SUCCESSFUL IMPLEMENTATION OF A REPORTING GUIDELINES POLICY:

STEPS TOWARDS LAUNCHING A PROCESS FOR IMPROVING REPORTING STANDARDS
8 STEPS TOWARDS LAUNCHING A PROCESS FOR IMPROVING REPORTING STANDARDS

Review 8 essential steps to ensure successful launch

- Each step is universal
  - Submission system agnostic (ScholarOne, Editorial Manager, EJP)
  - Journals can be society owned, publisher owned or independent entities
  - Commission only or willing to receive unsolicited submissions
  - Sensitive to different models of peer review

- The implementation plan considers:
  - Practical matters behind implementation
  - Developing a theoretical policy rationale to suit your journal
  - Navigating politics
  - Identifying pain points
  - Promoting the policy
8 STEPS TOWARDS LAUNCHING A PROCESS FOR IMPROVING REPORTING STANDARDS

- **Step 1** – Identify the needs of your journal
- **Step 2** – Select “champions” to support implementation of reporting checklists
- **Step 3** – Identify appropriate checklists
- **Step 4** – Determine enforcement level (mandatory compliance or simply recommend guidelines are consulted)
- **Step 5** – Phased or full launch
- **Step 6** – Write up proposal on implementing improved reporting standards
- **Step 7** – Preparations for launch
- **Step 8** – Launch activities
Despite many highly-cited papers on poor reporting standards, awareness of the issues and the implications for poor standards remains low:

“...the quality of reporting remains well below an acceptable level.”

STEP 1 – IDENTIFY THE NEEDS OF YOUR JOURNAL

Journals will be confronted by:

- **Apathy**
  - Editors
  - Authors

- **Entrenched Practices**
  - Accepted, but flawed, practices perpetuated
  - Subject thought leaders believing their research results trump methods/reporting standards

- **Misinterpretation**
  - Unable to comprehend reporting guidelines
  - Weak skills/no training to facilitate incorporating reporting criteria

- **Concern**
  - Asking too much?
  - Overly complex submission and review process?
STEP 1 - IDENTIFY THE NEEDS OF YOUR JOURNAL

- Assess scale/nature of reporting problem
  - Within your journal
  - Within your field or sub-specialty
- Analyze any steps towards improved reporting standards other journals in your field have adopted
- Consult authors to determine potential reactions
  - Broad range of authors based on experience/location
  - Determine pre-existing comprehension of reporting issues
  - Establish how authors could/should embrace reporting standards during manuscript composition
- Outline the benefits of improving reporting standards
- Define measurable policy objectives
Assess scale/nature of reporting problem:

- How comprehensively have recently published articles conformed to standards set forth in CONSORT, STROBE, and others
  - Guideline adherence as a proportion of all manuscripts
  - What reporting criteria are commonly missed

- Have any journals within your field already taken steps to enforce standards? Or, are the concepts alien to the field?

- Are any pre-existing standards policies comprehensive or narrow?
  - Just CONSORT for RCTs
  - Multiple guidelines adopted e.g. PRISMA for systematic reviews
Outline benefits for improving reporting standards:

- **Journal benefits**
  - Raise quality, consequently boosting reader experience
    - Enables heightened scrutiny ahead of acceptance
    - Burnish papers by ensuring reporting standards are excellent
  - Enhance the reproducibility of results
  - Improved transparency

- **Author benefits**
  - Consistently good advice that improves their paper
  - Perhaps, enhanced prospects of a paper being read and cited?
Set measurable objectives ahead of implementation:

- Plan for a pre-post analysis of criteria adherence (mandatory) or voluntary adoption (recommended) following policy launch
- Adherence to criteria upon initial submission for peer review
- Establish awareness of the issues driving a reporting policy
- Subsequent adoption of reporting guidelines by other journals in the field
- Track the fate of papers that fail to adhere to reporting guideline policies
Step 1: Identify Needs

Step 2: Select Supporters

Step 3: Identify Guidelines

Step 4: Set enforcement level

Step 5: Phased or full launch?

Step 6: Phased or full launch?

Step 7: Launch Preparation

Step 8: Launch
STEP 2 – SELECT “CHAMPIONS” TO SUPPORT IMPLEMENTATION OF REPORTING CHECKLISTS

- Unless editorial fiat can ensure quick adoption, the implementation process will be slow
  - Several potential layers of politics/approval

- Identify implementation leaders
  - Editor or members of the editorial board
  - Editorial office staff member

- Determine who will administer implementation
  - Who will check for compliance?
  - Does the editorial office have the skills to determine submission system capabilities? Can they make configuration changes?
  - Can your publisher play an active role in adapting workflows/systems to support the policy (if needed)
Champions (or facilitators) are needed to vocally, intellectually and even politically support a reporting policy and its adoption process.

- Shore up support
- Convince colleagues of the need for improved reporting standards
- Support the editorial office if criticisms emerge

Champions can also help shape policy rationale.
**Editorial Champions**

- Editors-in-Chief should consult their editorial board for input on nature and scope of a reporting policy.
- Editorial boards can discuss methods of monitoring adherence:
  - Incorporating a submitted reporting guideline checklist into manuscript evaluation.
  - Devising a sustainable, uniform, checking mechanism to ensure a manuscript has conformed to a reporting guideline.
- Editorial board support for a policy enhances prospects of both formal adoption and author compliance.
- Editorial board members could support educational outreach efforts to authors and reviewers.

**STEP 2 – SELECT “CHAMPIONS” TO SUPPORT IMPLEMENTATION OF REPORTING CHECKLISTS**
Editorial Staff as Facilitators

- Editorial staff must be engaged to devise new, sustainable, workflows
- Devise adaptations to the submission process

- Do editorial staff have the information they need to field queries?
- If a mandatory policy is enforced (requiring follow up with errant authors), can they handle the extra responsibilities?

STEP 2 – SELECT “CHAMPIONS” TO SUPPORT IMPLEMENTATION OF REPORTING CHECKLISTS
Thought leaders as champions

- Help overcome potentially negative perceptions
  - Prominent individuals can lead the way by evidently displaying adherence to reporting standards in their own work
- External advocacy: educating and informing authors and reviewers
- Internal advocacy: convince skeptics, particularly vocal critics or power-brokers on Publication Committees or society Board of Directors

- Thought-leader champions needed during policy development and implementation phase. Adds validity and support
Step 1 Identify Needs
Step 2 Select Supporters
Step 3 Identify Guidelines
Step 4 Set enforcement level
Step 5 Phased or full launch?
Step 6 Phased or full launch?
Step 7 Launch Preparation
Step 8 Launch
63% of CONSORT endorsers also endorsed other guidelines (Headache internal study, 2010)

- Most common adoptions alongside CONSORT:
  - STARD (diagnostic accuracy)
  - STROBE (observational studies in epidemiology)
  - MOOSE (for meta-analyses of observation studies in epidemiology)

**STEP 3 – IDENTIFY APPROPRIATE CHECKLIST**

- Consider extent of reporting policy
- Adopt multiple guidelines
- Consider just CONSORT for RCTs
STEP 3 – IDENTIFY APPROPRIATE GUIDELINES

- Identify article types published/received over interval of time
- Go to EQUATOR Network to review potential guidelines
- Decide how many checklists to adopt?
- Determine if new checklist is required
- Consult guides on preparing new reporting checklists
<table>
<thead>
<tr>
<th>Study Type</th>
<th>Reporting Guideline</th>
<th>% of submissions</th>
</tr>
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<tbody>
<tr>
<td>Randomized Controlled Trial</td>
<td>CONSORT</td>
<td>16%</td>
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<tr>
<td>Behavioral and Non-pharmacological Interventions</td>
<td>Behavioral/Non-pharmacological Clinical Trials Checklist</td>
<td>5%</td>
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<tr>
<td>Observational Epidemiological Studies</td>
<td>STROBE</td>
<td>53%</td>
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<td>Diagnostic Accuracy Studies</td>
<td>STARD</td>
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<td>Systematic Reviews</td>
<td>PRISMA</td>
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<tr>
<td>Meta-analyses of Controlled Trials</td>
<td>PRISMA</td>
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<tr>
<td>Meta-analyses of Observational Studies</td>
<td>MOOSE</td>
<td>1%</td>
</tr>
<tr>
<td>Quality Improvement Reports</td>
<td>SQUIRE</td>
<td>1%</td>
</tr>
<tr>
<td>Qualitative Research</td>
<td>COREQ</td>
<td>12%</td>
</tr>
</tbody>
</table>
Step 1: Identify Needs
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Step 7: Launch Preparation
Step 8: Launch
STEP 4 – LEVEL OF ENFORCEMENT

- **Mandatory Use** or **Recommend Consultation** of Guidelines
- How will compliance be monitored?
- Must authors complete a reporting guideline checklist to demonstrate compliance?
- Will editorial office workflows be impacted?
- Will submission systems need to be configured?
- Phased introduction with **Recommended Consultation** moving to **Mandatory Use**?
- Do your authors have a track record of complying with your directions?
- What are the reporting cultures at other journals within the field?
Mandatory completion of checklists

Do authors complete an accompanying reporting checklist at submission?

Authors upload checklist with manuscript via submission system

Authors supply completed checklist after submission (e.g. fax copy, scan)
STEP 4 - LEVEL OF ENFORCEMENT

How are checklists provided to authors?

As part of the submission process

As part of the instructions for authors

- Is that too late?
- Will authors go back and update?
- Will this step irritate authors?
- Might regular authors get used to the process quickly?
- What proportion of authors are repeat submitters?

- Link to sites where reporting checklists can be downloaded
- Checklists embedded within online instructions for authors
- Checklists embedded in submission site
Mandatory completion of checklists

“Many submissions to journals are now made electronically and we feel that RCT compliance with CONSORT should be hardwired into this process”


- Reconfigurations to the online submission systems will likely be needed
- Next 3 slides show how forms could be collected via:
  - ScholarOne
  - Editorial Manager
  - EJournalPress
EM
**STEP 4 - LEVEL OF ENFORCEMENT**

**Mandatory completion of checklists**

- Refuse to review *initial* submission until checklist supplied or manuscript is made compliant
- Ask for checklist/evidence of compliance with *revised* submission
- Do nothing
Mandatory completion of checklists

Who monitors non-compliance?

- Editorial Office Staff
- Editor-in-Chief
- Associate Editors/Editorial Board
- Reviewers
- Methodology Editor (if available)

How much effort will be required to consistently follow-up with non-compliant authors?
Mandatory completion of checklists

Are completed checklists to be made available to reviewers?  
or  
Are checklists to only be reviewed internally?
**STEP 4 - LEVEL OF ENFORCEMENT**

Mandatory completion

How are errors, omissions and general non-compliance communicated back to authors?

Managing Editor’s Comments to Author in *initial* submission decision letter

Instructions on downloading and completing checklist

Expectation that checklist is included with revised submission

Comments contain technical details. Must be addressed in revised submission
STEP 4 - LEVEL OF ENFORCEMENT

Strong Recommendation Authors Consult Guidelines

Simply *encourage* authors to include a checklist with submission

and

*Recommend* authors become familiar with reporting guideline criteria and ensure their manuscript adheres to the criteria
Provide links to checklists via Instructions for Authors. Include statement that consulting guidelines is encouraged:

“It is strongly recommended, where appropriate, that you ensure your manuscript conforms to a reporting guideline that best fits your type of manuscript. For example, a CONSORT statement should be completed and uploaded with your manuscript for a Randomized Controlled Trial. The International Society for Sexual Medicine (ISSM) Publication Reporting Guidelines detail the appropriate checklist to use per study type.”

Example from The Journal of Sexual Medicine Author Instructions
**STEP 4 - LEVEL OF ENFORCEMENT**

**Strong Recommendation Authors Consult Guidelines**

- Will your journal assess for guideline compliance if no checklist is required?
- Are your authors self-motivated enough to willingly ensure their manuscript meets reporting standards?
- Who will assess for compliance?
- Will the compliance assessor have to work from the guideline checklists?
Step 1 Identify Needs
Step 2 Select Supporters
Step 3 Identify Guidelines
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Step 5 Phased or full launch?
Step 6 Phased or full launch?
Step 7 Launch Preparation
Step 8 Launch
Phased launches may be politically expedient

Success of phased launch is somewhat predicated on assumption that many authors will return to submit new work
STEP 5 – PHASED OR COMPLETE LAUNCH OF REPORTING POLICY

Complete Launch

- A declarative policy containing multiple checklists and mandatory enforcement states firmly to authors that minimum standards must be met for ALL manuscript types.

- Short, sharp shock: quickly ensures compliance?

- Anecdotal reports from editorial offices:
  - Authors frequently fail to read Instructions for Authors
  - For smaller or lower ranked titles authors are often shopping papers around journals, rarely making changes to a paper – hard to get authors to comply to formatting and policy requests
  - Consider building checklists into the submission process

- Anecdotal evidence: “soft launches” have led to low take-up of reporting policy adherence
Step 1: Identify Needs
Step 2: Select Supporters
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Step 7: Launch Preparation
Step 8: Launch
STEP 6 – WRITE UP PROPOSAL FOR IMPLEMENTING POLICY

- Draft policy outline to include:
  - Goals
  - Expectations
  - Degrees of enforcement
  - Approach to monitoring compliance
  - Implementation plan

- Get approval from publication committee/board of directors/publisher

- Approval offers:
  - Support if the need for standards is challenged by influential figures within the field
  - Powerful backing if the policy is undermined by authors through non-compliance
Step 1: Identify Needs
Step 2: Select Supporters
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Step 4: Set enforcement level

Step 5: Phased or full launch?
Step 6: Phased or full launch?

Step 7: Launch Preparation
Step 8: Launch
STEP 7 – PREPARATIONS FOR LAUNCH

- Prepare editorial to outline policy rationale to authors, reviewers and readers
  - Outline reasons for launching a reporting standards policy
  - Present the evidence from previously published studies that shows benefits of consulting checklists
  - Explain what will be required of authors

- Schedule publication/posting of new Instructions for Authors upon launch of policy

- If applicable, provide guide for reviewers on the utilization of checklists supplied by authors

- Ensure system configurations are in place with policy launch
  - Develop template letters to respond to cases of non-compliance
STEP 7 – PREPARATIONS FOR LAUNCH

- Ensure editorial team (editors, staff) are properly trained to assess checklists/determine manuscripts meet reporting standards
  - Stress the importance of application of standards across those with decision making/recommendation making powers
  - Discuss how to support authors struggling to comprehend reporting standards expectations
  - If previously researched, highlight known areas where reporting standards fail
- Consider development of online training courses and presentations to be delivered at scientific meetings
- For policies featuring multiple checklists, consider instructional table to clearly delineate reporting expectations
- Develop multi-language instructions for authors
## Step 7 – Preparations for Launch

<table>
<thead>
<tr>
<th>Study Type</th>
<th>Study Type Category</th>
<th>Checklist of reporting standards</th>
<th>Checklist Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized controlled pharmacotherapy trials</td>
<td>RTC (Pharmacotherapy)</td>
<td>CONSORT – Consolidated Standards of Reporting Trials</td>
<td>CONSORT checklist</td>
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<tr>
<td>Case Reports</td>
<td>Case Reports</td>
<td>Headache Case Report Checklist</td>
<td>Headache Case Report Checklist</td>
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<tr>
<td>Other pharmacotherapy and herbal medicinal trials (noninferiority trials,</td>
<td>RCT (Other)</td>
<td>CONSORT extensions (tailored versions of the main CONSORT Statement produced by the CONSORT Group)</td>
<td>CONSORT checklist</td>
</tr>
<tr>
<td>pragmatic trials, cluster trials, reporting of harms)</td>
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<td></td>
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<tr>
<td>Trials examining behavioral and nonpharmacological interventions</td>
<td>Behavioral and Nonpharmacological Interventions</td>
<td>Behavioral/Nonpharmacological Clinical Trials Checklist for Headache (an unofficial extension of the CONSORT Statement and extension adapted from Guidelines for Trials of Behavioral Treatments for Recurrent Headache) (6)</td>
<td>Behavioral/Nonpharmacological Clinical Trials Checklist for Headache</td>
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<td>Observational epidemiology studies</td>
<td>Observational Epidemiological Studies</td>
<td>STROBE – Strengthening the reporting of observational studies in epidemiology</td>
<td>STROBE Checklist</td>
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<td>Diagnostic Accuracy Studies</td>
<td>Diagnostic Accuracy Studies</td>
<td>STARD – Standards for reporting diagnostic accuracy</td>
<td>STARD Checklist</td>
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<td>Step 7 - Preparations for Launch</td>
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| | (This is a CONSORT extension of CONSORT)
| **Research with non-pharmacological interventions** | **Behavioral/Non-pharmacological Intervention** | **Non-drug Clinical Trials Checklist** |
| | | **A Headache Journal's Behavior/Non-drug Clinical Trials Checklist** |
| **Observational epidemiologic studies** | **Observational Epidemiologic Studies** | **STROBE: Strengthening the Reporting of Observational Studies in Epidemiology Checklist** |
| | | **STROBE: Report on the conduct of observational studies** |
| **Diagnostic accuracy studies** | **Diagnostic Accuracy Studies** | **STARD: Standards for Reporting of Diagnostic Accuracy Studies Checklist** |
| | | **STARD: Report on the conduct of diagnostic accuracy studies** |
| **Systematic reviews** | **Systematic Reviews** | **PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses Checklist** |
| | | **PRISMA: Report on the conduct of systematic reviews and meta-analyses** |
| **Comparative trials** | **Comparative Trials** | **PRISMA: Promoting the Conduct of Systematic Reviews and Meta-Analyses Checklist** |
| | | **PRISMA: Report on the conduct of systematic reviews and meta-analyses** |
Step 1: Identify Needs
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Step 8: Launch
STEP 8 - LAUNCH

- Publish editorial and new instructions
- Consider email marketing/publicity campaign to previous authors – stress benefits
- After suitable time interval, publish a follow up editorial documenting success of policy, continued need for observation
  - Loder EW, Penzien DB. *Improving the Quality of Research Reporting: Headache Steps Up to the Plate* (Headache, 2009)
  - Roberts JL. Reporting Policies and Headache. (Headache 2010)
- Additional publicity mechanisms:
  - Member newsletters
  - Publish quotes from thought-leaders in support of policy
  - Social media
CONCLUSIONS

- Research your journal’s need and the potential author reaction to the imposition of a policy
- Ensure staff/editors can handle additional responsibilities
- Determine level of enforcement
- Decide upon phased or complete launch
- Devise coherent policy
- Secure support for policy
- Promote policy through published articles, instruction/educational courses and marketing

- Always stress the rewards of extra effort
- Be patient and supportive with authors unfamiliar with reporting guidelines