From protocol to publication: ensuring quality in the reporting of continence research

Workshop 20

Monday, August 23rd 2010, 14:00 - 17:00

Time	Time	Topic	Speaker
14:00	14:15	Introduction	Rufus Cartwright
14:15	14:35	CONSORT and friends	Dudley Robinson
14:35	15:10	Planning and reporting observational studies	Kari Tikkinen
15:10	15:30	Pitfalls of surgical cohort studies	Chris Maher
15:30	16:00	Coffee Break	
16:00	16:15	Reporting for success in conference abstract submission	Heinz Koelbl
16:15	16:55	Small group work	
16:55	17:00	Summary and Conclusions	Kari Tikkinen

Aims of course/workshop

High quality scientific reporting is an essential research skill. This workshop brings together expert methodologists with members of the ICS and IUGA scientific committees, and members of the editorial boards of specialty journals. In dialogue with workshop participants they will consider how researchers can implement formal reporting guidance, including CONSORT for randomized studies and STROBE for cohort, cross-sectional and case control studies. In interactive sessions we will assess the importance of good reporting for success in the submission of conference abstracts and papers.

Educational Objectives

Conference presentations and peer-reviewed publications are the main reports of any research, through which the methods and findings of studies are communicated, disseminated, and archived. Poor quality scientific reporting prevents critical appraisal of research, undermines the conclusions of meta-analyses, and may lead to implementation of ineffectual or even unsafe health care interventions. Accurate, appropriate scientific reporting is clearly a key research skill, but one which is rarely formally taught. Perhaps as a consequence, there is evidence that many studies are reported poorly.

The EQUATOR Network collects and promotes evidence-based guidance for research reporting. The best known of these recommendations is the CONSORT guideline. Implementation of this guideline has been shown to effectively improve reporting of randomized controlled trials (RCTs). It has been adopted by both the ICS and IUGA Scientific Committees for abstracts reporting RCTs, and by many journals for published reports of RCTs. The more recent STROBE guidance has received less recognition, but has also been adopted by many high impact journals. It is intended for cohort, cross sectional and case-control studies, which make up the majority of abstracts submitted to ICS and IUGA. The guidance collected by the EQUATOR network now covers the whole range of clinical continence studies, and is a valuable resource for both novice and experienced researchers.

For new researchers this workshop will provide an introduction to the range of available guidance, and a chance to learn the skills required to write a winning abstract. For more experienced researchers the workshop will provide expert advice about methodological best practice and insight into how journal reviewers and editors can help ensure accurate reporting.

Major Learning Points:

1. The problems associated with poor quality reporting
2. The links between formal reporting guidance, research conduct, publication ethics and evidence based medicine
3. The range of resources available to assist with trial reporting
4. Specific advice for epidemiological studies, drug studies, and surgical trials
5. Tips and tricks to write an accurate abstract
6. Practice in assessing abstracts for reporting quality

Online Handout

From protocol to publication: ensuring quality in the reporting of continence research

Workshop 20, Monday, August 23, 2010, 14:00 - 17:00

The standards movement began in 1997 with the publication of the CONSORT Statement for reporting randomized trials. This checklist has formed a model for the development of many other reporting guidelines, which are collected and catalogued by the EQUATOR network (http://www.equator-network.org). EQUATOR is an umbrella organization for developers of reporting guidelines, medical journal editors, peer reviewers, research funding bodies, and others interested in improving the quality of research and research publications.

In this online handout we have included checklists from the 2010 CONSORT statement for randomized trials, the 2007 STROBE statement for observational studies, and the 2009 PRISMA statement for systematic reviews and meta-analyses. There are however many other guidelines that are of direct relevance to the design and reporting of continence research:

CONSORT Extensions:

1. Campbell MK, Elbourne DR, Altman DG. CONSORT statement: extension to cluster randomised trials. BMJ 2004; 328(7441):702-708

2. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJW. Reporting of noninferiority and equivalence randomized trials: An extension of the CONSORT statement. JAMA. 2006; 295:1152-1160.

3. Boutron I, Moher D, Altman DG, Schulz K, Ravaud P, for the CONSORT group. Extending the CONSORT Statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. Ann Intern Med. 2008:295-309

4. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med 2004; 141(10):781-788.

5. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, Schulz KF and the CONSORT Group (2008) CONSORT for reporting randomised trials in journal and conference abstracts. Lancet: 371:281-283.

6. 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

Diagnostic Accuracy Studies:

1. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, Lijmer JG, Moher D, Rennie D, de Vet HC. Towards complete and accurate reporting of studies of diagnostic accuracy: the STARD initiative. Standards for Reporting of Diagnostic Accuracy BMJ 2003; 326(7379):41-4

2. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al. The STARD statement for reporting studies of diagnostic accuracy: explanation and elaboration. Clin Chem 2003; 49(1):7-18

Genetic Association Studies:

1. Little J, Higgins JP, Ioannidis JP, Moher D, Gagnon F, von Elm E, et al. STrengthening the REporting of Genetic Association Studies (STREGA): An Extension of the STROBE Statement. PLoS Med 2009;6(2):e22

Qualitative Research:

1. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007 Dec;19(6):349-57

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	
	4b	Settings and locations where the data were collected	
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	
	7b	When applicable, explanation of any interim analyses and stopping guidelines	
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	
	13b	For each group, losses and exclusions after randomisation, together with reasons	
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org

. STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding
		(*b*) Describe any methods used to examine subgroups and interactions
		(*c*) Explain how missing data were addressed
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy
		(*e*) Describe any sensitivity analyses

Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time
		Case-control study—Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included
		(*b*) Report category boundaries when continuous variables were categorized
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

PRISMA 2009 Checklist

Section/topic	#	Checklist item	Page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(6): e1000097. doi:10.1371/journal.pmed1000097

Special considerations for the analysis and reporting of drug studies –

Chris Chapple

Be critical……

Let us consider OAB as a case in point

- What does the writer and the reader mean by OAB
- Medicines have consistently over-promised and under-delivered in the management of OAB
- We were promised effective drugs which patients would happily continue to take
- What we've been given is a series of disappointing compounds
- Consistently failed to deliver the efficacy or real life tolerability they promised

Do the existing results show:-

- Similar levels of efficacy across all major symptoms of OAB
- Reproducible results across trials, including head to head studies
- Efficacy results from clinical trials translating into real life practice
- Good long-term efficacy and compliance

According to the adverts

…Rapid response

…sustained effect

…High proportion of patients respond

…Well tolerated

…Long term compliance

What is the consequence of the published trial?

- Expectations are set by the data collected in trials
  - Predominantly RCTs
  - Primary or post-hoc analysis
- Are these data reflective only of the ‘fictitious mean’ patient
- Is OAB in clinical practice as it is defined in clinical trials?
- How critical of data is your readership?

In reporting a drug trial...

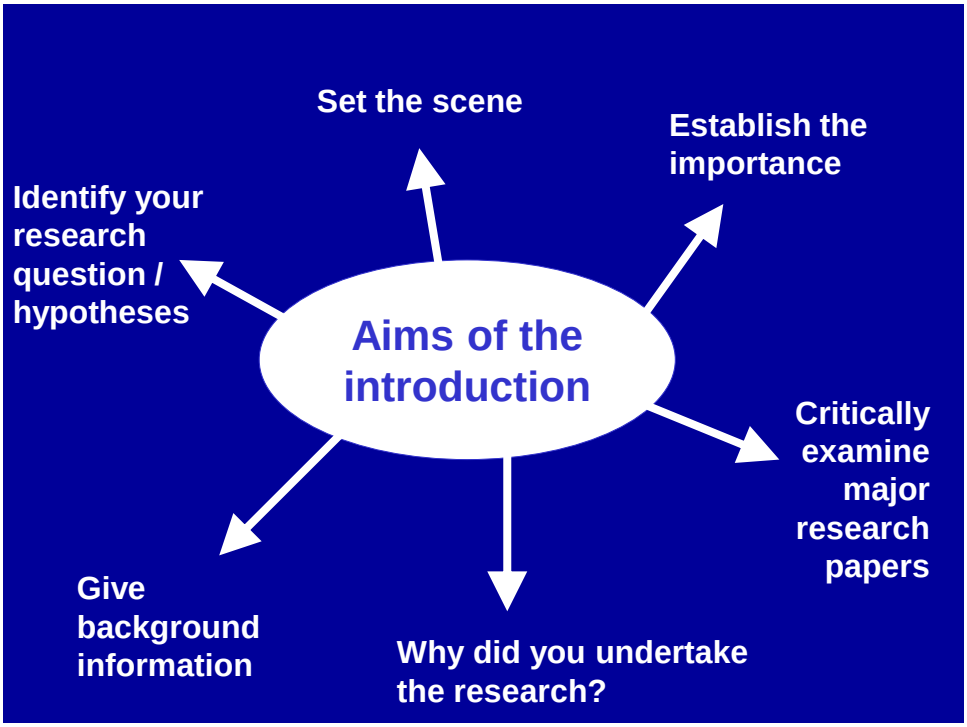
- State any Conflicts Of Interest
- Read the data carefully
- Write the paper yourself
- Acknowledge any support provided
- Avoid any commercial bias
- Bear in mind it is controversial with a whole lobby against clinicians reporting on clinical trials, they have valid opinions but their own bias

The Role of the reviewer and editor in ensuring high quality reporting

Chris Chapple

Sheffield UK

- Is your paper suitable for the journal?
- Are your conclusions justified?
- Is the article length acceptable?
- Are the data scientifically sound?
- Are the data new or original?
- Have you published the findings elsewhere?
- Has the study been conducted in an ethical fashion, ethics approval etc?
- Has any potential 'conflict of interest' been declared?



Common problems

- Fail to follow instructions to authors
- The manuscript may be appropriate for that journal - Is the chosen journal relevant for your desired target audience?
- It may be a poorly designed trial
- It may be badly written
- The conclusions are unjustified
- The grammar lets the paper down!
- Republishing data which been published elsewhere?
- Failing to explain how your study differs from others?
- Including irrelevant information?

Reporting for success in conference abstract submission

Heinz Koelbl

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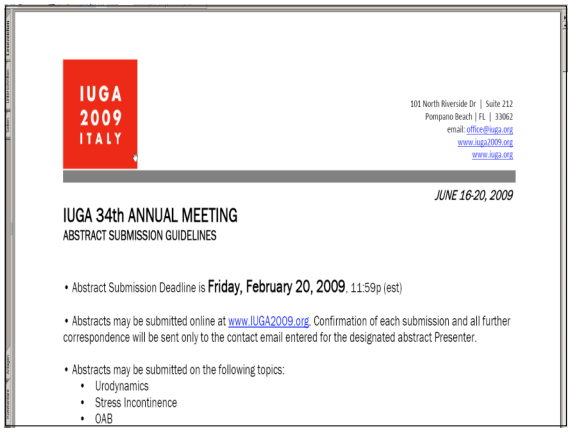
Aims of the presentation

- Recognise the importance allocated to high quality reported by the IUGA Scientific Committee
- Identify the common reporting errors that that lead to abstract rejection

My role as reviewer

- Member IUGA Scientific Committee 2003-2005
- Scientific Committee Chairman IUGA (2005-2007)
- Member ICS Scientific Committees 2007-
- Scientific Committee Chairman ICS (2008)
- Co-Editor: Neurourol/Urodyn, IUGJ,EJOGRB

Disclosures: Astellas/Pfizer Int Board Consults



IUGA 2009 ITALY

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JUNE 16-20, 2009

IUGA 34th ANNUAL MEETING
ABSTRACT SUBMISSION GUIDELINES

- Abstract Submission Deadline is **Friday, February 20, 2009**, 11:59p (est)
- Abstracts may be submitted online at www.IUGA2009.org. Confirmation of each submission and all further correspondence will be sent only to the contact email entered for the designated abstract Presenter.
- Abstracts may be submitted on the following topics:
  - Urodynamics
  - Stress Incontinence
  - OAB

Reviews
200-600 abstracts/year

- Originality
- Scientific merit
- Clinical relevance

Abstract submission

- carefully read abstract submission form
- follow all recommendation point by point
- stick to length of requested abstract
  - (n pages, words)
- avoid names, institutions
- Indicate industry support, cooperation
- Avoid multiple submissions with the same data - salami

Title

- try to attract the reviewer as much as possible
- Question
  - e.g. Does the tape procedure work in mixed urinary incontinence?
- Statement
  - The tape procedure works in mixed urinary incontinence

Methods

- use real number of pts.
- avoid salami
- mention ethical vote
- use of pt. informed consent
- clearly describe methodology

Results

- avoid two-fold presentation of results (figure and text)
- limit use of figures (max 1)
-

Conclusion

- Start with the key message first
- Do not draw false conclusion out of your results
- Do not overinterpretate your results
- Emphasize clincal relevance
- Translational relevance in case of basic research

Causes of rejection

- Names of authors, institutions within abstract text
- Topics not related to Urogynaecology
- „small abstract“

Summary

- Follow abstract submission form
- Avoid your identification within abstract text
- Indicate industry cooperation when necessary
- Attract the reviewer
  - title
  - conclusion
  - brief
  - no salami
  - appropiate conclusion