W33: ICS Core Curriculum (Free): Planning for effective and efficient clinical research and reducing the waste in incontinence research

Workshop Chair: Sakineh Hajebrahmi, Iran
15 September 2017 11:30 - 13:00

Start	End	Topic	Speakers
11:30	11:45	Introduction	Sakineh Hajebrahmi Sherif Mourad
11:45	12:05	Increasing value and reducing waste: addressing inaccessible research	Sajjad Rahnama'i
12:05	12:358	Increasing value and reducing waste in research design, conduct, and analysis	Homayoun Sadeghibazargani
12:35	12:55	Reducing waste from incomplete or unusable reports of biomedical research	Sakineh Hajebrahmi
12:55	13:00	Questions	All

Speaker Powerpoint Slides
Please note that where authorised by the speaker all PowerPoint slides presented at the workshop will be made available after the meeting via the ICS website www.ics.org/2017/programme Please do not film or photograph the slides during the workshop as this is distracting for the speakers.

Aims of Workshop
This workshop is designed to provide the audience with basic and advance knowledge of methodology and terminology for clinical and biomedical research, that explore the effective and efficient biomedical research such as research priorities setting, Increasing value and reducing waste in research design, conduct, and analysis, complete or unusable reporting of biomedical research report to increase the value .

Learning Objectives
How to increase value and reduce waste when research priorities are set
Increasing value and reducing waste in incontinence research design, conduct, and analysis
Increasing value and reducing waste: addressing inaccessible incontinence research

Learning Outcomes
After the course, the audiance will be able to aware of waste sources in biomedical research and they could direct they own researchs towards the best continence care.

Target Audience
Urologists, Gynecologists, Physiotherapists, Nurses or anyone who involves in clinical researches

Advanced/Basic
Advanced

Conditions for Learning
This is an interactive course but it is not restricted to small group.

Suggested Learning before Workshop Attendance
http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002049
Ioannidis JPA (2016) Why Most Clinical
Research Is Not Useful. PLoS Med 13(6): e1002049.
doi:10.1371/journal.pmed.1002049

Suggested Reading
1.Macleod MR, Michie S, Roberts I, Dirnagl U, Chalmers I, et al. Biomedical research: increasing value, reducing waste. Lancet. 2014; 383(9912):101–4. doi: 10.1016/S0140-6736(13)62329-6 PMID: 24411643
2. Ioannidis JP. Why most published research findings are false. PLoS Med. 2005; 2(8):e124. PMID: 16060722
3.Tunis SR, Stryer DB, Clancy CM. Practical clinical trials: increasing the value of clinical research for decision making in clinical and health policy. JAMA. 2003; 290(12):1624–32. PMID: 14506122
4. Buesching DP, Luce BR, Berger ML. The role of private industry in pragmatic comparative effectiveness

trials. J Comp Eff Res. 2012; 1(2):147–56. doi: 10.2217/cer.12.9 PMID: 24237375
5.Minelli C, Baio G. Value of information: a tool to improve research prioritization and reduce waste.
PLoS Med. 2015; 12(9):e1001882. doi: 10.1371/journal.pmed.1001882 PMID: 26418866

Other Supporting Documents, Teaching Tools, Patient Education etc

Sakineh Hajebrahimi, Sherif Mourad

Many people interested in research will go on to become authors, peer reviewers, and scientific editors of biomedical journals. However, the literature indicates that they are likely to be unprepared for any of these roles. If you're a young researcher in the health sciences, there's a high chance that you entered the field out of a strong desire to improve human health, directly or indirectly. Yet, according to a series published recently in The Lancet, biomedical research is doing a poor job of helping patients. Very little research ever reaches the bedside. One of the biggest reasons according to these series is waste. It has been estimated that in 2010, from nearly $240 billion invested in biomedical globally,85% of research which makes $200 billion- of all the money invested in biomedical research is wasted, Few biomedical researchers really consider the needs of the patients and clinicians, and some, before starting a new project; fail to systematically review what is already known. In addition, methodological problems lead to the overestimation of the under study effect and underestimation of experimental noise, poor research protocols and study design, inappropriate use and interpretation of statistics. In all types of research and in every section of a paper, Reporting problems do show up. Inadequate descriptions of studies' contexts and objectives, cherry-picking results, and failure to report how missing data were handled are all common. A fourth article looks at inaccessible research, noting that "half of health-related studies remain unreported, and few study protocols and participant-level datasets are accessible." A large part of the problem is selective publication—the non-reporting of negative or non-significant results—and the unwillingness of researchers to share datasets the authors write.
"The "Planning for effective and efficient clinical research and reducing the waste in incontinence research' workshop adopts a comprehensive, evidence -based approach to the conducting research and publication process by introducing participants to the sources of waste in biomedical research.
This workshop is designed to provide the audience with basic and advanced knowledge of methodology and terminology for clinical and biomedical research, and to explore the effective and efficient biomedical research such as research priorities setting, increasing value and reducing waste in research design, conduct and analysis. On the other hand, complete or usable reporting of biomedical research can increase the value. In addition, this workshop will be of interest to preclinical and clinical researchers engaged in research either as an investigator, author, peer reviewer, readers or users. The workshop will also appeal to anybody interested in the world of incontinence research and publication.

Homayoun S. Bazargani

At this session, we will focus to communicate with participants in order to improve their knowledge and skills on methodological considerations to improve the usefulness of clinical trials reducing the chance of producing research waste. Several methodological issues and misunderstandings will briefly be presented but considering the time restrictions, only issues of higher importance will be discussed with examples in the field of incontinence research. Following are the potential headings to be briefly explained through the workshop;
1- Selection of patients including sampling and eligibility.
2- Selection of the most appropriate outcomes from a variety of potential choices.
3- Criteria for selecting the primary, secondary and tertiary outcomes for clinical trials.
4- Use of scales for measuring the effect of the intervention and the validity of their use.
5- Subjective vs. objective measures of intervention effect.
6- The appropriate hypothesis type in clinical trials comparing the superiority, non-inferiority, equivalence and equality hypotheses.
7- Allocation concealment vs. blinding
8- Randomness of association vs. strength of association
9- Clinical significance margin and how to determine its size.
10- Randomization misunderstandings
11- Per-protocol vs. intention to treat analysis and dilemmas in intention to treat analysis approach in clinical trials.
12- Dosing selection choices in developing intervention protocol and standard treatment dosing.
Some examples of outcome measurement in the field of incontinence research that could be discussed or referred to through the presentation are as follows:
Outcome examples
- Change in Frequency of Urinary Incontinence, evaluating by valid questionnaire
- Improvement the quality of life
- change From Baseline in Closing Urethral Pressure
- The percent of the patients received unnecessary therapies
- The percent of completed but unpublished trials
- The percent of discontinued trials and reasons

Data collection instruments in completed trials

- Data collection instruments in the trials included: 3-day bladder diary, Urodynamics, Pad weight, Incontinence Quality of Life questionnaires, Incontinence Impact Questionnaire (IIQ-7), Uro-Genital Distress Index, SF-12 Health Survey, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF), International Consultation on Incontinence Modular Questionnaire Lower Urinary Tract Symptoms Quality of Life (ICIQ-LUTSqol)

Sajjad Rahnama'i

Addressing inaccessible research

We will discuss the issue of research accessibility from four various aspects

1- Factors related to the clinician or person looking for available evidence
2- Factors related to potential evidence producers
3- Factors related to the content of evidence and research to be accessible
4- Factors related to information retrieval resources including scientific databases

1: Factors related to the clinician or person looking for available evidence

a- The limitations basic computer and web use skills
b- The limitations in knowledge about the variety of available literature search resources
c- Language capabilities to access research
d- Lack of enough skill in forming an appropriate search strategy or use search engines
e- Limited access to skilled librarians and ability to transfer the clinicians need for help explained to the librarians.

2: Factors related to potential evidence producers

A: Weak intention to disseminate research findings and scientific information due to legal, social and political reasons
B: Weak intention to disseminate research findings and scientific information due to low motivation (such as in health systems)
C: Lack intention to fully disseminate research findings and scientific information due to potential conflict of interests.
D: lack of enough skill in scientific writing or language limits

3: Factors related to the content of evidence and research to be accessible

A: Quality of reporting affects full accessibility to produced research findings
B: The issue of gray literature and publication likelihood
C: Limited indexing and archiving of published research reports for various reasons.
D: Unstandardized web-publishing not using the recent advances in this field (SEO) which leads to lower likelihood of the published being discovered form among the gigantic mass of information in internet

4: Factors related to information retrieval resources including scientific databases

A: Economical limitations in access to purchasable research findings or access to commercial scientific databases that include many valuable research findings
B: The coverage rate limitation of the available literature databases
C: Technologic limitations and capabilities of search engines to ensue efficient search in literature
D: Existence of field-specific databases in incontinence science. There are such databases in other areas such as AIDS line, safety lit, etc.

Sakineh Hajebrahmi

Several avoidable reasons show that roughly 85% of healthcare research funding may be wasted, including poor research question selection, poor study design, selective non-publication and poor reporting. All actors in the research field—researchers, institutions, regulators, funders, publishers, and policy makers—have important roles in waste reduction. To reduce waste from poor reporting, many high-impact medical journals endorse and actively implement reporting guidelines that specify a minimum set of items required for a clear and transparent account of what was done and what was found in the study. For specific types of research, Over 300 reporting guidelines have so far been published. Key reporting guidelines include the CONSORT statement for randomized controlled trials, the STROBE statement for observational studies, the STARD statement for diagnostic accuracy studies, and the PRISMA statement for systematic reviews.

To improve poor reporting, it is necessary to provide more opportunities to researchers and reviewers (and even editors) to learn reporting guidelines. Which questions were addressed and why, what was done, what was shown, and what the findings mean is what adequate reports of research should clearly describe. However, substantial failures occur in each of these elements. The need to reduce waste and add value is pressing in low-income and middle-income countries. Surely, aligning their research with their public health and development needs is what such countries would benefit from. Even for clinical trials, research done in low-income and middle-income countries often pertains to diseases more relevant to wealthy nations.

Current workshop is held to talk about reporting guidelines. In addition to teach to the researchers the effectively write, publish, and disseminate research. Researchers, reviewers, and editors will benefit from participating in this workshop, which might contribute to waste reduction in research. Similar efforts should be made in entire international continence societies to provide learning opportunities for reporting guidelines.

A first step towards increasing the value and reducing research waste is monitoring the problems and develop solutions that aim to fix them. Randomized controlled trials are the gold standard tool for evaluating interventions. Nevertheless, the utility of this excellent tool is contingent on how it is used.

As real examples: out of 1088 studies in the field of urinary incontinence that were registered in ClincialTrials.gov, 881 trials were relevant to urinary incontinence interventional methods. From these, 117 studies were completed with results and 339 studies were without results. However, according to our primary search results, from pubmed.gov, 3045 clinical trial studies on human were reported. It shows that many trials are entirely lost, as they are not even registered. Moreover, most of journal editors not requested or encouraged trial registration.

Urinary incontinence is defined as involuntary loss of urine, such as leaking of urine. It is a symptom of various underlying pathological processes. Major types of incontinence include urinary urge and stress incontinence. These patients can be classified as uncomplicated or complicated.

The positive result of any screening test should be dealt with in the same way as a presenting symptom, by carefully considering its evidence based differential diagnosis.

In completed trials registered in ClincialTrials.gov, there are different definition of eligible criteria for patients with urinary incontinence: in some studies it classified as have a ≥ 3 month history of experiencing Stress Urinary Incontinence (SUI) per week (self-reported); while in another it considered as urge or stress urinary incontinence at least twice a week on average for at least 3 months. However in others it confirmed with urodynamics.

W33

Planning for:
effective and efficient clinical research and reducing the **waste in incontinence research**

Chair: Sakineh Hajebrahimi, MD, Professor of Urology , Tabriz University of Medical Sciences, Tabriz, Iran
Speakers:

Sherif Mourad, Professor of Urology, Egypt
Homayoun Sadeghibazargani, Associate professor of Epidemiology, Karolinska Institutet ,Sweden
M. Sajjad Rahnama'I, Urologist and senior Researcher from Maastricht University in the Netherlands

Sakineh Hajebrahimi,MD

Professor of Urology Department, Tabriz University of Medical Sciences,Tabriz , Iran
Iranian Research center for Evidence based Medicine
Chair, Developing world committee

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

- [*] Self-funded
- [*] Institution (non-industry) funded
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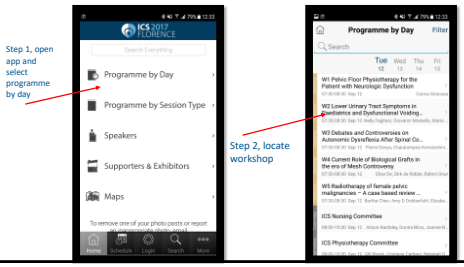
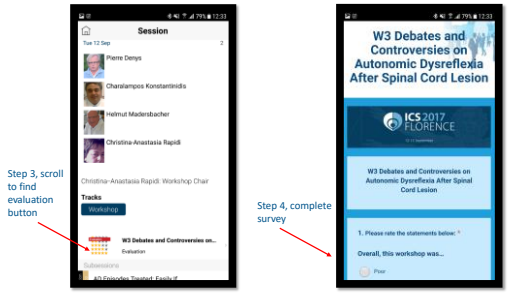
Please complete the in-app evaluation in the workshop before leaving.





- A shortened version of the handout has been provided on entrance to the hall
- A full handout for all workshops is available via the ICS website.
- Please silence all mobile phones
- Please refrain from taking video and pictures of the speakers and their slides. PDF versions of the slides (where approved) will be made available after the meeting via the ICS website.

Planning for effective and efficient clinical research and reducing the waste in incontinence research

Sakineh Hajebrahimi, MD, Professor of Urology Department

Tabriz University of Medical Sciences, Tabriz , Iran

Ice breaking!

Are you a researcher?

Are you a research results utilizer(user)?

BOTH???

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Majority of medical researched are useful and well directed?

1. TOTALLY AGREE
2. Agree
3. No comment
4. Disagree
5. Totally disagree

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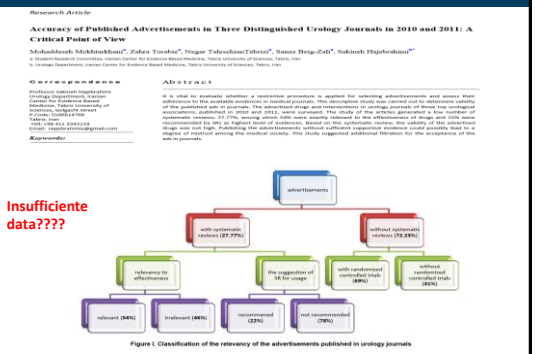

Research Article

Accuracy of Published Advertisements in Three Distinguished Urology Journals in 2010 and 2011: A Critical Point of View

Mohaddeseh Mokhtarkhani*, Zahra Torbic*, Negar TabeshimTabrizi*, Sanaz Beig-Zali*, Sakineh Hajebrahimi*

Abstract

Figure I. Classification of the relevancy of the advertisements published in urology journals

Insufficiente data????

Is it the only problem?

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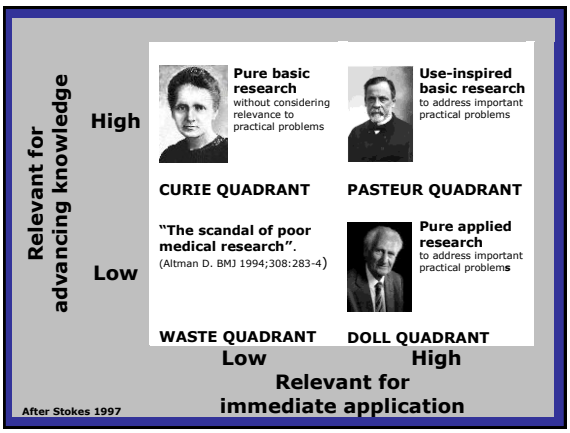
Mismatch between what clinical researchers do and what patients need

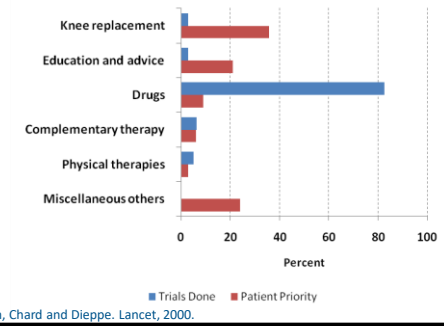


Public/charitable funding of medical research, by investment category, 2004/5 and 2009/10
(UK Clinical Research Collaboration, 2012).

Type of research (categories included)	2004/5	2009/10
Pure basic (aetiology and underpinning)	68.3	59.4
Pure applied (prevention, detection & diagnosis, treatment evaluation, disease management, health services)	21.2	27.2
Use-led basic (development of detection, diagnosis and treatment)	10.7	13.3

Promising ideas developed in basic research were not being translated into applied research; they were meeting a bottleneck in assessments of whether they could lead to advances in prevention and treatment.

Low priority questions addressed in research on treatments for osteoarthritis of the knee



Tallon, Chard and Dieppe. Lancet, 2000.

Waste in research

Questions relevant to clinicians & patients?	Unbiased and usable report?
Low priority questions addressed Important outcomes not assessed Clinicians and patients not involved in setting research agendas	Over 30% of trial interventions not sufficiently described Over 50% of planned study outcomes not reported Most new research not interpreted in the context of systematic assessment of other relevant evidence

Adopted from Lancet Series on Waste in research, with permission of Paul Glasziou

Waste at four stages of research

1 Questions relevant to clinicians & patients?	2 Appropriate design and methods?	3 Accessible full publication?	4 Unbiased and usable report?
Low priority questions addressed Important outcomes not assessed Clinicians and patients not involved in setting research agendas	Over 50% studies designed without reference to systematic reviews of existing evidence Over 50% of studies fail to take adequate steps to reduce biases, e.g. unconcealed treatment allocation	Over 50% of studies never published in full Biased under reporting of studies with disappointing results	Over 30% of trial interventions not sufficiently described Over 50% of planned study outcomes not reported Most new research not interpreted in the context of systematic assessment of other relevant evidence
50%	50%	50%	50%

85% Research waste = over $100 Billion / year

Avoidable waste in the production and reporting of research evidence

Iain Chalmers, Paul Glasziou www.thelancet.com **Published online June 15, 2009**

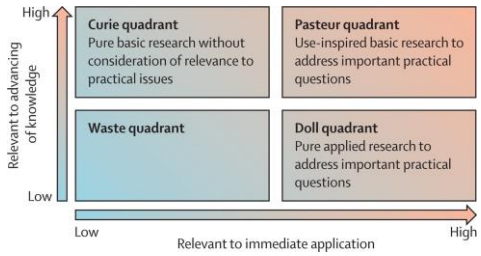
Paul Glasziou and Iain Chalmers

Questions relevant to clinicians and patients? → Appropriate design and methods? → Accessible full publication? → Unbiased and usable report?

Questions relevant to users of research?	Appropriate research design, conduct and analysis?	Efficient research regulation and delivery?	Accessible, full research reports?	Unbiased and usable reports?
High priority questions addressed Important outcomes assessed Clinicians and patients involved in setting research agendas	Studies designed with reference to systematic reviews of existing evidence Studies take adequate steps to reduce biases - e.g. unconcealed treatment allocation	Appropriate regulation of research Efficient delivery of research Good re-use of data	Studies published in full Reporting of studies with disappointing results	Trial interventions sufficiently described Reported planned study outcomes New research interpreted in the context of systematic assessment of relevant evidence

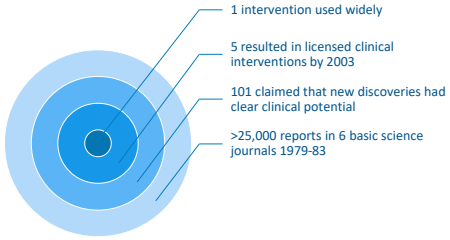
Adding Value in Research framework

1. Setting research priorities



1. Setting research priorities

The inefficiency of basic science research



Incontinence publication in Pubmed

- 39990 evidence for urinary incontinence research
  - -35580 human
  - -1820 animals,
  - -1332 SR or meta,
  - - Surgical 18123
  - **-Non surgical 1129**
  - -1764 RCT,

*119 guideline!

1. Setting research priorities

Set research in the context of systematic reviews

	May, 2009 (n=29)	May, 2012 (n=35)
Claims that clinical trial is the first to address the question	5	5
Contains an updated systematic review that was used to inform trial design	1	1
Previous systematic review* discussed that was not used in trial design	10	13
Contains references to other randomised trials	4	10
Does not contain references to other randomised trials or claim to be the first trial	9	6

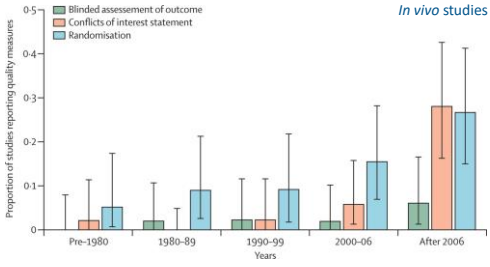
Analysis of reports published in *The Lancet*, *New England Journal of Medicine*, *British Medical Journal*, *Journal of the American Medical Association*, and *Annals of Internal Medicine*.[54] *Systematic review in the topic area of the trial cited.

Table 2: Analysis of Introduction sections of reports of controlled trials published in five medical journals in May, 2009, and May, 2012

From 16 almost 2 refferd the SR.
Unclear and different out comes and measurements
Referenced the previous RCT in half of Medical intervention in OAB

2. Design, conduct and analysis

High effect-to-bias ratio



3. Regulation and management

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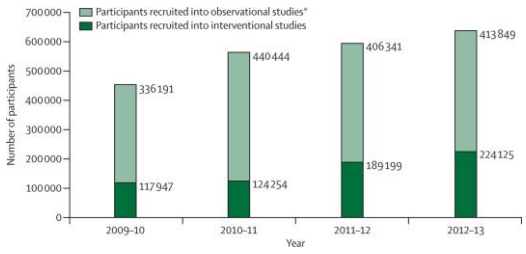
Better recruitment after UK clinical research networks



4. Accessible reporting

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Proportion of funded/completed research that is reported

50%

4. Accessible reporting

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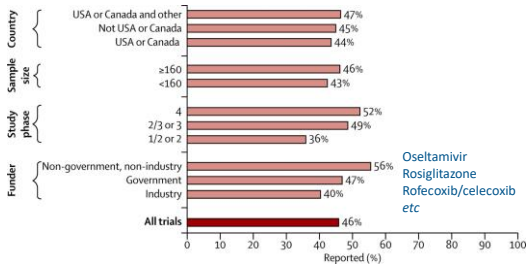
Associations with reporting



Oseltamivir
Rosiglitazone
Rofecoxib/celecoxib
etc

About 7% permanent loss / year

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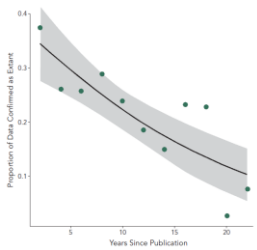
Of 516 papers that conducted a discriminant function analysis (DFA) on morphological data from plants, animals, or other organisms

For 2011, 37% data available

For 2001, 18%

For 1991, 7%



Vines TH, et al. **The Availability of Research Data Declines Rapidly with Article Age.** Current Biology, 2013. Online 19 Dec 2013

5. Complete & usable reporting

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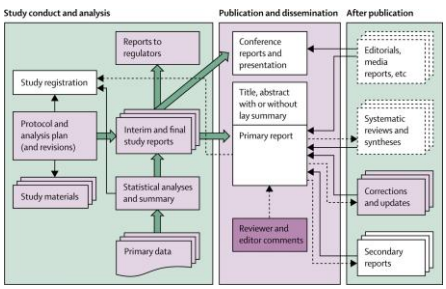

Poor reporting in publications: range of 24% to 89% "missing"

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Abstract
38%, 49%

Methods
40-89%, 33%
65%, 31%

Results
50%, 65%,
54%, 92%,
24%, 40%

Discussion
50%

Data
Almost all

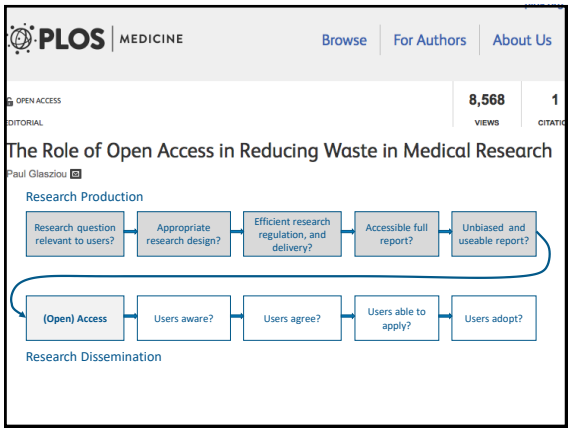
Abstract
Trials: missing effect size and confidence interval (38%); no mention of adverse effects (49%)[72]

Methods
Trials: 40–89% inadequate treatment descriptions[11,13]
fMRI studies: 33% missing number of trials and durations[3]
Survey questions: 65% missing survey or core questions[75]
Figures: 31% graphs ambiguous[45]

Results
Clinical trials: outcomes missing: 50% efficacy and 65% harm outcomes per trial incompletely reported[8]
Animal studies: number of animals and raw data missing[17] (54%, 92%); age and weight missing (24%)
Diagnostic studies: missing age and sex (40%)[35]

Discussion
Trials: no systematic attempt to set new results in context of previous trials (50%)[69]

Data
Trials: most data never made available; author-held data lost at about 7% per year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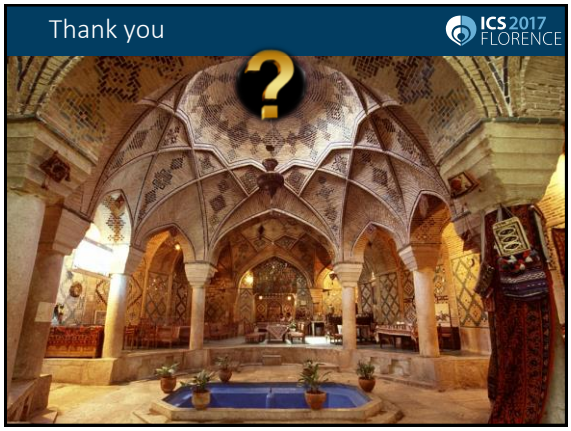
VIEWS
1
The Role of Open Access in Reducing Waste in Medical Research
Paul Glasziou
Research Production
Research question relevant to users?
Appropriate research design?
Efficient research regulation, and delivery?
Accessible full report?
Unbiased and useable report?
(Open) Access
Users aware?
Users agree?
Users able to apply?
Users adopt?
Research Dissemination


Thank you
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Maastricht University Medical Centre , The Netherlands

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Addressing Inaccessible Research

Sajjad Rahnama'i, MD. PhD. FEBU.

WIKI Quiz
Dr. M.S. Rahnama'i
@ Dr_SRah

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Affiliations to disclose†:

Research grant from Astellas
Travel grant by Ferring
Travel grant by Zambon
Travel grant by Pohl-Boskamp

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- ☐ Self-funded
- ☒ Institution (non-industry) funded
- ☐ Sponsored by:

What is inaccessible research?

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Research data that are not published.
Research data that are only partly published.
Research data that are hard or impossible to access.

Alessandro Liberati

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Italian healthcare researcher and clinical epidemiologist

Founder of the italian Cochrane Centre.

(1954 –2012)

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In 2010, *Alessandro Liberati* explained the difficulties he encountered when he had to make decisions about his treatment for multiple myeloma:

"When I had to decide whether to have a second bone-marrow transplant, I found there were 4 trials that might have answered my questions, but I was forced to make my decision without knowing the results because, although the trials had been completed some time before, they had not been properly published…."

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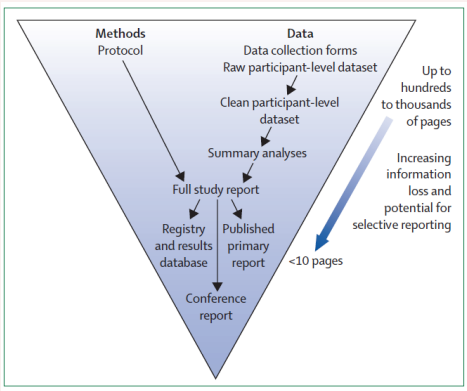
He believed that within a health system, **research should be an integral part of its mission**, especially where **lack of commercial interests** prevents the possibility of private investment,

Researchers should concentrate on what is **relevant to patients, not to their careers or to drug companies**.

Moreover, he strongly believed that developing alliances with consumers is necessary for setting research priorities, and that **research results should be easily accessible to people who need to make decisions about their own health**.

Alessandro Liberati

" I believe that research results must be seen as a public good that belongs to the community; especially patients."

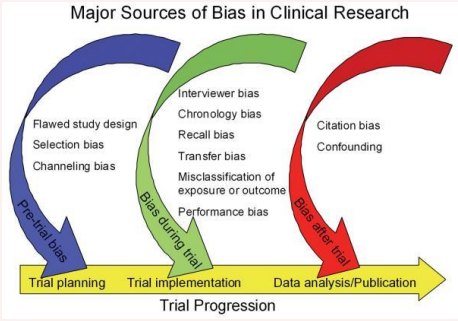


BIAS

Defined as any tendency which prevents unprejudiced consideration of a question.

In research, bias occurs when "systematic error [is] introduced into sampling or testing by selecting or encouraging one outcome or answer over others"

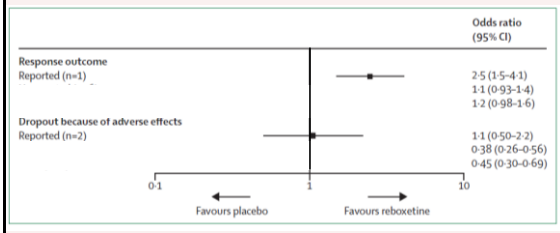
Bias can occur at any phase of research, including study design or data collection, as well as in the process of data analysis and publication.

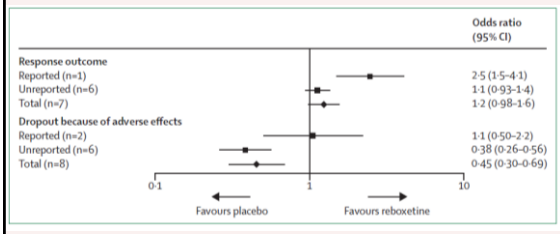


Scientific literature represents an <u>incomplete</u> and <u>biased</u> subset of research findings.

For example,
when <u>unreported trials</u> were included in a meta-analysis, **Reboxetine** was shown to be <u>more harmful</u> & <u>no more efficacious</u> than placebo for treatment of major depression

—a different finding from that when only reported trials were included !





Rosiglitazone

- **Not reported part of data:**

Unfavourable trials and sponsor's meta-analysis not reported
Increased risk of myocardial infarction confirmed by independent meta-analysis of 56 rosiglitazone trials, which included **36 unreported** trials for which data were obtained from the sponsor's trial Registry

- **Effects**

Number needed to harm of 37–52 for 5 years translates into 6000–8000 additional myocardial infarctions in 325 000 patients taking rosiglitazone in the USA and UK in 2010

About 83 000 additional myocardial infarctions potentially attributable to rosiglitazone in the USA from 1999 to 2006

Celecoxib

- **Selective reporting**

Only favourable 6-month harms data in trial report, with suppression of unfavourable 12–15-month data that no longer showed benefit for reduction of gastrointestinal ulcers. Discrepant reporting of cardiovascular mortality data between regulatory report and two published reports of the same trial

- **Effects**

In 2004, 600 000 users in the UK and more than 14 million prescriptions fi lled in the USA for an expensive drug with questionable benefi t rather than cheaper alternatives

Ezetimibe–Simvastatin

- Delayed reporting

Report of randomised trial showing no benefit of Ezetimibe–Simvastatin vs simvastatin alone delayed by 2 years!

Selective reporting of positive preclinical or observational research

Reported results of only 11–25% of promising preclinical studies can be independently replicated for drug development.

Clinical trials often do not confirm the benefit shown in previous reports of animal or clinical studies.

Inaccessible research can lead to redundant, misguided, or potentially harmful research assessing similar interventions.

Grey Literature

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Grey Literature

Defined as materials and research produced by organisations outside of the traditional commercial or academic channels.

e.g.

Reports, government documents, evaluations etc

Acces

Even when studies are reported, access to research reports is restricted.

Journal subscriptions are **costly**, particularly in low-income settings, but even for leading private academic institutions.

Although the number of open-access reports has been increasing,

But still, access to 78% of reported medical research was restricted to journal subscribers in 2009.

Language barriers

Most high profile scientific journals are published in English, but much of the scientific literature is in other languages.

More than 2500 biomedical journals are published in Chinese, fewer than 6% of which are indexed in Medline.

Publications in languages other than English are **often excluded** from **systematic reviews** because of inaccessibility or limited resources for translation and searching.

http://sci-hub.bz/

Conclusions

Majority of information on health research is inaccessible

Impact on science, policy, patient care

Action needed from key stakeholders
Incentives
Standards
Adherence mechanisms

Maastricht University Medical Centre , The Netherlands

Addressing Inaccessible Research

Sajjad Rahnama'i, MD. PhD. FEBU.

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INCREASING VALUE AND REDUCING WASTE IN RESEARCH DESIGN, CONDUCT, AND ANALYSIS

Homayoun Sadeghi-Bazargani MD, PhD

Clinical Epidemiologist

WHO Collaboration Center on Community Safety Promotion, PHS Department, Karolinska Institute, Sweden

Swedish Science Pioneers, Stockholm, Sweden

Clinical effectiveness department, Iranian center for evidence based medicine, Tabriz, Iran

Lecture sponsored by: ICS

Homayoun Sadeghi-Bazargani MD, PhD

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Affiliations to disclose†:

WHO Collaboration Center on Community Safety Promotion, PHS Department, Karolinska Institute, Sweden

Swedish Science Pioneers, Stockholm, Sweden

Clinical effectiveness department, Iranian center for evidence based medicine, Tabriz, Iran

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

Funding for speaker to attend:

- ☐ Self-funded
- ☐ Institution (non-industry) funded
- ☒ Sponsored by: *ICS*

Waste at four stages of research

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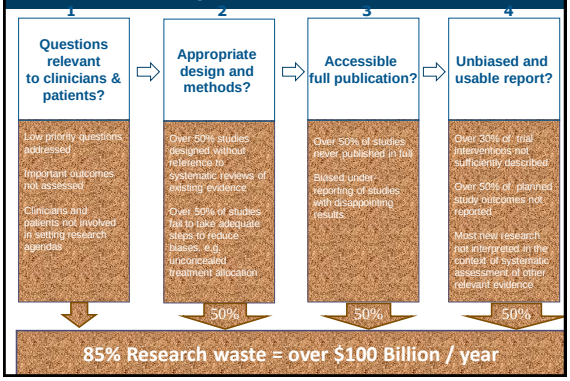

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Relevant reproducible protocol

Relevant and valid outcome

Relevant reproducible intervention protocol

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Think of details and provide them in your research protocol before your study

Consider variabilities regarding intervention implementers i.e. experience of surgeons, educators,

Consider variabilities in materials used in intervention such as producer, drug forms, ….

Consider variabilities in timing

Take care of dose variabilities for efficacy

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Solifenacin : 5-10mg **Tolterodine:2-4 mg**

Study A: Solifenacin 10 mg vs. Tolterodine 2 mg

Study B: Solifenacin 5 mg vs. Tolterodine 4 mg

Outcome

It should be :

Well defined

Unbiased

Stable

Reproducible

Valid and reliable scales for subjective outcomes

Ascertainable in all participants

Adequately address study hypothesis

Are you annoyed with your incontinence?

1- Yes 2-No

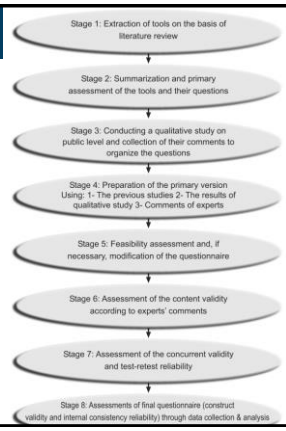
Treatment with Drug A was more effective than Drug B(P<0.05)

Scale development

Do not just put few questions based on your own experience and start your clinical trial.

Measuring is science itself!

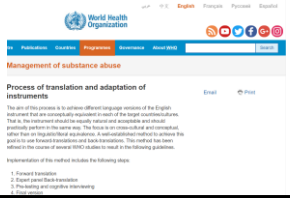
Follow the standards of scale development if you need a new one.



Translation or adaptation

I have done my fellowship on incontinence in US and my English is good. I will translate it and use it in my clinical trial.

There are standards for translation and adaptation of scales. Follow them or ask someone to do it before starting your clinical trial.



You may have even higher chance for publishing your scale translation than to publish your clinical trial!

Measure, analyze and report both on safety and effect.

Measuring only the efficacy not thinking of safety may lead to waste

Do we have to think of safety at all the 4 clinical trial phases?

Statistical power and sample size

Ethics of inappropriately small or large sample sizes

Compensation by systematic reviews?

Watch your conclusion especially for insignificant results

Solifenacin and tolterodine are equally effective in the treatment of overactive bladder symptoms.

At week 12, solifenacin and tolterodine demonstrated equal efficacy in reducing the number of micturition (–2.56 ± 3.31 vs. –2.44 ± 4.56, p = 0.58),

urgency (–1.70 ± 3.07 vs. –1.15 ± 2.68, p = 0.37) and

incontinence (–2.79 ± 2.82 vs. –4.67 ± 9.29, p = 0.28) episodes per 24 hours.

Statistical power: ???

The highest power(but not adequate) belonged to constipation/ 12.8% in Sol. 2.8% in Tol.

The major limitation of the present study, in comparison with previous studies in western countries, was the relatively small patient number. This could have decreased the power for detecting a difference between the two medications. However, the present study is still valuable in providing experience in the use of both drugs in a Taiwanese population, which has been rarely reported before. Another limitation was that only a few patients recorded their voids at bedtime. Therefore, the effects on reducing nocturia could not be analyzed.

Conclusion: Both solifenacin and tolterodine are effective in treating key OAB symptoms, including urinary frequency, urgency and incontinence in the Taiwanese population. Both medications are comparably effective and safe, with the most common adverse effects being dry mouth and constipation.

If I was the author: We cant conclude. Others should do it using our results in metaanlysis.

Types of hypotheses?

High effect-to-bias ratio

Think of clinical trial biases before starting your study

High effect-to-harm assessment/reporting ratio

Comparing Treatments

- **Fundamental principle**
  - **Groups must be alike in all important aspects that may have an effect on continence symptoms or development of unwanted conditions**
  - **Only differ in the intervention each group receives**
  - **In practical terms, "comparable treatment groups" means "alike on the average"**
- **Randomization**
  - **Each participant has the same chance of receiving any of the interventions under study**
  - **Allocation is carried out using a chance mechanism so that neither the participant nor the investigator will know in advance which will be assigned**
- **Blinding**
  - **Avoidance of conscious or subconscious influence**
  - **Fair evaluation of outcomes**

A **bias** is a systematic error, or deviation from the truth, in results or inferences.

Different biases can lead to underestimation or overestimation of the true intervention effect.

Biases can vary in magnitude

Selection bias

Selection bias refers to systematic differences between baseline characteristics of the groups that are compared.

The unique strength of randomization is that, if successfully accomplished, it prevents selection bias in allocating interventions to participants.

Randomization is a process through which study subjects are assigned to different trial interventions or treatments only by chance.

Random sequence generation

A, B,A, A,B,A,B,B

1,2,3,4,5,6,7,8

Allocation sequence concealment

Allocation implementation

RANDOM SEQUENCE GENERATION

'Low risk' of bias

Referring to a random number table;

Using a computer random number generator;

Coin tossing;

Shuffling cards or envelopes;

Throwing dice;

Drawing of lots;

Minimization.

RANDOM SEQUENCE GENERATION

'High risk' of bias

The investigators describe a non-random component in the sequence generation process. for example:

Sequence generated by odd or even date of birth;

Sequence generated by some rule based on date (or day) of admission;

Sequence generated by some rule based on hospital or clinic record number.

Allocation by judgement of the clinician;

Allocation by preference of the participant;

Allocation based on the results of a laboratory test or a series of tests;

Allocation by availability of the intervention

Allocation sequence concealment

'Low risk' of bias

Participants and investigators enrolling participants could not foresee assignment

Central allocation (including telephone, web-based and pharmacy-controlled randomization);

Sequentially numbered drug containers of identical appearance;

Sequentially numbered, opaque, sealed envelopes.

Allocation sequence concealment

'High risk' of bias

Using an open random allocation schedule (e.g. a list of random numbers);

Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered);

Alternation or rotation;

Date of birth;

Case record number;

Any other explicitly unconcealed procedure

Performance bias

Performance bias refers to systematic differences between groups in the care that is provided, or in exposure to factors other than the interventions of interest.

After enrolment into the study, **blinding** (or masking) **of study participants and personnel** may reduce the risk that knowledge of which intervention was received, rather than the intervention itself, affects outcomes.

Placebo example

BLINDING OF PARTICIPANTS AND PERSONNEL

'Low risk'

Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.

No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding;

BLINDING OF PARTICIPANTS AND PERSONNEL

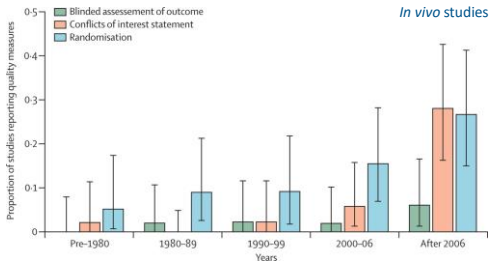
'High risk'

No blinding or incomplete blinding, but the review authors judge that the outcome is likely to be influenced by lack of blinding;

Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.

Detection bias

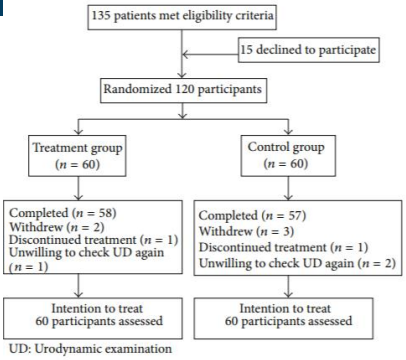
Detection bias refers to systematic differences between groups in how outcomes are determined. Blinding (or masking) of outcome assessors may reduce the risk that knowledge of which intervention was received, rather than the intervention itself, affects outcome **measurement**. Blinding of outcome assessors can be especially important for assessment of subjective outcomes, such as degree of postoperative pain.



Attrition bias

Attrition refers to situations in which outcome data are not available.

Attrition bias refers to systematic **differences** between groups in withdrawals from a study. Withdrawals from the study lead to incomplete outcome data.



INCOMPLETE OUTCOME DATA

Low risk

No missing outcome data;

Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias);

Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups;

For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate;

For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size;

Missing data have been imputed using appropriate methods.

INCOMPLETE OUTCOME DATA

High risk

Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups;

For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate;

For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size;

'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization;

Potentially inappropriate application of simple imputation.

Reporting bias

Reporting bias refers to systematic differences between reported and unreported findings.

Within a published report those analyses with **statistically significant** differences between intervention groups are more likely to be reported than non-significant differences.

This sort of 'within-study publication bias' is usually known as outcome reporting bias or selective reporting bias, and may be one of the most substantial biases affecting results from individual studies

Danger of overvaluing p values. Effect size

Danger of multiple p values not corrected for multiple test

Association of the Gene X expression with incontinence- a microarray study

One reason for the need to define primary outcome

There are other reasons either: Apriori-ness, Design tailoring

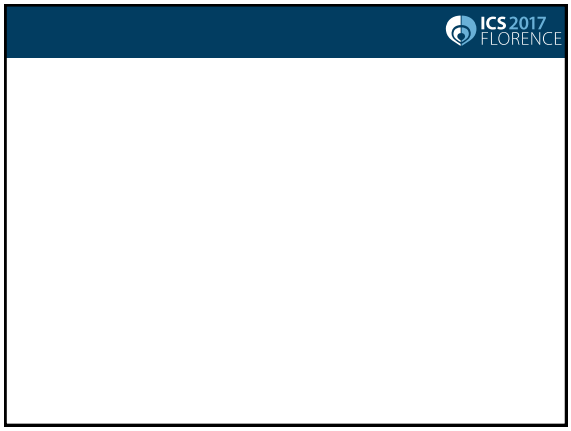
Thanks for your attention

Thanks to ICS

Any questions?

Ask now or send me an email

homayoun.sadeghi@swedensp.se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W33

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Planning for:

effective and efficient clinical research and reducing the **waste in incontinence research, good reporting**

Sakineh Hajebrahimi, MD, Professor of Urology , Tabriz University of Medical Sciences, Tabriz, Iran

Sakineh Hajebrahimi,MD

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Professor of Urology Department, Tabriz University of Medical Sciences,Tabriz , Iran

Iranian Research center for Evidence based Medicine

Chair, Developing world committee

† All financial ties (over the last year) that you may have with any business organisation with respect to the subjects mentioned during your presentation

- [*] Self-funded
- [*] Institution (non-industry) funded
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Research article

A Survey on the Amount of Adherence to STARD and CONSORT Standards in the Abstracts of Diagnostic Accuracy Studies and Randomized Controlled Trials Published in International Continence Society Abstract Book 2011

Kaura Kolahdouzan[a], Neda Madani [b], Neda Parniyanfard [c], Hadi Mostafaie[a], Kimia Madanlou[a], Arian Pourmalek[a], Morteza Ghojazadeh[b], Sakineh Hajebrahimi [a]

a: Students Research Committee, Iranian Center For Evidence Based Medicine, Tabriz University of Medical Sciences
b: Medical Education Research Center, Tabriz University of Medical Sciences
c: Iranian Center for EBM, Tabriz University of Medical Sciences

Correspondence

Professor Sakineh Hajebrahimi
Iranian Center for Evidence Based Medicine, Faculty of Medicine
Tabriz University of Medical Sciences
Tabriz, Iran
Tel: +984113342219
E-mail: hajebrahimis@gmail.com

Keywords:
International continence society
CONSORT
STARD

Abstract

Purpose: To assess reporting quality of Randomized Controlled Trials (RCTs) and Diagnostic Accuracy Studies (DASs) published in International Continence Society (ICS) abstract book 2011.

Methods: Reports of RCTs and DASs published in ICS abstract book 2011 were identified. The proportion of adherence to each item in the Consolidated Standards of Reporting Trials (CONSORT) and Standards for the Reporting of Diagnostic accuracy studies (STARD) checklists was evaluated for each article (abstract by two independent reviewers marked to each other's results giving one point to each item of the used checklists only if it was clearly defined in the abstract.

Results: Out of 287 articles, 67 articles matched our inclusion criteria (37 RCTs and 30 DASs). The mean scores were 10.70 and 15.03 out of 17 and 25, respectively. The highest scored items were items 5 and 15 (INTERVENTION and CONCLUSION) in the CONSORT group (both being reported in 97.3% of articles). In the STARD group, items 2, 3, and 25 (INTRODUCTION, PARTICIPANTS/POPULATION and DISCUSSION) were fully reported. the lowest scored items were item 2 (AUTHORS) in the consort group and item 11 (TEST METHODS/BLINDING) in the diagnostic accuracy group reported in 0% and 13.3% of articles respectively.

Conclusion: Our study revealed that the adherence level is moderate in both groups. In a high ranking society like ICS, we do believe that adopting these two tools would improve the reporting quality.

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Research article

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Table1: Analysis of Adherence of RCTs to CONSORT Checklist

Items	yes		no		unclear		PV
	number	percent	number	percent	number	percent	
Title	21	56.8	16	43.2	0	0	NS
Authors	0	0	37	100	0	0	NS
Trial Design	13	35.1	24	64.9	0	0	NS
Methods							
Participant	21	56.8	10	27.0	6	16.2	0.008
Intervention	36	97.3	1	2.7	0	0	0.00
Objective	32	86.5	4	10.8	1	2.7	0.00
Outcome	22	59.5	14	37.8	1	2.7	0.00
Randomization	27	73.0	10	27.0	0	0	0.005
Blinding	11	29.7	26	70.3	0	0	0.014
Results							
Numbers	21	56.8	16	43.2	0	0	NS
Recruitment	24	64.9	12	32.4	1	2.7	0.00
Numbers	27	73.0	9	24.3	1	2.7	0.00
Outcome	11	29.8	24	64.9	2	5.4	0.00
Harms	18	48.6	13	35.1	6	16.2	0.05
Conclusion	36	97.3	1	2.7	0	0	0.00
Registration	28	75.7	9	24.3	0	0	0.002
Funding	30	81.1	7	18.9	0	0	0.00

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Research article

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Table 2: Analysis of adherence of Diagnostic Accuracy Studies to STARD Checklist

items	yes		no		unclear		PV
	number	percent	number	percent	number	percent	
1.Title/Abstract/ Key Words	27	90	3	10	0	0	0.000
2.Introduction	30	100	0	0	0	0	0.000
Methods							
3.Participants/Population	30	100	0	0	0	0	0.000
4.Participants/Recruitment	26	86.7	4	13.3	0	0	0.000
5.Participants/Sampling	13	43.3	17	56.7	0	0	NS
6.Participants/Data Collection	23	76.7	1	3.3	6	20	0.000
7.Test Methods/Reference Standard	20	66.7	10	33.3	0	0	0.001
8. Test Methods/Technical Specification…	29	96.7	1	3.3	0	0	0.00
9. Test Methods/Unit Definition…	19	63.3	10	33.3	1	3.3	0.001
10. Test Methods/Executive Number, Training…	5	16.7	25	83.3	0	0	0.000
11. Test Methods/Blinding	4	13.3	26	86.7	0	0	0.001
12. Statistical Methods/Calculating Diagnostic Accuracy…	18	60	11	36.7	1	3.3	NS
13. Statistical Methods/Test Reproducibility	13	43.3	9	30	8	26.7	NS
Results							
14.Participants/Recruitment Beginning And End Dates	9	30	21	70	0	0	0.000
15. Participants/Clinical Characteristics…	29	96.7	0	0	1	3.3	0.000
16. Participants/The Number Of Satisfying…	14	46.7	14	46.7	2	6.7	NS
17.Test Results/Time Interval	5	16.7	23	76.7	2	6.7	0.001
18. Test Results/Disease Severity Distribution	23	76.7	4	13.3	3	10	0.000
19. Test Results/Cross Tab…	12	40	18	60	0	0	NS
20. Test Results/Adverse Events…	16	53.3	11	36.7	3	10	NS
21.Estimates/Diagnostic Accuracy Estimates	19	63.3	11	36.7	0	0	0.001
22. Estimates/Handling Missing Results	11	36.7	13	43.3	6	20	NS
23. Estimates/Variability Estimates	14	46.7	13	43.3	3	10	NS
24. Estimates/Test Reproducibility	11	36.7	9	30	10	33.3	NS
25.Discussion	30	100	0	0	0	0	0.000

Research: increasing value, reducing waste 5

Reducing waste from incomplete or unusable reports of biomedical research

Paul Glasziou, Douglas G Altman, Patrick Bossuyt, Isabelle Boutron, Mike Clarke, Steven Julious, Susan Michie, David Moher, Elizabeth Wager
GP, statisticians, clinical epidemiologists, systematic reviewer, psychologist, medical writer

Good Reporting of Clinical Trials

Austin Bradford Hill, 1965

Four questions to which readers want answers when reading reports of research.

1. Why did you start?
2. **What did you do?**
3. What answer did you get?
4. And what does it mean anyway?

Unbiased and usable reports?

Trial interventions sufficiently described

Reported planned study outcomes

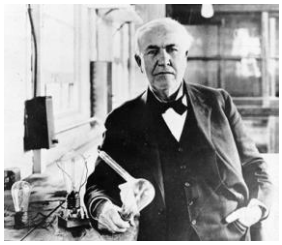
New research interpreted in the context of systematic assessment of relevant evidence

Adding Value in Research framework

Unavoidable "waste" in research

"Young man, why would I feel like a failure? And why would I ever give up?
I now know definitively over 2,000 ways that an electric light bulb will not work. Success is almost in my grasp."

Thomas Edison



Avoidable waste =
no or inadequate records of what has failed.

Details of fMRI methods in 241 studies

Research Digest
Blogging on brain and behaviour

Most brain imaging papers fail to provide enough methodological detail to allow replication

Comments on News Item

Q1: "… would make the paper quite inaccessible if every detail were published"

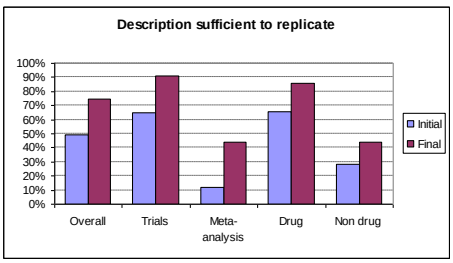
A: use a "supplementary information" system, posted online

Q2: "… contacting the author directly would provide a lot of the necessary information"

A: "I've gotten about a 10% response rate. Sometimes the authors of studies have died or moved out of the field and the **information is lost forever**."

Carp J. **The secret lives of experiments:** Methods reporting in the fMRI literature. *NeuroImage, 2012, 63* (1), 289-300

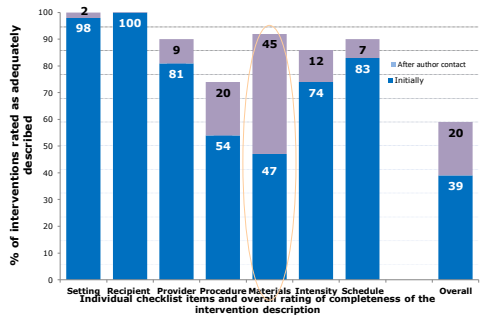
Adequacy of treatment descriptions in 80



Glasziou et al BMJ, 2008

Many problems are fixable

Checklist **initially** and **after** author contact



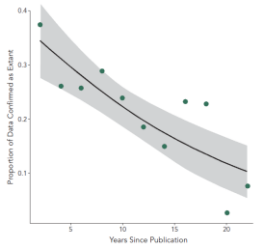
About 7% permanent loss / year

Of 516 papers on morphological data from plants, animals, or other organisms

For 2011, 37% data available

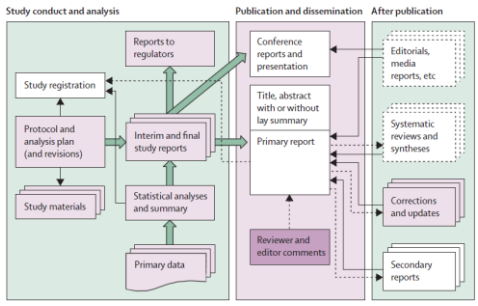
For 2001, 18%

For 1991, 7%



Vines TH, et al. **The Availability of Research Data Declines Rapidly with Article Age.** Current Biology, 2013. Online 19 Dec 2013

Reporting = paper + protocol + materials + data + … + links

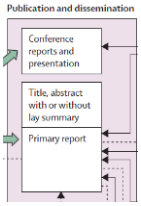


Reporting = paper + protocol + materials + data + … + links

Austin Bradford Hill, 1965

Four questions to which readers want answers when reading reports of research.

1. Why did you start?
2. **What did you do?**
3. What answer did you get?
4. And what does it mean anyway?



Poor reporting in publications: range of 24% to 89% "missing"

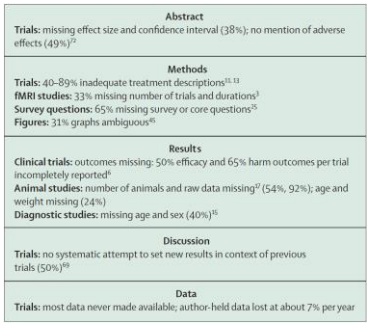
Abstract
38%, 49%

Methods
40-89%, 33%
65%, 31%

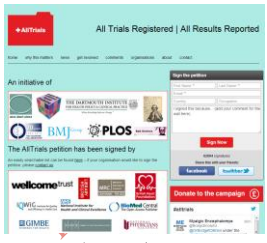
Results
50%, 65%,
54%, 92%,
24%, 40%

Discussion
50%

Data
Almost all



All trials registered
All results reported

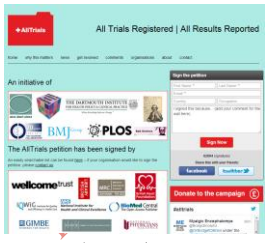


House of Commons
Committee of Public Accounts

Access to clinical trial information and the stockpiling of Tamiflu

Recommendation: *The Department and the MHRA should ensure, both prospectively and retrospectively, that clinical trials are registered on an appropriate registry and that the full methods and results of all trials should be available for wider independent scrutiny, beyond the work undertaken by regulators during the licensing process.*

All results methods & materials



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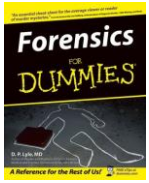
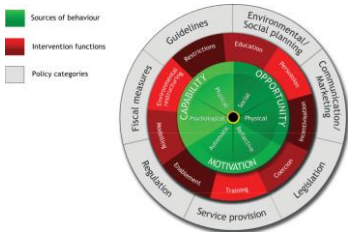
Our Recommendations

Motive
Means
Opportunity

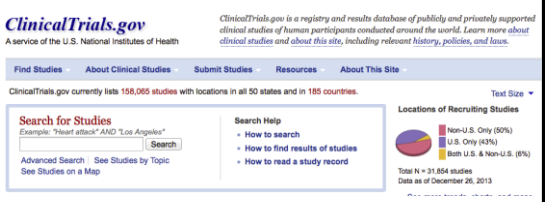




Michie et al. Implementation Science 2011, 6:42

Recommendation 2: Infrastructure

Research funders should take responsibility for reporting infrastructure that supports good reporting and archiving



In the future: "Whether the full protocol should be submitted .."

3085 incontinence research proposals that registered in clinical trial.gov:

- Complete 387(with out without submission of results
- Recruiting; 123
- Enrolment by invitation 13
- Suspended;1
- Active not recruiting 31
- terminated 43
- Withdrawn 78
- Unknown???????

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Recommendation 3: Capacity

Funders, institutions, and publishers should improve the capability and capacity of authors and reviewers in high-quality and complete reporting

INTERNATIONAL STANDARDS FOR CLINICAL RESEARCH

International, explicit, rules-based methods exist for all aspects of clinical trial implementation & reporting

STANDARDS include:

hypothesis formulation
literature searching, literature review
ethical review
trial planning, trial conduct
trial reporting
systematic review
meta-analysis

International standards for clinical research

AGREE STATEMENT www.agreecollaboration.org/
Clinical practice guidelines assessment

ASSERT STATEMENT www.assert-statement.org/
Ethical review of clinical trial proposals and monitoring Randomized controlled trial conduct and reporting

COCHRANE COLLABORATION www.cochrane.org
Systematic reviews of randomized controlled clinical trials

NICE STATEMENT www.nice.org.uk
Technology appraisal of clinical guidelines National Institute for Clinical Excellence

QUOROM – CONSORT STATEMENT www.consort-statement.org/QUOROM.pdf
Meta analysis of randomized controlled trials conduct and reporting

INTERNATIONAL STANDARDS FOR CLINICAL RESEARCH

CDISC http://www.cdisc.org
CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

DUET STATEMENT www.duets.nhs.uk
The Database of Uncertainties about the Effects of Treatments

MOOSE – CONSORT STATEMENT
www.consort-statement.org/MOOSE.pdf
Meta analysis of observational trials conduct and reporting

International standards for clinical research

SDTM: STANDARDS-BASED CLINICAL TRIAL DATA MANAGEMENT (based on CDISC)

STARD - CONSORT STATEMENT
www.consort-statement.org/stardstatement.htm
DIAGNOSTIC TRIALS CONDUCT & REPORTING

STROBE STATEMENT http://www.strobe-statement.org/
STrengthening the Reporting of OBservational studies in Epidemiology

TREND STATEMENT http://www.trend-statement.org/
Transparent Reporting of Evaluations with Nonrandomized Designs improves the reporting standards of nonrandomized evaluations of behavioral and public health interventions

The Recommendations

1. Funders and research institutions must shift the research regulations & rewards to align with better & more complete reporting
2. Research funders should take responsibility for reporting infrastructure that supports good reporting and archiving
3. Funders, institutions, and publishers should improve the capability and capacity of authors and reviewers in high-quality and complete reporting

Thank you