ICS 2014 Rio de Janeiro

W1: How to publish and review – tips and tricks from the editors

Workshop Chair: Paul Riss, Austria

20 October 2014 09:00 - 12:00

Start	End	Topic	Speakers
09:00	09:10	Introduction	• Paul Riss
09:10	09:25	Putting together a manuscript	• Robert Freeman
09:25	09:40	Reporting guidelines	• Paul Riss
09:40	09:55	Ethics – is this really important?	• Maria Augusta Bortolini
09:55	10:15	Group session: Application of PRISMA reporting guidelines to a review	None
10:15	10:30	Questions	All
10:30	11:00	Break	None
11:00	11:05	The journey of a manuscript	• Maria Augusta Bortolini
11:05	11:10	How does peer review work?	• Paul Riss
11:10	11:20	The challenge of reviewing a paper	• Robert Freeman
11:20	11:25	Becoming the editor's favorite reviewer	• Paul Riss
11:25	11:45	Group session: Grading reviews	None
11:45	11:55	Questions	All
11:55	12:00	Closing	• Paul Riss

Aims of course/workshop

Delegates will learn first-hand from editors of the International Urogynecology Journal how to structure a manuscript, how to use reporting guidelines – including ethical considerations – and how to avoid traps like salami publications and plagiarism. In the second part delegates will take the role of a reviewer. They will learn how to review a manuscript and how to write a good review which will be helpful to the authors and the editor. The workshop will feature short presentations, interactive group work and extensive question and answer sessions.

Putting together a manuscript

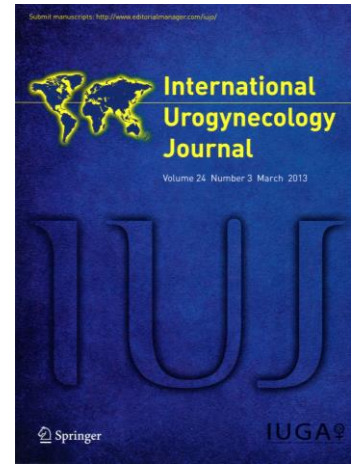
Professor Bob Freeman
Plymouth Hospitals NHS Trust
Plymouth University Peninsula Schools of Medicine and Dentistry
Scientific Editor IUJ
ICS Rio, Brazil 2014

Most journals want…

- Papers that will add to knowledge base, help meta-analyses and inform practice
- Address important research questions
- Are well designed, conducted, analysed
- Are well written up
- Will get cited to raise their Impact Factor

Constructing the Paper

- This will take time!
- Constantly revise e.g. important points, grammar
- Get some one to read it if English isn't your first language (Editing Service, Springer)
- Which Journal?
- Check that the scope of the paper is appropriate for the selected journal – change journal rather than submit inappropriately
- Check the requirements set out in the INSRUCTIONS FOR AUTHORS – again!



Author instructions

- ***Original Articles***
- Title page: authors and affiliations, corresponding author contact information (email mandatory)
- Conflict of interest statement for each author
- Maximum of 6 authors (more than 6 authors requires submission of a letter to the editorial office explaining the reasons)
- Each author's participation in the manuscript

www.editorialmanager.com/iujo

Author instructions

- Structured abstract (250 words) and Keywords (up to 6)
- Brief summary (25 words)
- Word limit of 4000 words (average is 2000 words)
- Maximum of 30 references
- Maximum of 6 figures/tables (If the article contains a large number of illustrations then the length of the text should be adjusted accordingly to a lower word count)

Start Writing

- Title
- Abstract and Keywords
- Introduction
- Methods
- Results
- Discussion
- Conclusions
- References

Title

- Titles should be specific.
- Think: "How will I search for this piece of information?" when you design the title.
- DON'T Use:
- Long titles
- Unnecessary jargon, abbreviations, unnecessary detail
- Make people want to read it e.g. pose a question

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Abstract

- It's what most people read
- Be brief and specific; main points only
- No references
- Structured abstracts: headings as required by the journal.
- Word count
- Use the abstract to "sell" your article

Start Writing

- Title
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Introduction

- 'KISS'! Long introductions 'put readers off'!
- Present the research question
- Known's and Unknown's
- No literature reviews
- Cite a couple of original and important works, including recent review articles only
- Aims and Objectives
- Use standardised Terminology e.g. IUGA/ICS

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Terminology

- Footnote to the Methods section:
- "Methods, definitions, and units conform to the standards jointly recommended by the International Urogynecological Association (IUGA) and the International Continence Society (ICS) , except where specifically noted".

Haylen et al. 2010

IUGA/ICS Standardisation Reports

- Haylen BT et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic floor dysfunction. Int Urogynecol J 2010 Jan;21(1):5-26.
- Haylen BT et al: Joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Int Urogynecol J 2011 Jan;22(1):3-15.
- **Haylen BT** et al: Joint terminology and classification of the complications related to native tissue female pelvic floor surgery. Int Urogynecol J 2012 May;23(5):515-26.
- Toozs-Hobson P et al: Joint report on the terminology for reporting outcomes of surgical procedures for pelvic organ prolapse. Int Urogynecol J 2012; 23:527-535

Best Form of Evidence

- Systematic reviews and Meta-analyses
- **BUT!**
- Not enough comparable studies
- Different methodologies and outcomes
- Therefore are recommendations appropriate?
- Use Standardised Outcome measures

Methods

- Follow CONSORT (even if not an RCT) *www.consort-statement.org/Downloads/download.htm*
- 'PICO' Define:
- The Population and the methods of sampling
- The Intervention in detail e.g. surgery
- The Controls
- The Outcome measures; standardised where possible
- Describe the analysis plan
- Describe any limitations of the methodology

CONSORT checklist for RCT protocols

PAPER SECTION And topic	Item	Description	Reported on page #
TITLE & ABSTRACT	1	How participants were allocated to interventions (e.g., "random allocation", "randomized", or "randomly assigned").	2
INTRODUCTION Background	2	Scientific background and explanation of rationale.	3-5
METHODS Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected.	8
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered.	8
Objectives	5	Specific objectives and hypotheses.	5
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors).	9
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.	9-10
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification).	8
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.	8
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.	8
Blinding (masking)	11	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated.	9
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); Methods for additional analyses, such as subgroup analyses and adjusted analyses.	10

www.consort-statement.org/Downloads/download.htm

Methods

- 'PICO' Define:
- The Population and the methods of sampling
- The Intervention in detail e.g. surgery
- The Controls
- The Outcome measures; standardised where possible
- Describe the analysis plan
- Describe any limitations of the methodology
- Statistics: get specialised help and advice

Start Writing

- Title
- Abstract and Keywords
- Introduction
- Methods
- Results
- Discussion
- Conclusions
- References

Results

- No need for text and tables (duplication)
- Statistics
- Number of tables
- Clear and easy to follow
- Reporting of Complications

Table 1. **Accuracy of Medical History for the Diagnosis of Allergic Rhinitis***

Medical History Category	Question	Positive Likelihood Ratio	Negative Likelihood Ratio	Reference	Patients, n	Were Patients Seen Consecutively?	Was the Chief Symptom Listed for Entry into Study?	Did All Patients Receive Gold Standard Test?	Was the Gold Standard Test Interpreted Independent of Index Test?	Notes
		Ratio	Ratio							
Triggers	Are allergic nasal symptoms from pollen or animals?	6.48	0.15	14	290	No	Yes	Yes	No	
	Do cats increase symptoms?	5.08	0.44	19	670	Yes	Yes	Yes	No	Computer-assisted
	Are allergic eye symptoms from pollen or animals?	4.43	0.09	14	290	No	Yes	Yes	No	
	Are symptoms from animals?	4.22	0.24	20	150	Yes	Yes	Yes	No	
	Do cats or dogs provoke or increase the nose problem?	4.21	0.81	21	269	Yes	Yes	Yes	No	At least 1 trigger needed
	Do weeds increase symptoms?	6.53	0.65	19	670	Yes	Yes	Yes	No	Computer-assisted
	Do trees increase symptoms?	4.86	0.52	19	670	Yes	Yes	Yes	No	Computer-assisted
	Does grass increase symptoms?	3.99	0.40	19	670	Yes	Yes	Yes	No	Computer-assisted
	Are symptoms provoked by pollen?	2.52	0.49	22	460	Yes	Yes	Yes	No	
	Do weeds increase symptoms?	2.09	0.73	19	670	Yes	Yes	Yes	No	Computer-assisted
	Do house dust, house dust mites, or pollen provoke or increase the nose problem?	5.34	0.28	25	269	Yes	Yes	Yes	No	At least 1 trigger needed
	Are symptoms provoked by dust?	1.76	0.49	19	670	Yes	Yes	Yes	No	Computer-assisted
		1.21	0.65	22	460	Yes	Yes	Yes	No	
	Do you have symptoms when house cleaning?	2.33	0.73	20	100	Yes	Yes	Yes	No	
History	Have you had hay fever?	4.90	0.58	22	460	Yes	Yes	Yes	No	
	Have you been tested for allergy (skin prick test or in vitro test) and were the results positive?	5.47	0.56	21	269	Yes	Yes	Yes	No	
	Have you been diagnosed with allergic rhinitis by a physician?	2.64	0.80	23	400	No	Yes	Yes	Yes	The only study that did not use index test in gold standard test; gold standard test is the PhadiaTop test†
		1.94	0.13	14	290	No	Yes	Yes	No	
	Has a doctor already diagnosed you with asthma, eczema, or allergic rhinitis?	2.08	0.76	21	269	Yes	Yes	Yes	No	
Family history	Does any family member have asthma, eczema, or allergic rhinitis?	3.41	0.70	21	269	Yes	Yes	Yes	No	
Months out of the year	Are symptoms worse in summer?	3.33	0.52	20	100	Yes	Yes	Yes	No	
	Seasonal: In which of the past 12 months (or in which season) did the nose problem occur?	1.68	0.75	21	269	Yes	Yes	Yes	No	Months listed should correlate with pollen calendar of the region
	Do you have seasonal symptoms?	1.59	0.59	22	460					
	Perennial: Did the nose problems occur in all of the past 12 months?	1.39	0.78	21	269	Yes	Yes	Yes	No	
Eyes	Are nasal symptoms accompanied by itchy-watery eyes?	2.49	0.51	21	269	Yes	Yes	Yes	No	
		1.23	0.50	22	460	Yes	Yes	Yes	No	
	Have you been told by your doctor that you have an allergic eye condition?	1.40	0.07	14	290	No	Yes	Yes	No	
	Is your eye irritation apart from repeating infections?	1.11	0.88	14	290	No	Yes	Yes	No	
General questions	Do you think you are allergic?	3.12	0.33	21	269	Yes	Yes	Yes	No	
	Have you ever had allergic nasal symptoms?	1.73	0.49	23	400	No	Yes	Yes	Yes	
Nasal symptoms	Nasal symptoms in the past year, excluding sneezing, runny nose, or blocked nose (if you did not have a cold or flu)?	1.33	0.65	14	290	No	Yes	Yes	No	
		1.38	0.14	21	269	Yes	Yes	Yes	No	At least 1 symptom; gold standard test based on definition of disease according to European consensus guidelines‡
	Do you have diurnal variation of symptoms?	1.06	0.89	22	466	Yes	Yes	Yes	No	

* All listed studies used a computer-aided method.
†Pharmacia Upjohn, Uppsala, Sweden.
‡ Data from reference 24, with permission.

Results

- No need for text and tables (duplication)
- Statistics
- Number of tables
- Clear and easy to follow
- Reporting of Complications

Bonhoeffer J et al. Vaccine 2002;21:298-302.

Ioannidis JPA et al. Ann Int Med 2004;141:781-788.

Complications

Generic

Intra-operative, Post-operative

- Clavien-Dindo classification
- Major complications e.g.:
  - Haemorrhage, transfusion
  - Return to OR/theatre
  - Severe infection requiring hospital admission
  - Long-term impairment on QOL and/or physical, mental functioning

Specific

- Complications of mesh, tapes and native tissue classification

(Haylen et al 2011,2012)

Table 2: A CLASSIFICATION OF COMPLICATIONS RELATED DIRECTLY TO THE INSERTION OF PROSTHESES (MESHES, IMPLANTS, TAPES) OR GRAFTS IN FEMALE PELVIC FLOOR SURGERY

CATEGORY

	General Description	A (Asymptomatic)	B (Symptomatic)	C (Infection)	D (Abscess)
1	**Vaginal**: no epithelial separation include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)	1A: Abnormal prosthesis or graft finding on clinical examination	1B: Symptomatic e.g. unusual discomfort / pain; dyspareunia (either partner); bleeding	1C: Infection (suspected or actual)	1D = Abscess
2	**Vaginal**: smaller ≤ 1cm exposure	2A: Asymptomatic	2B: Symptomatic	2C: Infection	2D = Abscess
3	**Vaginal**: larger >1cm exposure, or any extrusion	3A: Asymptomatic 1-3Aa if no prosthesis or graft related pain	3B: Symptomatic 1-3B (*b-e*) if prosthesis or graft related pain	3C: Infection 1-3C /1-3D (*b-e*) if prosthesis or graft related pain	3D = Abscess
4	**Urinary Tract**: compromise or perforation including prosthesis (graft) perforation, fistula and calculus	4A: Small intraoperative defect e.g. bladder perforation	4B: Other lower urinary tract complication or urinary retention	4C: Ureteric or upper urinary tract complication	
5	**Rectal or Bowel**: compromise or perforation including prosthesis (graft) perforation and fistula	5A: Small intraoperative defect (rectal or bowel)	5B: Rectal injury or compromise	5C: Small or Large bowel injury or compromise	5D = Abscess
6	**Skin and / or musculoskeletal**: complications including discharge pain lump or sinus tract formation	6A: Asymptomatic, abnormal finding on clinical examination	6B: Symptomatic e.g. discharge, pain or lump	6C: Infection e.g. sinus tract formation	6D = Abscess
7	**Patient**: compromise including hematoma or systemic compromise	7A: Bleeding complication including haematoma	7B: Major degree of resuscitation or intensive care*	7C: Mortality * *(additional complication - no site applicable - S 0)*	

TIME (clinically diagnosed)

T1: Intraoperative to 48 hours	**T2**: 48 hours to 2 months	**T3**: 2 months to 12 months	**T4**: over 12 months

SITE

S1: Vaginal: area of suture line	**S2**: Vaginal: away from from area of suture line	**S3**: Trocar passage Exception: Intra-abdominal (**S5**)	**S4**: other skin or musculoskeletal site	**S5**: Intra-abdominal

N.B.
1. **Multiple complications may occur in the same patient. There may be early and late complications in the same patient. i.e. All complications to be listed. Tables of complications may often be procedure specific.**
2. **The highest final category for any single complication should be used if there is a change over time. (patient 888)**
3. **Urinary tract infections and functional issues (apart from 4B) have not been included.**

IUGA ICS

CODE [ ][ ][ ] - T [ ] - S [ ]

The financial assistance from Boston Scientific towards printing of these reference tables is gratefully acknowledged.

TAPE EXPOSURE

- TVT-O
- At **6 weeks**:

Code: 2A T2 S2

<1cm tape exposure (2A) at 6 weeks (T2) away from area of vaginal suture line (S2)

Start Writing

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Discussion

- First study of…..
- Tell us about your results and what they mean
- Compare results with those of other studies
- No literature review (a critical review is ok)
- See CONSORT e.g. generalizability, sources of potential bias, dangers associated with multiplicity of analyses and outcomes.

Structure the Discussion

- Example: a Prolapse Surgery Paper:

  Subheadings:
- Subjective outcomes (Patient reported), QOL
- Objective outcomes e.g. POPQ
- Comparison with other studies
- Strengths and Weaknesses
- Conclusions and Recommendations

Start Writing

- Title
- Abstract and Keywords
- Introduction
- Methods
- Results
- Discussion
- Conclusions
- References; use correct method: see instructions for authors. Try reference manager, endnote etc.

Start Writing

- Title: Simple and easy to reference
- Abstract: 'Sell' your paper
- Introduction: KISS
- Methods: PICO, Standardised outcome measures, CONSORT, statistics
- Results: Clear and understandable tables, figures
- Discussion: Structured, compare your results
- Conclusions: Generalizability, what to do next?
- References: See instructions for authors

Constructing the Paper

- It takes time!
- Make the message clear
- Discuss with all the authors and statistician
- Get others to check the English
- Good luck!

Reporting guidelines

Paul Riss
paul.riss@gmail.com

ICS 2014 Rio de Janeiro
Workshop #1 | How to publish and review | 20 Oct 2014

Aim of reporting guidelines

- Standardize reporting
- Making reporting complete
- Facilitate comparison between studies

- Improve quality of studies

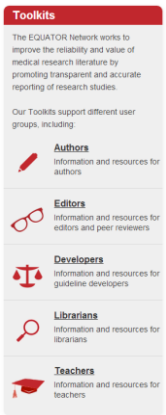
How to access reporting guidelines

Go to
EQUATOR
network homepage

EQUATOR Network

Enhancing the QUAlity and Transparency Of health Research

http://www.equator-network.org/



EQUATOR Network
Toolkits

http://www.equator-network.org/

Elements of a reporting guideline

1. Publication where reporting guideline is described
   - Is freely available (Open Access)
   - Can be cited in manuscript
2. Checklist
   - The tool of the reporting guideline
   - Can be submitted with manuscript
3. Flowchart
   - To be used in the manuscript

When to use reporting guidelines

- When writing a study protocol
- When writing a manuscript

How to use reporting guidelines

- Identify type of study
- Choose the corresponding reporting guideline
- Go to the website of the reporting guideline
- Download checklist
- Apply checklist to study protocol

- Apply checklist to the manuscript
- Mention reporting guideline in the methods section

Characteristic of a reporting guideline

Specific for study type

- RCT
- Observational study
- Systematic review / meta-analysis
- Case report
- Diagnostic study
- . . .

Addresses all aspects of a study protocol / manuscript

- Title and abstract
- Introduction
- Methods
- Results
- Discussion
- Other information
- . . .

CONSORT

Acronym

CONsolidated Standards Of Reporting Trials

Study type

Randomized Controlled Trials

Checklist

Number of items 25

PRISMA

Acronym

Preferred Reporting Items of Systematic reviews and Meta-Analyses

Study type

Systematic reviews and meta-analyses

Checklist

Number of items 27

STROBE

Acronym

STrengthening the Reporting of OBservational studies in Epidemiology

Study type

Observational studies (cohort study, case-control study, cross-sectional study)

Checklist

Number of items 22

CARE

Acronym

CAse REporting

Study type

Case reports

Checklist

Number of items 13 (writing template available)

STARD

Acronym

STAndards for Reporting of Diagnostic Accuracy

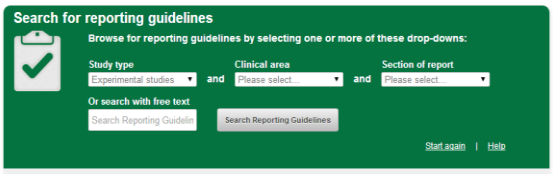
Study type

Studies of diagnostic accuracy

Checklist

Number of items 25

More reporting guidelines on the EQUATOR homepage



Currently 220 reporting guidelines

Example: specialized CONSORT guidelines

CONSORT Harms: Ioannidis JPA, Evans SJW, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D, for the CONSORT Group. Better reporting of harms in randomized trials: an extension of the CONSORT Statement. Ann Intern Med. 2004;141(10):781-788. PMID: 15545678

CONSORT Non-inferiority: Piaggio G, Elbourne DR, Pocock SJ, Evans SJW, Altman DG, for the CONSORT Group. Reporting of noninferiority and equivalence randomized trials. Extension of the CONSORT 2010 statement. JAMA. 2012; 308(24): 2594-2604. PMID: 23268518

CONSORT Cluster: Campbell MK, Piaggio G, Elbourne DR, Altman DG; CONSORT Group. Consort 2010 statement: extension to cluster randomised trials. BMJ. 2012;345:e5661. PMID: 22951546

CONSORT Herbal: Gagnier JJ, Boon H, Rochon P, Moher D, Barnes J, Bombardier C, for the CONSORT Group. Reporting randomized, controlled trials of herbal interventions: an elaborated CONSORT Statement. Ann Intern Med. 2006;144(5):364-367. PMID: 16520478

CONSORT Non-pharmacological treatment interventions: Boutron I, Moher D, Altman DG, Schulz K, Ravaud P, for the CONSORT group. Methods and processes of the CONSORT Group: example of an extension for trials assessing nonpharmacologic treatments. Ann Intern Med. 2008:W60-W67. PMID: 18283201

CONSORT Abstracts: Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF, the CONSORT Group. CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. PLoS Med. 2008; 5(1):e20. PMID: 18215107

CONSORT Pragmatic Trials: Zwarenstein M, Treweek S, Gagnier JJ, Altman DG, Tunis S, Haynes B, Oxman AD, Moher D; CONSORT group; Pragmatic Trials in Healthcare (Practihc) group. Improving the reporting of pragmatic trials: an extension of the CONSORT statement. BMJ. 2008;337:a2390. PMID: 19001484

STRICTA Controlled trials of acupuncture: MacPherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, Moher D; STRICTA Revision Group. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement. PLoS Med. 2010;7(6):e1000261. PMID: 20543992

CONSORT PRO: Calvert M, Blazeby J, Altman DG, Revicki DA, Moher D, Brundage MD; CONSORT PRO Group. Reporting of patient-reported outcomes in randomized trials: the CONSORT PRO extension. JAMA. 2013;309(8):814-22. PMID: 23443445

Future of reporting guidelines

- More reporting guidelines
- Specific reporting guidelines for subspecialties
- Specific reporting guidelines for study question

- Too many reporting guidelines ?

Conclusion Reporting guidelines

Use reporting guidelines
- Complete manuscript
- Better manuscript
- Study replicable
- Study comparable
- Study can be used in systematic reviews / meta-analyses

Mention reporting guidelines in your manuscript
- Editors and reviewers will take note

Ethics – Is this really important?

Maria Bortolini, MD, PhD
Editor *IUJ*

Responsible Conduct of Research

Singapore Statement

Preamble

- The value and benefits of research are vitally dependent on the integrity of research
- While there can be and are national and disciplinary differences in the way research is organized and conducted, there are also principles and professional responsibilities that are fundamental to the integrity of research wherever it is undertaken

link

Responsible Conduct of Research

Singapore Statement

Principles

- *Honesty* in all aspects of research
- *Accountability* in the conduct of research
- *Professional courtesy* and *fairness* in working with others
- *Good stewardship* of research on behalf of others

link

Publishing Misconduct

- Increasing examples of publishing misconduct
- Unethical practices and attitudes
- Growing concern among the public and research community
- Urgent need to address this problem
- Policy statements on **"Good publication practice"**

World Association of Medical Editors
www.wame.org

International Committee of Medical Journal Editors
www.icmje.org

Research & Publishing Misconduct

- Scientific fraud (data fabrication and falsification)
- Plagiarism
- Duplication of publication
- Violation of government rules of research
- Informed consent / Ethical committee approval
- Conflict of interest: not declared
- Authorship issues (guest or ghost)
- Failure to retain original data

Guidelines: Ethics in Research

- **Ethical standards for human and animal experimentation**

  World Medical Association **Declaration of Helsinki**: *recommendations guiding physicians in biomedical research involving human subjects. JAMA 1997;277:925-6*

  International Association of Veterinary Editors' Consensus Author Guidelines on Animal Ethics and Welfare.
  http://veteditors.org/ethicsconsensusguidelines.html

- **Declaration of IRB approval and/or case number**
  - All journals: paper and cover letter
  - Retrospective, chart review and data base studies
  - Most journals require patient consent for case reports

Guidelines: Ethics in Research

- **Clinical Trial Register: Clinicaltrials.gov, others**
- **Conflict of Interests: mandatory to declare**

Current subject of great debate

May reflect the influence of industry in the study outcomes and results

Plagiarism

"Plagiarists are either fools or desperate people"

John Maddox, Nature 286, 831–832 (1980)

Plagiarism: use of others' published and unpublished ideas or words (or other intellectual property) without attribution or permission, and presenting them as new and original rather than derived from an existing source

- Copying text, but providing new data
- Duplicate figures in two separate publications
- Republication of papers already published (in non-English
- journals); the original publication must always be cited

Publication Ethics Policies for Medical Journals, World Association of Medical Editors

Self-Plagiarism

Duplicate publication that occurs when an author reuses substantial parts of his or her own published work without providing the appropriate references.

This can range from getting an identical paper published in multiple journals, to 'salami-slicing', where authors add small amounts of new data to a previous paper

From Nature journal editorial policies

Detecting Plagiarism

Copied text can easily be detected…

- CrossCheck, powered by iThenticate
-
- DOC Cop (doccop.com)
- eTBLAST (biomedical literature only)
- *www.plagiarism.com*

Scientific Fraud

- Data fabrication and falsification

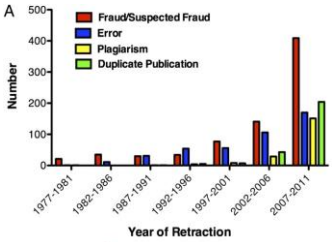
Biomedical & Life-Science Research
2047 retracted articles in PubMed

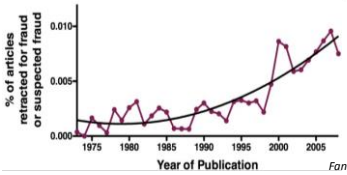
- 21.3% attributed to error
- 67.4% attributed to misconduct

- Fraud or suspected fraud (43.4%)
- Duplicate publication (14.2%)
- Plagiarism (9.8%)

Fang F C et al. PNAS 2012;109:17028-17033

- ↑ frauds
- ↑ retractions





Fang F C et al. PNAS 2012;109:17028-17033

Authorship

- The nature of each author's participation should be stated in the cover letter and preferably in the manuscript
- Criteria for authorship: ***Substantial* and *intellectual*** contribution (study concept, design, analysis, interpretation, writing or editing)
- Not mentioned: "**ghost authorship"**
- Including authors only because of their reputation, authority or friendship: **"guest authorship"** (violation of publishing ethics)
- Acknowledgment: technical services, translator, recruiters, funding, administrative or logistic support people

Dealing with Ethical Issues

Committee on Publication Ethics [COPE]
www.publicationethics.org

- Independent and non-profit of experts
- Provides advices and suggests action
- Offers algorithms and decision flowcharts in cases of publishing misconduct

Final Considerations

Publishing misconduct can be ONLY MINIMIZED by:

- Perceiving the value of combining ethical research conduct, open reporting of results with good clinical practice
- Treating our professional signature with the respect it deserves
- Understanding the politics of industrial sponsorship
- Inhibiting our personal and scientific prejudice
- Be honest, have professional courtesy, be fair and be accountable

Ethics in Research & Publication
Is this really important?

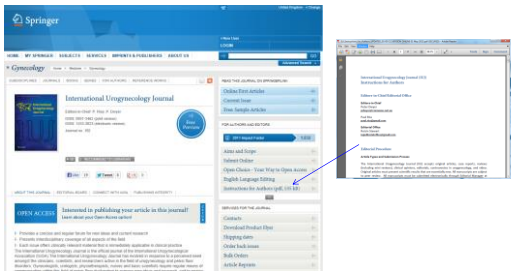
- Total science is cumulative and built by every scientific discovery
- Science is the true source of knowledge (discoveries) for humanity and contributes to the overall well-being, health and quality of life in general
- At the end, it is for all of us!

The Journey of a Manuscript

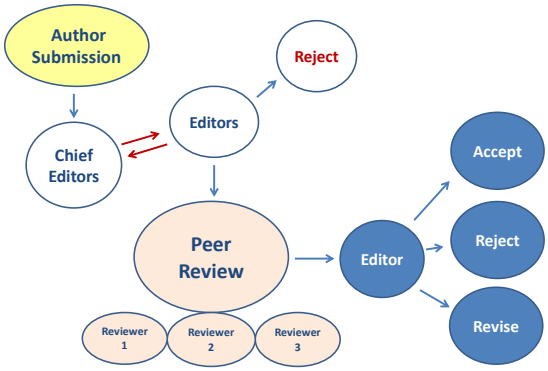
Maria Bortolini, MD, PhD
Editor *IUJ*

Manuscript Preparation

Instructions to authors !! www.springer.com/journal/192



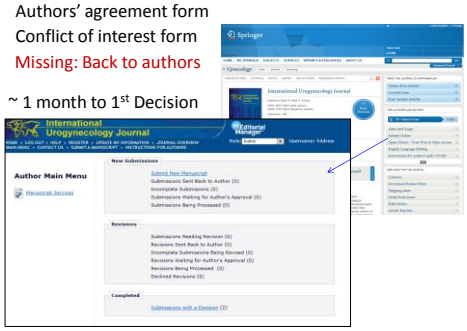
Editorial Process



Submission & Peer Review

Submission steps

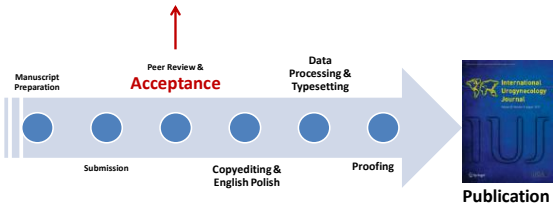
- Authors' agreement form
- Conflict of interest form
  Missing: Back to authors
- ~ 1 month to 1st Decision



Peer Review & Acceptance

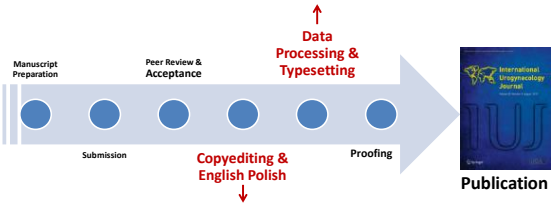
Questionnaire emailed to corresponding author:

- Option to publish Open Access
- Transfer copyright to IUJ
- Option to purchase manuscript checked for spelling & style



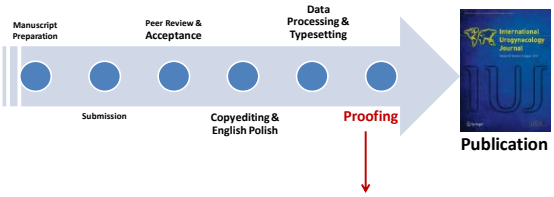
After Acceptance …

- Conversion and XML creation
- Image processing
- Typesetting



- Reference style corrected
- Printed 'off-prints'

Checking the Article: Proofing



- Proofs sent 14 days after completion of questionnaire
- Check for typesetting and conversion errors
- Check metadata sheet, authors names

Publication

- Online: ~1 week from receipt of proof corrections
- Pubmed: 2 days after online publication
- DOI (Digital Object Identifier)
- Published in final version ("backlog")
- IUJ indexed by:

• Science Citation Index Expanded (SciSearch), Journal Citation Reports/Science Edition, PubMed/Medline, SCOPUS, EMBASE, Google Scholar, EBSCO, Academic OneFile, Current Abstracts, Current Contents/Clinical Medicine, Gale, OCLC, SCImago, Summon by Serial Solutions

How does peer review work?

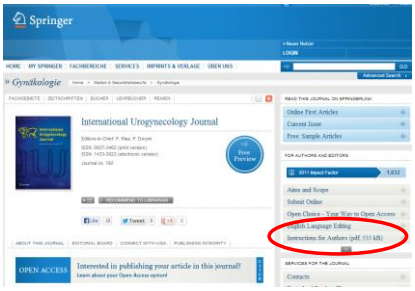
Paul Riss
paul.riss@gmail.com

ICS 2014 Rio de Janeiro
Workshop #1 | How to publish and review | 20 Oct 2014

Choosing a Journal

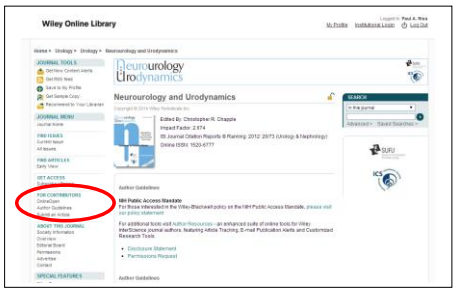
- Quality of your work
- Scope of the journal
- Reaching the readership

Go to instruction for authors



http://www.springer.com/medicine/gynecology/journal/192

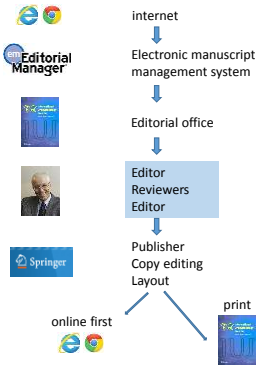
Go to instruction for authors



http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1520-6777/homepage/ForAuthors.html

Following the instructions for authors

- Helps the editorial office
- Facilitates review
- Makes a good impression on reviewers
- Increases chances of acceptance



The passage of a manuscript

Disclosure vs. Conflict of Interest

Disclosure
- Tell everything which is required & expected
- Disclosure of funding

Conflict of interest

Anything that may impact on your work
- Personal relationships
- Financial arrangements
- Employment by industry

Possible Scientific Misconduct

- Undeclared conflict of interest
- Disputed authorship
- Plagiarism
- Duplicate publication
- Data fabrication or falsification

- Salami publication

A Personal Checklist before Submission

- Scope of this journal ?
- Paper good enough for this journal ?
- Interest to the readers of this journal ?

Impact Factor
The Holy Grail of Publishing

?

Peer Review

Definition of a peer
- "someone equal in such respects as age, education or social class"

Definition of peer-review
- "a process by which something proposed is evaluated by a group of experts in the appropriate field"

http://en.wikipedia.org/wiki/Peer
http://www.merriam-webster.com/dictionary/peer%20review

Who are the Reviewers?

Fellow

Peer

Big Chief

The 5 Steps of the Peer Review Process

1. Selection of reviewers
2. Review
3. Revision
4. Re-review
   ---
5. Decision by editor

A Good Review

- Is returned in time
- Is polite and balanced
- Is well structured
  - Confidential comments to the editor
  - Comments to the authors
    - Characterization of the manuscript
    - General comments (strengths/weaknesses)
    - Specific remarks

- *Is helpful*

Types of Review Process

- Double blinded
- Single blinded (used by IUJ)
- Signed reviews

- *Open review process*
- *Post publication review*

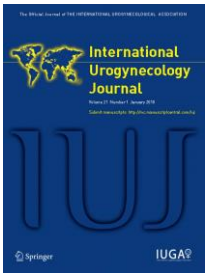
Keep in mind …

… if reviewers do not understand or appreciate a manuscript it is very unlikely that the general readership of the journal will take a better view of the paper

Play the Game

Always follow the requests and suggestions of the reviewers

Good luck with your submission !



- http://www.elsevier.com/reviewers/reviewer-guidelines#youve-been-asked-to-review
- added by PR on May 3, 2014

Reviewer Guidelines from the Elsevier website

- The most helpful review is one that articulates the strengths of a paper while also assiduously identifying the limitations of the manuscript that can be addressed in a revision.
- Nevertheless, even if a paper is well received overall, reviewer comments on manuscripts are commonly "negative".

Roberts et al. Academ Psych 2004; 28: 81-87

Helpful Hints

- When a reviewer is contacted an abstract is usually provided or should be reviewed first.
- Some things to considered before deciding whether or not to accept an invitation to review.
  - Be honest, do you have any conflict of interest that prevents a fair and objective review? If **yes** recuse yourself.
  - Is the topic inside your area of expertise? If **no** recuse yourself?
  - Finally, Can you complete the review on time? If **no** recuse yourself.
- Remember all manuscripts sent to reviewers are confidential, and they should not be discussed with others until they are published.

Should you accept?

1). Read the manuscript through once for an overall impression.
- Was it interesting and readable?, Did they authors ask an important question and did they answer it?, Was it too long or confusing?, Was it organized and did it flow logically?

2). After you have formed your impression go back to consolidate your thoughts.
- Look for examples that lead to your impressions?
- Ask questions of the authors?

Some tips for reviewing

- It should be short and sweet.
  - 4-5 paragraphs
  - A logical and concise discussion leading the reader to the hypothesis or concern being addressed.
- It should set up the concern (one or two paragraphs).
  - Going from broad to specific
- It should describe how these concerns can be addressed (one or two paragraphs)
  - What are the specific problems and how can they be addressed.
- It should state how this manuscript will assess a hypothesis or address the concerns (one paragraph).

Introduction

- The Methods should be clear and accurate.
  - Another investigator should be able to use this section to exactly reproduce the experiment.
  - If in the reading the order of events (i.e.. how subjects were selected, how and when data was collected) it is not clear the reviewer should question the authors.
- The study population should be characterized clearly.
  - This will allow readers to determine its generalizability.
- Sample size is important and its size should be justified.
  - Avoid type 2 or Beta errors (a difference exists but none is found because the sample size is too small).
- A discussion of any instruments used to include;
  - Validity (the extent to which an instrument measures what it purports to measure) and reliability (the extent to which an instrument provides consistent measurements).

Methods

- The Results should be clear.
- Statistical tests should be appropriate to the question.
- Important findings should be emphasized in a table or figure.
  - Less important information should be in the text.
  - No data should be presented in full in both places in both places.
- Common weaknesses of manuscripts are inappropriate or incomplete statistics, omission of data, inconsistent or inaccurate data, and defective or unclear tables or figures.
  - If you have concerns about statistics we have a statistical consultant that can be requested.

Results

- The Discussion section should honestly assess strengths and limitations of the research.
- The reviewer should comment as to whether the conclusions are adequately supported by the data presented.
- Overstating results is a common practice.
  - Speculative, unsubstantiated, or unsupported comments should be noted by the reviewer.

Discussion

- The abstract should be assessed for its accuracy as a summary of the manuscript.
  - It should be read again after the manuscript has been read to make certain it is accurate.
- Reviewers should judge the adequacy of the references.
  - I look at the dates of the cited papers
  - If papers cited are >10 years old I run a quick Google Scholar search.

Abstract and References

- A review is a critique.
- It is almost by definition somewhat critical but this should never be viewed as a negative.
- Avoid reviewing manuscripts you have no interest in.
- Write clear questions for authors to address in order to make their manuscript stronger.

Summary

- The Art of Reviewing
  J Joy, McClure N. The Obstetrician and Gynaecologist 2014;16(2):129-134.

Int Urogynecol J
DOI 10.1007/s00192-011-1559-0

EDITORIAL

The peer review process I: submitting a manuscript

Paul Riss

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Putting together a manuscript is hard work. After so many months of doing a study or organizing a review, the manuscript has to be written, edited, rewritten, and revised again until it is in its final form and ready for submission to a journal. But everything is not done yet. In order to increase the chances of having the manuscript reviewed favorably and finally accepted for publication, the final touches to the manuscript and the choice of the right journal are essential.

At this stage, it is a good idea to ask some questions regarding the manuscript to increase the chances of acceptance by a journal (Table 1). First of all, a healthy dose of self criticism is in order to assess the quality of one's work. The answer to this question will help decide the choice of the journal a manuscript is submitted to. If the paper describes a randomized controlled trial trying to answer a very relevant and timely study question, authors should not hesitate to submit their work to a top journal. If it is only an interesting case report, it might be advisable to submit to a journal farther down the list of ranked journals.

A second question is of course whether a manuscript fits into the spectrum of a particular journal. An author has to expect that his work will be sent back if the study question is not within the scope of a journal. By looking at the table of contents of a journal, one gets a good idea of the kind of articles the journal is accepting.

Once a decision is made as to where to submit a manuscript, the next step is to go to the instruction for authors and to read them carefully [1]. It is not only an act of courtesy but also a practical requirement to follow the instructions to authors of this particular journal meticulously. Following the instructions and revising the manuscript accordingly will not only help to be accepted by the editorial office for further consideration but also is the most important step an author can take to facilitate the review of his manuscript and to make a good impression on the reviewer.

It goes without saying that the instructions for structuring the manuscript, for layout and for citing references must be followed, and no author wants his manuscript to be sent back because of incompleteness or for having to modify the layout. Depending on the type of article, another important question is whether generally recognized criteria and guidelines have been followed [2]. Here, it is advisable to read closely the instructions to authors because requirements might differ between journals.

When the manuscript describes a randomized controlled trial very often the journal wants a statement that for example the CONSORT criteria have been followed. CONSORT is an acronym for Consolidated Standards of Reporting Trials [3]. With reviews becoming more common, reviewers and journals often ask for the MOOSE statement to be considered (Meta-analysis of Observational Studies in Epidemiology). All these criteria and guidelines are freely available on the internet [4].

Another very important point in clinical trials is to register a trial before initiation, and many journals require the registration of trial before even considering it for peer review. At the *International Urogynecology Journal*, it is strongly encouraged that prospective, randomized trials are registered with a public clinical trial registry such as www.clinicaltrials.gov prior to commencing patient recruitment.

Two other editorials in this series on the peer review process can be found at doi:10.1007/s00192-011-1560-7 and doi:10.1007/s00192-011-1561-6.

P. Riss (✉)
Dept. of Gynecology and Obstetrics,
Landesklinikum Thermenregion Moedling,
Sr. Maria Restituta Gasse 12,
2340 Moedling, Austria
e-mail: paul.riss@gmail.com

Published online: 08 September 2011

Table 1

A personal checklist
Is my manuscript within the scope of this journal?
Is my manuscript good enough for this journal?
Will my manuscript be of interest to the readers of this journal?

Also, proof of Institutional Review Boards approval is mandatory or an explanation for an exemption or waiver.

No manuscript is complete without a statement by the authors on disclosure, conflicts of interest, and funding of the work presented. The specific criteria are still evolving, but there is no doubt that these questions have to be addressed and answered to the satisfaction of the journal. In every manuscript, there must be a clear statement if and how the present work was funded: where did the money come from for the study or for organization of a review? Was industry involved? Was funding provided by an institution? If no special funding was necessary, then this has to be clearly stated.

Many authors do not seem to be fully aware of what disclosure and conflict of interest mean. Disclosure means that the author—all authors—have to tell the public what their relationships with industry are and what financial activities could have an influence on the submitted work in the eyes of a reader. The International Committee of Medical Journal Editors has developed a form which many journals require and the *International Urogynecology Journal* strongly recommends to use [5, 6]. This information is then made available to the readership.

While disclosure is just what it says—to give information to the editor, the reviewer, and finally to the reader so that they can make an informed decision about the potential implications of the financial activities of the authors—conflict of interest goes much further. Conflict of interest concerns not only financial aspects but also every activity or personal or institutional relationships which could have an influence on the work presented. It is the responsibility of the authors to think about these aspects of their work and to signal potential conflicts of interest to the editors of the journal and to the readers.

It goes without saying that any form of scientific misconduct is severely frowned upon, although it might be argued that there can be a gray area. The instructions for authors of the International Urogynecology Journal list five types of scientific misconduct: undeclared conflict of interest, disputed authorship, plagiarism, duplicate publication, and data fabrication or falsification [1]. Misconduct might entail disciplinary action from the journal, but first and foremost, it is an abuse of the trust on which the scientific community operates [7, 8].

A form of scientific misconduct which occurs not infrequently is salami publication, which means dividing a study into even smaller pieces to generate the highest number of publications. Often authors also do not reference their previously published work giving the impression that every publication is original. With the help of various search engines, this is more easily detected and reflects very negatively on the authors.

On a practical note, authors are encouraged to ask when they have questions. Authors should write to the editorial office or to the editor if they are in doubt about aspects of their manuscript. Once a manuscript is managed by the editorial office, authors have the right to expect answers in a timely fashion and are encouraged to inquire about the status of their manuscript when there is a time lag.

In summary, authors are advised to choose a journal where they themselves would expect their paper to be published. It does not make sense and is a waste of time—for the authors and for the reviewers—to automatically go for the journal with the highest impact factor. Second, authors should meticulously follow the criteria set by the journal they submit to—if nothing else, this is an act of politeness—and always remember that they want the journal to accept their work for publication. Happy authors make a good journal.

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Int Urogynecol J
DOI 10.1007/s00192-011-1560-7

EDITORIAL

The peer review process II: to review and be reviewed

Paul Riss

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The time a paper is reviewed until the moment a final decision is made is always a time of apprehension and uncertainty for the authors. Who are the people who are examining my work? Are they qualified enough? Will they understand what I have written and tried to demonstrate? And above all, will they offer constructive criticism and recommend acceptance—or at least revision—to the editor making the final decision?

It will help authors to live through these difficult weeks if they understand the review process better. After all many authors have also experienced the other side in the past as reviewers for a journal. But there is no doubt that the whole peer review process is confusing and messy.

First of all who are the so-called peers? Wikipedia defines a peer as "someone equal in such respects as age, education or social class" [1]. However, according to the Merriam–Webster dictionary peer review is "a process by which something proposed (as for research or publication) is evaluated by a group of experts in the appropriate field" [2]. Obviously there is a difference between someone equal in education and an expert in the appropriate field. Behind the mask of an anonymous reviewer, there might be a junior fellow from the same field or a senior professor.

Second although the whole peer review is structured—selection, invitation, review, and recommendation—it is still a messy process full of uncertainties. Did the editor select the right peers? Were they knowledgeable enough? Did they take enough time to fully understand the paper? Did the various reviewers come to the same conclusion?

One thing to keep in mind is that the reviewers are the first members of a hopefully large audience. If reviewers do not understand or appreciate a manuscript, it is very unlikely that the general readership of the journal will take a better view of the paper.

The selection of reviewers is the responsibility of the editor managing the submission and is of utmost importance. Sometimes authors are invited to suggest reviewers, even then there is no way for the authors of knowing whether the editor has followed the suggestion, and if so whether the suggested reviewers have given a positive review. When the editor has to select reviewers, he or she is confronted with several options: should she choose reviewers whom she knows personally or select them randomly from an anonymous database? Experienced editors tend to rely on trusted and proven reviewers—reviewers who reliably give good reviews in a timely fashion—and also aim for a balance of younger and more experienced reviewers. In an international journal, it will also make sense to choose reviewers from different geographical regions. In very small fields and particularly for basic science manuscripts, it can be difficult to find reviewers because the pool of potential experts is small.

Many authors feel that the choice of reviewers influences the eventual decision on their manuscript, and this is certainly true. Editors can be biased, and when they lean toward rejection or acceptance of a manuscript, they might subconsciously—or consciously—invite someone whom they know to share their view. Of course a good editor will always try to hold his or her own bias to a minimum but, it can never be ruled out completely.

Two other editorials in this series on the peer review process can be found at doi:10.1007/s00192-011-1559-0 and doi:10.1007/s00192-011-1561-6.

P. Riss (✉)
Dept. of Gynecology and Obstetrics,
Landesklinikum Thermenregion Moedling,
Sr. Maria Restituta Gasse 12,
2340 Moedling, Austria
e-mail: paul.riss@gmail.com

Published online: 08 September 2011

The *International Urogynecology Journal* uses a single-blinded review process. This means that the reviewers know the names of the authors and where the paper comes from but the identity of the reviewers is not revealed to the authors—and also to the other reviewers. Blinding the authors to the reviewers has proven impractical since the identity of the institution and thus the names of potential authors could often be deduced from the manuscript and from references to previous work. On the other hand, it is felt that the anonymous review process gives the reviewer greater freedom in expressing her or his views and criticizing a manuscript. After all next time around, it could be one of the authors who is called to review a paper or a grant application of the reviewer.

When a reviewer accepts the invitation to review a manuscript, he or she must be sure that there is no conflict of interest with the authors of the manuscript or their institution. This could be personal or professional relationships or competing interests, but there are no strict guidelines for this kind of conflict of interest. It is the responsibility of the reviewer to decline the invitation if he or she feels that something might interfere with a balanced evaluation of the submission.

A reviewer is expected to read and evaluate the manuscript and to provide the editor with two types of comments and a recommendation as to the final disposition. The first comments should be confidential comments for the editor only. These comments will not be forwarded to the authors so the reviewer can be quite open to express his or her views to the editor. The second part of the comments will be the comments for the authors. These comments should explain to the authors what the reviewer thinks of their work and which changes and improvements he or she would suggest. The recommendations for the final disposition (acceptance, revision, rejection) are meant for the editor only and must not be part of the comments to the authors.

A good review is clearly structured into general and specific comments. The general comments should summarize what the paper is in one sentence and should state positive and negative things about the paper. The specific comments address the different sections of the manuscript (abstract, introduction, methods, results, and discussion) pointing out missing aspects or suggesting changes and improvements. The remarks should be consistent: it does not make sense for the reviewer to praise a paper in the general comments and then criticizing it harshly in the specific comments.

Authors naturally are very sensitive to what a reviewer says and how he or she says it. Authors have a right to expect that reviews do not contain impolite or even abusive remarks. In such cases it is the duty of the editor to edit the "comments to the authors" and to delete inappropriate passages.

On the positive side, reviews can be extremely valuable. The author gets candid feedback from someone knowledgeable in the field of his or her work. The peer review process is a rare opportunity where the result of one's work is evaluated and discussed by people from outside the inner circle of the research group. Everyone wants to hear praise, but critical comments can be very valuable when developing new study protocols and they are a great learning experience for fellows or researchers at the beginning of their careers.

In summary reviewers must take their task seriously, and authors should appreciate the time and expertise given by the reviewers. Reviewers get the opportunity to learn about new research and are giving back what they themselves have received from their peers at earlier stages in their careers. Authors must be grateful for the critical evaluation of their work which can make their work better and help them in their careers. If we look at the review process in this way, everyone will benefit.

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2. http://www.merriam-webster.com/dictionary/peer%20review. Accessed 8 Aug 2011

Int Urogynecol J
DOI 10.1007/s00192-011-1561-6

EDITORIAL

The peer review process III: when the decision is made

Paul Riss

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From the author's perspective, the decision by the editor is the long-awaited final event in the peer review process. Although every author wants to have his or her work accepted for publication and to see it in print-on paper or digital, everybody realizes that acceptance is not possible every time. In fact the so-called rejected rate, the percentage of submissions which are not published but sent back to the authors, is taken as one indicator for the standing and popularity of a journal.

It is important for authors to understand how decisions by a journal are made. Most journals use several categories to summarize the editorial decision at the end of the peer review process: accept as is, revision, and rejection. It is unreasonable to assume that a manuscript is accepted as submitted for the simple reason that most manuscripts require some modification to make them suitable for publication. Rejection leaves no doubt about its meaning and is the end of the peer review process for this submission with a particular journal.

But some clarifications are in order: the *International Urogynecology Journal* has a modified category "accept pending English revision" because with submissions from all over the world, sometimes a manuscript is accepted on the basis of its scientific merit but is not ready yet to be sent to the copy editor who makes the final touches before the manuscript is actually put online and printed. Some journals—but not the *International Urogynecology Journal*—have a category "reject and resubmit." This means that the manuscript will no longer be considered for publication, but the authors are given the opportunity to write a completely new manuscript, without necessarily redoing the study, and to submit it again. This would be considered a new submission by the journal and undergo a new review process possibly with other reviewers being invited.

The most common decision is minor or major revision and this decision is often difficult to interpret. Authors tend to think that if they make the required changes, their manuscript will certainly be accepted for publication. Editors will have to send out the revised manuscript for another round of reviews (to the same reviewers) before being able to make the final decision which could still be reject. Authors should look closely at the decision letter and at the comments to the authors to see what they really mean. Sometimes the changes requested by the reviewers are too extensive—add more patients, change the protocol of the study—that it becomes impossible for the authors to comply with them. Authors should read the reviews carefully and decide whether they can respond to each recommendation made by the reviewer. If so they should revise the manuscript and return it to the editorial office.

But how do editors actually make the decision? There is no simple answer to this question because the decision depends on many factors: the number of reviews, the recommendations by the reviewers, and the opinions of the reviewers expressed in their confidential comments to the editor and in their comments to the authors. The *International Urogynecology Journal* also asks the reviewers to rate a manuscript on the basis of scientific merit, novelty, interest to the readership, etc. On the other hand, some reviews are practically worthless because they are not

Two other editorials in this series on the peer review process can be found at doi:10.1007/s00192-011-1559-0 and doi:10.1007/s00192-011-1560-7.

P. Riss (✉)
Department of Gynecology and Obstetrics,
Landesklinikum Thermenregion Moedling,
Sr. Maria Restituta Gasse 12,
2340 Moedling, Austria
e-mail: paul.riss@gmail.com

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detailed enough to give the reasons for the recommendation of the reviewer.

The biggest problem for the editor making the decision, however, is that reviewers often do not agree in their recommendations. What should an editor do when one reviewer recommends minor revision, the other reviewer major revision, and the third reviewer rejection? Keeping in mind that it is the editor who makes the decision about the final disposition of a manuscript and not the reviewers, the editor reads the reviews carefully, maybe rereads the manuscripts to get a feeling whether the manuscript can be improved sufficiently to be acceptable for publication. The main criteria are scientific quality of the paper and eventual interest to the readership of the journal.

Authors are often disappointed when they get a negative decision letter from the editor, but the comments of the reviewers communicated to them seem to be quite positive. Here authors should keep in mind the explanations given above, namely that it is the editor who makes the decision based on many different factors and not the reviewers. An editor never has to follow the recommendations of the reviewers blindly and it is up to him or her which recommendation is given more weight in reaching the final decision.

For the same reason authors should never argue with the reviewers. Reviewers are colleagues and experts who generously give their time and expertise to evaluate a paper and write a review. They must be respected even if an author does not agree with their conclusions. Authors should always ask themselves: if I cannot convince the reviewers of the merits of my submission, maybe the general readership of the journal also will have difficulty appreciating my contribution.

If there are serious disagreements or misunderstandings, the author should write to the editor or the editorial office and explain their point of view. Formal appeals of an editorial decision are strongly discouraged, but in exceptional cases, it can become necessary to give additional explanations and to continue the discussion with the editor beyond the editorial decision.

At the *International Urogynecology Journal*, every manuscript is assigned to one editor who has sole responsibility for the editorial decision. This may not be the case with other journals where the editor recommends a final decision to the editor in chief or where the editorial decision might be a decision by a group of editors.

To paraphrase a line from a Monty Python song “Always look at the bright side of (life) rejection” [1]. A scientific journal is also a publishing enterprise, and its contents must be varied and of interest to its readers. Authors should and must be grateful for a structured review process which involves so much work, expertise, and goodwill from their peers even if the final outcome is not what they had hoped for. Authors should never despair. Good science will always find an audience or as another saying goes: Every good manuscript gets published eventually.

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RESEARCH ARTICLE Open Access

The CARE guidelines: consensus-based clinical case reporting guideline development

Joel J Gagnier[1,2], Gunver Kienle[3], Douglas G Altman[4], David Moher[5,6], Harold Sox[7], David Riley[8*] and the CARE Group[9]

Abstract

Background: A case report is a narrative that describes, for medical, scientific, or educational purposes, a medical problem experienced by one or more patients. Case reports written without guidance from reporting standards are insufficiently rigorous to guide clinical practice or to inform clinical study design.
Primary Objective. Develop, disseminate, and implement systematic reporting guidelines for case reports.

Methods: We used a three-phase consensus process consisting of (1) pre-meeting literature review and interviews to generate items for the reporting guidelines, (2) a face-to-face consensus meeting to draft the reporting guidelines, and (3) post-meeting feedback, review, and pilot testing, followed by finalization of the case report guidelines.

Results: This consensus process involved 27 participants and resulted in a 13-item checklist—a reporting guideline for case reports. The primary items of the checklist are title, key words, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic interventions, follow-up and outcomes, discussion, patient perspective, and informed consent.

Conclusions: We believe the implementation of the CARE (CAse REport) guidelines by medical journals will improve the completeness and transparency of published case reports and that the systematic aggregation of information from case reports will inform clinical study design, provide early signals of effectiveness and harms, and improve healthcare delivery.

Keywords: Case report, Case study, EQUATOR Network, Patient reports, Meaningful use, Health research reporting guidelines

Introduction

A case report is a detailed narrative that describes, for medical, scientific, or educational purposes, a medical problem experienced by one or several patients

Case reports present clinical observations customarily collected in healthcare delivery settings. They have proved helpful in the identification of adverse and beneficial effects, the recognition of new diseases, unusual forms of common diseases, and the presentation of rare diseases [1]. For example, our understanding of the relationship between thalidomide and congenital abnormalities [2] and the use of propranolol for the treatment of infantile hemangiomas began with case reports [3]. Case reports may generate hypotheses for future clinical studies, prove useful in the evaluation of global convergences of systems-oriented approaches, and guide the individualization and personalization of treatments in clinical practice [4,5]. Furthermore, case reports offer a structure for case-based learning in healthcare education and may facilitate the comparison of healthcare education and delivery across cultures.

Case reports are common and account for a growing number of articles in medical journals [6]; however their quality is uneven [7,8]. For example, one study evaluated 1316 case reports from four peer-reviewed emergency-medicine journals and found that more than half failed to provide information related to the primary treatment that would have increased transparency and replication [9]. Written without the benefit of reporting guidelines,

* Correspondence: driley@gahmllc.com
[8]Global Advances in Health and Medicine, Portland, OR, USA
Full list of author information is available at the end of the article

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case reports often are insufficiently rigorous to be aggregated for data analysis, inform research design, or guide clinical practice [7,9].

Reporting guidelines exist for a variety of study designs including randomized controlled trials (Consolidated Standards of Reporting Trials, or CONSORT) [10], observational studies (Strengthening the Reporting of Observational studies in Epidemiology, or STROBE) [11], and systematic reviews and meta-analyses (Preferred Reporting Items for Systematic Reviews and Meta-Analyses, or PRISMA) [12]. Empirical evidence suggests that a journal's adoption of the CONSORT statement as a guide to authors is associated with an increase in the completeness of published randomized trials [13]. Guidelines have been developed for adverse-event case reports [14]; however, general reporting guidelines for case reports do not exist. Our primary objective was to develop reporting guidelines for case reports through a consensus-based process.

Methods

Research design

We followed the Guidance for Developers of Health Research Reporting Guidelines [15] and developed a three phase consensus process [16]. This consisted of (1) a pre-meeting literature review followed by interviews to generate items for a case report checklist, (2) a face-to-face consensus meeting for drafting a reporting guideline, and (3) post-meeting feedback and pilot testing followed by finalization of the case report guidelines.

Participants

We contacted 28 individuals who fulfilled at least one of four criteria [17-19]: (1) publication of articles related to case reports; (2) publication of a manual, handbook, or method guidelines related to case reports; (3) publication of a systematic review of methods or reporting related to case reports; and (4) publication of other reporting guidelines for clinical research.

Consensus process

Phase 1: Four of the authors, the steering committee (JG, GK, DM, and DR), searched the literature for publications on the role of case reports, recommendations for their publication, and surveys on reporting quality. A letter was sent to 28 potential participants explaining the purpose of the meeting, details of the consensus technique, and requesting their participation in generating specific recommendations for case reporting. Twenty-seven people agreed to participate and were scheduled for a telephone interview and sent a selection of key articles on case reports. During the telephone interview, participants were asked (1) what information was required to be included in case-reporting guidelines, (2) the rationale for their suggestions, and (3) for references that supported their reasoning.

Three of the authors (JG, GK, and DR) grouped the recommendations from the literature search and interviews by theme together with their rationale, references, and operational definitions. No quantitative scoring was done.

Phase 2: The face-to-face consensus meeting at the University of Michigan in Ann Arbor (October 2012) included 18 participants from Phase 1, one research assistant and two student observers. The meeting began with a review of the blinded recommendations elicited during the Phase 1 interviews, in whole group and small group sessions. On the second day, open discussion of each potential item continued, during which clarifications, opinions, justifications, operational definitions, and new ideas were expressed. By the end of the second day, the group had agreed upon a set of preliminary reporting recommendations.

Phase 3: The draft checklist was refined by the steering committee and sent for two rounds of review to the complete group (Phase 1 and 2 participants). The finalized reporting guidelines incorporated the feedback from the entire CARE group.

Results

The CAse REport (CARE) guidelines checklist is structured to correspond with key components of a case report and capture useful clinical information (including 'meaningful use' information mandated by some insurance plans).

The checklist begins with a statement that describes the narrative of a case report. The meeting CARE group felt that a case report should tell a story using prose that has a consistent style across all sections, including the rationale for any conclusions and take-away messages.

We recommend a timeline (item 7) in the form of a table or figure that gives the specific dates and times of important components of the case. This might include family and past medical history, genetic information, current symptoms, diagnostic test results, interventions, and events that occurred during follow-up. The timeline should show how the key events of the case unfolded.

We created separate checklist items for diagnostic assessments (item 8) and therapeutic interventions (item 9) with the recognition that both items will often be relevant in a case report.

The group discussed at length whether to include the patient's perspective on his or her experience. In the end, we advocated for patient-reported outcomes and experiences whenever possible (item 12). There was also discussion about the need for guidelines for patient-reported outcomes of their care. In a similar vein, a recent extension of the CONSORT statement was published for patient-reported outcomes in randomized trials; CONSORT-PRO [20].

Finally, we included an item on informed consent (item 13). We believe that authors have an ethical duty to obtain informed consent from the patient to publish patient information in a case report. Consent becomes informed when the patient or a relative reads the case report and approves its contents. If the patient cannot give consent and attempts to find a relative to give proxy consent have failed, the authors should seek permission to publish from an institutional committee. There may be other circumstances where an ethics committee or Institutional Review Board (IRB) approval may be necessary. The CARE guidelines are shown in the following Table 1.

Table 1 The CARE guidelines checklist

The Narrative: A case report tells a story in a narrative format that includes the presenting concerns, clinical findings, diagnoses, interventions, outcomes (including adverse events), and follow-up. The narrative should include a discussion of the rationale for any conclusions and any take-away messages.

Item name	Item no.	Brief description
Title	1	The words "case report" (or "case study") should appear in the title along with phenomenon of greatest interest (eg, symptom, diagnosis, test, intervention)
Keywords	2	The key elements of this case in 2-5 words
Abstract	3	a) Introduction—What does this case add?
		b) Case Presentation:
		- The main symptoms of the patient
		- The main clinical findings
		- The main diagnoses and interventions
		- The main outcomes
		c) Conclusion—What were the main "take-away" lessons from this case?
Introduction	4	Brief background summary of this case referencing the relevant medical literature
Patient Information	5	a) Demographic information (eg, age, gender, ethnicity, occupation)
		b) Main symptoms of the patient (his or her chief complaints)
		c) Medical, family, and psychosocial history—including diet, lifestyle, and genetic information whenever possible, and details about relevant comorbidities including past interventions and their outcomes
Clinical Findings	6	Describe the relevant physical examination (PE) findings
Timeline	7	Depict important dates and times in this case (table or figure)
Diagnostic Assessment	8	a) Diagnostic methods (eg, PE, laboratory testing, imaging, questionnaires)
		b) Diagnostic challenges (eg, financial, language/cultural)
		c) Diagnostic reasoning including other diagnoses considered
		d) Prognostic characteristics (eg, staging) where applicable
Therapeutic Intervention	9	a) Types of intervention (eg, pharmacologic, surgical, preventive, self-care)
		- Administration of intervention (eg, dosage, strength, duration)
		- Changes in intervention (with rationale)
Follow-up and Outcomes	10	a) Summarize the clinical course of all follow-up visits including
		- Clinician and patient-assessed outcomes
		- Important follow-up test results (positive or negative)
		- Intervention adherence and tolerability (and how this was assessed)
		- Adverse and unanticipated events
Discussion	11	a) The strengths and limitations of the management of this case
		b) The relevant medical literature
		c) The rationale for conclusions (including assessments of cause and effect)
		d) The main "take-away" lessons of this case report
Patient Perspective	12	The patient should share his or her perspective or experience whenever possible
Informed Consent	13	Did the patient give informed consent? Please provide if requested

Discussion

This 13-item checklist provides a framework to satisfy the need for completeness and transparency for published case reports. We attempted to strike a balance between adequate detail and the concise writing that is one of the appealing characteristics of a case report. Our consensus process resulted in a set of essential items for authors to consider when submitting a case report for publication.

While case reports have long been an important source of new ideas and information in medicine [21], it appears that case reports are likely to begin to play a role in the discovery of what works and for whom. BioMed Central launched the *Journal of Medical Case Reports* in 2007 [22] and a Cases Database in 2012 with more than 11,000 published case reports from 50 medical journals. In 6 months, it has grown to more than 26,000 case reports from 212 medical journals [23]. The CARE guidelines checklist is part of a growing effort to improve the reporting of case reports.

There is substantial empirical evidence that reporting guidelines improve the completeness of published scientific reports eg, see references [13,24,25]. A recent Cochrane review examining the influence of journal endorsement of the CONSORT statement on reporting included 53 publications assessing 16,604 randomized controlled trials and found that CONSORT-endorsing journals consistently have better overall reporting [13]. However, the potential impact of the CONSORT statement and related reporting guidelines has not been fully realized. A study examining the instructions to peer reviewers of 116 health research journals found that only 41 (35%) provided online instructions to peer reviewers. Of those, only 19 (46%) mentioned or referred to reporting guidelines as a useful resource [26]. In response, the authors provide several recommendations for editors to improve the peer review of submitted manuscripts, suggesting that journals have a responsibility to support peer reviewers [26].

The developers of reporting guidelines have a responsibility to plan a dissemination and implementation strategy that supports guidelines utilization [15]. Our efforts have several components:

1. The CARE guidelines will be presented at international conferences and workshops including the Peer Review and Biomedical Publication Congress in Chicago on September 10, 2013.
2. This article will be published simultaneously in multiple medical journals and outreach to the 212 journals depositing case reports into the BioMed Central Case Report Database.
3. We will develop a more detailed explanation and elaboration article to outline the rationale for each item and include empirical evidence and examples of good reporting from published case reports.
4. The CARE guidelines are being pilot tested, and preliminary results support the guidelines as currently written (personal communication with Helmut Kiene, Erika Oberg, Bill Manahan). Guidelines extensions for specialties are being developed.
5. The CARE guidelines and related documents will be available on a dedicated website (www.CARE-statement.org), the EQUATOR Network website (www.equator-network.org), and translated into multiple languages.
6. Authors, journal editors, peer reviewers and the wider medical community are encouraged to use the CARE checklist and provide feedback that can be incorporated into regular updates of the CARE guidelines.
7. We will conduct and support research into the impact of the CARE guidelines on the reporting of case reports.

Limitations

The CARE guidelines and their development have several possible limitations. First, these guidelines were developed through a consensus method and thus represent the opinions of the participants. However, consensus was easily reached during our meeting, we referred to the empirical evidence where available, and we received feedback from a wide selection of individuals, beyond those involved in our consensus meeting. Second, we recognize that causality determinations are a challenge for case reports even when following reporting guidelines [27,28]. The CARE guidelines emphasize information quality independent of causality assessments. Different specialties, practitioners, and patients are likely to require extensions of the CARE guidelines with specialty specific information. We welcome discussions with groups interested in using the CARE guidelines as the basis for their specific reporting needs.

Though not mentioned in our guidelines, medical journals often require authors to address three issues: (a) potential competing interests, (b) de-identification of patient-related data, and (c) ethics committee or Institutional Review Board (IRB) approval if obtained or necessary.

Conclusions

Anticipating a long future for case reports, we have provided guidance in the form of reporting standards for use by healthcare stakeholders around the world. The growth of case reports in an era in which clinical trials and systematic reviews dominate the tables of content of medical journals indicates that case reports have value, particularly with the increasing importance of individualized care.

Unlike randomized controlled trials, case reports are individual reports related to the care of individual patients where the sample size is one. When systematically collected and combined into larger datasets, they can be analyzed, enhancing the early discovery of effectiveness and harms.

We anticipate that the analysis of systematically aggregated information from patient encounters (now mandated by some insurance plans) will provide scalable, data-driven insights into what works for which patients in real time, facilitating comparisons across medical systems and cultures. Practitioners will soon be able to provide—and in some cases they are required to provide—patients with information from their encounters. This will transform how we think about "evidence" and revolutionize its creation, diffusion, and use—opening new opportunity landscapes. When it becomes clear how new data contributes to evidence, the stewardship needed to produce high-quality data will be more rewarding and our attitude toward "observation" will shift. The CARE guidelines provide a framework to satisfy the need for precision, completeness, and transparency.

Author contributions

JG, GK, DGA, DM, HS, and DR met the ICMJE criteria for authorship. JG and DR wrote the first draft of the article. DGA, JG, GK, DM, DR, and HS critically reviewed and edited drafts. The entire CARE group participated in parts or all of the guidelines development process and contributed to the editing and revision of the CARE guidelines and this article. All authors read and approved the final manuscript.

The CARE group

1. Alyshia Allaire, BA, Portland, OR, USA
2. Douglas G. Altman, DSc, Centre for Statistics in Medicine, University of Oxford, Oxford, UK
3. Jeffrey Aronson, MB, ChB, MA Dphil, FRCP, FB, PharmacolS, University of Oxford, Oxford, UK*
4. James Carpenter, MD, Department of Orthopaedic Surgery, University of Michigan, Ann Arbor, MI, USA
5. Joel Gagnier, ND, MSc, PhD, Departments of Orthopaedic Surgery and Epidemiology, University of Michigan, Ann Arbor, MI, USA
6. Patrick Hanaway, MD, Director of Medical Education, Institute for Functional Medicine, Asheville, NC, USA*
7. Carolyn Hayes, PhD, RN, NEA-BC, Dana-Farber Brigham and Women's Cancer Center, Boston, MA, USA
8. David Jones, MD, President, Institute for Functional Medicine, Ashland, OR, USA
9. Marietta Kaszkin-Bettag, PhD, University of Frankfurt, Pharmalex GmbH, Mannheim, Germany
10. Michael Kidd, AM, MD, Editor-in-Chief *Journal of Medical Case Reports*, Faculty of Health Sciences, Flinders University, Adelaide, Australia*
11. Helmut Kiene, Dr med, Editor, *Global Advances in Health and Medicine,* Institute for Applied Epistemology and Research Methodology, University of Witten/Herdecke, Freiburg, Germany
12. Gunver Kienle, Dr med, Editor, *Global Advances in Health and Medicine,* Institute for Applied Epistemology and Research Methodology, University of Witten/Herdecke, Freiburg, Germany
13. Ben Kligler, MD, MPH, Co-Editor-in-Chief *Explore*, Beth Israel Medicine Center, New York, NY, USA*
14. Lori Knutson, RN, BSN, HN-BC, Integrative Healthcare Solutions, Minneapolis, MN, USA
15. Christian A. Koch, MD, PhD, FACP, FACE, Deputy Editor *Journal of Medical Case Reports,* University of Mississippi, Jackson, MS, USA*
16. Karen Milgate, MPP, Independent Health Policy Consultant, Washington, DC, USA*
17. Michele Mittelman, RN, MPH, Editor, *Global Advances in Health and Medicine*, Dover, MA, USA
18. David Moher, PhD, Ottawa Hospital Research Institute; Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, ON Canada*
19. Hanna Oltean, MPH, University of Michigan, Ann Arbor, MI, USA
20. Greg Plotnikoff, MD, MTS, FACP, Editor, *Global Advances in Health and Medicine,* Allina Center for Healthcare Innovations and the Penny George Institute for Health and Healing, Minneapolis, MN, USA
21. Richard Alan Rison, MD, FAANEM, Deputy Editor, *Journal of Medical Case Reports,* Section Editor, *BMC Research Notes*, PIH Health Hospital, Whittier, University of Southern California, Los Angeles, CA, USA*
22. David Riley MD, Editor-in-Chief, *Global Advances in Health and Medicine*, Portland, OR, USA
23. Anil Sethi, MS, Johns Hopkins School of Medicine - Information architecture and IT, Palo Alto, CA, USA*
24. Larissa Shamseer, MSc, Ottawa Hospital Research Institute, Ottawa, ON, Canada
25. Richard Smith, MB, ChB, MSc, United Healthcare Chronic Disease Initiative, London, UK
26. Harold Sox, MD, The Dartmouth Institute, Hannover, NH, USA
27. Peter Tugwell, MD, FRCP, University of Ottawa, Ottawa, ON, Canada

* Participated in the guidelines development process, the review and editing of the CARE guidelines and this article, but did not attend the face-to-face consensus meeting.

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Author details

[1]Department of Orthopaedic Surgery, University of Michigan, Ann Arbor, MI, USA. [2]Department of Epidemiology, School of Public Health, University of Michigan, Ann Arbor, MI, USA. [3]Institute for Applied Epistemology and Medical Methodology, University of Witten/Herdecke, Freiburg, Germany. [4]Centre for Statistics in Medicine, University of Oxford, Oxford, UK. [5]Ottawa Hospital Research Institute, Ottawa, Canada. [6]Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa, ON, Canada. [7]The Dartmouth Institute and Geisel School of Medicine at Dartmouth, Hannover, NH, USA. [8]Global Advances in Health and Medicine, Portland, OR, USA. [9]For a complete list of the CARE Group see the Author Contributions.

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CARE Checklist (2013) of information to include when writing a case report

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Topic	Item	Checklist item description	Reported on Page
Title	**1**	The words "case report" should be in the title along with what is of greatest interest in this case	
Key Words	**2**	The key elements of this case in 2 to 5 key words	
Abstract	**3a**	Introduction—What is unique about this case? What does it add to the medical literature?	
	3b	The main symptoms of the patient and the important clinical findings	
	3c	The main diagnoses, therapeutics interventions, and outcomes	
	3d	Conclusion—What are the main "take-away" lessons from this case?	
Introduction	**4**	Brief background summary of this case referencing the relevant medical literature	
Patient Information	**5a**	Demographic information (such as age, gender, ethnicity, occupation)	
	5b	Main symptoms of the patient (his or her chief complaints)	
	5c	Medical, family, and psychosocial history including co-morbidities, and relevant genetic information	
	5d	Relevant past interventions and their outcomes	
Clinical Findings	**6**	Describe the relevant physical examination (PE) findings.	
Timeline	**7**	Depict important milestones related to your diagnoses and interventions (table or figure)	
Diagnostic Assessment	**8a**	Diagnostic methods (such as PE, laboratory testing, imaging, questionnaires).	
	8b	Diagnostic challenges (such as financial, language, or cultural)	
	8c	Diagnostic reasoning including other diagnoses considered	
	8d	Prognostic characteristics (such as staging in oncology) where applicable	
Therapeutic Intervention	**9a**	Types of intervention (such as pharmacologic, surgical, preventive, self-care)	
	9b	Administration of intervention (such as dosage, strength, duration)	
	9c	Changes in intervention (with rationale)	
Follow-up and Outcomes	**10a**	Clinician-assessed outcomes and when appropriate patient-assessed outcomes.	
	10b	Important follow-up test results	
	10c	Intervention adherence and tolerability (How was this assessed?)	
	10d	Adverse and unanticipated events	
Discussion	**11a**	Discussion of the strengths and limitations in the management of this case	
	11b	Discussion of the relevant medical literature.	
	11c	The rationale for conclusions (including assessment of possible causes)	
	11d	The main "take-away" lessons of this case report	
Patient Perspective	**12**	Did the patient share his or her perspective or experience? (Include when appropriate)	
Informed Consent	**13**	Did the patient give informed consent? Please provide if requested	**Yes** ☐ **No** ☐

case reports
THE CARE GUIDELINES

CASE REPORT WRITING TEMPLATE FOR AUTHORS

Title. Include the words "case report" in the title. Describe the phenomenon of greatest interest (eg, symptom, diagnosis, diagnostic test, intervention, outcome).

Abstract. Summarize the following information if relevant: (1) Rationale for this case report, (2) Presenting concerns (eg, chief complaints or symptoms, diagnoses), (3) Interventions (eg, diagnostic, preventive, prognostic, therapeutic exchange), (3) Outcomes, and (4) Main lesson(s) from this case report.

Key Words. Provide 3 to 8 key words that will help potential readers search for and find this case report.

Introduction. Briefly summarize the background and context of this case report.

Presenting Concerns. Describe the patient characteristics (eg, relevant demographics—age, gender, ethnicity, occupation) and their presenting concern(s) with relevant details of related past interventions.

Clinical Findings. Describe: (1) the medical, family, and psychosocial history including lifestyle and genetic information; (2) pertinent co-morbidities and relevant interventions (eg, self-care, other therapies); and (3) the physical examination (PE) focused on the pertinent findings including results from testing.

Timeline. Create a timeline that includes specific dates and times (table, figure, or graphic).

Diagnostic Focus and Assessment. Provide an assessment of the (1) diagnostic methods (eg, PE, laboratory testing, imaging, questionnaires, referral); (2) diagnostic challenges (eg, financial, patient availability, cultural); (3) diagnostic reasoning including other diagnoses considered, and (4) prognostic characteristics (eg, staging) where applicable.

Therapeutic Focus and Assessment. Describe: (1) the type(s) of intervention (eg, preventive, pharmacologic, surgical, lifestyle, self-care) and (2) the administration and intensity of the intervention (eg, dosage, strength, duration, frequency).

Follow-up and Outcomes. Please describe the clinical course of this case including all follow-up visits as well as (1) intervention modification, interruption, or discontinuation, and the reasons; (2) adherence to the intervention and how this was assessed; and (3) adverse effects or unanticipated events. Please describe (1) patient-reported outcomes, (2) clinician-assessed and -reported outcomes, and (3) important positive and negative test results.

Discussion. Please describe (1) the strengths and limitations of this case report including case management, (2) the literature relevant to this case report (the scientific and clinical context), (3) the rationale for your conclusions (eg, potential causal links and generalizability), and (4) the main findings of this case report: What are the take-away messages?

Patient Perspective. The patient should share his or her experience or perspective of the care in a narrative that accompanies the case report whenever appropriate.

Informed Consent. Did the patient give the author of this case report informed consent? Provide if requested.

Case Report Submission Requirements for Authors

1. Competing interests. Are there any competing interests?

2. Ethics Approval. Did an ethics committee or Institutional Review Board give approval? If yes, please provide if requested.

3. De-Identification. Has all patient related data been de-identified?