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 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 SSC 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.

Key words: standards; evidence-based medicine

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 19881 and the 20022 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

© 2011 Wiley Periodicals, Inc.
EBM as a strategy to improve healthcare is not disputed, but the implications in a rapidly expanding field of knowledge are substantial. 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**

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>The composition needs to be multidisciplinary and multinational, representing the most important stakeholders (including, e.g., patient representatives, health economists, and others as appropriate)</td>
<td></td>
</tr>
<tr>
<td>Non-ICS members can be part of the WG as experts or representatives of specific stakeholders</td>
<td></td>
</tr>
<tr>
<td>The WG should generally not include more than 15 people</td>
<td></td>
</tr>
<tr>
<td>Selection of WG members should follow a transparent process, which is recorded and publically available</td>
<td></td>
</tr>
<tr>
<td>Additional contributions to a WG's deliberations can be received from outside individuals</td>
<td></td>
</tr>
<tr>
<td>The WG should not receive any sponsorship from industry and the members should disclose all relationships</td>
<td></td>
</tr>
<tr>
<td>All members of the WG will be responsible for the entire content of the document as a group.</td>
<td></td>
</tr>
<tr>
<td>The WG has a chairman who:</td>
<td></td>
</tr>
<tr>
<td>will propose the key question or topics of discussion to the SSC, together with a strategic plan (see form 1).</td>
<td></td>
</tr>
<tr>
<td>will keep a digital working log of the WG activities</td>
<td></td>
</tr>
<tr>
<td>will make sure that the composition of the WG is well balanced and that the process of standardization is transparent</td>
<td></td>
</tr>
<tr>
<td>will use web-based and e-mail exchange of information and monitor the execution of assignments within the assigned timeline</td>
<td></td>
</tr>
<tr>
<td>will adhere to EBM principles, where appropriate</td>
<td></td>
</tr>
<tr>
<td>will report to the SSC</td>
<td></td>
</tr>
<tr>
<td>will be responsible for production of a first draft of the report within a stipulated time frame (generally 18 months)</td>
<td></td>
</tr>
<tr>
<td>will be responsible for submission for publication and dissemination.</td>
<td></td>
</tr>
<tr>
<td>After publication of the standard, the WG will be dissolved.</td>
<td></td>
</tr>
</tbody>
</table>

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.
Neurourology and Urodynamics /C0

TABLE III. Development of an ICS Standard

<table>
<thead>
<tr>
<th>Stages of a Standard</th>
<th>Timescale (months)</th>
<th>WG</th>
<th>SSC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposal stage</td>
<td>– 6 to 0</td>
<td>Applications for Chairmanship or membership.</td>
<td>Call for applications. Review subject, Chair, Group, criteria, timeline and starting date.</td>
</tr>
<tr>
<td>Preparatory stage</td>
<td>0 to 18</td>
<td>WG constituted. Development of draft.</td>
<td>Evaluate progress. Appoint mentor. Evaluation (at least every 6 months).</td>
</tr>
<tr>
<td>Committee stage</td>
<td>18 to 21</td>
<td>Draft submitted to SSC.</td>
<td>Review of the process and document against criteria. Approval by consensus.</td>
</tr>
<tr>
<td>Enquiry stage</td>
<td>21 to 24</td>
<td>Draft on ICS website.</td>
<td>Internal and external review. Comments by ICS members and stakeholders.</td>
</tr>
<tr>
<td>Approval stage</td>
<td>24 to 27</td>
<td>Submit final document to SSC.</td>
<td>Process review. Submission to ICS Board of Trustees.</td>
</tr>
<tr>
<td>Implementation stage</td>
<td>&gt; 36</td>
<td></td>
<td>Support implementation. Education (with ICS Education Committee). Register of comments. Identify research needs. Support health technology and economic assessment.</td>
</tr>
</tbody>
</table>

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. 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 SSC 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
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 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. 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.

REFERENCES

Dear Author,

During the copyediting of your paper, the following queries arose. Please respond to these by annotating your proofs with the necessary changes/additions.

- If you intend to annotate your proof electronically, please refer to the E-annotation guidelines.
- If you intend to annotate your proof by means of hard-copy mark-up, please refer to the proof mark-up symbols guidelines. If manually writing corrections on your proof and returning it as a scanned pdf via email, do not write too close to the edge of the paper. Please remember that illegible mark-ups may delay publication.

Whether you opt for hard-copy or electronic annotation of your proofs, we recommend that you provide additional clarification of answers to queries by entering your answers on the query sheet, in addition to the text mark-up.

<table>
<thead>
<tr>
<th>Query No.</th>
<th>Query</th>
<th>Remark</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q1</td>
<td>Please check the conflict of interest statement.</td>
<td></td>
</tr>
<tr>
<td>Q2</td>
<td>A running head short title was not supplied; please check if this one is suitable and modify to suit as per the style of up to 45 characters that can be used instead.</td>
<td></td>
</tr>
<tr>
<td>Q3</td>
<td>Please provide the other details for the affiliation and complete postal address for correspondence.</td>
<td></td>
</tr>
<tr>
<td>Q4</td>
<td>Please check the reference.</td>
<td></td>
</tr>
</tbody>
</table>
***IMMEDIATE RESPONSE REQUIRED***

Please follow these instructions to avoid delay of publication.

☐ READ PROOFS CAREFULLY
  • This will be your **only** chance to review these proofs.
  • Please note that the volume and page numbers shown on the proofs are for position only.

☐ ANSWER ALL QUERIES ON PROOFS (Queries for you to answer are attached as the last page of your proof.)
  • Mark all corrections directly on the proofs. Note that excessive author alterations may ultimately result in delay of publication and extra costs may be charged to you.

☐ CHECK FIGURES AND TABLES CAREFULLY
  • Check size, numbering, and orientation of figures.
  • All images in the PDF are downsampled (reduced to lower resolution and file size) to facilitate Internet delivery. These images will appear at higher resolution and sharpness in the printed article.
  • Review figure legends to ensure that they are complete.
  • Check all tables. Review layout, title, and footnotes.

☐ COMPLETE REPRINT ORDER FORM
  • Fill out the attached reprint order form. It is important to return the form even if you are not ordering reprints. You may, if you wish, pay for the reprints with a credit card. Reprints will be mailed only after your article appears in print. This is the most opportune time to order reprints. If you wait until after your article comes off press, the reprints will be considerably more expensive.

☐ COMPLETE DISCLOSURE STATEMENT
  • It is essential that this form be completed and returned in order to proceed with publication.

☐ ADDITIONAL COPIES
  • If you wish to purchase additional copies of the journal in which your article appears, please contact Jill Gottlieb at (201) 748-8839, fax (201) 748-6021, or E-mail at jgottlieb@wiley.com

☐ COLOR CHARGE FORM
  • Fill out the attached color charge form **even if you do not have color figures**.
  Please indicate if you want to pay for color in print or color online only at no charge.

RETURN
  ☐ PROOFS
  ☐ REPRINT ORDER FORM
  ☐ DISCLOSURE STATEMENT
  ☐ CTA (If you have not already signed one)
  ☐ COLOR CHARGE FORM

RETURN WITHIN 48 HOURS OF RECEIPT TO Sarah Whalen at swhalen@wiley.com

QUESTIONS? Sarah Whalen, Production Editor
E-mail: swhalen@wiley.com
Refer to journal acronym (NAU) and article production number
Additional reprint and journal issue purchases

Should you wish to purchase additional copies of your article, please click on the link and follow the instructions provided: https://caesar.sheridan.com/reprints/redir.php?pub=10089&acro=NAU

Corresponding authors are invited to inform their co-authors of the reprint options available.

Please note that regardless of the form in which they are acquired, reprints should not be resold, nor further disseminated in electronic form, nor deployed in part or in whole in any marketing, promotional or educational contexts without authorization from Wiley. Permissions requests should be directed to mailto: permissionsus@wiley.com

For information about ‘Pay-Per-View and Article Select’ click on the following link: http://wileyonlinelibrary.com/ppv
Neurology And Urodynamics (NU) Disclosure Statement

Neurology And Urodynamics wishes to ensure independence, objectivity, scientific rigor and a fair balance of representation, in all its activities. In order to ensure this, individuals participating in these activities are expected to disclose their financial or in-kind relationships with for-profit health industry entities that develop, manufacture, distribute or sell health care materials or services. Such relationships exclude personal or family medical care. NU recognizes that these relationships do not necessarily imply bias or decrease the value of participation in professional activities. Disclosure of these relationships is necessary for others to make an informed decision about the impact of the disclosed relationship. In addition, certain disclosures will require management, such as refusal from the review process.

Each NU author, reviewer and editor is requested to complete this form. All relationships over the previous two calendar years and the current year (including future commitments which are foreseen over the coming year) must be disclosed. Lead authors must also provide a written statement specifying what they believe to be the most relevant conflicts of interest to their paper. If in doubt, reviewers should seek guidance from the editor who has contacted them as to whether they should proceed with a review. Editors with a COI will be excluded from supervising the review process.

First Name:  
Last Name:  

**I, the undersigned do not have any existing or known future financial relationships or commercial affiliations to disclose:**

Signed:  
Dated:  

**I, the undersigned have the following existing or known future financial relationships or commercial affiliations to disclose**

Signed:  
Dated:  

Use the following list to declare your existing or known future financial relationships or commercial affiliations. Mark a cross in the appropriate box and indicate the name of the company.

1. Equity interests (or entitlement to same) of stocks, stock options, royalties, etc, including income from patents or copyrights
2. Service as a director or employment by a commercial organisation, whether or not remuneration is provided for such service
3. Sole ownership, partnership, or principal of a commercial enterprise
4. Ownership of patent(s)
5. Receipt of royalties
6. Consultant to company including positions on medical or scientific advisory boards
7. Honoraria for speaking at company sponsored meetings or events.
8. Participation in clinical trials
9. Support in the form of fellowships, travel grants, gifts, in-kind donations, etc.
10. Research grants, partial or full salary support from a commercial organisation for self or employees for whom you are managerially responsible (i.e. laboratory technical/research fellow for whom you are managerially responsible).
11. Any other type of financial or other relationship
<table>
<thead>
<tr>
<th>Company Name</th>
<th>Company Name</th>
<th>Company Name</th>
<th>Company Name</th>
<th>Company Name</th>
<th>Company Name</th>
<th>Company Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Equity interests</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Director or employee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Owner</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Owner of patent(s)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Royalties</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Consultant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Speaker Honorarium</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Trial participation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. Fellowship, travel grants</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. Research grant</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Other – please indicate</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Lead Author’s Statement on most relevant Conflict of Interest:**

<table>
<thead>
<tr>
<th>Conflict of Interest</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
COPYRIGHT TRANSFER AGREEMENT

Date: ____________ Contributor name: ________________________

Contributor address: ____________________________________________

Manuscript number (Editorial office only): __________________________

Re: Manuscript entitled __________________________________________

________________________________________________________________________

for publication in ____________________________________________________________________________

published by ________________________________________________________________________________("Wiley-Blackwell").

Dear Contributor(s):

Thank you for submitting your Contribution for publication. In order to expedite the editing and publishing process and enable Wiley-Blackwell to disseminate your Contribution to the fullest extent, we need to have this Copyright Transfer Agreement signed and returned as directed in the Journal's instructions for authors as soon as possible. If the Contribution is not accepted for publication, or if the Contribution is subsequently rejected, this Agreement shall be null and void. Publication cannot proceed without a signed copy of this Agreement.

A. COPYRIGHT

1. The Contributor assigns to Wiley-Blackwell, during the full term of copyright and any extensions or renewals, all copyright in and to the Contribution, and all rights therein, including but not limited to the right to publish, republish, transmit, sell, distribute and otherwise use the Contribution in whole or in part in electronic and print editions of the Journal and in derivative works throughout the world, in all languages and in all media of expression now known or later developed, and to license or permit others to do so.

2. Reproduction, posting, transmission or other distribution or use of the final Contribution in whole or in part in any medium by the Contributor as permitted by this Agreement requires a citation to the Journal and an appropriate credit to Wiley-Blackwell as Publisher, and/or the Society if applicable, suitable in form and content as follows: (Title of Article, Author, Journal Title and Volume/Issue, Copyright © [year], copyright owner as specified in the Journal). Links to the final article on Wiley-Blackwell's website are encouraged where appropriate.

B. RETAINED RIGHTS

Notwithstanding the above, the Contributor or, if applicable, the Contributor's Employer, retains all proprietary rights other than copyright, such as patent rights, in any process, procedure or article of manufacture described in the Contribution.

C. PERMITTED USES BY CONTRIBUTOR

1. Submitted Version. Wiley-Blackwell licenses back to the Contributor the following rights with respect to the final published version of the Contribution:

   a. After publication of the final article, the right to self-archive on the Contributor's personal website or in the Contributor's institution/employer's institutional repository or archive. This right extends to both in-transit and the Internet. The Contributor may not update the submission version or replace it with the published Contribution. The version posted must contain a legend as follows: This is the pre-peer reviewed version of the following article: FULL CITE, which has been published in final form at [Link to final article].

   b. The right to transmit, print and share copies with colleagues.

2. Accepted Version. Re-use of the accepted and peer-reviewed (but not final) version of the Contribution shall be by separate agreement with Wiley-Blackwell. Wiley-Blackwell has agreements with certain funding agencies governing reuse of this version. The details of those relationships, and other offerings allowing open web use, are set forth at the following website: http://www.wiley.com/go/funderstatement. NIH grantees should check the box at the bottom of this document.

3. Final Published Version. Wiley-Blackwell hereby licenses back to the Contributor the following rights with respect to the final published version of the Contribution:

   a. Copies for colleagues. The personal right of the Contributor only to send or transmit individual copies of the final published version in any format to colleagues upon their specific request provided no fee is charged, and further-provided that there is no systematic distribution of the Contribution, e.g. posting on a listserve, website or automated delivery.

   b. Re-use in other publications. The right to re-use the final Contribution or parts thereof for any publication authored or edited by the Contributor (excluding journal articles) where such re-used material constitutes less than half of the total material in such publication. In such case, any modifications should be accurately noted.

   c. Teaching duties. The right to include the Contribution in teaching or training duties at the Contributor's institution/place of employment including in course packs, e-reserves, presentation at professional conferences, in-house training, or distance learning. The Contribution may not be used in seminars outside of normal teaching obligations (e.g. commercial seminars). Electronic posting of the final published version in connection with teaching/ training at the Contributor's institution/place of employment is permitted subject to the implementation of reasonable access control mechanisms, such as user name and password. Posting the final published version on the open Internet is not permitted.

   d. Oral presentations. The right to make oral presentations based on the Contribution.

4. Article Abstracts, Figures, Tables, Data Sets, Artwork and Selected Text (up to 250 words).

   a. Contributors may re-use unmodified abstracts for any non-commercial purpose. For on-line uses of the abstracts, Wiley-Blackwell encourages but does not require linking back to the final published versions.

   b. Contributors may re-use figures, tables, data sets, artwork, and selected text up to 250 words from their Contributions, provided the following conditions are met:

      (i) Full and accurate credit must be given to the Contribution.

      (ii) Modifications to the figures, tables and data must be noted. Otherwise, no changes may be made.

      (iii) The reuse may not be made for direct commercial purposes, or for financial consideration to the Contributor.

      (iv) Nothing herein shall permit dual publication in violation of journal ethical practices.
D. CONTRIBUTIONS OWNED BY EMPLOYER

1. If the Contribution was written by the Contributor in the course of the Contributor's employment (as a "work-made-for-hire" in the course of employment), the Contribution is owned by the company/employer which must sign this Agreement (in addition to the Contributor's signature) in the space provided below. In such case, the company/employer hereby assigns to Wiley-Blackwell, during the full term of copyright, all copyright in and to the Contribution for the full term of copyright throughout the world as specified in paragraph A above.

2. In addition to the rights specified as retained in paragraph B above and the rights granted back to the Contributor pursuant to paragraph C above, Wiley-Blackwell hereby grants back, without charge, to such company/employer, its subsidiaries and divisions, the right to make copies of and distribute the final published Contribution internally in print format or electronically on the Company's internal network. Copies so used may not be resold or distributed externally. However, the company/employer may include information and text from the Contribution as part of an information package included with software or other products offered for sale or license or included in patent applications. Posting of the final published Contribution by the institution on a public access website may only be done with Wiley-Blackwell's written permission, and payment of any applicable fee(s). Also, upon payment of Wiley-Blackwell's reprint fee, the institution may distribute print copies of the published Contribution externally.

E. GOVERNMENT CONTRACTS

In the case of a Contribution prepared under U.S. Government contract or grant, the U.S. Government may reproduce, without charge, all or portions of any applicable fee(s). Also, upon payment of Wiley-Blackwell's reprint fee, the institution may distribute print copies of the published Contribution externally.

F. COPYRIGHT NOTICE

The Contributor and the company/employer agree that any and all copies of the final published version of the Contribution or any part thereof distributed or posted by them in print or electronic format as permitted herein will include the notice of copyright as stipulated in the Journal and a full citation to the Journal as published by Wiley-Blackwell.

G. CONTRIBUTOR'S REPRESENTATIONS

The Contributor represents that the Contribution is the Contributor's original work, all individuals identified as Contributors actually contributed to the Contribution, and all individuals who contributed are included. If the Contribution was prepared jointly, the Contributor agrees to inform the co-Contributors of the terms of this Agreement and to obtain their signature to this Agreement or their written permission to sign on their behalf. The Contribution is submitted only to this Journal and has not been published before. (If excerpts from copyrighted works owned by third parties are included, the Contributor obtains written permission from the copyright owners for all uses as set forth in Wiley-Blackwell's permissions form or in the Journal's Instructions for Contributors, and show credit to the sources in the Contribution.) The Contributor also warrants that the Contribution contains no libelous or unlawful statements, does not infringe upon the rights (including without limitation the copyright, patent or trademark rights) or the privacy of others, or contain material or instructions that might cause harm or injury.

CHECK ONE BOX:

[ ] Contributor-owned work

ATTACH ADDITIONAL SIGNATURE PAGES AS NECESSARY

Contributor's signature

Date

Type or print name and title

[ ] Company/Institution-owned work

(made-for-hire in the course of employment)

Company or Institution (Employer-for-Hire)

Date

Authorized signature of Employer

Date

[ ] U.S. Government work

Note to U.S. Government Employees

A contribution prepared by a U.S. federal government employee as part of the employee's official duties, or which is an official U.S. Government publication, is called a "U.S. Government work," and is in the public domain in the United States. In such case, the employee may cross out Paragraph A.1 but must sign (in the Contributor's signature line) and return this Agreement. If the Contribution was not prepared as part of the employee's duties or is not an official U.S. Government publication, it is not a U.S. Government work.

[ ] U.K. Government work (Crown Copyright)

Note to U.K. Government Employees

The rights in a Contribution prepared by an employee of a U.K. government department, agency or other Crown body as part of his/her official duties, or which is an official government publication, belong to the Crown. U.K. government authors should submit a signed declaration form together with this Agreement. The form can be obtained via http://www.opsi.gov.uk/advice/crown-copyright/copyright-guidance/publication-of-articles-written-by-ministers-and-civil-servants.htm

[ ] Other Government work

Note to Non-U.S., Non-U.K. Government Employees

If your status as a government employee legally prevents you from signing this Agreement, please contact the editorial office.

[ ] NIH Grantees

Note to NIH Grantees

Pursuant to NIH mandate, Wiley-Blackwell will post the accepted version of Contributions authored by NIH grant-holders to PubMed Central upon acceptance. This accepted version will be made publicly available 12 months after publication. For further information, see www.wiley.com/go/nihmandate.
Acrobat annotation tools can be very useful for indicating changes to the PDF proof of your article. By using Acrobat annotation tools, a full digital pathway can be maintained for your page proofs.

The NOTES annotation tool can be used with either Adobe Acrobat 4.0, 5.0 or 6.0. Other annotation tools are also available in Acrobat 4.0, but this instruction sheet will concentrate on how to use the NOTES tool. Acrobat Reader, the free Internet download software from Adobe, DOES NOT contain the NOTES tool. In order to softproof using the NOTES tool you must have the full software suite Adobe Acrobat 4.0, 5.0 or 6.0 installed on your computer.

**Steps for Softproofing using Adobe Acrobat NOTES tool:**

1. Open the PDF page proof of your article using either Adobe Acrobat 4.0, 5.0 or 6.0. Proof your article on-screen or print a copy for markup of changes.

2. Go to File/Preferences/Annotations (in Acrobat 4.0) or Document/Add a Comment (in Acrobat 6.0) and enter your name into the “default user” or “author” field. Also, set the font size at 9 or 10 point.

3. When you have decided on the corrections to your article, select the NOTES tool from the Acrobat toolbox and click in the margin next to the text to be changed.

4. Enter your corrections into the NOTES text box window. Be sure to clearly indicate where the correction is to be placed and what text it will effect. If necessary to avoid confusion, you can use your TEXT SELECTION tool to copy the text to be corrected and paste it into the NOTES text box window. At this point, you can type the corrections directly into the NOTES text box window. **DO NOT correct the text by typing directly on the PDF page.**

5. Go through your entire article using the NOTES tool as described in Step 4.

6. When you have completed the corrections to your article, go to File/Export/Annotations (in Acrobat 4.0) or Document/Add a Comment (in Acrobat 6.0).

7. **When closing your article PDF be sure NOT to save changes to original file.**

8. To make changes to a NOTES file you have exported, simply re-open the original PDF proof file, go to File/Import/Notes and import the NOTES file you saved. Make changes and re-export NOTES file keeping the same file name.

9. When complete, attach your NOTES file to a reply e-mail message. Be sure to include your name, the date, and the title of the journal your article will be printed in.
Color figures were included with the final manuscript files that we received for your article. Because of the high cost of color printing, we can only print figures in color if authors cover the expense.

Please indicate if you would like your figures to be printed in color or black and white. Color images will be reproduced online in Wiley InterScience at no charge, whether or not you opt for color printing.

**Failure to return this form will result in the publication of your figures in black and white.**

<table>
<thead>
<tr>
<th>JOURNAL</th>
<th>Neurourology &amp; Urodynamics</th>
<th>VOLUME</th>
<th>ISSUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>TITLE OF MANUSCRIPT</td>
<td>___________________________</td>
<td>_______</td>
<td>_______</td>
</tr>
<tr>
<td>MS. NO.</td>
<td>___________________________</td>
<td>_______</td>
<td>_______</td>
</tr>
<tr>
<td>NO. OF COLOR PAGES</td>
<td>___________________________</td>
<td>_______</td>
<td>_______</td>
</tr>
<tr>
<td>AUTHOR(S)</td>
<td>___________________________</td>
<td>_______</td>
<td>_______</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. Color Pages</th>
<th>Color Charges</th>
<th>No. Color Pages</th>
<th>Color Charges</th>
<th>No. Color Pages</th>
<th>Color Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>950</td>
<td>5</td>
<td>3400</td>
<td>9</td>
<td>5850</td>
</tr>
<tr>
<td>2</td>
<td>1450</td>
<td>6</td>
<td>3900</td>
<td>10</td>
<td>6350</td>
</tr>
<tr>
<td>3</td>
<td>1950</td>
<td>7</td>
<td>4400</td>
<td>11</td>
<td>6850</td>
</tr>
<tr>
<td>4</td>
<td>2450</td>
<td>8</td>
<td>4900</td>
<td>12</td>
<td>7350</td>
</tr>
</tbody>
</table>

***Please contact the Production Editor (swhalen@wiley.com) for a quote if you have more than 12 pages of color***

☐ Please print my figures in black and white

☐ Please print my figures in color

$ ________________________________

**International orders must be paid in currency and drawn on a U.S. bank**
Please check one: ☐ Check enclosed ☐ Bill me ☐ Credit Card
☐ American Express ☐ Visa ☐ MasterCard
If credit card order, charge to: ☐ American Express ☐ Visa ☐ MasterCard

Credit Card No ____________________ Signature ____________________ Exp. Date __________

BILL TO:
Name ________________________________ Purchase Order No. ________________________________
Institution ____________________________ Phone ________________________________
Address ______________________________ Fax _________________________________
____________________________________ E-mail ________________________________