

## **Standardised operating procedure, and memorandum of understanding, for collaboration between the European Stroke Organisation and national guideline producers**

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### **Background and context:**

Promoting the highest quality, evidence-based research across Europe is one of the major priorities of the European Stroke Organisation (ESO). ESO have used clinical practice guidelines as their vehicle to raise standards and ensure consistency in practice. This has been a success and ESO now offers a portfolio of guidelines that cover the most important topics across the stroke pathway.

By necessity the guidance produced by ESO should be relevant for clinicians across all of Europe. However, between country differences in healthcare funding, resources available, skills mix and other factors, mean that a pan-European guideline may not always be applicable to a particular healthcare setting. The ideal would be a modification of existing guidance to suit the needs of a local population.

Producing a guideline is time and resource intensive. ESO guidelines typically take 18 months from inception to publication, and production requires a team of dedicated in-house staff as well as volunteers, topic and methodological experts. If national societies or other professional groups require a guideline specific to their stakeholder group there is a danger of duplication of effort if they complete this process de-novo when a relevant guideline is already available from ESO.

In this memorandum of understanding we outline a process whereby data and other materials from ESO guidelines can be shared to support other professional groups in guideline production.

### **Eligibility for receiving ESO guideline resources:**

ESO are happy to consider approaches from any national guideline producer, or recognised professional society with a remit around producing guidelines for stroke care. We anticipate that then majority of approaches will be from European organisations, as our guidance may not be suitable for other international healthcare systems. We would not immediately exclude working with non-European groups, but would consider these approaches on a case by case basis in discussion with the applicants.

### **Process for receiving ESO guideline resources:**

In the first instance an email request from the head of the relevant organisation, or their delegate, would be made to the ESO Guideline Board. This request should describe the nature of the organisation requesting support, the topic and questions in the proposed guideline, and the details of the materials requested from the ESO guideline board. Applications will be considered at the weekly meeting of the guideline boards, and this will usually be followed by a virtual meeting of the guideline board chairs and representatives of the organisation requesting support. If after this initial approach both parties are happy to proceed, then a bespoke memorandum of understanding, based on a generic template (below), will be created for all stakeholders to sign.

### **Potential materials available from ESO Guidelines:**

Maximising the visibility and availability of the guidance produced by ESO is core to the work of the guideline board. To this end, much of the content that may be required by a partner organisation is already in the public domain, either in the published guideline, online supplemental materials or in our

guideline web resource. However, if these materials are to be directly used by another organisation, we would still expect due process to be followed as outlined in this document.

Potential materials that could be shared include, but are not limited to:

- background / introductory text,
- search syntax and/or full search strategy,
- data extraction tables,
- risk of bias assessments at individual study and aggregate level,
- data required for meta-analysis,
- code used for non-standard analyses,
- figures, tables, illustrations,
- component data to inform strength of recommendation,
- full details of recommendations and expert consensus statements,
- data on usage of guidelines as available.

ESO will consider sharing any data that could reasonably be assumed to support local guideline production. However, we will not share data that is potentially sensitive or could identify the opinions of a member, or members, of a module writing group, for example the results of individual voting on an expert consensus statement.

Interpretation of the component data that informs a guideline is not always straightforward. In ESO we benefit from in-house methodological expertise. We would not routinely offer access to our methodologists to other groups requesting our data. This may be of particular relevance where the search that informed the ESO guideline needs updated for the local guideline or where a meta-analysis need updated with new data. The anticipation is that the group requesting resource will have their own team to work with the ESO offering and complete any additional work necessary. On a case-by-case basis we may consider sharing methodological support, but if the requirement for support is more than a single meeting or email advice, then we may seek financial compensation at our usual hourly rate.

There may be instances where the detail required is not held in ESO files but could be available from the module writing group (MWG) of the guideline. In this instance, ESO will broker a conversation between the requesting party and the chairs of the MWG. Acknowledgement in the final guideline, and the limits of data to be shared, will be agreed between the parties.

### **Expectations of the requesting organisation:**

ESO are keen to foster collaborative working and to facilitate this we have preferred a memorandum of understanding rather than a formal contract with potential partners. However, to protect the reputation of ESO, support our guideline authors, and uphold our standards, we have certain expectations of the groups we share our guideline resources with.

- The input and support of ESO should be made explicit in the text of the guideline (see section below).
- Organisations should not ask for ESO materials that have not yet been peer reviewed or otherwise quality controlled. In most instances this implies that organisations should only request materials from ESO guidelines that have been presented and published. The primary ESO publication should always be published before the partner guideline.
- Where ESO share materials that are not yet in the public domain, these should be treated in confidence.
- It is understood that in any data sharing, the intellectual property remains with ESO.
- Organisations should share with the guideline board the full text draft of any guidelines that are wholly or partly based on ESO materials.
- Guidelines that make use of ESO materials should adhere to the standards that are expected of ESO guidelines. (see text below)
- There will be a minimum of two meetings with the Guideline Board chairs, an initial planning meeting, and a final meeting where the use of the ESO materials are discussed and the recommendations shared.

In situations where ESO are working in partnership with the Guideline producer (see below)

- The Guideline board will review submissions, offer comment, and publication would be dependent on ESO approval.

### **Expectations of European Stroke Organisation:**

We anticipate forming partnerships with guideline producers that will facilitate harmonious working on multiple guidelines and updates as needed. In this regard ESO will commit to the following:

- The ESO Guideline Board office will field requests and act as a first point of contact and liaison between the applicant group and Guideline Board chairs, other members of the original module writing group, the publisher SAGE, and any other relevant stakeholders.
- The ESO President, Executive Manager, and Secretary General will be kept informed of each step of the process through regular communication with the Guideline Board.
- On request, ESO Guideline Board will share details of recent and upcoming guidelines including component 'PICO' questions and stage of production.
- ESO Guideline Board chairs will ensure timely responses to requests (typically within weeks)
- ESO will promote partner guidelines that make use of ESO materials, for example by listing the Guideline title on the ESO online guideline directory.
- ESO and the guideline publisher SAGE will not request any fees for general sharing of guideline data.

### **Approval of guidelines:**

At the initial meeting between ESO Guideline Board Chairs and partners, an agreement would be made on whether ESO would endorse the final guideline.

For most guidelines the default would be that ESO shares the resources requested if available, but has no further input to the guideline process or content.

In some situations, both parties may wish a closer involvement, with ESO reviewing and approving the final guideline products.

In this instance, draft text of the complete guideline should be shared with the ESO Guideline Board for review and approval. The Guideline Board would focus on use and interpretation of the ESO data, alignment of recommendations with ESO guidance, and suitable acknowledgment of the input from ESO in the guideline development. The Guideline Board would not usually have voting rights on guideline recommendations.

Where the new guideline is written a language other than English, ESO will identify an in-house reviewer to assist the Guideline Board in giving final approval. This should be complemented by a 'sign off' meeting where the use of ESO data and content of guideline is discussed with the Guideline Board chairs.

The anticipation is that by working in partnership with ESO, and following the processes described, final ESO approval should be straightforward. In instances where the ESO Guideline Board are not comfortable to approve the guideline or the use of ESO data, a meeting of the guideline representatives, the ESO Guideline Board and the ESO Executive will be convened. If the issues are not resolved, ESO can withdraw any endorsement of the guideline.

In both situations, ESO would expect a certain standard for guidelines they support. As a minimum, guidelines using ESO materials should include a comprehensive literature search, critical appraisal using a recognised and validated tool and offer recommendations that include assessment of the strength of supporting evidence. Where the organisation asking for ESO materials has produced previous guidelines the text should be shared with the ESO Guideline Board at the planning stage.

### **Acknowledgement of the role of ESO:**

The final guideline and any related materials should have an acknowledgement of the input from ESO guidelines.

We propose the following text:

*The European Stroke Organisation (ESO) through its Guideline Board assisted with the development of this guideline. The following materials <insert details of data or other materials used> from ESO Guideline <insert full citation of ESO Guideline> were used to inform these sections of the guideline <insert reference to sections>.*

*ESO involvement was in contribution of materials only, and the Organisation have not reviewed the subsequent guidance or endorsed the recommendations.*

For those guidelines that have been developed with ESO review and approval, the following text will be added in place of the last sentence:

*The ESO Guideline Board reviewed and gave final approval to the text as published. In this process ESO were a partner but the guideline is not an ESO product, and ESO are not liable for losses or damages related to the guideline.*

### **Translations and guideline partnerships with ESO:**

This process and memorandum of understanding does not apply to those groups who wish to translate ESO guideline content but make no modifications to content. A separate document outlines the procedure for translations of ESO materials. <hyperlink>

This process and memorandum of understanding does not apply to those groups who wish to partner with ESO on a novel guideline. A separate document outlines the procedure for prospective partnership on a guideline. <hyperlink>

**Template agreement:**

- European Stroke Organisation (ESO) and <insert name of external organisation> agree to share relevant materials for the purposes of creating the following product <insert name of guideline> , process will follow the Standard Operating Procedure described above.
- ESO Guideline Board chairs will meet with the designated representatives of <insert name of external organisation> for an initial planning meeting, with further meetings as required.
- ESO Guideline Board will be kept informed of guideline process at quarterly intervals.
- The final guideline will contain text acknowledging the role of ESO, the text will be agreed between parties.

**Non mandatory clause to be agreed at initial meeting:**

- The completed guideline will be shared with ESO Guideline Board for review and approval.