips

→ Document the WG member selection process and roles to ensure transparency.

→ Consider the optimum group size for the WG (e.g. too small of a group may lack sufficient experience, content expertise and wide representation, too large of group may lack cohesiveness and effective group interaction).

→ Record within the Recommendations for Good Practice document that its development was without external funding.

→ Set expectations and awareness of the group process through an introduction, training, and support for the WG members (e.g. setting ideal conditions for group discussion and decision-making).

→ Set a quorum for meetings (e.g. 75% of group must be present to formulate recommendations) but expect that all group members attend all meetings as far as possible.

→ Record competing interests of the WG within the Recommendations for Good Practice document, particularly where the conflicts bear on specific recommendations.

Available forms/checklists:

- Ⓑ Disclosure form
- © Confidentiality form

3. 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 WG should define the content of the Recommendations for Good Practice 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 WG 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 WG and be acceptable to all members.

The agreed scope, outline and, where relevant, proposed questions will be published on the ESHRE website for stakeholder comments for 2-4 weeks.

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.

4. 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 summarised, 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 WG 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 WG 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 summarise the results. The WG 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 "Recommendations for Good Practice" document. The research specialist will store the search protocol and summarise 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 WG 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 (Le Clef et al., 2026).

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 WG 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, analysing and performing SWOT (strengths, weaknesses, opportunities, and threats) analysis on these practices, 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. 12-14).

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 WG meeting. This strategy has been used in several ESHRE documents.

In short, the WG 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 WG members by performing a literature search, collecting full text papers, or summarising 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.

Table 4.1: The implications of the strong, conditional and research only recommendations, adapted from (Le Clef et al., 2026):

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.	Most of the 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, patients and policy makers are informed of the advice on the WG regarding a certain recommendation.
Clinicians	Most patients should receive the recommended course of action.	Recognise 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	
Researchers	The recommendation is supported by credible evidence or other compelling considerations, making it unlikely that further research would change the recommendation. In some cases, a strong recommendation may be issued despite low or very low certainty of evidence.	The recommendation may be strengthened by additional research. Evaluating the conditions and criteria underlying the conditional recommendation can help identify relevant research gaps.		

** 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 consider all the often-compelling unique features of individual patients and clinical circumstances.*

*** A good practice point or GPP is written by the WG to support the recommendations. Advice can for instance be provided on how to establish shared decision making, and on factors to be considered for a specific test or intervention.*

There should not be any label to the recommendations, but consistent language should be used. Standardised 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 4.2: Recommended phrasing for recommendations in the ESHRE documents.

RECOMMENDED PHRASING	
Strong recommendation	Clinicians should/should not * It is recommended/it is not recommended * It is indicated/it is not indicated Do/Do not *
Weak recommendation	It is conditionally recommended* It is probably recommended* It is suggested* Clinicians might* Clinicians could consider Clinicians may/might consider
Good practice point (GPP)	The WG recommends

5. DISCUSSION AND REACHING CONSENSUS

Working group consensus meeting(s)

Up to two in-person meetings will be organised to discuss all recommendations until consensus is reached within the WG. Ideally, the draft and recommendations are prepared and sent to the research specialist two 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 WG 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 co-chairs of the group are 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 summarised, 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 WG for written comments. The leading author of the section should review the written comments and address them if relevant.

Finalisation 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 WG.

ESHRE documents should be written in English and within a European scope. Furthermore, they should be comprehensive and flexible 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. 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.

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 (Murphy et al., 1998). 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 summarised in table 5.1.

Table 5.1 Characteristics of informal and formal consensus development methods, adopted from (Murphy et al., 1998)

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

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 others 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 (Murphy et al., 1998, Steyaert and Lisoir, 2005).

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 (Murphy et al., 1998).

6. 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 COI that could have influenced the recommendations.

Procedure

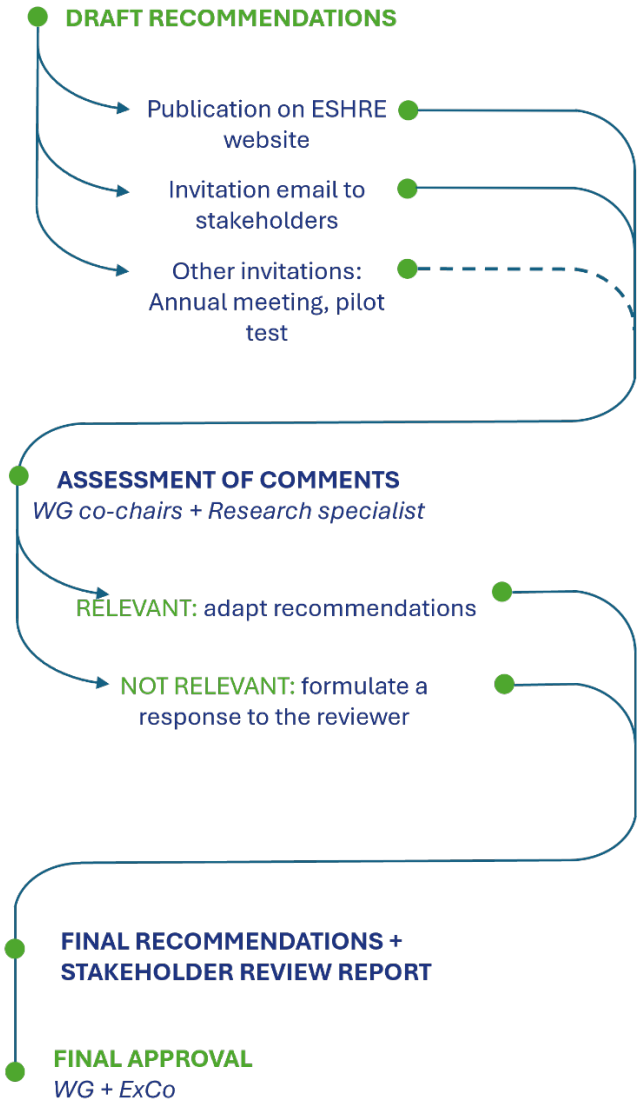
Following the final meeting of the WG, a pre-registration period of 2-4 weeks will open for a sample of the target group, all members of the involved SIGs, patients' representatives (lay reviewers), and representatives of national organisations. This will be announced via email and on social media. During pre-registration, reviewers must declare their COI (Reviewer disclosure form Ⓓ). After this pre-registration period, the draft recommendations will be published online and opened for stakeholder review. Pre-registered reviewers will be invited to submit their comments within four weeks (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.

A draft version of the Recommendation for Good Practice document can also be pilot tested before a wider launch. This step can detect problems in formatting, usability and acceptance.

Summary



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 enrolment 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.

7. APPROVAL

Final version & authorisation

After stakeholder consultation, the entire WG should formally approve the final version of the Recommendations for Good Practice 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.

Summary

8. 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 for Good Practice documents are (most) effective if their dissemination and implementation are carefully considered and vigorously pursued. The standard dissemination procedure for ESHRE Recommendations for Good Practice comprises publishing and announcement.

Publication

As soon as a "Recommendations for Good Practice" document is accepted for publication by the ESHRE Executive Committee, it will be submitted for publication at the ESHRE pages of Human Reproduction.

The document will also be added to the website of ESHRE (www.eshre.eu/guidelines).

The relevance of a patient version of the document should be assessed by the WG 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"
- 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 Recommendations for Good Practice is always sought from relevant National Societies by informing their presidents.

ESHRE and the WG members put significant effort into developing recommendations documents. Furthermore, we try to involve different nationalities in the WGs, and to organise a broad stakeholder review. By doing so, we provide Recommendations for Good Practice written to apply to a broad population which ideally should be endorsed by national societies, and if wished upon, translated verbatim.

National Societies and organisations can request permission to translate (verbatim) one of the recommendations documents, or any specific content related to the recommendations documents, in their language. For an official ESHRE approved translation, a straightforward 4-step procedure of approval, translation, validation and publication is outlined in a policy.

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 recommendations document is insufficient for national uptake, ESHRE will allow for national societies to use the ESHRE Recommendations for Good Practice as the basis of their national

documents. To ensure transparency, the methodology should clearly refer to the ESHRE Recommendations for Good Practice (including the weblink www.eshre.eu/Guidelines) and state how this document was used, including which text blocks / search strings have been used from the ESHRE recommendations document and for which topics the recommendations differ significantly between the documents. The resulting document will be considered a national recommendations document, not an ESHRE Recommendations for Good Practice document.

ESHRE gives National Societies and organisations the optional right to publish the translated guideline or recommendations document in their own national journals. All costs of carrying out these rights and of translating the document are for the National Societies.

The above information applies only to documents to which ESHRE holds the copyright. For translation of recommendations documents, permission of Oxford University Press (OUP) should also be requested.

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 recommendations document and should be discussed within the WG. 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 of the clinical decision pathway

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 (Shiffman et al., 2005) (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 (Le Clef et al., 2026).

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 WG meeting(s), by asking WG 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 randomised 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.

Background information

Policy for translation of ESHRE® Documents

Please note that this policy sets out general rules regarding the translation of ESHRE® Documents (as defined below). Depending on the type of ESHRE® Document, 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.

Definitions:

ESHRE®:	The international non-profit organisation "European Society of Human Reproduction and Embryology" with its registered office at BXL7 Building 1 Nijverheidslaan 3 (1st floor) |1853 Strombeek-Bever, Belgium, VAT BE-0430.069.888, RLE Brussels;
ESHRE® Document(s):	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.;
National Society:	An association or organised group of professionals/patients with a significant background/experience in the field of (in)fertility.

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 to) undertakes to:

(i) give full credit to ESHRE® for the ESHRE® Document by including on the title page of the translated document:
  (a) the ESHRE® copyright statement (as mentioned below),
  (b) the ESHRE® logo,
  (c) full reference to the original publication of the ESHRE® Document on ESHRE's® website and in ESHRE's® official journals ('Human Reproduction');
(ii) foresee the appropriate ESHRE® disclaimer, as mentioned below, in the translated document;
(iii) mention in the title of the translated document the name of each ESHRE® WG member who is (co-) author of the ESHRE® Document; and
(iv) clarify in the (sub)title of the translated document that it entails a translation of 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, if 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 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:

(i) Be organised by the ESHRE® central office;
(ii) be performed by a native speaker from the ESHRE® WG or the committee of national representatives; and
(iii) 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 on 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 the 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', which is available on the ESHRE® website (www.eshre.eu).

The translation of the original ESHRE® document is made by and under supervision of [name of the National Society], which is solely responsible for the content of this translation. Prior validation by ESHRE® of this translation does not affect such responsibility.

If any questions arise related to the accuracy of the information contained in the translation and/or its scientific value, please refer to the original ESHRE® document. Any discrepancies or differences created in the translation are not binding to ESHRE® and shall have no legal effect for compliance or enforcement purposes. The English version, being the language in which the original ESHRE® document is published, shall always prevail."

Implementation and evaluation

Guidelines do not implement themselves. Local ownership of the implementation process is crucial for changing practice. ESHRE is responsible for the development of European guidelines and their implementability, but not directly for their implementation into local practice. Nevertheless, the identification of barriers to guidelines' acceptance is one of the first steps of an implementation process and has ideally been part of the guideline developmental phase. Instruments like 'The Guideline Implementability Appraisal instrument' can be helpful for identifying obstacles to guideline implementation (Shiffman et al., 2005) (http://nutmeg.med.yale.edu/glia/doc/GLIA_v2.pdf).

There are different types of barriers to guideline implementation:

- internal to the guideline 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).

After the determination of factors affecting guideline adoption, the currently recommended approach is to plan a targeted intervention. However, there is no specific guidance available for translating identified barriers into tailor-made implementation interventions. Each implementation strategy is effective under certain circumstances, and a multifaceted approach is more likely to succeed than a single approach. Evaluation of such complex interventions is therefore important and mostly undertaken by investigators with research funding.

Focusing on individual recommendations rather than on the guideline as a whole, makes the implementation initiative more manageable. Criteria reflecting one or more of the six quality domains defined by the Institute of Medicine (safety, effectiveness, patient-centeredness, timely, efficiency and equitability) can help to prioritise guideline's recommendations for this purpose.

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

- Guideline dissemination

- Change in practice performance
- Change in health outcomes
- Change in consumer's knowledge and understanding
- Economic consequences

Practice performance is usually measured by a clinical audit and indicators. The frequently used definition for an indicator is "a measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality and hence change in the quality of care provided". Based on the manual by the Agency for Healthcare Research and Quality (AHRQ) and additional literature on quality indicators in infertility, a set of quality indicators for each ESHRE guideline can be developed in a 3-step process:

- The WG members rank the recommendations on priority for implementation to obtain key recommendations.
- The WG members propose quality indicators for each key recommendation.
- The WG members determine the importance and the preparedness to measure for each quality indicator, in a stepwise process.

For each step specific structured questionnaires should be developed.

The resulting set of key quality indicators will be used to evaluate the quality of care and the impact of the guideline on the quality of care within Europe.

9. UPDATING

Updating of a Recommendations for Good Practice 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 responsible SIG coordinator and the Guidelines Committee 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.

Complete or partial update

Initiating the update process

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. The research specialist will notify the responsible SIG coordinator, who will complete the application form (form Ⓐ). Approval for the update must then be requested from the Guidelines Committee, which will prepare an assessment report for final approval by the ExCO. A complete review, approved by the ESHRE ExCO, will follow the standard 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.

Forming the Working Group

WG members, including the co-chairs, may serve a maximum of two consecutive terms in the development of a single Recommendations for Good Practice document. After a minimum interval of one version, a former WG member may rejoin the WG for the same Recommendations for Good Practice document.

To ensure both continuity and renewal, some members will be replaced after one term, allowing new experts to join the WG while maintaining institutional knowledge within the group.

Members of the previous WG will be invited to submit an application to be part of the WG for the update of the Recommendations for Good Practice document. In addition, an open call will be published on the ESHRE website and social media platforms to invite ESHRE members to submit an application. The Guidelines Committee will review all applications and COI of the aspiring WG members and make a proposal for the WG to be approved by the ESHRE ExCO.

Scope and outline of the document

For updates, the Recommendations for Good Practice document scope needs to indicate which sections will be updated and any changes from the current Recommendations for Good Practice document. The revised scope and outline of the document will be published for stakeholder comments, in survey form, for two weeks.

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 WG 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.

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FORMS

Ⓐ Application form

Ⓑ Disclosure form

Ⓒ Confidentiality form

Ⓓ Reviewer disclosure form

Ⓔ Reviewer comments form

A. APPLICATION FORM

New evidence-based 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)[5]

……

Topic

PROPOSED TITLE:

……

EVIDENCE-BASED 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)

……

Other existing guidelines/consensus documents (to be completed by RS)

EXISTING GUIDELINES WITHIN THE FIELD OF THE PROPOSED TOPIC:

……

OVERLAP WITH OTHER ESHRE DOCUMENTS:

……

The completed application form should be sent to guidelines@eshre.eu

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

A. APPLICATION FORM UPDATE

Update evidence-based guideline / Good practice recommendations document

Applicants

CONTACT PERSON(S):

……

ESHRE SPECIAL INTEREST GROUP(S):

……

Topic

EXPECTED EXTENT OF UPDATE:

……

B. DISCLOSURE FORM

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 organisations to avoid the perception of a conflict of interest. Our work relies on trust, independence and transparency. Having an interest does not automatically prevent participation. Declaring interests allows us to manage them proportionately and openly.

Recommendations for Good Practice document title	

Before completing this form, please carefully read the ESHRE manual for Recommendations for Good Practice including the instructions for completing this form. The information provided will be treated confidentially by the ESHRE Guidelines Committee for purposes of GPR development and not shared with any third-party without your explicit consent. This form should be completed during application and submitted to the ESHRE central office (guidelines@eshre.eu). Updates should be made annually, before the in-person meeting and if changes occur during the development process.

Having an interest does not automatically disqualify you or limit your participation in the development of Recommendations for Good Practice documents. Your answers will be reviewed by the Guidelines Committee to determine whether you have a conflict of interest relevant to the topic(s) of the Recommendations for Good Practice document. If you are unable or unwilling to disclose the details of an interest that may pose a real or perceived conflict, you must disclose that a conflict of interest may exist and the Guidelines Committee may decide that you be totally recused from the meeting or work concerned, after consulting with you.

Contact information of the working group member

Please complete the table below and indicate if you wish to be considered for a leadership role.

Name: ……

Institution, Address: ……

……

E-mail address: ……

Area(s) of expertise relevant to this work ……

☐ **I would like to be considered for a co-chair position**

Please disclose your direct financial interests (past 36 months), direct non-financial interests (past 12 months), and any anticipated interests during the development period (~24 months) of the Recommendations for Good Practice document.

Direct financial interests

(personally held by the individual and directly related to the topic of the Recommendations for Good Practice document)

☐ I have no direct financial interests from the past three years to report, nor any anticipated during the development of this Recommendations for Good Practice document.

☐ I have the following direct financial interests from the past three years or anticipated during the development of this Recommendations for Good Practice document, to report (please complete the table below):

Type of interest	Description of the interest			Time period (from MM/YYYY-to MM-YYYY)
	From which company, organisation, or institution	Range of the amount of income or value of interest (≤€1000; €1001-€5000; €5001-€10000; >€10000) If not disclosed, assumed to be significant	Relevance to the guideline topic (please specify)	
Commercial business (proprietorships, partnerships, joint ventures, board memberships, etc.)				
Ownership (Stocks, bonds, stock options, etc.)				
Salary or position funding directly linked to activities related to the guideline topic				
Patents, royalties, or intellectual property				
Directorship or consultancy fee(s) (advisory boards, legal testimony, etc.)				
Honoraria, speaker fees, teaching payments, paid event attendance.				
Expert testimony or legal advice				
Personal research funding or grants including institutional grants on which you are explicitly named as recipient or investigator				
Travel, accommodation, or other -in-kind support				
Other financial benefits related to the topic of this guideline and not captured by the checklist.				

Note: Institutional grants on which the individual is not explicitly named as a recipient, investigator, or co-investigator are considered indirect financial interests and should be declared in the indirect interest's section.

Direct non-financial interests

(non-financial, professional, academic, or personal interests personally held and directly related to the topic of the Recommendations for Good Practice document)

☐ I have no direct non-financial interests from the past 12 months to report, nor any anticipated during the development of this Recommendations for Good Practice document.

☐ I have the following direct non-financial interests from the past 12 months or anticipated during the development of this Recommendations for Good Practice document, to report (please complete the table below):

Type of interest	**Description of the interest**		**Time period (from MM/YYYY-to MM/YYYY)**
	From which company, organisation, or institution	**Nature of the relationship/ Relevance to the guideline topic**	
Advocacy or membership in lobbying or pressure group			
Unpaid board membership or leadership roles			
Office or position of authority in a professional organisation			
Involvement in an ongoing or scheduled trial/ research related to the topic of the guideline			
Published topic-related opinions			
Authorship or co-authorship of evidence relevant to one of the topics of the guideline			
Leadership or participation in related guideline development elsewhere			
Other non-financial benefits related to the topic of this guideline and not captured by the checklist.			

Note: Institutional affiliations are considered indirect non-financial interests unless the individual holds a leadership or topic-specific role directly related to the guideline topic.

Indirect interests

(financial and non-financial interests not personally held and/ or not directly related to the topic of the Recommendations for Good Practice document, including institutional, employer, and family-related interests)

- Do any third-party closely associated with you (e.g., close relatives, employer, department, research unit, or close collaborator) have any financial or non-financial interests related to this Recommendations for Good Practice document and which may be perceived as unduly influencing your judgment?

☐ No.

☐ Yes (please provide details including the nature of the interest, the parties involved, and its relevance to the topic of the Recommendations for Good Practice document).

……
……

- Do you hold any institutional roles, affiliations, or responsibilities, in an organisation whose activities is related to the topic of this Recommendations for Good Practice document (without receiving a personal financial benefit)?

☐ No.

☐ Yes (Please describe the role, the organisation, and its relevance to the topic of the Recommendations for Good Practice document).

……
……

☐ **Declaration: I hereby declare on my honour that the disclosed information is true and complete to the best of my knowledge**

Should there be any change to the above information during the development of the Recommendations for Good Practice document and before the publication of the final document, I will promptly notify the responsible ESHRE staff and complete a new declaration of interest form that describes the change.

Date Signature

C. CONFIDENTIALITY FORM

As a writer of an ESHRE Recommendations for Good Practice 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.

Guideline/ GPR title	

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 Recommendations for Good Practice document development procedure.

SIGNATURE (OR STATE YOUR NAME):

……

DATE:

……

D. REVIEWER DISCLOSURE FORM

All reviewers are expected to provide completed and signed disclosure statements about all financial, personal, or professional relationships with industry, individuals, or organisations from the last three years to avoid perception of COI.

GPR title	

Contact information of the reviewer

Name: ……

E-mail address: ……

- ○ I HAVE NO POTENTIAL COI FROM THE LAST THREE YEARS TO REPORT.
- ○ I HAVE THE FOLLOWING POTENTIAL COI FROM THE LAST THREE 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 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 INSITUTIONAL COI IN THE TOPICS OR ISSUES ADDRESSED IN THE DOCUMENT
    ……

SIGNATURE (OR STATE YOUR NAME):

……

DATE:

……

E. REVIEWER COMMENTS FORM

GPR title	
Review period	

Contact information of the reviewer

Name: ……

E-mail address: ……

I AM PARTICIPATING

- ○ AS AN INDIVIDUAL
- ○ ON BEHALF OF A (INTER)NATIONAL ORGANISATION, 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.
- ➔ 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 the review procedure.

SIGNATURE (OR STATE YOUR NAME):

……

DATE:

……

Comments on the document

PAGE	LINE	COMMENT

(Add more lines if you need to)

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 summarised in a review report which will be available on the ESHRE website.

By submitting this form, you will be listed as an expert reviewer of the Recommendations for Good Practice paper. The list of reviewers will be published in the review report and in an annex of the Recommendations for Good Practice document.
For more information on the review, you can contact guidelines@eshre.eu.