

SOPs FOR THE ESGO GUIDELINES

The ESGO recommendations are developed using a five-step process (Figure 1). The strengths of the process include multidisciplinary of an international development group, scientific evidence and/or international expert consensus to support the recommendations, patients' involvement in the process, use of an external review process (international validation by physicians and patients), and management of potential conflicts of interests. This development process involves at least one physical meetings of an international development group.

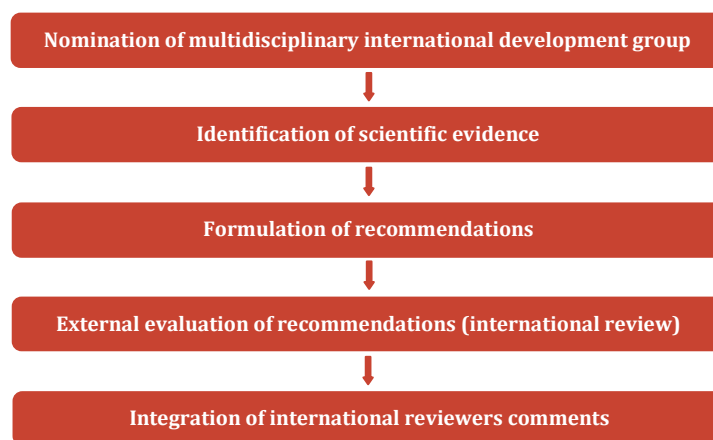


Figure 1. Development process

1.1 Definition of the scope of the project

The scope of the project must be clearly defined. Tumor site, pathology type, inclusion or not of management of recurrent disease, inclusion or not of follow-up must be specified. The definition is elaborated by the ESGO Guidelines, Recommendations and Quality Assurance Committee and approved by the Council. The corresponding budget is established.

1.2 Nomination of a multidisciplinary international development group

The ESGO Guidelines, Recommendations and Quality Assurance Committee nominates practicing clinicians who provide care to the cancer patients concerned by the guidelines and had demonstrated leadership in management of patients through research, administrative responsibilities, and/or committee membership. The ESGO Council appoints the experts panel members and appoints a chairman. The objective is to put together a multidisciplinary panel. It is essential to include professionals on the panel from relevant disciplines so that their multidisciplinary perspective would influence the validity and acceptability of the recommendations (gynecologic oncology, medical oncology, pathology, radiation oncology, surgery). Another requirement is a balanced representativity of countries across Europe. A maximum of 20 members is appointed.

The experts of the multidisciplinary international development group are required to complete a declaration of interest form, and to promptly inform the ESGO council if any change in the disclosed information occurred during the course of this work.

1.3 Identification of scientific evidence

To ensure that the statements made are evidence based, the current literature is reviewed and critically appraised. A systematic literature review of the studies is carried out by a professional methodologist using the MEDLINE database. The indexing terms and the date limits are decided by the Chair and the methodologist.

The literature search is limited to publications in English. Priority is given to high-quality systematic reviews, meta-analyses, and randomized controlled trials but lower levels of evidence are also evaluated. The search strategy excludes editorials, letters, and *in vitro* studies. The reference list of each identified article is reviewed for other potentially relevant papers. The bibliography is also be supplemented by additional references provided by the international development group.

Another bibliographic search is carried out to identify previous initiatives using a systematic literature search in the MEDLINE database (no restriction in the search period, indexing terms: clinical practice guidelines, evidence-based medicine, guidelines, methodology, recommendations) and a bibliographic search using selected websites of other national/international learned societies or governmental organizations. All retrieved articles are methodologically and clinically appraised. After the selection and critical appraisal of the articles, a summary of the scientific evidence is developed.

1.4 Formulation of recommendations

The IDG develops recommendations at the time of a physical meeting. The recommendations are retained if they are supported by sufficient high level scientific evidence and/or when a large consensus among experts is obtained. By default, a guideline is the clinical approach that is unanimously recognized by experts as being the criterion-standard clinical approach. If an approach is judged to be acceptable but is not unanimously recognized as a criterion-standard clinical approach, indication is given that it is still subject to discussion and/or evaluation. In the absence of any clear scientific evidence, judgment was based on the professional experience and consensus of the development group (expert agreement). The reliability and quality of the evidence given throughout this document is graded following the SIGN grading system.

1.5 External evaluation of the recommendations - International review

The ESGO office selects a panel of practicing clinicians who provide care to cancer patients and patients. The objective is to assemble a multidisciplinary panel. The international reviewers are independent from the development group. Another requirement is a balanced representativity of countries across Europe. International reviewers are asked to evaluate each recommendation according to their relevance and feasibility in clinical practice (only physicians). Quantitative and qualitative evaluations of the recommendations are proposed to be performed. Patients group representatives are also consulted. The total number of external reviewers is around 100.

1.6 Integration of international reviewers comments

Responses are pooled and discussed by the development group at the time of a second meeting or email forum. The final recommendations are elaborated. When necessary, a modified Delphi approach is used to reach consensus.