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Developing Evidence-Based Standards for Diagnosis and Management of Lower Urinary Tract or Pelvic Floor Dysfunction

Peter F.W.M. Rosier, Dirk de Ridder, Jane Meijlink, Ralph Webb, Kristene Whitmore, and Marcus J. Drake*
International Continence[Q3] Society Standardization Steering Committee, UK

The International Continence Society (ICS) has a key role in standardizing terminology related to lower urinary tract and pelvic organ dysfunction. The ICS Standardization Steering Committee (SSC) presents the new structure and process by which future ICS Standards will be developed. The new processes aim to meet present-day evidence-based practice requirements, and to foster unbiased, inclusive, and transparent development. For each new ICS Standard, the SSC will oversee a dedicated ad hoc Working Group (WG). Applications to chair or contribute to a WG will be invited from the ICS membership. The SSC will select the Chairperson, and work with him or her to select the WG composition, balanced to represent key disciplines, stakeholders, and regions. Consultants can be invited to contribute to the WG where specific need arises. Every WG will review current knowledge, adhering to evidence-based medicine requirements. Progress reports will be reviewed by the SSC, and amendments recommended, culminating in a first draft. The draft will be offered to the ICS membership and additional relevant experts for comment. Further revision, if needed, will result in a document, which the SSC will submit to the ICS Trustees, as arbiters of whether the document should be adopted as an ICS Standard. The SCC will then coordinate with the WG to ensure that the new ICS Standard is published and disseminated. Implementation strategies, such as education, audit, accreditation, and research initiatives will be linked to the Standards where appropriate. Revisions of ICS Standards will be undertaken to maintain contemporaneous relevance. *Neurourol. Urodynam. 9999:1–4, 2011.* © 2011 Wiley Periodicals, Inc.

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INTRODUCTION

One of the most recognized activities of the International Continence Society (ICS) has been the publication of standardizations of terminology for diagnosis and testing in functional urology. This work started in 1976, with subsequent updates. The 1988[1] and the 2002[2] reports, with ± 1,000 and ± 2,500 citations, respectively, are amongst the most widely quoted publications in urology.

There have been two particularly important categories of publication. The first is the standardization of terminology, such as the "Standardization of Terminology of Lower Urinary Tract Function".[2] Standardized definitions of key medical terms with international consensus are increasingly needed as analysis and registration in healthcare become ever more automated and communication increasingly global. The establishment of the International Health Terminology Standards Development Organization (IHTSDO; http://www.ihtsdo.org/index.php?id=502) signifies the increasing weight attached to the agreed definitions of terminology to describe conditions at a fundamental level in medicine. The second category deals with the provision of guidelines for quality control and improvement of standards, which serve as a benchmark for professional activity, exemplified by the "Good Urodynamic Practice" document.[3]

ICS standards and standardization have led the way and have been widely accepted. The process by which they have been produced has been based on intensive expert discussion and consensus with input from the ICS membership, but without inclusion of the published evidence in a systematically weighed and transparent manner. The most recent report, a joint report with the International Urogynecological Association,[4,5] was developed in a similar manner. Ease of modern electronic communication has allowed more experts to monitor the content of draft editions of newer documents. This has meant that expert opinions were included in a "numerically" more balanced manner. However, no "methods" paragraph was given to explain explicitly how decisions on topics to include were made, nor how evidence and expert opinion were prioritized, included or excluded beyond acknowledgement of the commenting experts in a final paragraph.

Ideally, only "genuine evidence" is included in standards and guidelines. Where genuine evidence is lacking or conflicting, it is preferable that expert opinion is separately added to recommendations in a transparent and explicit manner. In the mid-eighties a group around David Sackett, a key figure in evidence-based medicine (EBM),[6] developed a systematic approach to evaluate published evidence, after he analyzed the problem of "observer error" in the interpretation of medical literature.[7] "EBM is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. The practice of EBM means integrating individual clinical expertise with the best available external clinical evidence from systematic research".[8] Standards to produce evidence-based clinical practice guidelines have been developed,[9] with guidance manuals.[10]

Peter F.W.M. Rosier and Dirk de Ridder contributed equally to this work.
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Roger Dmochowski led the review process.
*Correspondence to: Marcus J. Drake, International Continence Society Standardization Steering Committee. E-mail: marcus_drake@bui.ac.uk
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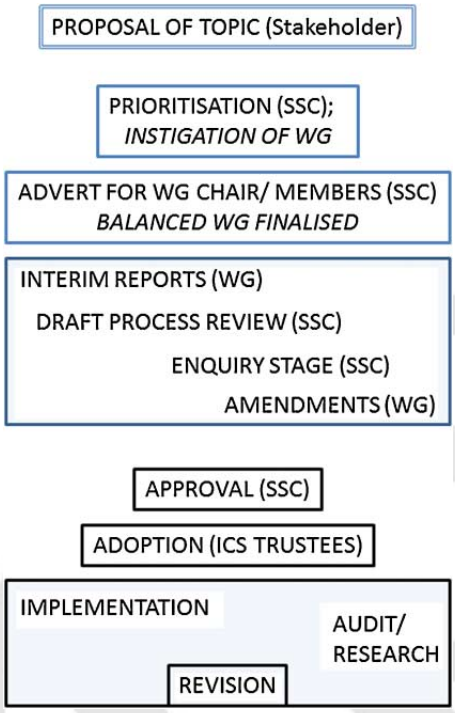

Fig. 1. Summary diagram of the key stages in development of an ICS Standard. (SSC, Standardization Steering Committee; WG, Working Group).

EBM as a strategy to improve healthcare is not disputed, but the implications in a rapidly expanding field of knowledge are substantial.[11] In the modern era of information technology, transparency, accountability, and complex multidisciplinary responsibilities cannot be ignored; expert opinion is only acceptable where evidence is lacking and must be clearly marked and explained as being expert opinion.

The ICS Standardization Committee recognized the importance of adhering to EBM principles. In 2010, a reorganization took place from which the renamed Standardization Steering Committee (SSC) emerged. A key difference between the new SSC and the old Standardization Committee is that the SSC does not itself deliver standardization documents; instead it oversees ad hoc Working Groups (WGs) (see below) which deliver the documents, aiming to ensure transparency, balance, and adherence to the methods and principles of EBM. The SSC Chairman is elected from the ICS membership according to the ICS articles and bylaws. The Chairman and the SSC members serve for a term of 3 years, once renewable.

The ICS SSC aims to ensure ongoing development of high quality terminology and/or practice standards, for guidance of professionals dealing with the basic scientific investigation, diagnosis, and management of lower urinary tract, pelvic floor, genital, and anal function and dysfunction. Developing these standards requires transparency and integrity; the SSC's process and expectations for modern-day development of some of the most important ICS documents are described below and illustrated in Figure 1.

PROCESS OF DEVELOPING AN ICS STANDARD

Topics selected by the SSC for development or revision of standardization reports will be based on areas of priority need, whether identified by the SSC itself, or in response to stakeholder suggestions. The delivery of a standardization document on a selected topic will be the remit of a specifically created ad hoc WG, which will focus on that specific subject (see Table I). The SSC's role is to agree the scope of the WG's activity, instigating and steering activity, checking compliance with suitable working practices, monitoring progress, ensuring adequate stakeholder input and evaluating the end result.

Once the need for a new or revised standard has been identified, the SSC will invite applications from ICS members wishing to chair the relevant WG. The person selected will have submitted the proposal with the best strategy for developing the document in the opinion of the majority of SSC members. The SSC will evaluate proposals according to key criteria (Table II).

WG Composition

The selected Chairperson will establish a WG of interested and knowledgeable individuals from a multinational and interdisciplinary background, representing all key stakeholder groups. Technical expertise relevant to the WG's remit will be taken into consideration in the selection of members. The WG

TABLE I. Structure and Function of Standardization Document WG

The composition needs to be multidisciplinary and multinational, representing the most important stakeholders (including, e.g., patient representatives, health economists, and others as appropriate)
Non-ICS members can be part of the WG as experts or representatives of specific stakeholders
The WG should generally not include more than 15 people
Selection of WG members should follow a transparent process, which is recorded and publically available
Additional contributions to a WG's deliberations can be received from outside individuals
The WG should not receive any sponsorship from industry and the members should disclose all relationships
All members of the WG will be responsible for the entire content of the document as a group.
The WG has a chairman who:
will propose the key question or topics of discussion to the SSC, together with a strategic plan (see).
will keep a digital working log of the WG activities
will make sure that the composition of the WG is well balanced and that the process of standardization is transparent
will use web-based and e-mail exchange of information and monitor the execution of assignments within the assigned timeline
will adhere to EBM principles, where appropriate
will report to the SSC
will be responsible for production of a first draft of the report within a stipulated time frame (generally 18 months)
will be responsible for submission for publication and dissemination.
After publication of the standard, the WG will be dissolved.
A typical lifespan for an ad hoc WG will maximally be 36 months. If the WG fails to be productive, the SSC dissolves the WG.
The ICS or ICS SSC will not provide financial budget for face-to-face meetings of any ad hoc WG.

TABLE II. SSC Criteria for Assessing WG Proposals

Title of the project
Name of applicant to chair the WG
Description of the topic: The arguments for creating the WG are:
(Explain why one or more of the following arguments is relevant)
- area of clinical uncertainty or "debate" exists
- evidence of better treatment is available
- evidence for renewal of the existing standard is available
- evidence of practice variation is available
- other clinical or scientific relevance
- there is significant controversy in practice or literature
- there is conflicting or incomplete evidence
- there are cultural differences in practices or viewpoints
- there is socio-economic relevance

List of proposed names (with CVs):
- confirmation that individuals have agreed to contribute
- evidence of multinational and interdisciplinary balance
- opportunity for ICS members to apply to join the WG and transparent, documented process for selection
- process to register contributions from individuals or groups not in the WG

Description of the methodology and how it will be used:
- web-based approach
- e-mail
- conference calls or webcasts
- face-to-face meeting (mainly during ICS international meetings)
- proposed timeline

Description of topic, proposed WG composition, likelihood of implementation, likelihood of publication, innovation of approach, realistic timeline, use of electronic tools.

will also be permitted or asked by the SSC to invite input from outside consultants where this is needed. This will typically be applicable in specialist contexts that are not widely represented within the ICS, such as engineering, computer sciences, or data handling. It may also be relevant in other fields, such as consumer perspectives, or economic issues, for example.

The SSC will ensure a transparent process for selection of WG members, and will evaluate and adapt the composition to ensure a balance between different viewpoints (professional, patient, and other stakeholders' perspectives). Once agreed, the proposal and the names of the WG's members will be published on the ICS website. If a member of the SSC is also a member of a WG, he/she will not be included in SSC decisions related to that particular WG. All (potential) conflicts of interest will be published on the ICS website.

Stages of a Standard

Stages through which a standardization document will progress are summarized in Table III. These will be listed in the project management-working log of the WG and the Chairperson of the WG should report progress to the SSC. The SSC will provide a mentor for the WG, who will evaluate the progress at least every 6 months and be available if any problems arise. The mentor will keep a log of these contacts.

Preparation of a Draft Report

The WG will prepare successive working drafts, circulating the drafts, and amending according to comments, until the group is satisfied that it has developed the best solution for the subject being addressed. Standards should adhere to EBM principles, where appropriate and possible. At an early stage, therefore, the WG has to devise a strategy for a comprehensive review of published literature and use an inclusive and transparent approach to derivation of expert opinion. It might sometimes be necessary to use the Delphi method.[12] Each WG will ensure a strategy for capturing and assimilating the views of all groups of stakeholders and criteria for inclusion or exclusion of these views in the finished document.

Throughout, the WG's Chairperson is responsible for:

- keeping a digital log of the WG's activities
- documenting the methods that were used to produce the draft document
- promoting web-based and e-mail exchange of information and monitoring the execution of assignments within the agreed timeline
- reporting to the SSC
- producing a first draft of the report within 18 months.

Committee Stage (Assessing the Process of Standardization)

As soon as a draft is available, the Chairperson of the SSC will forward it to all the members of the SCC for internal process review. The process by which the draft standard was created will be evaluated according to preset criteria. The document requires SSC approval prior to progressing to the next stage of development. The SSC may require revisions or amendments which will need to be undertaken by the WG in a defined time frame. A document that fails to meet the

TABLE III. Development of an ICS Standard

	Timescale (months)	WG	SSC
Proposal stage	−6 to 0	Applications for Chairmanship or membership.	Call for applications. Review subject, Chair, Group, criteria, timeline and starting date.
Preparatory stage	0 to 18	WG constituted. Development of draft.	Evaluate progress. Appoint mentor. Evaluation (at least every 6 months).
Committee stage	18 to 21	Draft submitted to SSC.	Review of the process and document against criteria. Approval by consensus.
Enquiry stage	21 to 24	Draft on ICS website.	Internal and external review. Comments by ICS members and stakeholders.
Approval stage	24 to 27	Submit final document to SSC.	Process review. Submission to ICS Board of Trustees.
Publication	27 to 36	Final text to ICS office for web publication. Journal submissions.	Official ICS document. WG dissolved.
Implementation stage	>36		Support implementation. Education (with ICS Education Committee). Register of comments. Identify research needs. Support health technology and economic assessment.
Revision stage		Submit proposal to SSC	Start new process

objectives or was not developed in accordance with the appropriate approach will be rejected, and the WG will be dissolved.

Enquiry Stage (Wider Assessment of the Content of the Document)

The actual assessment of the content of the document will be undertaken by internal and external experts (invited by the SSC) and the ICS membership. The draft standard will be circulated to all members by website publication for commenting over a period of 3 months.

Approval Stage

The WG should resubmit the final version based on the comments received. Explicit criteria for the inclusion or exclusion of comments should be developed and each comment should be accompanied by a narrative explaining the reason why it was either included in or excluded from the final version. All comments and accompanying narrative will be published on the relevant document web forum. The revised version should be resubmitted to the SSC for process review and assessment of the amendments. If approved, the document and the log of the development process will be sent to the ICS Board of Trustees for confirmation and adoption.

Publication

Once the Board has confirmed and adopted the document and the process, the final text will be published on the ICS website and will then be referred to as the new ICS Standard, superseding previous Standards. Thus, the new report must outline where it differs from previous reports. The WG will be encouraged to submit the document as an ICS Standard to *Neurourology and Urodynamics*, and the SSC will advise in this process. Co-publication with other journals can be considered if relevant, within copyright regulations. Publication of the respective ICS Standard will conclude the WG's activities.

Implementation Stage

The ICS SSC will promote implementation of the standards by publication, dissemination and education, and the proposing of new standards to its affiliate and collaborating societies and organizations. Additionally, the SSC will monitor the undertaking of clinical audit based on the ICS Standards' recommendations as a key aspect of successful introduction of the documents into mainstream practice,[13] and the undertaking of the research and development necessary for ongoing development of the evidence base.

Standards will be written in UK English. Translation into other languages will be supported; for terminology standards, this will require that appropriate linguistic validation procedures are followed (for an example of the application of linguistic validation in the context of translation of symptom assessment tools, see Acquadro et al., 2006).

Revision of Standards

The ICS SSC will also keep track of comments that are received for consideration during a future revision of the standard text, as well as identifying future research needs. A revision or update can be proposed by the SSC or any ICS member or group of ICS members when there is a perceived need, and the timescale for anticipated revision of a standard will be specified at the time of adoption- subject to future developments in the field. The SSC can discuss not to revise outdated documents and declare them obsolete.

CONCLUSIONS

In developing evidence-based standardization documents, the ICS SSC aims to ensure inclusiveness, responsiveness, transparency, accessibility, flexibility, and evolution. The ICS SSC presents a structured process for ad hoc WGs to develop ICS standards, and a strategy to guide that process. Consequently, each WG will be responsible for several stages of development, each clearly documented, until a high quality document has been approved as an ICS standard.

The presented structure and strategy place emphasis on the principles of EBM and transparency in the development of ICS standards. They also provide the flexibility necessary for the varied nature of the initiatives established by the ICS, where multiple stakeholders are generally present, and also circumstances in which the evidence base may be limited. ICS standards will continue to be adopted and promoted as the basis for good professional practice, suitable for the demands of the modern era of EBM.

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