

FORMAT AND STRUCTURE SUMMARY FOR CIRSE GUIDELINE DOCUMENTS

All CIRSE guideline documents shall adhere to the format and structure outlined in this summary. Any deviation from the required format and structure requires explicit approval by the Standards of Practice Committee (SOPC) Chairperson and is subject to ratification by the Executive Board.

To smooth the passage from review stages to publication, the following structure must be used for the initial outline for CIRSE guidelines as well as for the manuscript itself.

In order to ensure documents are easy to read, and can be published in CVIR, they should be as short and practicable as possible.

CIRSE guidelines shall not exceed 5000 words (excluding references) and 50 references.

CIRSE guidelines are not review papers. CIRSE guidelines are quality assurance documents and shall recommend standards for the delivery of a given IR procedure ensuring best patient care.

It is recommended that Writing Groups utilise Levels of Evidence (see below), and the CIRSE Classification System for Complications if possible. Wherever possible, a summary of the key recommendations together with levels of evidence for each of them should appear at the front of the document so they can be easily found.

Format and structure requirements:

For all CIRSE guidelines it is mandatory to include headlines and paragraphs as following.

Title	All titles for CIRSE guidelines must begin with "CIRSE Guidelines on...". Example: CIRSE Guidelines on Percutaneous Needle Biopsy.
Summary of Recommendations	Wherever possible, please start the document with a summary of the key recommendations, ideally in table format – two columns: Recommendation and Level of evidence (see examples on the page 4).
Introduction	This section should include a brief summary of the historical evolution of the given IR treatment and its current / new role.
Definitions	This section should include a definition of the disease or procedure, including anatomy, (clinical) symptoms, treatment methods, etc.

Pre-Procedural Imaging Evaluation	if applicable, include clinical evaluation of patient in this chapter or include it in the section Patient Preparation
Indications for Treatment	if applicable, also divided into <u>absolute</u> and <u>relative</u> and contraindications.
Patient Preparation	if applicable, it should include risk evaluation, informed consent, anaesthesia, etc ...
Equipment Specifications	When describing required and recommended equipment, it should be avoided to name specific companies / products.
Procedural Features	It is important to describe the technique with most accumulated evidence and variations of the technique(s). The level of evidence for each variation should be reported (see appendix 1) and wording should be carefully considered (see appendix 1, example2).
Medication and Peri-procedural Care	if applicable, this should be a section on its own; in case no major medication and peri-procedural care is required it may be included in the section patient preparation.
Post-procedural follow-up care	Description of post-procedural and follow-up care should include required imaging follow up.
Outcome	Recommended thresholds for technical success, clinical success, and complications should be provided. Please note that tables can be used in this section to reduce the need for extensive text.
Effectiveness	include clinical as well as technical success. Randomised clinical comparisons with competing surgical or conservative treatment should be included if available. If randomised study is not available, at least controlled trials or registries should be mentioned.
Complications and their Management	When describing complications please use the CIRSE Classification System for Complications, if applicable (see page 5).
Conclusion	Keep conclusions short and concise.
References	Please do not include more than 50 references.

LEVELS OF EVIDENCE

CIRSE Guidelines should include clear recommendations based on levels of evidence (see example below).

To ensure that only the highest quality sources are used in the documents, SOP Writing Groups are required to evaluate their sources and rank them in Levels of Evidence Tables.

Levels of evidence
1a Evidence from systematic review or meta-analysis of randomized controlled trials
1b Evidence from at least one randomized controlled trial
2a Systematic reviews (with homogeneity) of retrospective cohort studies
2b Individual retrospective cohort study or low quality randomized controlled trial
3a Systematic review (with homogeneity) of case-control studies
3b Individual case-control study
4 Case series
5 Evidence from a panel of experts

The levels of evidence are based on the Oxford (UK) CEBM Levels of Evidence [1].

RECOMMENDATION GRADES

Wording to be used for recommendations, based on the respective level of evidence.

Grade	Definition	Suggested wording to use
Grade I	Evidence and/or general agreement that a given treatment or procedure is beneficial, useful, and effective	Is recommended/is indicated
Grade II	Conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of the given treatment or procedure	Evidence unclear
Grade IIa	Weight of evidence/opinion is in favour	Should be considered
Grade IIb	Usefulness/efficacy is less well established	May be considered
Grade III	Evidence or general agreement that the given treatment or procedure is not useful/effective and in some cases, may be harmful	Is not recommended

EXAMPLES: RECOMMENDATIONS AND A TABLE SUMMARY

Recommendations	Level of evidence
If the structured bleeding history is negative, and in the absence of antithrombotic treatment, no further coagulation testing is indicated for procedures with low bleeding risk.	Level 1 (because: Consensus of expert opinion and/or data derived from small prospective studies / registries and/or retrospective studies.)
Dual antiplatelet therapy is recommended for 1 month following carotid artery stenting. This may be prolonged in the presence of recent myocardial infarct (MI) (<12 months) and low bleeding risk.	Level 5 (because: Data derived from multiple Randomised Controlled Trials (RCT) or the meta-analyses of RCT's.)

CIRSE CLASSIFICATION SYSTEM FOR COMPLICATIONS

In 2017, CIRSE released guidelines outlining European classification system for complications [1]. For the sake of unified and consistent grading of complications in IR within Europe, CIRSE Standards of Practice documents shall use the following CIRSE classification system where possible.

Grade Description

1. Complication during the procedure which could be solved within the same session; no additional therapy, no post-procedure sequelae, no deviation from the normal post-therapeutic course
2. Prolonged observation including overnight stay (as a deviation from the normal post-therapeutic course\48 h); no additional post-procedure therapy, no post-procedure sequelae
3. Additional post-procedure therapy or prolonged hospital stay ([48 h) required; no post-procedure sequelae
4. Complication causing a permanent mild sequelae (resuming work and independent living)
5. Complication causing a permanent severe sequelae (requiring ongoing assistance in daily life)
6. Death

When documenting complications that may or may not be related to the IR procedure itself, additional classifications shall be used such as unrelated, unlikely, possibly, probably and definitely related to the IR procedure [2].

REFERENCES

1. Phillips B, Ball C, Sacket D, Badenoch D, Straus S, Haynes B. Oxford Centre for Evidence-Based Medicine–Levels of Evidence (2009). Centre for Evidence-Based Medicine. [Link](#)
2. Filippiadis DK, Binkert C, Pellerin O, Hoffmann RT, Krajina A, Pereira P. CIRSE Quality Assurance Document and Standards for Classification of Complications: The CIRSE Classification System. Cardiovasc Intervent Radiol. 2017;40:1141-1146. [Link](#)

NOTE: CIRSE Guidelines will be published in CVIR together with an online supplementary document providing an overview of all tables used for producing the Guidelines: levels of evidence, grades of recommendation and the CIRSE complications system; unless exceptionally necessary, please do not include these tables directly into the main text of the Guidelines.