

**SUCCESSFUL IMPLEMENTATION
OF A REPORTING GUIDELINES
POLICY:**

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

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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

STEP 1 – IDENTIFY THE NEEDS OF YOUR JOURNAL

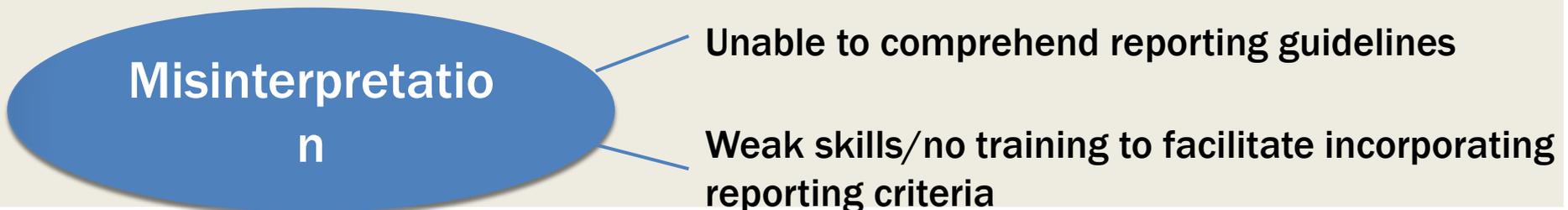
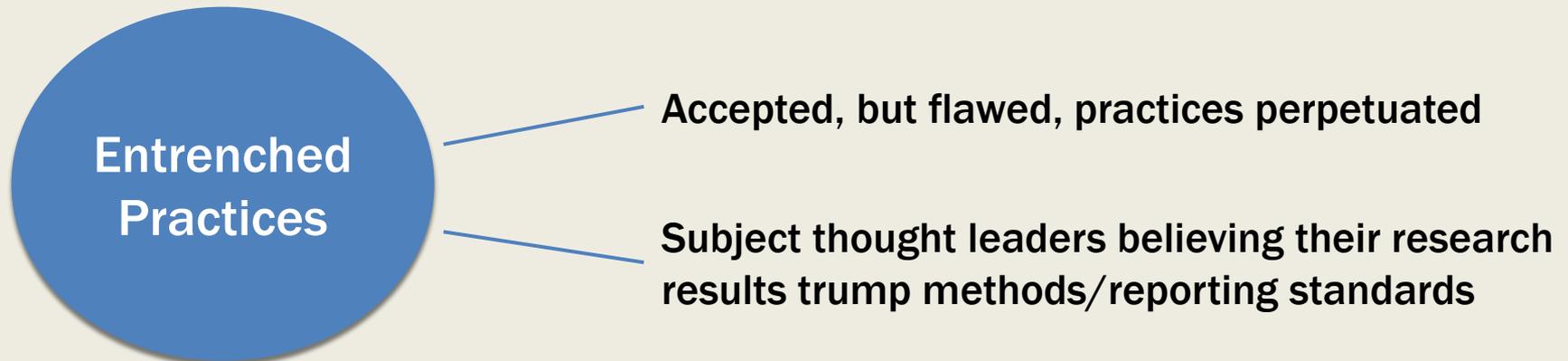
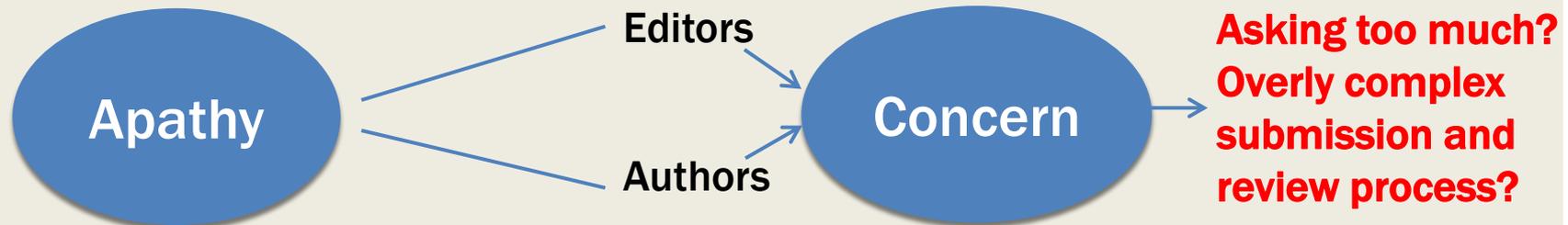
Despite many highly-cited papers on poor reporting standards, awareness of the issues and the implications for poor standards remains low

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

Hopewell S, Dutton S, Yu LM, Chan AW, Altman DG. The quality of reports of randomised trials in 2000 and 2006: comparative study of articles indexed in PubMed. [BMJ](#). 2010 Mar 23;340:c723

STEP 1 – IDENTIFY THE NEEDS OF YOUR JOURNAL

Journals will be confronted by:



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**

STEP 1 – IDENTIFY THE NEEDS OF YOUR JOURNAL

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

STEP 1 – IDENTIFY THE NEEDS OF YOUR JOURNAL

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?

STEP 1 – IDENTIFY THE NEEDS OF YOUR JOURNAL

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
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Step 2
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Step 3
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full launch?

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Preparation

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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)

STEP 2 – SELECT “CHAMPIONS” TO SUPPORT IMPLEMENTATION OF REPORTING CHECKLISTS

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

STEP 2 – SELECT “CHAMPIONS” TO SUPPORT IMPLEMENTATION OF REPORTING CHECKLISTS

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

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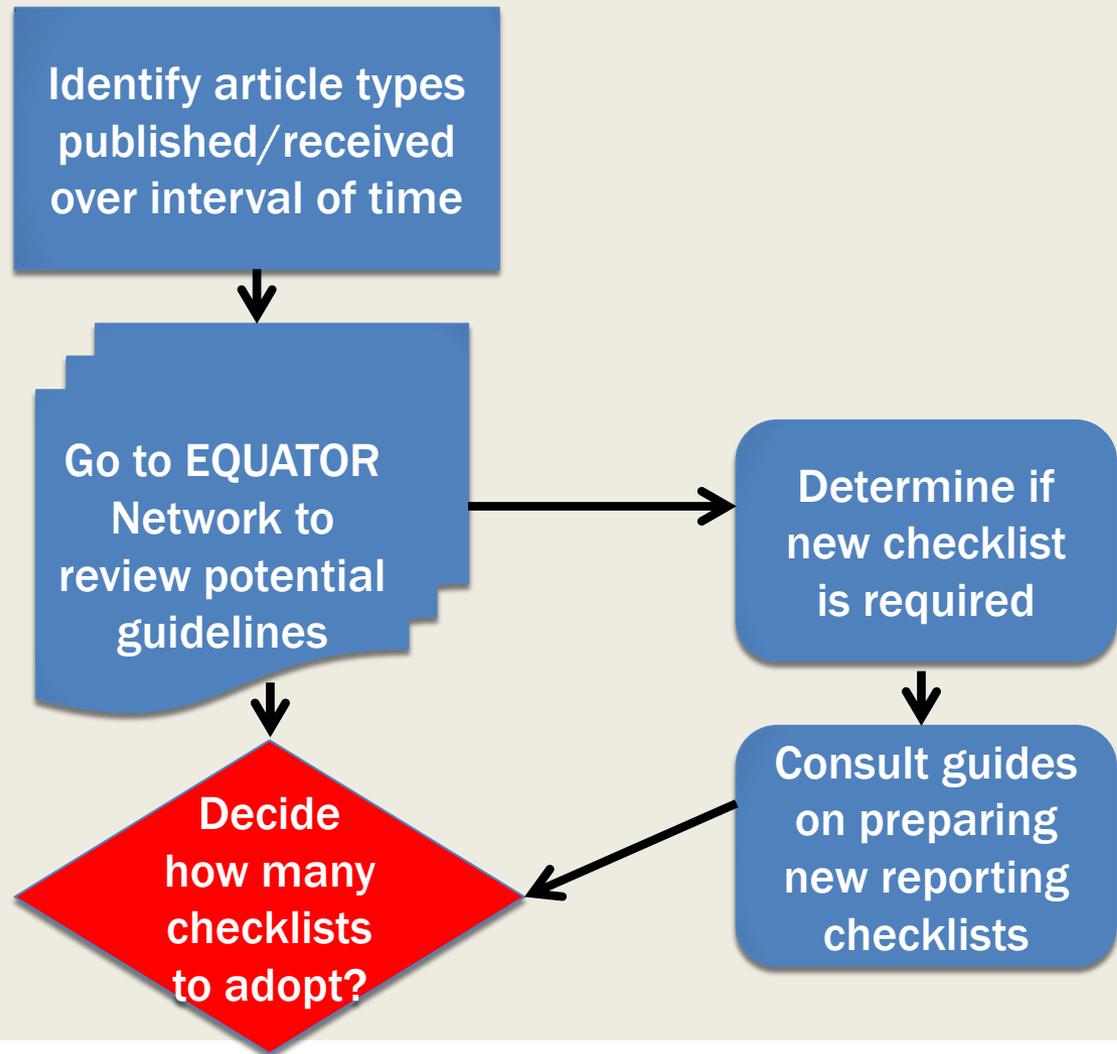
STEP 3 – IDENTIFY APPROPRIATE CHECKLIST

Consider extent of reporting policy

- Adopt multiple guidelines
- Consider just CONSORT for RCTs

- 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 GUIDELINES



STEP 3 – IDENTIFY APPROPRIATE GUIDELINES – GUIDELINES ENDORSED BY HEADACHE

Study Type	Reporting Guideline	% of submissions
Randomized Controlled Trial	CONSORT	16%
Behavioral and Non-pharmacological Interventions	Behavioral/Non-pharmacological Clinical Trials Checklist	5%
Observational Epidemiological Studies	STROBE	53%
Diagnostic Accuracy Studies	STARD	5%
Systematic Reviews	PRISMA	5%
Meta-analyses of Controlled Trials	PRISMA	2%
Meta-analyses of Observational Studies	MOOSE	1%
Quality Improvement Reports	SQUIRE	1%
Qualitative Research	COREQ	12%

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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?

STEP 4 - LEVEL OF ENFORCEMENT

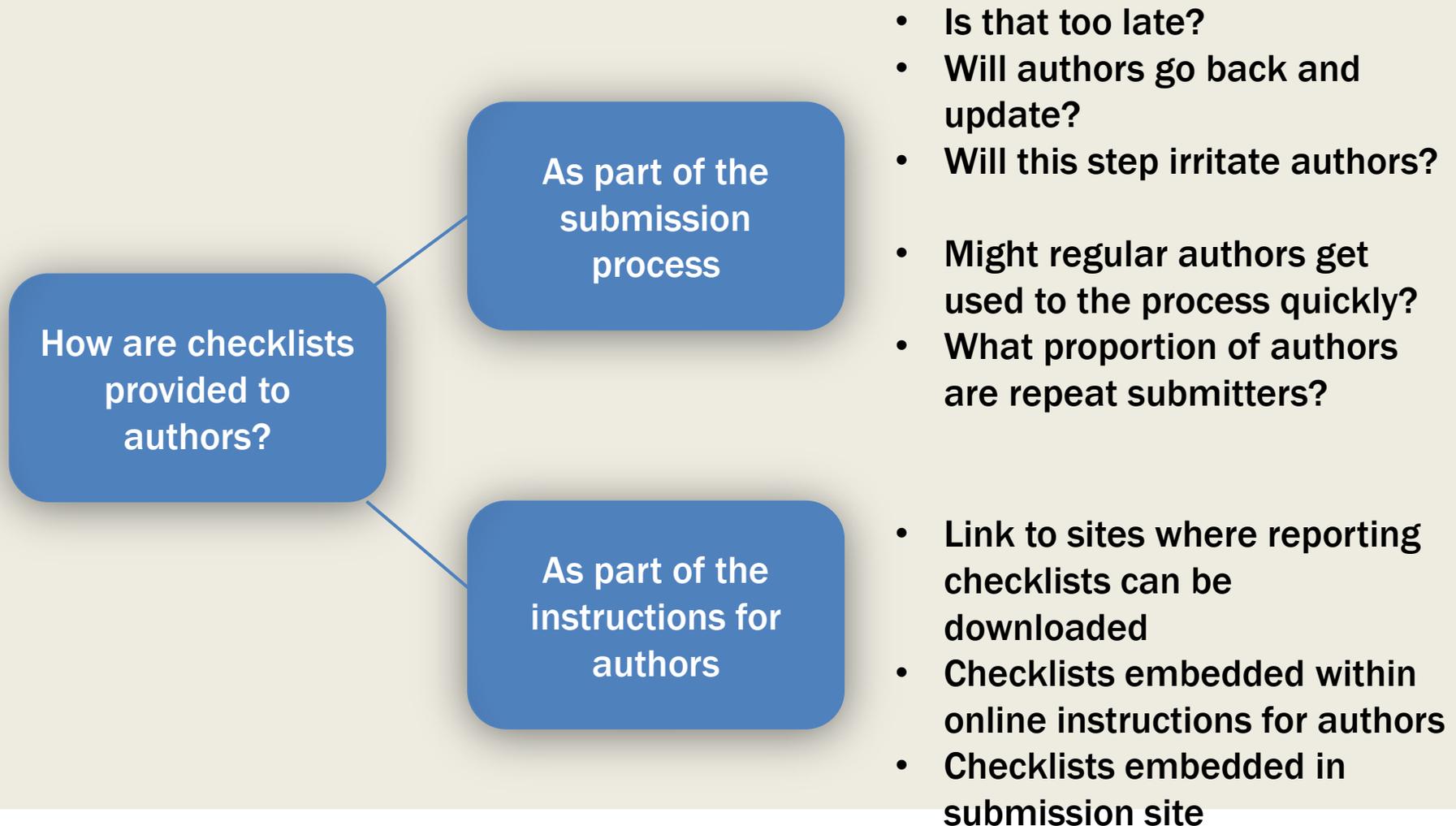
Mandatory completion of checklists

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



STEP 4 - LEVEL OF ENFORCEMENT

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”

Fowler, A. J. and Agha, R. A. (2013), Poor reporting of randomized controlled trials in solid organ transplantation is indicative of a wider problem in surgery. *Transplant International*.

- Reconfigurations to the online submission systems will likely be needed
- Next 3 slides show how forms could be collected via:
 - ScholarOne
 - Editorial Manager
 - EJournalPress

S1

EM

EJP

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/evid
ence of
compliance
with *revised*
submission

Do
nothing

STEP 4 - LEVEL OF ENFORCEMENT

Mandatory completion of checklists



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

STEP 4 - LEVEL OF ENFORCEMENT

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

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

STEP 4 - LEVEL OF ENFORCEMENT

Strong Recommendation Authors Consult Guidelines

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?

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STEP 5 – PHASED OR COMPLETE LAUNCH OF REPORTING POLICY

Phased Launch

Initial launch with one guideline (either recommended consultation or mandatorily enforced). Other guidelines added later if needed

Initial launch involves recommendation to consult guidelines



Subsequent move to mandatory enforcement

- 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

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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

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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

Study Type	Study Type Category	Checklist of reporting standards	Checklist Name
Randomized controlled pharmacotherapy trials	RTC (Pharmacotherapy)	CONSORT – Consolidated Standards of Reporting Trials	CONSORT checklist
Case Reports	Case Reports	Headache Case Report Checklist	Headache Case Report Checklist
Other pharmacotherapy and herbal medicinal trials (noninferiority trials, pragmatic trials, cluster trials, reporting of harms)	RCT (Other)	CONSORT extensions (tailored versions of the main CONSORT Statement produced by the CONSORT Group)	CONSORT checklist
Trials examining behavioral and nonpharmacological interventions	Behavioral and Nonpharmacological Interventions	Behavioral/Nonpharmacological Clinical Trials Checklist for <i>Headache</i> (an unofficial extension of the CONSORT Statement and extension adapted from <i>Guidelines for Trials of Behavioral Treatments for Recurrent Headache</i>) (6)	Behavioral/Nonpharmacological Clinical Trials Checklist for Headache
Observational epidemiology studies	Observational Epidemiological Studies	STROBE – Strengthening the reporting of observational studies in epidemiology	STROBE Checklist
Diagnostic Accuracy Studies	Diagnostic Accuracy Studies	STARD – Standards for reporting diagnostic accuracy	STARD Checklist

STEP 7 – PREPARATIONS FOR LAUNCH

与中草药试验 (非劣效性试验、实用性试验、群体试验、伤害报告)		(此为由CONSORT组织制订之主要CONSORT声明延伸的版本)	
研究行为与非药物干预的试验	行为与非药物干预	头痛杂志的行为/非药物临床试验清单 (一个由CONSORT声明延伸的非正式版本以及由复发型头痛的行为治疗试验准则延伸的版本)	头痛杂志的行为/非药物临床试验清单
观察性流行病学研究	观察性流行病学研究	STROBE- 加强观察性流行病学研究的报告	STROBE清单
诊断准确性研究	诊断准确性研究	STARD-报告诊断准确性的标准	STARD清单
系统性回顾	系统性回顾	PRISMA (以往称作QUOROM)- 促进随机对照试验的综合分析报告品质)	QUOROM清单
对照试验的综合分析	对照试验的综合分析	PRISMA(以往称作QUOROM)- 促进随机对照试验的综合分析报告品	QUOROM清单

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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