EUROPEAN CENTRE FOR GUIDELINES DEVELOPMENT

European Dermatology Forum

CHARITÉ d:EBM

EuroGuiDerm Guideline and Consensus Statement Development Manual

A pragmatic Manual for the development of high-quality guidance in dermatology

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Contents

Tables and figures

1. Introduction

What is the European Dermatology Forum (EDF)?

- A non-profit professional organisation dedicated to improving the skin health of people in Europe
- Founded in 1997 by a group of leading European Professors of Dermatology
- Currently restricted to 200 active members consisting of heads of academic departments and experts in dermato-venereology across Europe (1).

What are clinical practice guidelines?

When selecting a treatment, dermatologists and health professionals, together with people suffering from skin disease, commonly face some level of uncertainty. Despite drawing upon dermatological expertise and patient preferences in making an informed decision, this situation may sometimes still be challenging considering the explosion of scientific information, as well as financial and time limitations. The World Health Organisation (WHO) (2) defines guidelines as 'recommendations intended to assist providers and recipients of health care and other stakeholders to make informed decisions´ (p.1). Guidelines may help in dealing with uncertainty and in making a more informed decision more quickly. The WHO (2) also emphasises that recommendations must be 'based on a comprehensive and objective assessment of the available evidence' (p.1), and that the process used to develop the recommendations must be clear.

Why European level dermatological guidelines?

Many dermatologists coming from different European countries have contributed to important steps in understanding skin diseases, and then improving their prevention, diagnostics and treatment. The result of this collective effort is the level of dermatological care we have today. One of the key aims of the EDF is to continue along this path of improvement and to promote the highest possible standard of prevention and care for skin and sexually transmitted infections across Europe. The EDF sees clinical practice guidelines as an important step on that path and has, to date, published more than 35 guidelines on the management of skin disease (1).

The development, dissemination and implementation of guidelines is a very complex challenge, especially in a European setting. However, technological advancements enable European dermatologists today to respond to this challenge through closer collaboration, sharing their different perspectives, exchanging ideas, expertise and experience. To help facilitate this collective effort and mutual learning process in the future, to ensure more effective use of limited resources, and to standardize the development of high quality European dermatological guidelines, the EDF has established a European Centre for Guidelines Development (EuroGuiDerm). It shall act as a reliable, central point of reference for high quality recommendations based on timely expert syntheses of evidence, it shall drive collaboration, equality of care and access to treatments throughout Europe. Guidelines shall be adapted according to the societal, cultural and health needs in any particular country, and in accordance with the health care system. There are two EuroGuiDerm-related standing EDF boards and a number of individual guideline-specific entities.

Standing boards

A Board of EuroGuiDerm Directors with a maximum of five seats is selected on a two-year term by the EDF Board of Directors. The EDF has a majority status, with a maximum of three seats, whereas two seats are available for delegated representatives of supporting stakeholders of the EuroGuiDerm. The Board of EuroGuiDerm Directors is responsible for prioritizing and selecting guidelines and consensus

statement topics. They are involved in the strategic aspects of the methods development, developing management strategies for conflicts of interest and the final selection of experts.

A **Pan-European Guideline Methods Board** is a group of experts in methods for guidelines development. They are involved in aspects of methods development, and in implementing current knowledge and methods in guideline development, dissemination and implementation.

Guideline and Consensus Statement specific entities

A **Guideline/Consensus Statement Coordinator** is a person who is responsible for the coordination of the topic-specific guideline development in line with the pre-defined project plan and methodological requirements of the EDF. The EuroGuiDerm Board of Director appoints the Guideline Coordinator (one or more persons due to workload and/or conflicts of interest). The Guideline Coordinator has the right to vote on recommendations. The coordinator or the co-coordinator has to be a member of the EDF.

A **Guideline/Consensus Statement Subcommittee** consists of individuals from all relevant professional groups, including, but not limited to, dermatologists (academic and office-based), dermatology residents, and physicians of other specialties as relevant for individual guideline, nurses, other relevant healthcare professionals, patients, carers etc. Guideline Subcommittee members have the right to vote on recommendations.

EuroGuiDerm Methods Team consists of one or more guideline methods experts and administrative support staff member, who facilitate the guideline development process and help the Guideline Subcommittee produce guidelines in line with the methodological expectations of the EDF in a timely manner. Members of the Methods Teams do not have the right to vote on recommendations.

A **Guideline/Consensus Statement Development Group (G/CSDG)** is a group consisting of the Guideline/Consensus Statement Coordinator, the Guideline/Consensus Statement Subcommittee and the Guideline/Consensus Statement-designated EuroGuiDerm Methods Team.

A **EuroGuiDerm Collaborating Group** is a broader group of collaborators who contribute to the guideline with their expertise or other relevant advice. This group is not involved directly in developing the guideline or in making the recommendations.

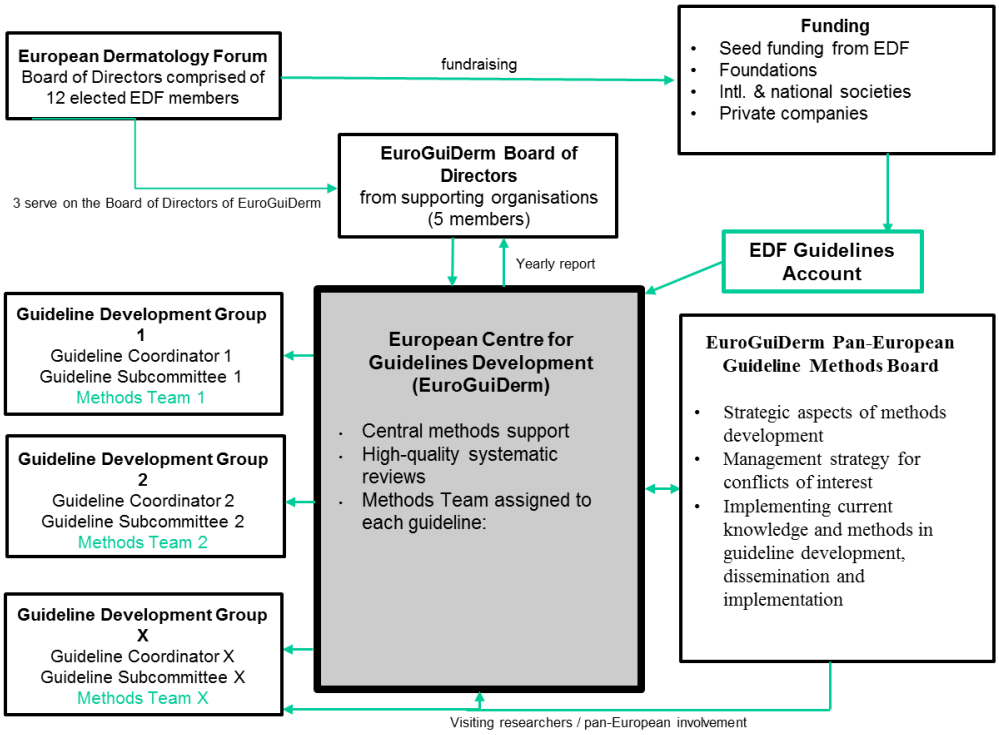


Figure 1: European Centre for Guidelines Development (EuroGuiDerm), Standing Boards and Guideline-Specific entities

Overview of guideline and consensus statement development process

The development of **EuroGuiDerm Guidelines** and **EuroGuiDerm Consensus Statements** follows a standardized process, briefly outlined in Figure 2.

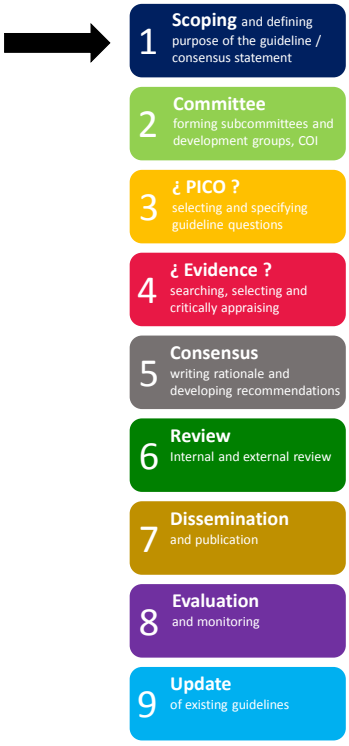


Figure 2: EuroGuiDerm Guideline and EuroGuiDerm Consensus Statement development process steps [Modified from (2-5)]

*Methods applied in this step are the key difference between the EuroGuiDerm Guidelines and the EuroGuiDerm Consensus Statements. What is the difference between the EuroGuiDerm Guidelines and the EuroGuiDerm Consensus Statements?

The EuroGuiDerm Guidelines are developed according to a current methodological gold standard: a combination of a representative guideline subcommittee, presented with rigorously synthesized and appraised evidence, who reach consensus in a structured way (2-5) (Table 1, Figure 2).

The EuroGuiDerm Consensus Statements are developed through reaching consensus in a structured way, but the evidence is not searched for, synthesised nor appraised in a systematic way (Table 1, Figure 2).

Table 1: EuroGuiDerm methodological approaches

European level	German level (4)	Methods	Explanation	
EuroGuiDerm Guideline	S3	Evidence and consensus	Representative subcommittee	YES
			Systematic evidence search and evaluation	YES
			Reaching consensus in a structured way	YES
EuroGuiDerm Consensus Statement	S2k	Consensus	Representative subcommittee	YES
			Systematic evidence search and evaluation	NO
			Reaching consensus in a structured way	YES

The EDF does not intend to commission new guidelines equivalent to former S1 methodological level (3) and aims to update existing guidelines equivalent to S1 level using higher-level methods, i.e. EuroGuiDerm Consensus Statement (equivalent to German S2k methodological level) or EuroGuiDerm Guidelines (equivalent to German S3 methodological level) (3).

A transitional period of two years (2019/20) will be instated during which ongoing guideline projects may be completed using currently established EDF processed and procedures. Those will be called 'EDF guideline'. Only those adhering to the methods presented in this manual will be called EuroGuiDerm Guideline/Consensus Statement.

Why is the methodological rigour important?

Guidelines have many potential benefits for patients, healthcare professionals and health systems (6). However, there are also potential harms if recommendations lead to unfavourable outcomes for patients. Misleading recommendations may be developed for different reasons, such as (6):

- Choosing evidence selectively without a thorough assessment of all of the available literature
- Evidence about certain interventions is often lacking; studies may be poorly designed and thus easily misinterpreted or misleading
- Recommendations include committees' members' subjective judgements possibly not corresponding to the population norms or the patients' preferences, especially if the patients are not represented in the panel and if consensus was not reached in a structured way.

Complex methodological processes have been developed to prevent such harms (2, 3, 6, 7). A high quality of guidelines is also important for their dissemination and implementation to be successful (7) - this is yet another reason why the EDF is committed to ensuring the highest feasible methodological standards of the EuroGuiDerm Guidelines and the EuroGuiDerm Consensus Statements.

2. How is a guideline and consensus statement topic selected and scoped out

To ensure the usefulness and appropriateness of the EuroGuiDerm Guidelines and Consensus Statements, every new project should start with a scoping process Based on non-systematic searches and collaborations with national societies taking a number of factors into account (Table 2), the aim of the scoping process is to identify:

- Areas with the greatest potential for improvement of skin health and reducing skin health inequalities in Europe
- Possible obstacles to putting future dermatological guideline and consensus statement recommendations into practice in Europe
- Uncertainty or disagreement on best practice
- Potential to improve outcomes or make better use of resources
- Identify areas that change rapidly

A search for existing guidelines and their potential for adaptation should be conducted.

The EuroGuiDerm staff prepare a standardised scoping document, which includes:

1. Planned methodological approach (guideline or consensus statement)
2. Broadly defined scope population/region/setting/interventions/comparisons/outcomes
3. The purpose and objectives of guideline/ consensus statement
4. Targeted users of guideline/consensus statement
5. Existing guidelines which may be considered for adaptation
6. Connecting with relevant other organisation
7. Stakeholder recruitment (also see section *How to form Guideline or Consensus Statement Development Groups*)
8. Other key issues (specifically concerning new guidelines)

The scoping document is then sent to relevant stakeholders (such as patient organisations), including, but not limited to, all EDF members for comments and subsequently finalised.

Standard Operating Procedure Box 1: Scoping

#	Step	Person(s)	Output
1	Approving the guideline/consensus statement topic and preliminary budget	EuroGuiDerm Board of Directors	Letter/e-mail confirming the approved topic and preliminary budget
2	Scoping: - Identifying topic areas with greatest potential for improvement through internal discussion of the EuroGuiDerm staff and Board of Directors - Establish preliminary PICO/PIRT - Identify existing guidelines (GIN database); determine quality (AMSTAR II/GIN) if applicable - Check for existing and ongoing systematic reviews (PROSPERO) - Connect with Cochrane; HTA, Joanna Briggs and other relevant institutions such as the 'core outcome set- groups'	EuroGuiDerm staff	First Draft of the Scoping document, including existing guidelines and their quality if applicable
3	Inform national societies about the planned activities and invite experts to participate and comment on the scoping document		See SOP 2
4	(Optional) Sending the refined scope document to patient organizations, and individual patients with the health problem for sharing their views and preferences (Optional) Systematic review of patient preferences	EuroGuiDerm staff	Views and preferences of patients, list of patients, or individuals recommended by patient organizations to be considered for the Guideline/Consensus statement Subcommittee
4.1	Reviewing and incorporating comments	EuroGuiDerm staff	Final Scope document
5	Developing guideline/consensus statement project plan with timelines	EuroGuiDerm staff in collaboration with GL/CS coordinator	Guideline/consensus statement project plan with timelines
6	Approving the guideline/consensus statement project plan with timelines and final budget	EuroGuiDerm Board of Directors	Letter approving project plan with timelines and final budget

For limited updates of guidelines, the necessity of a scoping process will be decided upon on an individual base and may be shortened.

3. How to form Guideline or Consensus Statement Development Groups

A Guideline/Consensus Statement Development Group is a group consisting of the Guideline/Consensus Statement Coordinator (when applicable also a Co-Coordinator), the Guideline/Consensus Statement Subcommittee and the Guideline/Consensus Statement-designated EuroGuiDerm Methods Team. Additionally, the **EuroGuiDerm Collaborating Group**, who contribute to the guideline with their expertise or other relevant advice, is formed (also see Chapter 3: How to declare interests and manage conflicts of interests).

When establishing a representative **Guideline or Consensus Statement Subcommittee** it is important to aim at creating a multi-disciplinary and, if appropriate, multi-specialty group. Every effort should be made to include individuals from all relevant stakeholder groups: those with diverse views as well as those representatives from different European countries. In addition, the balance of membership needs to be considered, for example, not only dermatologists and one patient.

The following individuals should be considered:

- Experts and junior colleagues nominated by the EuroGuiDerm Board of Directors
- Suggestions made by the national societies that financially support the EDF Guidelines Development Centre EuroGuiDerm (open call)
- EDF members with little or no conflicts of interest based on their substantial reputation for clinical expertise in the field, in dermatology or related fields as relevant for individual guideline/consensus statement
- Researchers with substantial research output in the clinical field and/or in evidence-based medicine (scientific publications and citations), in dermatology or related fields as relevant for individual guideline/consensus statement
- Patients and carers, or individuals recommended by patient organizations
- Individuals not meeting the above criteria with interest and long-term potential to contribute to capacity-building in evidence-based dermatology in their respective countries and regions

The process is briefly presented in Figure 3.

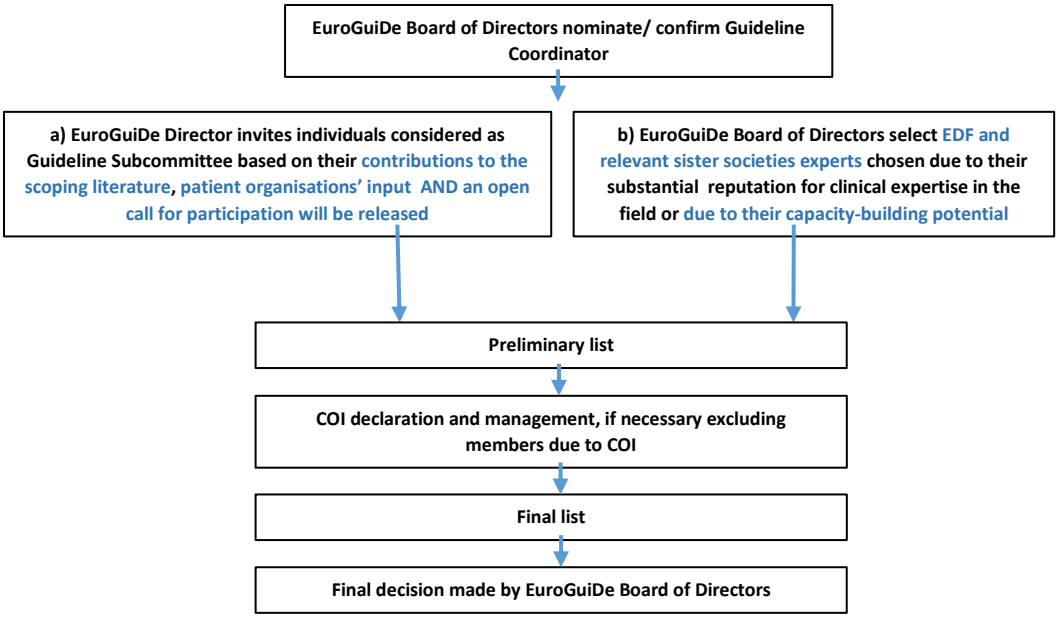


Figure 3: Process of forming the Guideline Subcommittee

The EuroGuiDerm staff explore the training needs of the Subcommittee members concerning evidence-based medicine and may organize additional workshops, if necessary and feasible.

The process of forming EuroGuiDerm Collaborating Groups follows the one for forming the Guideline/Consensus Statement Subcommittee. Potential and motivation to contribute to the implementation of guidelines (e.g. national adaptation and dissemination) are considered.

Standard Operating Procedure Box 2: Establishing the Guideline/Consensus Statement Development Group and EuroGuiDerm Collaborating Group Members

#	Step	Person(s)	Output
1	Nominating/confirming guideline/consensus statement coordinator responsible for the coordination; Appointing Guideline/Consensus-Statement Co-coordinator when necessary due to COI	EuroGuiDerm Board of Directors	Letter of guideline/consensus statement coordinator /co-coordinator nomination/confirmation
2	Appointing EuroGuiDerm staff member to support the guideline development process	EuroGuiDerm Director	Letter/e-mail to guideline/consensus statement coordinator introducing the appointed EuroGuiDerm staff member.
3	Open call for participation of interested individuals, with pre-specified criteria tailored to individual guideline/consensus statement requirements	EuroGuiDerm Staff, Guideline Coordinator/ Co-coordinator	E-mail with open call for participation to the EDF members
4	National societies that contribute financially to EuroGuiDerm/EDF will be contacted individually and can nominate a candidate to be included in each guideline group (if in line with COI policy) or contribute with their expert or other relevant advice	EuroGuiDerm Staff – national supporting societies	Set list of individuals to be included in the guideline subcommittee. and of those individuals willing and able to contribute their expert or other relevant advice
5	Recommending experts for the Guideline/Consensus Statement Subcommittee and EuroGuiDerm Collaborating Group	EuroGuiDerm Board of Directors	Letter with list of recommended individuals to the Guideline Coordinator/co-Coordinator and EuroGuiDerm Director
6	Creating a preference list of guideline development group/ EuroGuiDerm Collaborating Group members as per criteria (all relevant stakeholders should be considered including physicians of all relevant specialties, patients, carers, nurses)	Guideline coordinator/ Co-coordinator	Letter with a preference list of recommended individuals
7	Sending out invitation letters to potential Subcommittee members and collaborators, and standardized COI declaration forms to potential guideline Subcommittee members	EuroGuiDerm Staff	Invitation letters and standardized COI declaration forms

8	Collecting acceptance / rejection of participation and COI declarations, (initial invitation, reminder after 2 weeks, if no reply after three weeks, considered declined)	EuroGuiDerm Staff	List of Subcommittee / EuroGuiDerm Collaborating Group members who accepted/rejected; COI declaration of Subcommittee members
9	Ensuring management of COI as per Standard Operating Procedure 3: Conflicts of interests	EuroGuiDerm Staff, Guideline coordinator/ Co-coordinator	COI evaluation and management decision for individual members
10	If necessary, excluding members due to COI/ selecting alternative members as above.	EuroGuiDerm Staff, Guideline coordinator/ Co-coordinator	Letter with reason for exclusion to potential subcommittee members
11	Creating the list of Guideline/Consensus Statement Development Group Members + list of Guideline/Consensus Statement EuroGuiDerm Collaborating Group	EuroGuiDerm Staff, Guideline coordinator/ Co-coordinator	Completed template with: Name, discipline/expertise, institution, institution type, city/state/country, role in guideline/consensus statement development
12	Deciding on the final list of Guideline/Consensus Statement Development Group Members + EuroGuiDerm Collaborating Group	EuroGuiDerm Board of Directors	Final list and complete template with: Name, discipline/expertise, institution, institution type, city/state/country, role in guideline development
13	Sending final approval and confirmation letter to selected Guideline/Consensus Statement Subcommittee members including suggestion on COI management (e.g. abstention during voting/from writing) for questions with COIs) Sending final confirmation letter to selected EuroGuiDerm Collaborating Group	EuroGuiDerm Staff, Guideline coordinator/ Co-coordinator	Final approval and confirmation letter to selected Guideline/Consensus Statement Subcommittee members with COI management suggestion, final letter to selected EuroGuiDerm Collaborating Group Members

4. How to declare interests and manage conflicts of interests

A conflict of interest exists when professional judgment concerning a primary interest (such as patients' welfare or the validity of research) may be influenced by a secondary interest (such as financial gain). Perceptions of conflict of interest (COI) are as important as actual conflicts of interest (8).

All Guideline/Consensus Statement Development Group members are requested to declare their financial, non-financial, personal and non-personal interests specific to the matter under discussion . Interests must be declared for the 12 months prior to the commencement of the guidelines/consensus statements work and for the entire duration of the development process.

Currently, there are two options concerning conflict of interest management[1] (transitional period for 2 years)

A) Declaration of COIs only.
B) Declaration of COIs. More than 50% of the GDG should not have any personal conflicts of interest specific to the matter under discussion. Those with personal financial interests abstain from voting on recommendations (see below). The coordinator cannot have any personal financial interests that are specific to the matters, the option of appointing a c-chair remains.

Table 2: Conflict of interest management

<table>
<tr><th>Classification</th><th>Coordinator/Chair</th><th>Subcommittee members</th></tr>
<tr><td rowspan="3">Not acceptable</td><td colspan="2">• Any shareholdings in the commercial sector held personally or by their family member</td></tr>
<tr><td colspan="2">• Funds which include investments in the commercial sector that are held in a portfolio where the person has the ability to instruct the fund manager as to the composition of the fund</td></tr>
<tr><td>• Any specific personal financial conflicts of interests</td><td>• A subcommittee with >= 50 % of the group members having personal financial interests specific to the matter [1]</td></tr>
<tr><td>Can participate but not vote</td><td>N/A</td><td>• Those with personal financial interests that are specific to the matters.</td></tr>
<tr><td>Acceptable</td><td colspan="2">• Non-personal financial specific interests
• Personal non-financial interests that are specific to the matters</td></tr>
</table>

Interests* can be:

- **specific** (if it refers directly to the 'matters under discussion' which include products being evaluated) **or non-specific** (if it does not refer directly to the 'matters under discussion' which include products being evaluated)
- **financial** (payments received in cash or in kind) or **non-financial** ('reputational risk'); financial interests can be **personal** (payments received personally in cash or in kind) **or non-personal** (payments not received personally in cash or in kind)

*modified British Associations for Dermatologists (BAD) Policy for Declaring Conflicts of Interest for BAD Clinical Guideline Authors (July 2017 Version)

[1]The subcommittee should consist of a minimum of 51% of members with no personal financial interests.

[1] At the European Dermatology Forum meeting in Montreux in 2019, the EDF Board postponed a final decision on COI management.

Guideline/consensus statement development group members with any specific personal financial interests during and 12 months prior to the commencement of the guideline/consensus statement work shall not be the first or last author of the published guideline.

The feasibility of the envisioned long-term conflict of interest management strategy will be evaluated during the transitional period.

In case new interests arise during the Guideline/Consensus Statements development, the Guideline/Consensus Statement Development Group members need to inform the group, declare changes, and refrain from new interactions if necessary. Interest declarations need to be updated through the guidelines/consensus statements development process until the external review has been completed.

Standard Operating Procedure Box 3: Conflicts of interests

#	Step	Person(s)	Output
1	Sending conflict of interest standardized form (amended BAD COI Form, **Appendix 2**) to the suggested Guideline/ Consensus Statement Subcommittee together with the invitation as per Standard Operating Procedure 2: Establishing the Guideline/Consensus Statement Development Group	EuroGuiDerm staff, Guideline/ Consensus Statement Subcommittee members under consideration	Completed COI Forms for individual Guideline/ Consensus Statement Development Group members under consideration. No reply to 3 reminders considered a decline of participation.
Proceed as follows, if option B – declare and manage COIs - was chosen:			
2	Collecting and assessing declarations of interests	EuroGuiDerm staff, Guideline coordinator/Guideline co-coordinator	List of individuals as per COI category (none, PF, NPF, PNF)
3	Discuss suggested members and COIs	EuroGuiDerm Board of Directors	Final list of subcommittee members
4	Taking individual COI decision into account when deciding on further distribution of tasks and preparing any voting material (e.g. abstentions)	Guideline coordinator/Guideline co-coordinator	Guideline/Consensus Statement plan with suggestions of management of moderate COI for individual guideline development group members sections /recommendations
5	Deciding on management of COI based on management level	Guideline/ Consensus Statement Development Group during Kick-off meeting	Consensual management procedure on individual COI situation
6	Update of COIs prior to publication of guidelines/consensus statement	Guideline/ Consensus Statement Development Group Members	Updated COI Declarations
7	Reporting of management of COI in a standardized way using table in **Appendix 3**	EuroGuiDerm staff	Standard table with COI of guideline development group members for individual guideline

5. How to select and specify guideline questions

Drafting questions & Ranking outcomes

Based on the results of the scoping process, key questions will be drafted to address the relevant issues. For questions to be answered based on a systematic search, the PICO approach for questions on interventions, or PIRT approach for diagnostic questions will be used (Table 4). Outcome sets developed by the Cochrane Skin Group - Core Outcome Set Initiative (COUSIN) (9), as well as the COMET database (10) are considered for core outcome sets, the maximum number of outcomes shall be limited to a maximum of seven due to aspects of feasibility. Negative outcomes (such as adverse events) must be included. Ideally, outcomes should be ranked, as suggested by GRADE, on a scale of 1-9 (11).

The process and all decisions made should be documented. Ideally, key questions should be finalized (and voted on) during the kick-off conference.

Table 3: Guideline questions using PICO/PIRT approach

Intervention question (**PICO**)	**P**atients/Population(s) **I**ntervention(s) **C**omparator(s) **O**utcome(s)
Diagnosis question (**PIRT**)	**P**atients **I**ndex test(s) **R**eference standard **T**arget condition

An example for the development of a PICO-question from a published guideline (12, 13) is shown below:

Key question: Is [redacted] useful as add-on treatment in patients unresponsive to high doses of [redacted]

Structured question: Is [redacted] 300mg as add-on treatment more effective and safer than placebo in patients with [redacted] unresponsive to [redacted]?

- **P**atients**:** Patients with [redacted] unresponsive to [redacted]
- **I**ntervention**:** [redacted] 300mg as add-on treatment
- **C**omparator**:** Placebo
- **O**utcomes**:** Complete suppression, Good or excellent response (desirable outcomes); Withdrawal due to Adverse Events, Patients with at least one Adverse Event (undesirable outcomes)

Kick-off conference and final selection of questions

The main aim of the kick-off conference is for all member of the Guideline/Consensus Statement Development Group to finalize the guideline key questions, to determine tasks and responsibilities during the guideline development process and to agree on conflicts of interest management of all members.

Web-based software are the preferred tools to facilitate consensus processes, but other options may also be considered to accommodate a fruitful collaboration between all Guideline Development Group members, including e-mail, telephone conferences and face-to-face meetings

EuroGuiDerm Guideline reports, Guideline Methods Reports and Consensus Statement Reports contain pre-defined sections, together with additional sections, specific for individual guideline/consensus statement.

Standard Operating Procedure Box 4: Questions

#	Step	Person(s)	Output
1	Developing pre-draft key questions and PICO/PIRT if applicable, based on the results of the scoping searches	Guideline/Consensus Statement coordinator, Methods Team, EuroGuiDerm staff	Draft list of questions
2	Deciding which questions are evidence-based (if any) and which consensus –based, which recommendations can be adapted	Guideline/Consensus Statement coordinator, Methods Team, EuroGuiDerm staff	Draft list of questions categorized into evidence based and consensus based; those for which recommendations can be adapted marked accordingly
4	Circulate scoping document/preliminary KQ to GDG and vote on outcomes/ranking outcomes	Guideline/Consensus Statement coordinator, Methods Team, EuroGuiDerm staff	Collect feedback, Ranking
3	Optional step 3: : Drafting preliminary EuroGuiDerm outline and Dissemination Plan Template	Guideline/Consensus Statement coordinator	Preliminary EuroGuiDerm outline (see reporting guideline) and Dissemination Plan Template
4	KICK- OFF CONFERENCE 1. Finalizing key questions 2. Confirming PICO/PIRT 3. Agreement on COI management 4. Distributing further tasks to guideline/consensus statement development group members using EuroGuiDerm GL/CS outline 5. Agreement on Dissemination Plan 6. Agreement on what warrants authorship	Guideline/Consensus Statement development group	Final EuroGuiDerm GL/CS outline, Completed Dissemination Plan Template, Draft of respective sections in the Methods report
5	Refining guideline project plan with timelines	Guideline Coordinator, Methods Team	Refined guideline project plan with assigned tasks and timelines

6. How to search for evidence and critically appraise the literature

Systematic search for, and appraisal of evidence only applies to EuroGuiDerm Guidelines. For EuroGuiDerm Consensus Statements - these are done at the discretion of the Development Group – no systematic review process has to be completed.

The first step includes evaluating the quality and applicability of existing guidelines for evidence-based key questions. If such guidelines are identified, the ADAPTE toolkit is used for adapting them (14), see '1. Scoping'. The next step includes searching for adequate systematic reviews and meta-analyses. Only if no suitable reviews can be identified a search for primary data studies should be conducted (for selected key questions).

For all EuroGuiDerm Guidelines, the Methods Team must produce a systematic review protocol and publish it on the EDF website. This fosters a transparent and structured way of assembling the body of evidence. The methods and details for each of the following steps should be specified a priori:

- Specifying structured key questions
- Developing a literature search strategy based on PICO/PIRT and selecting appropriate databases
- Identifying potentially relevant evidence through systematic and reproducible searches in multiple databases and clinical trials registers
- Selecting relevant evidence in line with the eligibility criteria
- Extracting relevant data using a standardized data extraction form
- Critically appraising the available evidence using established tools
- Synthesizing the results, narratively or quantitatively (i.e. meta-analysis, vote counting)
- Interpreting the body of evidence, including descriptions of strengths and limitations

Standard Operating Procedure Box 5: Evidence search for new key questions

#	Step	Person(s)	Output
1	Developing protocol, generating list of relevant data and outcomes to be extracted involving Guideline Subcommittee	Methods Team	Systematic review protocol, published on the EDF website or registered with PROSPERO if appropriate
2	Developing search strategies for at least two appropriate databases (such as Medline or EMBASE), if reasonable and funding allows also include: clinicaltrials.gov and EU Clinical Trials Registers	Methods Team	Defined search strategies for selected databases
3	Performing searches as per Step 2	Methods Team	Search results
4	Screening of titles and abstracts independently by two researchers, resolution through discussion, in case of further disagreement involve third researcher	Methods Team	Screened titles and abstracts results, documented using a PRISMA flow chart
5	Screening of full texts independently by two researchers, resolution through discussion, in case of further disagreement involve third researcher	Methods Team	Screened full text results, documented using a PRISMA flow chart
6	Developing a draft data extraction form	Methods Team	Draft data extraction form
7	Piloting draft data extraction form	Methods Team	Piloted data extraction form
8	Extracting data using the piloted extraction form/Excel sheet from step 7 by two independent researchers	Methods Team	Extracted data
9	Critically appraising the literature independently, preferably by two researchers, resolution through discussion, in case of further disagreement involve third researcher	Methods Team	Results Table
10	Synthesizing results (e.g. meta-analysis), including performing sensitivity analysis if necessary	Methods Team	Forest plots or similar
11	Performing GRADE evaluations	Methods Team	Summary of findings tables
12	Synthesizing results (certainty of the evidence and qualitative)	Methods Team	Narrative text with clear indication of study ID and/or effect estimates/meta-analysis results

The preferred methodology for critical appraisal of the evidence in EuroGuiDerm Guidelines is that of The Grading of Recommendations Assessment, Development and Evaluation (short GRADE) working Group (15, 16), 'a common, sensible and transparent approach to grading quality (or certainty) of evidence and strength of recommendations', considered a current standard in guideline development. An explicit consideration of the GRADE domains (risk of bias, inconsistency , indirectness, imprecision, publication bias) leading to one of four possible *certainty of the evidence* judgement for each outcome assessed, also known as *quality of evidence or confidence in the estimates* (Table 4, **Appendix 4**). Additionally, Evidence to Decision Frameworks may be created (**Appendix 5**).

Table 4: GRADE Certainty (Quality) of evidence and definitions (15, 16)

Quality of evidence	Definition
High ++++	We are very confident that the true effect lies close to that of the estimate of the effect.
Moderate +++0	We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low ++00	Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect.
Very Low +000	We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

The above-mentioned steps need to be documented as part of the Methods Report.

7. How to reach consensus and develop guideline recommendations

EuroGuiDerm Guidelines

The Methods Team prepare draft recommendations for **EuroGuiDerm Guidelines**. The Methods Team also prepare the GRADE Summary of Findings (SoF) Tables and a narrative text summarizing the findings. Methods teams are encouraged to develop GRADE Evidence to Decision (EtD) frameworks (17, 18).

Please see examples of an SoF table, and EtD framework Summary of Judgement and Conclusion from previous guidelines (12, 13) in **Appendices 4 and 5.**

EuroGuiDerm Consensus Statements

The chapter authors draft the guideline text and the recommendations prior to the consensus conference for EuroGuiDerm Consensus Statement.

As shown in Table 8, all draft recommendations in the **EuroGuiDerm Guidelines** and **EuroGuiDerm Consensus Statements** must use the GRADE wording (15, 16, 19, 20) and symbols as shown in Table 8. Modified GRADE wording as per Table 5 must be used in EuroGuiDerm Consensus Statements for consistency reasons. Uniform recommendation format also simplifies the implementation of a recommendation. However, methods used (or not used) must be clearly specified (15, 16).

Table 5: Wording of recommendations (15, 16, 19, 20)

Strength	Wording	Symbols	Implications
Strong recommendation for the use of an intervention	'We recommend . . .'	↑↑	We believe that all or almost all informed people would make that choice. Clinicians will have to spend less time on the process of decision-making, and may devote that time to overcome barriers to implementation and adherence. In most clinical situations, the recommendation may be adopted as a policy.
Weak recommendation for the use of an intervention	'We suggest . . .'	↑	We believe that most informed people would make that choice, but a substantial number would not. Clinicians and health care providers will need to devote more time on the process of shared decision-making. Policy makers will have to involve many stakeholders and policy making requires substantial debate.
No recommendation with respect to an intervention	'We cannot make a recommendation with respect to . . .'	0	At the moment, a recommendation in favour or against an intervention cannot be made due to certain reasons (e.g. no reliable evidence data available, conflicting outcomes, etc.)
Weak recommendation against the use of an	'We suggest against . . .'	↓	We believe that most informed people would make a choice against that intervention, but a substantial number would not.

intervention			
Strong recommendation **against** the use of an intervention	'We recommend against . . .'	↓↓	We believe that all or almost all informed people would make a choice against that intervention. This recommendation can be adopted as a policy in most clinical situations.

The consensus process

During the consensus conference, the drafts of all recommendations are presented to the Guideline Subcommittee.

Methods that may be used for reaching consensus are the following (4):

- Nominal group process (15-20 participants)
- Structured consensus conference (30-60 participants)
- (Modified) Delphi process (50-200 participants)

The minimal consensus level needed for the recommendation to be included in the guideline is > 50%. The consensus levels for individual recommendations are classified and additionally visually presented in a consistent way (Table 6).

Table 6: Consensus levels. Adopted from (4)

100 % consensus	100% agreement	
Strong consensus	Agreement of >95% participants	
Consensus	Agreement of >75-95% participants	
Agreement of the majority	Agreement of >50-75% participants	

To improve implementation, the final recommendations must be presented in a summary format (**Table 7)** with key information on the strength of recommendation, consensus level and links to the relevant Summary of Findings Tables (EuroGuiDerm Guideline) or relevant evidence (EuroGuiDerm Consensus Statement). The fact that the references were found through a non-systematic literature search must be clearly specified in the EuroGuiDerm Consensus Statements summary of recommendations Tables.

Table 7: Two examples of the final presentation of a recommendation

We **recommend** …	↑↑	Strong consensus 95%		Table xxx
We **suggest against** . . .	↓	Consensus >75-95%		Expert consensus

Along with guideline recommendations, the EuroGuiDerm Guideline/Consensus Statement Subcommittee is encouraged to define **quality standards** (**3 to 5)** in line with the guideline recommendations for that specific topic, as well as **monitoring indicators** for those standards. Data quality standards and indicators need to be described in a standardized way, and added to EtD table for relevant recommendations. If standards or indicators have already been developed by dermatological societies (e.g. currently done by the British Association of Dermatologists) for the topic at hand, they are used as a starting point for adoption or adaptation (5). Similarly, EuroGuiDerm

Guideline Subcommittees may agree on **research priorities** in individual EtD table for individual questions and include **a summary of recommendations for research** in the Methods Report (17, 18).

The consensus and dissemination process on the standards, indicators and research priorities follows the one for guideline/consensus statement recommendations.

Additionally, the EDF aims at hosting a web EuroGuiDerm database on the European quality standards and indicators in dermatology, which will be freely accessible.

Standard Operating Procedure Box 6: Recommendations and consensus process

#	Step	Person(s)	Output
1	Collecting: • EuroGuiDerm Consensus Statement- chapter drafts and draft recommendations from authors • EuroGuiDerm Guidelines- GRADE SoF Tables and/or EtD Frameworks including recommendations	Guideline Coordinator, EuroGuiDerm Staff	EuroGuiDerm Consensus Statement: Chapter drafts and draft recommendations EuroGuiDerm Guidelines: Chapter drafts and GRADE SoF Tables and/or EtD Frameworks including recommendations
2	Assembling chapter drafts and recommendations in a single document and ensuring consistency	Guideline Coordinator assisted by Methods Team	A single guideline draft, which includes draft recommendations
3	Sending out guideline draft with draft recommendations to Guideline/Consensus Statement Subcommittee, asking for suggestions and changes/amendments to chapters and recommendations from Subcommittee members: • Directly via email or • More formally using a survey tool which can include preliminary voting on recommendations	Guideline Coordinator Methods Team (if applicable)	E-mail with guideline draft sent to Guideline/Consensus Statement Subcommittee (optionally with information how to access the survey, e.g. survey link)
4	Collecting any suggestions for changes/amendments, if applicable analysing survey responses, preparing suggestions for consensus conference	Guideline Coordinator	A document with suggestions for consensus conference
5	Implementation & Dissemination plan	Guideline Coordinator assisted by Methods Team	Plan with tasks to be assigned during cc
5	Consensus conference: • Reviewing COI management strategy • Presenting original and alternative suggestions of draft recommendations to group; • Using the nominal group technique (or other if appropriate) to reach consensus (face-to-face or via online meeting software)	Guideline Coordinator, independent Moderator, Methods Team (if applicable), EuroGuiDerm staff for admin. support	Document with final wording and the voting result for each recommendation (including abstentions), consensus level and evidence sources if applicable

8. How to organize the internal and the external review of your guidelines

The internal and external reviews are important to ensure that the final guideline is of adequate (methodological) quality. To make sure that the guideline is accurate, consistent and has a clear message, first, an internal review process takes place. The draft of the guideline and the Methods Report are first send to all members of the Guideline/Consensus Statement Development Group for commenting.

Next, the Guideline/Consensus Statement moves on to the external review. As at this stage, the Guideline/Consensus Statement has gone through an extensive consensus process and changes to consented sections require another consensus. The external review is therefore not meant as an opportunity to ask for revisions in recommendations unless some major aspect has been omitted.

The external review consists of an invited peer-review done by experts with focus on:

- Methods
- Format
- Inconsistency
- Clarity of message

At the same time, further relevant stakeholders and all EDF members are invited to share their comments. The draft (including Methods Report draft) will be sent via e-mail and additionally uploaded to the EDF website.

The draft (including Methods Report draft) is simultaneously submitted to a journal for publication for parallel peer review through the journal.

The Guideline Coordinator and the chapter authors consider all received comments. Amendments are made at the discretion of the Guideline Development Group. All of the comments, guideline development group replies, and changes to the draft made are documented transparently.

After incorporation of all changes and approval by the Guidelines Development Group, the EuroGuiDerm Board of Directors and the EDF Board are asked for final approval.

Standard Operating Procedure 7: Internal and external review

#	Step	Person(s)	Output
	Internal review		
1	Finalizing the guideline/consensus statement and guideline methods report drafts in line with the scoping document	Guideline coordinator, EuroGuiDerm staff	Guideline/consensus statement and, if applicable, methods report pre-draft
2	Checking the draft for consistency, cross-checking with protocol, and sending it to the Guideline/Consensus Statement Subcommittee for internal review;	Guideline coordinator, EuroGuiDerm staff	Cross-checked guideline/consensus statement, and, if applicable methods report draft
3	Considering and incorporating comments	Guideline development group	Internally reviewed report draft
	External review		
4	Submit guideline/consensus statement draft and methods report for EuroGuiDerm Guideline to journal; the same draft version (including Methods report draft) is made available for external review to relevant stakeholders (funding societies, selected non-EDF experts, EDF members, EuroGuiDerm Boards, EDF-Board and all EDF members, patient organisations, website, relevant stakeholders from the industry and/or the public)	Guideline coordinator, EuroGuiDerm staff	External reviewers comments
5	Collect all comments from external review including journal comments, generate overview and management strategy	EuroGuiDerm staff, guideline coordinator	Document with all received comments in standardized form and management strategy
6	Incorporate comments concerning typos and other simple changes	EuroGuiDerm staff, Guideline Coordinator	Drafts with corrected minor changes
7	Forward remaining content comments to the Guideline/Consensus Statement Subcommittee	Guideline Coordinator	Document with received comments in standardized form, and corrected minor comments
8	Providing list of comments with responses and final draft to EuroGuiDerm staff	Guideline Stakeholder panel	Document with received comments and responses in standardized form, draft corrected in line with considered comments
9	Respond to all stakeholders, who had submitted comments with feedback	Guidelines coordinator	E-mails with responses to comments
10	Final guideline will be send out final approval to EuroGuiDerm Board of Directors, changes derived from the review will be made visible in an accompanying document.	Board of Directors	Approval (with feedback)
11	Resubmit final version to the journal	EuroGuiDerm staff, Guideline coordinator	Submitted final journal version
12	Making the document with received comments and responses in standardized form available on request	EuroGuiDerm staff, Guideline coordinator	The document with received comments and responses in standardized form available on request through contact provided in the guideline report

9. How to foster implementation of Clinical Practice Guidelines

"Clinical practice guidelines" has been defined as "tools for making decisions in health care more rational, for improving the quality of health care delivery, and for strengthening the position of the patient" (21). "Implementation" is the process of ensuring that patient care follows the recommendations presented in the guideline as closely as possible. Clinical guidelines implementation is a component of "quality of care." "Quality of care" has been defined as "the extent to which health care services provided to individuals and patient populations improve desired health outcomes [...] In order to achieve the task, health care must be safe, effective, timely, efficient, equitable and people-centred." "Effective" in the definition means "providing services based on scientific knowledge and evidence-based guidelines" (22).

Translating guidelines into practice is a challenging task (23-25). A naïve model for implementation assumes that: 1. The acquisition of information leads *per se* to a change in behaviour, and that 2. Decisions to change are not affected by environmental issues. As a matter of fact, a range of factors influences implementation and actual behaviour. These factors include, among the others, the characteristics of the innovation, the adopters, the context or setting, and the specific implementation activities (26). It is important to be aware and recognise these factors when planning for implementation since they can both obstruct or facilitate clinical practice changes (Figure 4).

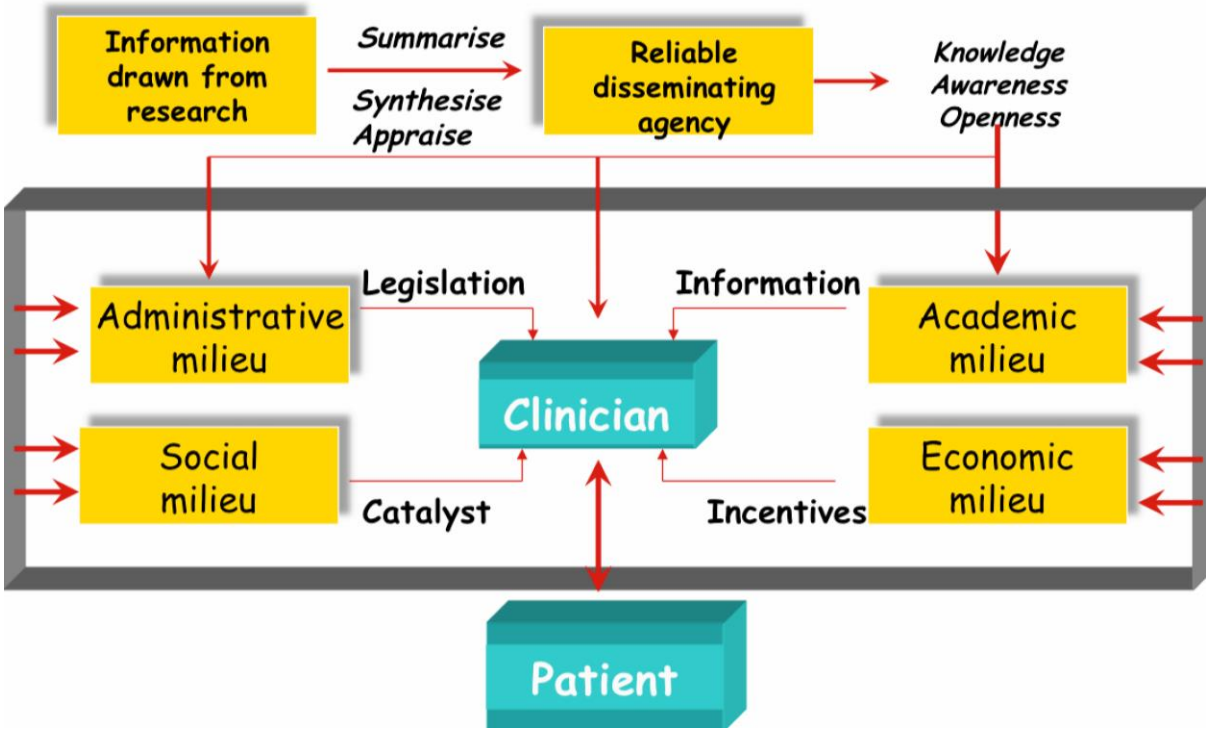


Figure 4: The black box of barriers to the implementation of clinical practice guidelines

As mentioned above as one of the factors, the implementation process is a country and an area specific activity and no generalization is possible. However, whatever the setting of the implementation, three main questions should be addressed:

1. Which specific aspects of the guidelines are worth of being transferred ?

2. How to implement them ?

3. How to assess the impact achieved ?

The first step involves the analysis of the local clinical practice and the identification of specific areas of improvement. The complete guideline documents are quite lengthy and detailed, which makes it difficult to identify the most important clinical aspects of the guideline. A list of key elements should be developed for each guideline according to the application setting. For example, if the implementation of a guideline on psoriasis is aimed at general practitioners, severity assessment and criteria for referral should be probably better emphasised.

The second step requires that a strategy for the dissemination and implementation of the guidelines into practice is clearly defined (see also chapter 10, table 11 for guidance).

The implementation process involves the removal of barriers for the guideline adoption and the use of strategies to facilitate a change in behaviour in line with the guideline recommendations. Transferring guideline findings can conflict with organisational and structural order of health care services as well as with attitudes and motivations of individuals. Several systematic reviews of implementation strategies have been conducted. Table 8 presents a list of interventions according to their effectiveness as evaluated by the Cochrane Effective Practice and Organisation of Care (EPOC) Group (27). The review conclusion is that "we lack a coherent theoretical framework based upon considerations of barriers and facilitators to change, and likely causal mechanisms that could inform the choice of interventions to be tested in future rigorous evaluations."

Table 8: Efficacy of different modalities for the implementation of clinical practice guidelines (data from the Cochrane Effective Practice and Organisation of Care (EPOC) Group, 2004)

Ineffective strategies
Dissemination of educational materials
Educational meetings
Strategies of variable but modest effectiveness
Audit e feedback
Opinion leader
Local consensus processes
Patient mediated intervention
Moderately effective strategies
Outreach visits
Reminders
Multifaceted interventions
Interactive educational meetings

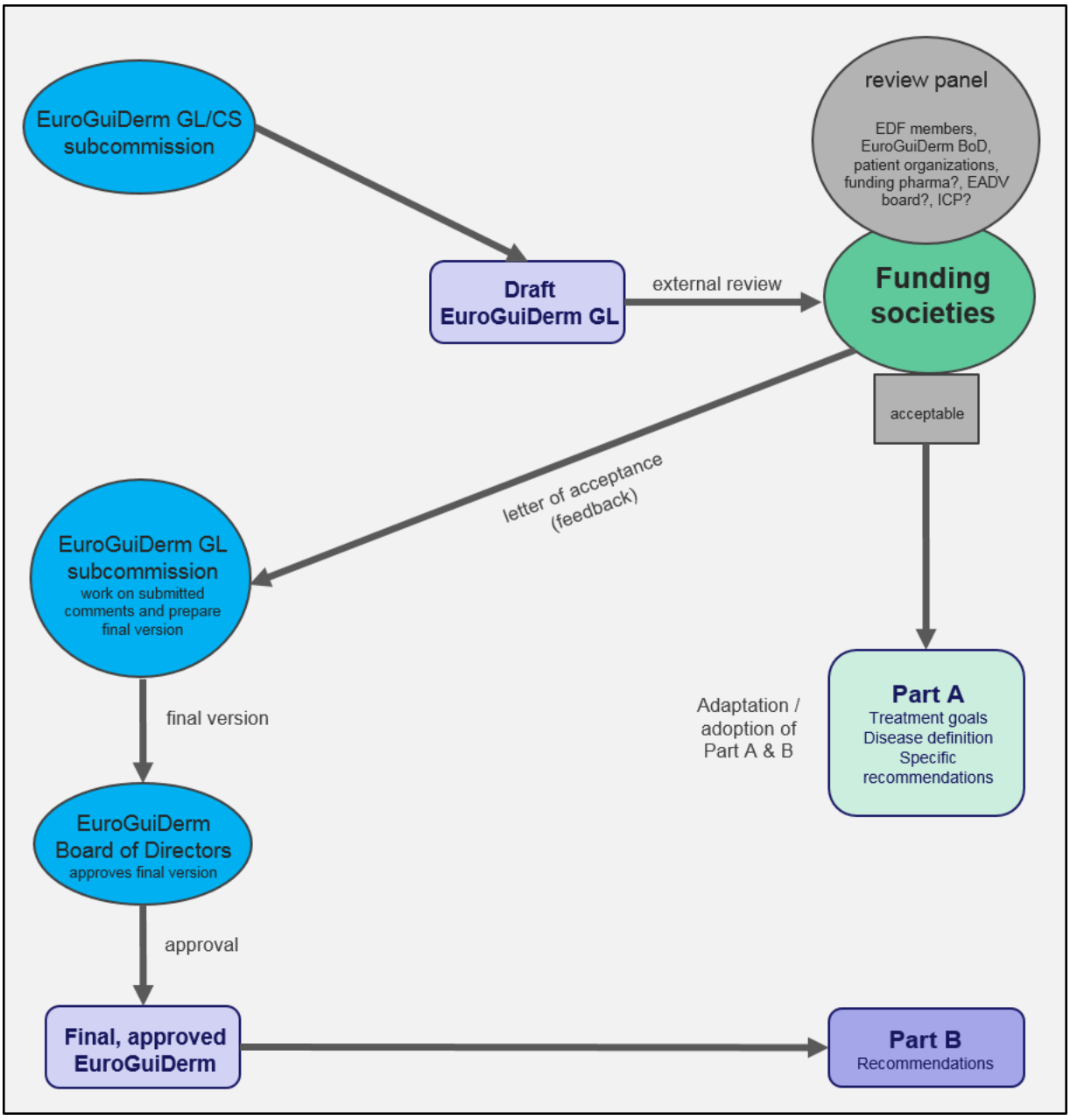
All in all, the most effective interventions are those using an integration of strategies.

The implementation of guidelines is an ongoing iterative process. The third step, is to assess the impact of the guideline adoption/adaptation. To this end, indicators should be defined and monitoring systems

should be put in place (see chapter 12). Monitoring systems may have different degree of details according to the level of evaluation (international, national, regional, local). Registry data can be used to assess short-medium term outcomes (28). Linked electronic administrative databases may offer a broader view on several aspects of the disease management (e.g., hospitalization, major complications and comorbidities) (29). Within the linked administrative databases, algorithms may be used to identify selected patient categories to be followed up over time (30). Field surveys are a more expensive way to assess the outcome of guideline adoption. Specific degree of improvement of selected outcomes can be taken as indicators.

To summarise, the development of clinical practice guidelines is only the first step to improve health care. Implementation into practice is the next step. It is a challenging task which needs thorough assessment. When evidence thresholds are met, adopting healthcare innovations should add value, and this is forgone when evidence is not translated into practice (25).

10. How to manage national roll out



Strategy for EuroGuiDerm guidelines adaptation by national/regional dermatological societies

EuroGuiDerm guidelines are developed for adaptation or adoption on national levels. The guidelines developed on the European level will not in all details be implementable or applicable in all European countries and treatment goals, and treatment algorithms among other things may have to be tailored to necessary local requirement and circumstances. For authorship and copyright issues, see next chapter.

Standard Operating Procedure 8: national roll out

#	Step	Person(s)	Output
1	All supporting national societies (SNS) will be informed at the beginning of a new guideline project *(see scoping and expert nomination SOP 1& 2)*	EuroGuiDerm staff	
2	About 3 months prior to the envisioned finalisation of the EuroGuiDerm GL/CS, supporting national societies will be informed about the time frame and invited to nominate national adaptation committees. Reminder email will be send one month before envisioned finalisation date.	EuroGuiDerm staff	Letter/e-mail
3	The final draft including the methods report and the evidence tables will be send out to the supporting national societies for review and commenting (time period 4-6 weeks). Some sections of the EuroGuiDerm GL/CS (e.g. treatment goals, treatment algorithms will be left open for specification by national societies in line with their local needs. *[see SOP 7 external & internal review]*	EuroGuiDerm staff	Letter/e-mail final draft (step 2; SOP 7)including GL/CS and standardized feedback form (appendix 4)
4	National societies provide feedback to the draft and indicate acceptability of the EuroGuiDerm GL/CS in their respective country and continue to work on the country specific guidelines.	National societies	Feedback form
5	EuroGuiDerm guideline group will work on submitted comments and perform changes on/additions to the GL/CS if indicated.	EuroGuiDerm guideline group	Final guideline / consensus statement
6	Final guideline will be send out final approval to EuroGuiDerm Board of Directors (see SOP 7, Step 10), changes derived from the review will be made visible.	EuroGuiDerm staff	Approved final guideline/ consensus statement
7	National societies will receive final version of EuroGuiDerm GL/CS. National guideline groups in line with previous review results can a) Accept and adopt the EuroGuiDerm in its current version as valid guideline for their country b) Adapt the EuroGuiDerm guidelines, when the guidelines are displayed as guidelines after national adaptation, changes should be clearly marked. c) Accept the guideline without an adaptation or adoption	EuroGuiDerm staff	Final, approved EuroGuiDerm GL/CS

11. How to publish and give appropriate credit

The suggested authorship rules for EuroGuiDerm GL/CS are:

- Substantial contribution to drafting GL/CS text
- Participation in meetings / consensus conference
- Substantial contribution reviewing and editing; help with working through the external comments received

Either highly relevant contribution to one of the above or contribution to at least two of the above

Authorship rules for adaptation/adoption of EuroGuiderm guidelines and consensus statements

EuroGuiDerm guidelines will always be published using open access licences (CC BY NC) on the EDF webpage. This allows for further non-commercial use of the guidelines/consensus statements including national adaptation and the generation of derivatives. Copyright will be transferred to the EDF. Copyright remains with the European Dermatology Forum (EDF) under CC-BY-NC and cannot be transferred elsewhere.

> *[original name of GL/CS] by EDF is licensed under CC BY-NC 4.0*

1. If the EuroGuiDerm guideline/consensus statement is accepted without any further changes, the author group remains unchanged, the group having approved the guidelines nationally shall be added as the endorsing people. Additionally, please give appropriate credit as follows:

> *[original name of GL/CS] by EDF is licensed under CC BY-NCA 4.0*

2. If the EuroGuiDerm guideline/ consensus statement is accepted without any further changes but translated into another language, the responsible persons are to ensure correctness of the translation and shall be added to the original author group. The same applies if only minor changes are applied to the guideline. Additionally, please give appropriate credit as follows:

> *[[new] name of GL/CS] is a derivative of [original name of GL/CS] by EDF is licensed under CC BY-NC- 4.0. [[new] name of GL/CS] is licensed under CC BY-NC- 4.0*

3. In case of major[2] changes leading to a document that is substantially different from the EuroGuiDerm guideline/ consensus statement, the EuroGuiDerm guideline shall be mentioned as a source and text passages taken without changes should be marked accordingly.

When republishing a guideline/ consensus statement in a (national) journals, the original publication needs to be credited as mentioned above. No copyright of the original version can be transferred to any subsequently publishing journal. Additional publication costs to maintain the license agreement may occur.

Commercial user may contact euroguiderm@debm.de to discover their options.

[2] A major change constitutes, for example, newly consented & substantially different recommendations, substantial changes to the main text; other evidence, analysis or questions addressed.
Examples for minor changes would be: adding national treatment goals & disease definitions but not changing the main text including monitoring recommendations.

Authorship and copyright issues for already published guidelines with transfer copyright to a third party

In case of an update/adaptation of an already published guideline, which is not open access please use the following disclaimer: The present guidelines were developed on the basis of the European guideline *[title] + [full reference].* The first author of the aforementioned source guideline, *[first author name*], has granted us permission to modify and partially use certain sections thereof. For permission requests, please contact the publisher: permissions@wiley.com.

12. How to disseminate your guideline or consensus statement

According to the WHO (2): 'dissemination involves making guidelines accessible, advertising their availability and distributing them widely' (p. 51).

To reach different stakeholders, in particular the intended users of the guideline and to ensure successful guideline implementation, the guideline development groups develop a dissemination plan, using a template, see Table 9. and agree on it during the kick-off meeting.

The plan includes a list of audiences (relevant societies, dermatologists, other health professionals, patients, basic scientists, public, policy makers etc.) or at least intended guideline users who the guidelines should reach. For each audience, the Guideline Coordinator and the Guideline Subcommittee Members decide on responsible persons who will coordinate the development of the materials. Communication and implementation tools specifically tailored to reach different audiences from the list (e.g. derivative scientific journal articles, patient summaries, press releases, conference presentations, sharing on social networks etc.) also need to be listed in the plan.

Times when certain materials, communication or implementation activities are expected to be developed, piloted or to take place are also documented in the plan. Finally, the subcommittee members need to mark tools and activities in which they will need support from the EuroGuiDerm staff.

Table 9: Template for the guideline dissemination plan

Audience	Responsible Subcommittee member(s)	Communication and implementation tools to be used	Time at which they are to be developed, piloted or to take place	Is EuroGuiDerm support needed, and if yes what kind of support?
Intended users group 1				
Intended users group 2				
Intended users group 3				
Other stakeholder group 1				
Other stakeholder group 2				

(*Based on Cochrane Skin dissemination template, modified)*

Please also consult the dissemination checklist below when creating content and tools such as algorithms or decision aids (inspired by the Cochrane Dissemination list (31).

Table 10: Dissemination checklist

1.	Have you used plain language?	Include a plain language summary: Use active voice, keep sentence and paragraph short, avoid abbreviations and research jargon; Explaining terms or concept in pop-up or links to glossary (GET-IT glossary) on internet or add glossary
2.	If you have used numbers to present the findings, have you used absolute numbers and labelled numbers clearly?*	Always label numbers, describe the scale, use absolute effects, use tables and figures and include confidence interval, certainty of evidence if necessary – particularly relevant for guidelines that develop an algorithm/decision aid/or similar (report most important benefits and harm also, when evidence was not found, report in the same way, focus on important rather than statistically significant, do not confuse "lack of evidence" with "no effect")
3.	Have you made the content easy for people to quickly scan and read?	Most important content first (key results), avoid large blocks of text, use short meaningful headings, highlight keywords in bold (for example in newsletters, support summary formats or infographics that can be used in newsletter)
4.	Have you presented the results in more than one way?	Use words and numbers in different media to present findings or link to additional products that use other formats (plain language summary, summary of findings table, graphs)
5.	Where the topic or results may be upsetting, controversial, or disappointing: have you handled this sensitively?	Let people know about evidence gaps, highlight research in progress and remind them that decision making also takes into account cost, availability, preferences.
6.	Have you involved your target audience or sought their feedback?	See scoping document (chapter2) and external/internal review (chapter 8) – pilot your tool
7.	Is it easy for people to find information about this guideline?	Identify source as guideline, consider mentioning PICO, include year of publication, include authors, funding and COI declaration/management

* only applicable for EuroGuiDerm guidelines not for EuroGuiDerm consensus statements

Standard Operating Procedure 9: Dissemination

#	Step	Person(s)	Output
1	Developing a topic-specific guideline dissemination plan (including standard materials outlined in Step 3, with additional materials tailored to the specific guideline); consult the dissemination checklist (includes involvement of funding societies)	Guideline Subcommittee Members /Guideline coordinator	Dissemination Plan Draft sent to EuroGuiDerm, Draft dissemination materials and activities in line with the plan
2	Agreeing on the Dissemination plan and tasks at the Kick-off Conference	Guideline Subcommittee Members /Guideline coordinator	Final Dissemination Plan, Draft dissemination materials and activities in line with the plan with appointed responsible Subcommittee members
3	At minimum, developing and piloting (prior to external review) standard implementation tools, including: • guideline visual algorithm • summary of key recommendations presented in a standard way • lay summary/lay version	Guideline Subcommittee Members /Guideline coordinator	Piloted standard implementation tools: guideline visual algorithm and summary of key recommendations
4	(Optional) For the main journal publication agreeing on and developing interactive materials in line with journal possibilities, as well as on responsible subcommittee members for those materials	Guideline Subcommittee Members /Guideline coordinator	Interactive materials in line with journal possibilities
5	(Optional) Support in tailoring messages and materials for different audiences and ensuring meaningful cross-linking of the materials (e.g. mentioning guideline app available on the EDF website in the journal podcast or video interview)	EuroGuiDerm staff	Updated dissemination materials
6	If applicable, storing final versions of the materials on the EDF website	EuroGuiDerm staff	Final versions of the developed materials stored on the EDF website

13. How to monitor dissemination and evaluate the implementation of your guideline

Considerations of the implementation of the EuroGuiDerm Guideline/Consensus Statement, i.e. putting EuroGuiDerm Guideline/Consensus Statement into practice, are included in the scoping phase, as guidelines aim to target topic areas with the greatest potential for improvement and reducing skin health inequalities in Europe. However, the implementation is done at a country level, so all the generic implementation tools developed by the EDF may need to be adapted to national or regional contexts, and translated to local languages.

After consideration of individual conflicts of interest, motivated national or regional development groups wishing to adapt the EuroGuiDerm Guideline/Consensus Statement to their context are welcome to join the "EuroGuiDerm Collaborating Group" early on in the process (See Chapter 2: How to form Guideline or Consensus Statement Development Groups). The coordinator of the national adaptation may be included as author of EuroGuiDerm Guidelines/Consensus Statement, other group members as collaborators in the EuroGuiDerm Collaborating Group. When the work on national adaptation starts, they are better informed of the existing evidence and other important aspects. Joining the EuroGuiDerm Collaborating Group also aids the coordination of regional/national guidelines, and the process of EuroGuiDerm Guideline/Consensus Statement adaptation to national context may thus be accelerated. The same principle applies to developing the dissemination plan and the development of standard, and, if applicable, additional implementation tools in different languages.

The scoping document also includes a section on possible obstacles to a successful implementation of guidelines, which, if considered relevant by the Guideline Development Group, may be further explored as a special set of questions within the guidelines, and also adapted to national contexts simultaneously during the process of the EuroGuiDerm Guidelines/Consensus Statement development.

The EDF routinely monitors each EuroGuiDerm Guideline/Consensus Statement dissemination two to three years after the guideline publication including, but not limited to, the following:

- Number of accesses and/or downloads from the EDF website for the guideline and its dissemination materials
- Altmetric-Score of the journal publication or equivalent measure
- Number of Web of Science citations
- Number of countries which adopted (translated the guideline as is, without change of content); this is presented separately for European countries, regions and non-European countries
- Number of countries which adapted the guideline (used parts of the guideline, or some recommendations); this is presented separately for European countries, regions and non-European countries

The Guideline/Consensus Statement Subcommittee may wish to develop a guideline/consensus statement-specific dissemination or implementation monitoring protocol to complement the standard monitoring performed by the EuroGuiDerm staff, for Europe as a whole, specific regions, or individual countries. The EuroGuiDerm staff can assist in developing those protocols.

The situation described in the Scoping document represents a baseline measure, and can be presented with different levels of details, depending on the level of priority and funding. Ideally, an evaluation study is done to measure the impact of the Guideline/Consensus Statement. This is

particularly the case for the EuroGuiDerm Guidelines, which include recommendations on quality standards. According to the WHO (2), guideline implementation may be evaluated by measuring:

- Guideline dissemination
- Change in practice performance
- Change in health outcomes
- Change in end-user knowledge and understanding
- Economic consequences' (p. 56).

If applicable, evaluation protocols are developed specifically for each guideline, for Europe as a whole, specific regions, or individual countries. The EuroGuiDerm staff can assist in developing those protocols and performing evaluation studies.

During the transitioning period (2019-2021), a long-term communication, dissemination and implementation strategy will be developed in line with the results of studies exploring the research gaps around guideline users (including people suffering from skin disease and STIs) and trends in guideline use at European level.

Standard Operating Procedure 10: Monitoring and evaluation

#	Step	Person(s)	Output
1	Sending a list of standard dissemination monitoring measures to the guideline coordinator	EuroGuiDerm staff	Letter with list of standard monitoring measures
2	(Optional) Developing a supplementary guideline dissemination monitoring protocol	EuroGuiDerm staff, Guideline coordinator, Guideline subcommittee, interested experts	Supplementary guideline dissemination monitoring protocol
3	After 2-3 years, sending a list with measures for the individual guideline monitored as planned in Letter from Step 1	EuroGuiDerm staff	Letter with guideline performance measure
4	(Optional) Developing an implementation evaluation protocol for guidelines at a specified level (Europe, individual countries or regions), preferably measuring the health effects of implementation	EuroGuiDerm staff, Guideline coordinator, Guideline subcommittee, interested experts	Supplementary guideline implementation evaluation protocol
5	(Optional) Performing monitoring and evaluation as per steps 2 and 4, and preparing journal publication	EuroGuiDerm staff, Guideline coordinator, Guideline subcommittee, interested experts	Published monitoring and/or evaluation report

14. How to define the expiration date of a guideline and how to update them

The same formal process used to reach consensus on recommendations in individual EuroGuiDerm Guidelines/Consensus statements is used for:

- Defining the guideline expiration date
- The need for a living guideline

For most EuroGuiDerm Guidelines/Consensus Statements, the defined time lines for updating are based on the size of the current body of evidence and the guideline subcommittee's view of the evidence generation speed. In most cases, the guidelines are updated after 3-5 years. Methods used in original guidelines are usually applied for updates and the original protocol followed. We record and justify all deviances from the protocol in the "Difference between the protocol and the guideline update" section of the "Methods report".

If a protocol for EuroGuiDerm Guideline evidence review does not exist, it should be developed for update purposes to increase the quality of the guideline update. The changes in the guidelines made in the course of the update will be recorded.

For certain guidelines, automatic searches may be run. In case new evidence appears, and in line with a predetermined update strategy, an earlier update may be proposed to the Guideline Coordinator.

For selected, high-impact guidelines in research active areas, we aim to use living systematic reviews and update the guidelines regularly.

Standard Operating Procedure 11: Updating

#	Step	Person(s)	Output
1	Assessing guideline/consensus statement update need, as per published guideline/consensus statement or regular searches for guidelines a) Regularly checking validity date b) Consulting with guideline coordinator with regard to relevant changes in the field	EuroGuiDerm staff, Guideline coordinator	Information of guideline update need
2	Scoping of update as per SOP1 if not an EuroGuiDerm Guideline/EuroGuiDerm Consensus Statement, and following steps using the guideline/consensus statement to be updated as a starting point, with adequate methodological adjustments tailored on a case to case basis	EuroGuiDerm staff	Scoping document
3	For EuroGuiDerm Guidelines Statement, checking whether there is a published guideline protocol for evidence search, and if yes, whether it is up to date with the EuroGuiDerm methodological standards	EuroGuiDerm staff	Protocol status information, including need for developing it from scratch or update of existing one
4	Developing new protocol or updating existing one if necessary, in line with the EuroGuiDerm methodological standards	EuroGuiDerm staff	New protocol
5	Following further steps as per SOP1-SOP9	EuroGuiDerm staff, Guideline/Consensus Statement development group	Guideline/Consensus Statement Update Report, Methods Report

15. Endorsement of other guidelines

The EDF has collaborated with a number of related societies when developing guidelines. Guidelines commissioned and funded mainly from other societies may get endorsed by the EDF and will then be called "**EDF-endorsed guidelines"**. Preferably, the EDF is involved at the very beginning and nominates experts to participate in the guideline development.

The collaborating societies are invited to provide EuroGuiDerm staff with their project plan for the guideline. EuroGuiDerm staff will check if the guideline:

- Can be classifiable as the EuroGuiDerm Guideline or EuroGuiDerm Consensus Statement (as per Table 1), implying a representative guideline/consensus statement subcommittee, structured consensus, and, if applicable, systematic evidence search and evaluation.
- AGREE-relevant sections (7), crucial for achieving an acceptable quality level are included in the plan, as judged appropriate by the guideline coordinator, EuroGuiDerm liaison person(s) and the EuroGuiDerm Director.
- Includes declarations of conflicts of interest as per EuroGuiDerm guidance, and a guideline development group with a minimum of 50% members without any relevant COI.
- Was developed using appropriate methods for critical appraisal of the evidence. For EuroGuiDerm Guidelines, the preferred method is the GRADE approach, but others may be considered on a case-by-case basis
- Has internal and external review planned, comparable to the EuroGuiDerm methods

If resources allow, respective feedback and guidance will be given.

In exceptional cases, guidelines that have been fully developed and are in a field of interest to the EDF, a draft written without EDF nominees may be endorsed (before approval, guidelines will be sent out to all EDF members, board of directors and methods board, and final approval needs to be confirmed by EDF board).

Endorsement can be mentioned in the title as "endorsed by Society 1, EDF, Society 2" or in the text information of the guideline.

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Appendix 1: Form used to declare Conflicts of Interests

All conflict of interest declaration will be collected online. http://ask.debm.de/index.php/981542?lang=en

1. **Declaration of Interests for EuroGuiDerm Guideline and Consensus Statement Authors**

The EuroGuiDerm Manual contains information on its policy for declaration of interests for EuroGuiDerm Guidelines and Consensus Statements.

Please carefully read *Chapter 3 How to declare interests and manage conflicts of interests* and *appendix 2* of the Manual.

2. **Your details**

Surname, First name(s), Employer, Position held:

Guideline/Consensus Statement you are helping with:

You will now be asked to declare:

1. **Personal Financial Interest**
2. **Non- Personal Financial Interest**
3. **Personal Non-Financial Interest**

Interests can be:

- **specific** (if it refers directly to the 'matters under discussion' which include products being evaluated) **or non-specific** (if it does not refer directly to the 'matters under discussion' which include products being evaluated
- **financial** (payments received in cash or in kind) or **non-financial** ('reputational risk'); financial interests can be **personal** (payments received personally in cash or in kind) **or non-personal** (payments not received personally in cash or in kind)

1. **Declaration – Personal Financial Interest**

Personal Financial Interest specific to matters under discussion

Description (if you have no interests in this category, state 'none')

2. **Declaration – Non- Personal Financial Interest**

Non-Personal Financial Interest specific to matters under discussion

Description (if you have no interests in this category, state 'none')

3. **Declaration – Personal Non-Financial Interest**

Personal Non-Financial Interest specific to matters under discussion

Description (if you have no interests in this category, state 'none')

4. **Date of declaration**

Appendix 2: Example of Summary of Findings Table

From a published guideline (12, 13)

Evidence week 4:

Is omalizumab 300mg as add-on treatment more effective and safer in patients with CSU unresponsive to 2nd gen H1-AH than placebo?

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with placebo	**Risk difference with add-on omalizumab 300mg every 4w**
complete suppression - w4	701 (4 RCTs)	⊕⊕⊕⊕ HIGH	**RR 20.51** (5.86 to 71.82)	4 per 1.000	**74 more per 1.000** (18 more to 268 more)
good or excellent response - w4	701 (4 RCTs)	⊕⊕⊕⊕ HIGH	**RR 6.10** (3.40 to 10.92)	68 per 1.000	**348 more per 1.000** (164 more to 676 more)
mean difference CU-Q2oL - w4	91 (1 RCT)	⊕⊕⊕⊕ HIGH	-		MD **20.7 lower** (29 lower to 12.5 lower)
withdrawal due to AE - w4	46 (1 RCT)	⊕⊕⊕⊕ HIGH	not estimable	0 per 1.000	**0 fewer per 1.000** (0 fewer to 0 fewer)
patients with at least 1 AE - w4	46 (1 RCT)	⊕⊕⊕◯ MODERATE [1]	**RR 1.01** (0.55 to 1.85)	476 per 1.000	**5 more per 1.000** (214 fewer to 405 more)

Appendix 3: Example Evidence to Decision Framework

Summary of Judgements and Conclusion only, example from a published guideline (12, 13)

Summary of judgements

	JUDGEMENT							IMPLICATIONS
DESIRABLE EFFECTS	Trivial	Small	Moderate	**Large**		Varies	Don't know	Favors add-on omalizumab 300mg every 4w
UNDESIRABLE EFFECTS	Large	Moderate	Small	**Trivial**		Varies	Don't know	Favors add-on omalizumab 300mg every 4w
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	**High**			No included studies	Favors add-on omalizumab 300mg every 4w
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	**Favors the intervention**	Varies	Don't know	Favors add-on omalizumab 300mg every 4w
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know	

Conclusions

TYPE OF RECOMMENDATION	Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	Conditional recommendation for the intervention ○	Strong recommendation for the intervention ●
RECOMMENDATION	We recommend add-on omalizumab 300mg every 4 weeks for the treatment of patients with CSU unresponsive to 2nd generation H1-AH.				
JUSTIFICATION	Omalizumab 300mg was superior to placebo for 'complete suppression' (high quality), 'good or excellent response' (high quality), 'mean change in UAS7' (moderate quality), 'mean change in DLQI' (high quality) and 'mean difference in CU-Q2oL' (moderate/high quality). No difference was found for 'withdrawal due to AE' (high quality) and 'patients with at least one AE' (moderate/high quality).				
SUBGROUP CONSIDERATIONS	No evidence was available for children (< 18 years of age), pregnant or lactating women.				
IMPLEMENTATION CONSIDERATIONS	-				
MONITORING AND EVALUATION	-				
RESEARCH PRIORITIES	-				

Appendix 4: Feedback form for the review

Name:	
email address:	
Address:	
Institution:	

Feedback on implementation tools:	

Document	Section/ page	Text passage in guideline or report	Suggested to change in… *[please provide concrete suggestions]*	Reason (with references)