

8<sup>th</sup> International Conference for EBHC Teachers and Developers

### The ecosystem of evidence

Connecting generation, synthesis and translation

Taormina, 25<sup>th</sup> – 28<sup>th</sup> October 2017

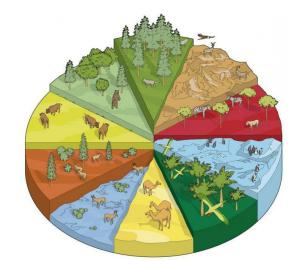
# The ecosystem of evidence: the way forward

Nino Cartabellotta
GIMBE Foundation



### **Ecosystem**

A community of **living organisms** in conjunction with the **nonliving components** of their **environment** (air, water, mineral soil), interacting as a system











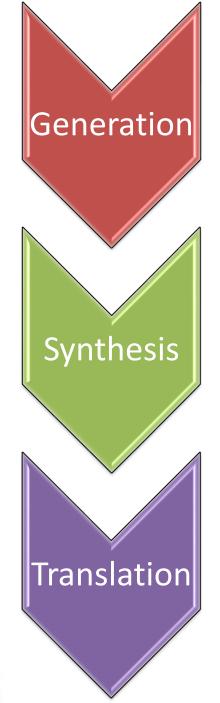


### The ecosystem of evidence

### An ecosystem influenced by:

- **Living organisms**: stakeholders, with their competition, collaboration and conflicts of interest
- Environment: social, cultural, economic, political context
- Non living component: evidence

























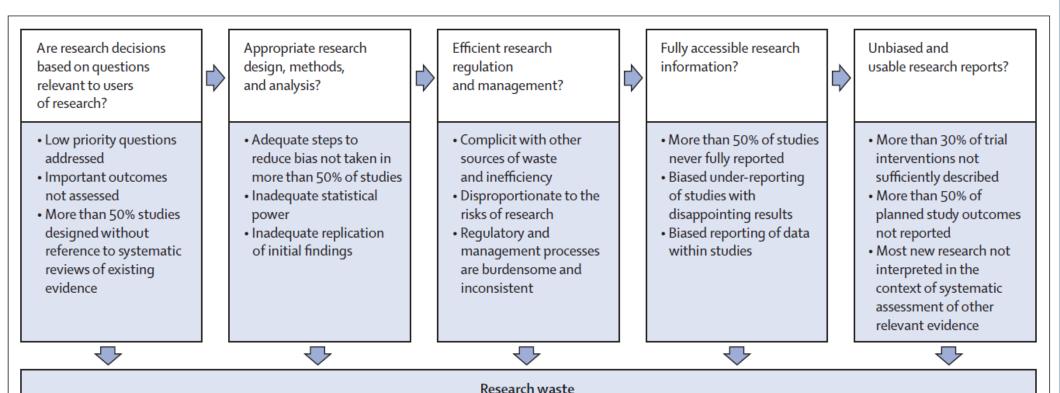
### **Evidence Generation**

### **WHAT'S GOOD?**





### Avoidable waste or inefficiency in biomedical research





### 17 REWARD recommendations

Relevance (1-4)

Methodology (5-7)

Regulation & management (8-11)

Accessibility (13-14)

**Usability (15-17)** 



# Increasing value and reducing waste in biomedical research: who's listening?

David Moher, Paul Glasziou, Iain Chalmers, Mona Nasser, Patrick M M Bossuyt, Daniël A Korevaar, Ian D Graham, Philippe Ravaud, Isabelle Boutron

The biomedical research complex has been estimated to consume almost a quarter of a trillion US dollars every year. Unfortunately, evidence suggests that a high proportion of this sum is avoidably wasted. In 2014, *The Lancet* published a series of five reviews showing how dividends from the investment in research might be increased from the relevance and priorities of the questions being asked, to how the research is designed, conducted, and reported. 17 recommendations were addressed to five main stakeholders—funders, regulators, journals, academic institutions, and researchers. This Review provides some initial observations on the possible effects of the Series, which seems to have provoked several important discussions and is on the agendas of several key players. Some examples of individual initiatives show ways to reduce waste and increase value in biomedical research. This momentum will probably move strongly across stakeholder groups, if collaborative relationships evolve between key players; further important work is needed to increase research value. A forthcoming meeting in Edinburgh, UK, will provide an initial forum within which to foster the collaboration needed.

Lancet 2016; 387: 1573-86

Published Online September 28, 2015





Home

About the JLA

The PSPs

Top 10s JLA Guidebook

**News and Publications** 

Making a difference

You are in: Home

### The James Lind Alliance

The James Lind Alliance (JLA) is a non-profit making initiative established in 2004. It brings patients, carers and clinicians together in <a href="Priority Setting Partnerships">Priority Setting Partnerships</a> (PSPs) to identify and prioritise the <a href="Top 10 uncertainties">Top 10 uncertainties</a>, or unanswered questions, about the effects of treatments.

The aim of this is to make sure that health research funders are aware of the issues that matter most to patients and clinicians.







The PSPs Top 10s

The JLA Guidebook



### **The Evidence-Based Research Network**





Home About the EBRNetwork

Resources

Links



### **ANALYSIS**



### Towards evidence based research

To avoid waste of research, no new studies should be done without a systematic review of existing evidence, argue **Hans Lund and colleagues** 

Hans Lund *professor*<sup>1,2</sup>, Klara Brunnhuber *product manager*<sup>3</sup>, Carsten Juhl *associate professor*<sup>1,4</sup>, Karen Robinson *associate professor*<sup>5</sup>, Marlies Leenaars *associate professor*<sup>6</sup>, Bertil F Dorch *director*<sup>7</sup>, Gro Jamtvedt *dean*<sup>2,8</sup>, Monica W Nortvedt *dean*<sup>2</sup>, Robin Christensen *professor*<sup>9</sup>, Iain Chalmers *coordinator*<sup>10</sup>



### Research and Reporting Methods | Annals of Internal Medicine

### SPIRIT 2013 Statement: Defining Standard Protocol Items for **Clinical Trials**

An-Wen Chan, MD, DPhil; Jennifer M. Tetzlaff, MSc; Douglas G. Altman, DSc; Andreas Laupacis, MD; Peter C. Gøtzsche, MD, DrMedSci; Karmela Krleža-Jerić, MD, DSc; Asbjørn Hróbjartsson, PhD; Howard Mann, MD; Kay Dickersin, PhD; Jesse A. Berlin, ScD; Caroline J. Doré, BSc; Wendy R. Parulekar, MD; William S.M. Summerskill, MBBS; Trish Groves, MBBS; Kenneth F. Schulz, PhD; Harold C. Sox, MD; Frank W. Rockhold, PhD; Drummond Rennie, MD; and David Moher, PhD

The protocol of a clinical trial serves as the foundation for study planning, conduct, reporting, and appraisal. However, trial protocols and existing protocol guidelines vary greatly in content and quality. This article describes the systematic development and scope of SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) 2013, a guideline for the minimum content of a clinical trial protocol.

The 33-item SPIRIT checklist applies to protocols for all clinical trials and focuses on content rather than format. The checklist recommends a full description of what is planned; it does not prescribe how to design or conduct a trial. By providing guidance

for key content, the SPIRIT recommendations aim to facilitate the drafting of high-quality protocols. Adherence to SPIRIT would also enhance the transparency and completeness of trial protocols for the benefit of investigators, trial participants, patients, sponsors, funders, research ethics committees or institutional review boards, peer reviewers, journals, trial registries, policymakers, regulators, and other key stakeholders.

Ann Intern Med. 2013;158:200-207.

www.annals.org

For author affiliations, see end of text.

This article was published at www.annals.org on 8 January 2013.



### **RESEARCH METHODS & REPORTING**

# Preferred reporting items for systematic review and meta-analysis protocols (PRISMA-P) 2015: elaboration and explanation

Larissa Shamseer<sup>1</sup>, David Moher<sup>1</sup>, Mike Clarke<sup>2</sup>, Davina Ghersi<sup>3</sup>, Alessandro Liberati (deceased)<sup>4</sup>, Mark Petticrew<sup>5</sup>, Paul Shekelle<sup>6</sup>, Lesley A Stewart<sup>7</sup>, the PRISMA-P Group

¹Ottawa Hospital Research Institute and University of Ottawa, Canada; ²Queen's University Belfast, Ireland; ³National Health and Medical Research Council, Australia; ⁴University of Modena, Italy; ⁵London School of Hygiene and Tropical Medicine, UK; ⁵Southern California Evidence-based Practice Center, USA; <sup>7</sup>Centre for Reviews and Dissemination, University of York, UK





Reproducibility and reliability of biomedical research: improving research practice

Symposium report, October 2015











#### Data dredging

Also known as p-hacking, this involves repeatedly searching a dataset or trying alternative analyses until a 'significant' result is found.

Errors

Technical errors may

exist within a study, such

as misidentified reagents

or computational errors.



#### **Omitting null** results

When scientists or journals decide not to publish studies unless results are statistically significant.



#### Underpowered study

Statistical power is the ability of an analysis to detect an effect, if the effect exists – an underpowered study is too small to reliably indicate whether or not an effect exists.



#### Issues



#### Underspecified methods

A study may be very robust, but its methods not shared with other scientists in enough detail, so others cannot precisely replicate it.



#### Weak experimental design

A study may have one or more methodological flaws that mean it is unlikely to produce reliable or valid results.

#### Open data

Openly sharing results and the underlying data with other scientists.





#### Pre-registration

Publicly registering the protocol before a study is conducted.











#### Collaboration

Working with other research groups, both formally and informally.







#### Automation

Finding technological ways of standardising practices, thereby reducing the opportunity for human error.





Open methods Publicly publishing the detail of a

study protocol.







#### Post-publication review

Continuing discussion of a study in a public forum after it has been published (most are reviewed before publication).







Guidelines and checklists that help researchers meet certain criteria when publishing studies.









## Sharing clinical trial data: a proposal from the International Committee of Medical Journal Editors



Published **Online** January 20, 2016

As a condition of consideration for publication of a clinical trial report in our member journals, the ICMJE proposes to require authors to share with others the de-identified individual-patient data (IPD) underlying the results presented in the article (including tables, figures, and appendices or supplementary material) no later than 6 months after publication





### Editorial

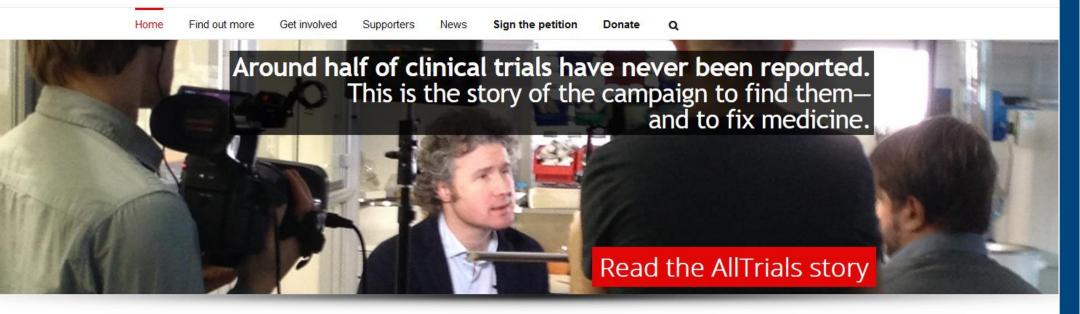
Clinical Trial Registration: A Statement from the International Committee of Medical Journal Editors







#### All Trials Registered | All Results Reported





**ESSAY** 

### Rationale for WHO's New Position Calling for Prompt Reporting and Public Disclosure of Interventional Clinical Trial Results

Vasee S. Moorthy\*, Ghassan Karam, Kirsten S. Vannice, Marie-Paule Kieny

World Health Organization, Geneva, Switzerland









**Health topics** 

Data

Media centre

**Publications** 

Countries

Programmes

Governance

**About WHO** 

Search

#### International Clinical Trials Registry Platform (ICTRP)

#### Welcome to the WHO ICTRP

The mission of the WHO International Clinical Trials Registry Platform is to ensure that a complete view of research is accessible to all those involved in health care decision making. This will improve research transparency and will ultimately strengthen the validity and value of the scientific evidence base.



WHO/P. Virot

The registration of all interventional trials is a scientific, ethical and moral responsibility.







#### Enhancing the QUAlity and Transparency Of health Research



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#### Your one-stop-shop for writing and publishing high-impact health research

find reporting guidelines | improve your writing | join our courses | run your own training course | enhance your peer review | implement guidelines



#### Library for health research reporting

The Library contains a comprehensive searchable database of reporting guidelines and also links to other resources relevant to research reporting.



Search for reporting auidelines



Not sure which reporting quideline to use?



Reporting guidelines under development



Visit the library for more resources



#### Reporting guidelines for main study types

Randomised trials	CONSORT	<u>Extensions</u>	<u>Other</u>
Observational studies	STROBE	<u>Extensions</u>	Other
Systematic reviews	<u>PRISMA</u>	<u>Extensions</u>	<u>Other</u>
Case reports	CARE	<u>Extensions</u>	Other
Qualitative research	SRQR	COREQ	Other
Diagnostic / prognostic	STARD	TRIPOD	<u>Other</u>
studies			
Quality improvement studies	SQUIRE		Other
Economic evaluations	<u>CHEERS</u>		<u>Other</u>
Animal pre-clinical studies	<u>ARRIVE</u>		<u>Other</u>
Study protocols	<u>SPIRIT</u>	PRISMA-P	<u>Other</u>
Clinical practice guidelines	<u>AGREE</u>	<u>RIGHT</u>	<u>Other</u>

See all 382 reporting guidelines





### **Evidence Generation**

### **WHAT'S GOOD?**

- REWARD recommendations
- James Lind Alliance
- EBR Network
- Reporting guidelines for protocols (SPIRIT, PRISMA-P)
- Statement of AMS on reproducibility & reliability of research
- Trial registration: AllTrials, WHO and ICMJE statement, WHO ICTRP
- Sharing clinical trials data (ICMJE proposal)
- EQUATOR network



### **Evidence Generation**

### WHAT'S BAD?





# What are funders doing to minimise waste in research?

\*Mona Nasser, Mike Clarke, Iain Chalmers, Kjetil Gundro Brurberg, Hanna Nykvist, Hans Lund, Paul Glasziou

www.thelancet.com Vol 389 March 11, 2017

	Table 1 – Funding agencies used in the survey and samples of data from the project (further details					
	available in S5 and S6) Funding agency	Country	Are patients and the public involved?	New research requires systematic reviews of	Public access to full protocols for completed or ongoing	Funding to undertake "research on research"?
				existing evidence?	research?	
g,	National Institute for Health Research (NIHR)	UK				
	Medical Research Council (MRC)	UK				
017	National Health and Medical Research Council (NHMRC)	Australia				
	Canadian Institutes of Health Research (CIHR)	Canada				
	National Institutes of Health (NIH)	USA				
	Deutsche Forschungsgemeinschaft (German Research Foundation) (DFG)	Germany				
	French Ministry of Health (FoH)	France				
	l'Agence Nationale de la Recherche (ANR)	France				
	Nederlandse organisatie voor gezondsheidsonderzoek en zorinnovatie (ZonMw)	Netherlands				
	Danske Regioner (DR)	Denmark				
	Regional Health Authorities in Norway (RHA)	Norway				





### RESEARCH ARTICLE

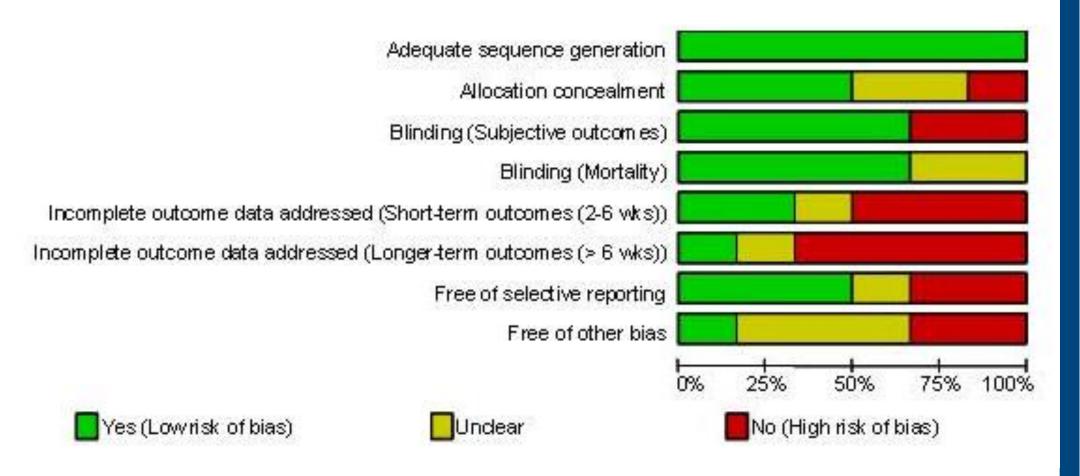
**Open Access** 

# Patient engagement in research: a systematic review

Juan Pablo Domecq<sup>1,2,5</sup>, Gabriela Prutsky<sup>1,2,5</sup>, Tarig Elraiyah<sup>1,5</sup>, Zhen Wang<sup>1,5,6</sup>, Mohammed Nabhan<sup>1,5</sup>, Nathan Shippee<sup>1,5,6</sup>, Juan Pablo Brito<sup>1,4,5</sup>, Kasey Boehmer<sup>1,5</sup>, Rim Hasan<sup>1,5,8</sup>, Belal Firwana<sup>1,5,8</sup>, Patricia Erwin<sup>1,7</sup>, David Eton<sup>1,5,6</sup>, Jeff Sloan<sup>1,5,6</sup>, Victor Montori<sup>1,2,4,5,6</sup>, Noor Asi<sup>1,5</sup>, Abd Moain Abu Dabrh<sup>1,5</sup> and Mohammad Hassan Murad<sup>1,3,5,6\*</sup>



### The Cochrane Collaboration's tool for assessing risk of bias

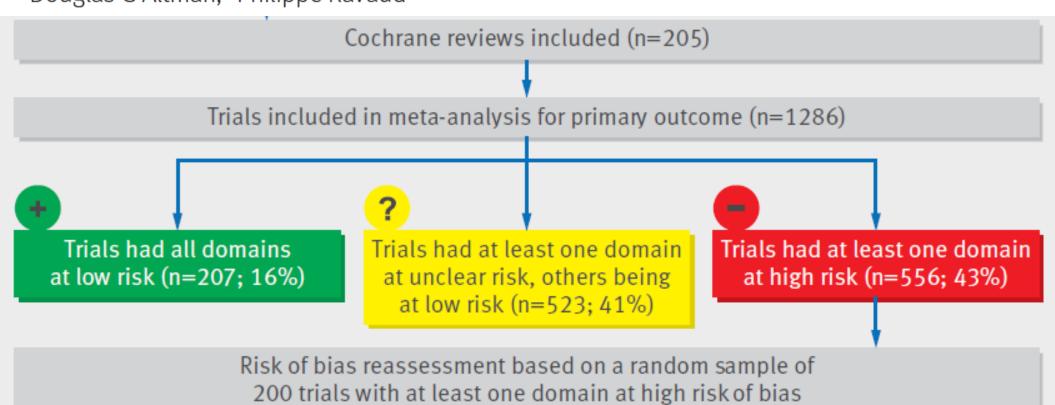


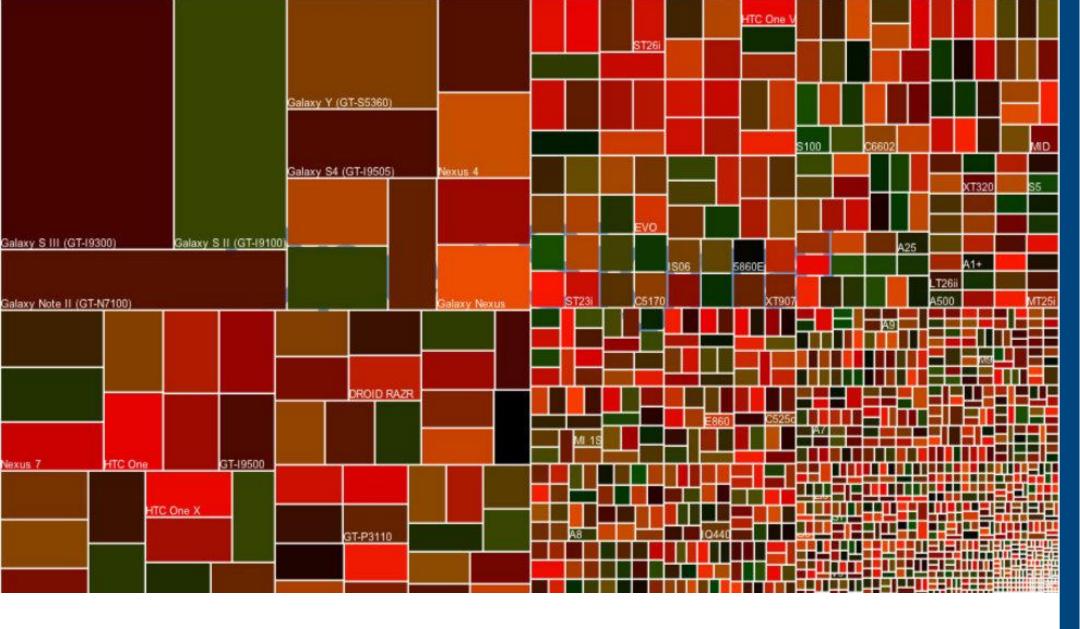


BMJ 2015;350:h809

## Avoidable waste of research related to inadequate methods in clinical trials

Youri Yordanov,<sup>1, 2</sup> Agnes Dechartres,<sup>1, 3, 4</sup> Raphaël Porcher,<sup>1, 3, 4</sup> Isabelle Boutron,<sup>1, 3, 4, 5</sup> Douglas G Altman,<sup>6</sup> Philippe Ravaud<sup>1, 3, 4, 5, 7</sup>







## Panel 1: An example from Sweden of the bureaucracy involved in applications for central research ethics committee approval

In 2010, a group of researchers in Sweden wanted to pool data from several cohort studies to identify risk factors for subarachnoid haemorrhage. They identified about 20 studies, and spent about 300 h contacting all investigators and getting signed data-sharing agreements and data security processes agreed. Sweden has a central research ethics committee to approve projects. The team recorded the time taken for each step of the approval process. About 200 h of office time was spent on the ethics approval and resubmission process alone. The research ethics committee wanted to see all information that the participants of all cohorts had been given about the purpose of the study. These documents had to be provided as 18 copies and submitted manually. It took the team 6 months to collect all the information sheets from the 20 different cohorts, several of which began recruitment in the 1960s and for which little knowledge about what information was given by whom to whom in the recruitment phase was poor. The research ethics committee eventually had the team advertise in national newspapers about the pooling project, listing all original cohorts so that all individuals who did not want the team to use their data for this project could withdraw their consent for the study. Not one participant withdrew. It took more than 3 years to reach the stage of pooling data from the cohorts, ready for analysis.



Figure 1: Paperwork required for regulatory review of the research described in panel 1

### Who's not sharing their trial results?

Trials registered on <u>ClinicalTrials.gov</u> should share results on the site shortly after completing, or publish in a journal. But many organisations fail to report the results of clinical trials. We think this should change. Explore our data (last updated October 2016) to see the universities, government bodies and pharmaceutical companies that aren't sharing their clinical trial results.

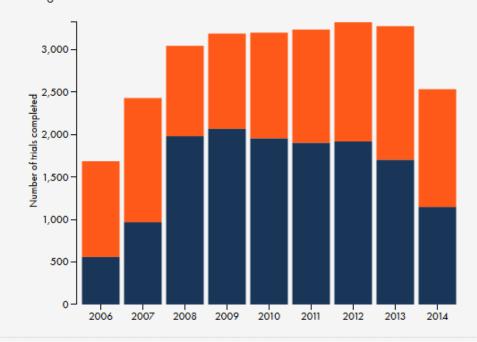
#### Trial sponsors

We've ranked the major trial sponsors with the most unreported trials registered on ClinicalTrials.gov. Click on a sponsor's name to find out whether it's getting better at reporting completed trials - or worse.

	Name of sponsor	Trials missing results	Total II eligible trials	Percent missing	
1	Sanofi	285	435	65.5%	^
2	Novartis Pharmaceuticals	201	534	37.6%	
3	National Cancer Institute (NCI)	194	558	34.8%	
4	Assistance Publique - Hôpitaux de Paris	186	292	63.7%	
5	GlaxoSmithKline	183	809	22.6%	
6	Mayo Clinic	157	312	50.3%	
7	Yonsei University	139	194	71.6%	
8	Seoul National University	131	207	63.3%	V

#### Trials by year

Since Jan 2006, **all major trial sponsors** completed 25.927 eligible trials and **haven't published results for 11.714 trials**. That means 45.2% of their trials are missing results.





Here's what we found.

67

TRIALS CHECKED

9

TRIALS WERE PERFECT

354

OUTCOMES NOT REPORTED

357

NEW OUTCOMES SILENTLY ADDED

On average, each trial reported just 58.2% of its specified outcomes. And on average, each trial silently added 5.3 new outcomes.

58

**LETTERS SENT** 

18

**LETTERS PUBLISHED** 

8

LETTERS
UNPUBLISHED AFTER 4
WEEKS

32

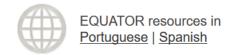
LETTERS REJECTED BY EDITOR

Learn why we did this this, more about our methodology, or see the full results for every trial.



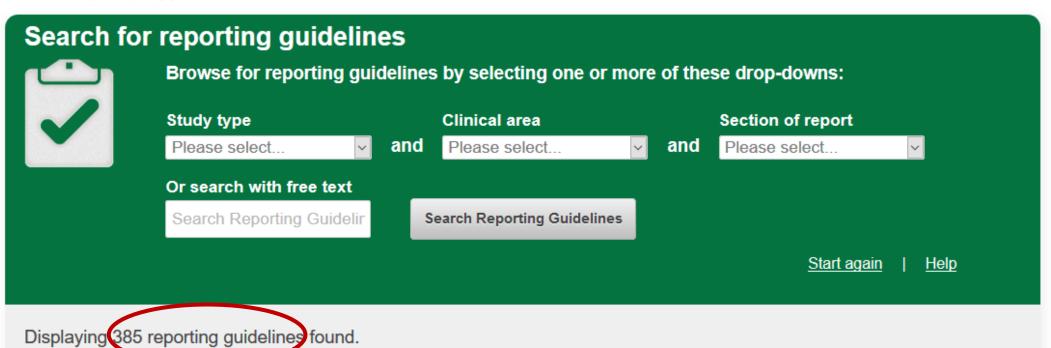


### **Enhancing the QUAlity and Transparency Of health Research**



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Home > Library > Reporting guideline





### Consolidated standards of reporting trials (CONSORT) and the completeness of reporting of randomised controlled trials (RCTs) published in medical journals (Review)

Turner L, Shamseer L, Altman DG, Weeks L, Peters J, Kober T, Dias S, Schulz KF, Plint AC, Moher D





### Further emphasis on research in context

Sabine Kleinert, Laura Benham, David Collingridge, William Summerskill, Richard Horton

www.thelancet.com Vol 384 December 20/27, 2014

#### Panel: Research in context

#### Evidence before this study

This section should include a description of all the evidence that the authors considered before undertaking this study. Authors should state: the sources (databases, journal or book reference lists, etc) searched; the criteria used to include or exclude studies (including the exact start and end dates of the search), which should not be limited to English language publications; the search terms used; the quality (risk of bias) of that evidence; and the pooled estimate derived from meta-analysis of the evidence, if appropriate.

### Added value of this study

Authors should describe here how their findings add value to the existing evidence (including an updated meta-analysis, if appropriate).

### Implications of all the available evidence

Authors should state the implications for practice or policy and future research of their study combined with existing evidence.

### **Evidence Generation**

### WHAT'S BAD?

- Funders' low adherence to REWARD recommendations
- Lack of evidence on the best ways to engage patients in research



- Low reproducibility of research
- Too many primary studies without SRs of available evidence
- Lack of results reporting of registered trials (TrialsTracker)
- Switching outcomes in clinical trials (COMPare)
- Reporting guidelines: too many, unknown impact
- Too little "research in context"



# **WHAT'S GOOD?**





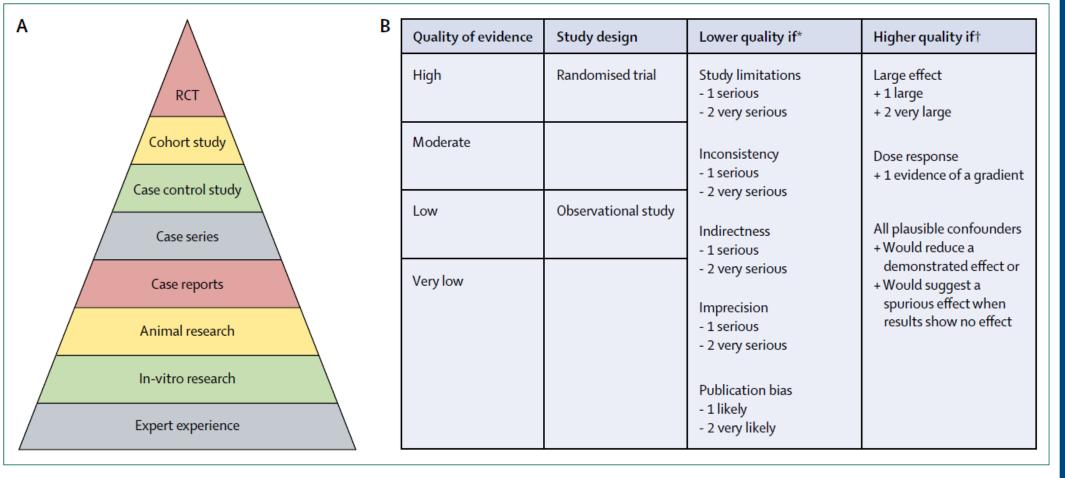


Figure 1: Hierarchy of evidence: traditional EBM versus GRADE



### **ORGANIZATIONS**

More than 100 organizations from 19 countries around the world have endorsed or are using GRADE.



Welcome to the GRADE working group

From evidence to recommendations – transparent and sensible

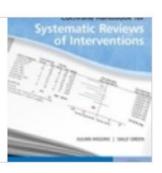




Trusted evidence.
Informed decisions.
Better health.

### **Guides and handbooks**

Cochrane Handbook for Systematic Reviews of Interventions



Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy



**GRADE Handbook** 



Cochrane Style Manual



Cochrane Information Specialists' Handbook



Cochrane Standards for conduct and reporting of new reviews of interventions







# **PRISMA**

### TRANSPARENT REPORTING OF SYSTEMATIC REVIEWS AND META-ANALYSES

- PRISMA Statement
- PRISMA-P (for developing review Protocols)
- PRISMA-IPD (Individual Patient Data)
- PRISMA-NMA (Network Meta-Analyses)





### **Annals of Internal Medicine**

### CLINICAL GUIDELINE

# **Guidelines International Network: Toward International Standards for Clinical Practice Guidelines**

Ann Intern Med. 2012;156:525-531

Amir Qaseem, MD, PhD, MHA; Frode Forland, MD, DPH; Fergus Macbeth, MD; Günter Ollenschläger, MD, PharmD, PhD; Sue Phillips, PhD; and Philip van der Wees, PhD, PT, for the Board of Trustees of the Guidelines International Network\*





# APPRAISAL OF GUIDELINES for Research & Evaluation II



INSTRUMENT

The AGREE Next Steps Consortium May 2009

UPDATE: September 2013



Advancing the science of practice guidelines



# CLINICAL PRACTICE GUIDELINES WE CAN TRUST

INSTITUTE OF MEDICINE

### RESEARCH AND REPORTING METHODS Annals of Internal Medicine

# Guidelines International Network: Principles for Disclosure of Interests and Management of Conflicts in Guidelines

Holger J. Schünemann, MD, PhD, MSc; Lubna A. Al-Ansary, MBBS, MSc; Frode Forland, MD, DPH; Sonja Kersten, MSc; Jorma Komulainen, MD, PhD; Ina B. Kopp, MD; Fergus Macbeth, MA, DM; Susan M. Phillips, BSc (Hons), DPhil; Craig Robbins, MD, MPH; Philip van der Wees, PT, PhD; and Amir Qaseem, MD, PhD, MHA, for the Board of Trustees of the Guidelines International Network\*

Ann Intern Med. 2015;163:548-553.





### WHAT'S GOOD FOR SYSTEMATIC REVIEWS?

- Cochrane handbooks
- PRISMA reporting guidelines and their extensions
- GRADE methods in Cochrane reviews





### WHAT'S GOOD FOR CLINICAL PRACTICE GUIDELINES?

- Guidelines International Network (G-I-N)
- International standards: G-I-N, AGREE II, IOM
- Growing use of GRADE to formulate CPGs recommendations
- Reporting standards: AGREE II, RIGHT





# WHAT'S BAD?







# Original Investigation

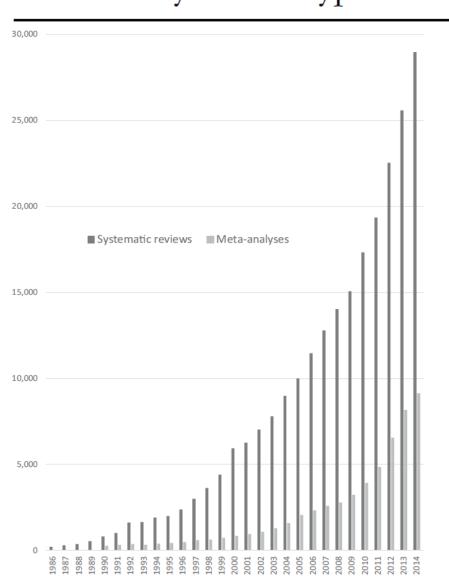
# The Mass Production of Redundant, Misleading, and Conflicted Systematic Reviews and Meta-analyses

JOHN P.A. IOANNIDIS

The Milbank Quarterly, Vol. 94, No. 3, 2016 (pp. 485-514)



Figure 1. Number of PubMed-Indexed Articles Published Each Year Between 1986 and 2014 That Carry the Tag "Systematic Review" or "Meta-analysis" for Type of Publication



- The production of systematic reviews has reached epidemic proportions
- The large majority are unnecessary, misleading, and/or conflicted
- Good and truly informative systematic reviews are a small minority

# Cochrane reviews and protocols published over last 12 months

2016/17	Total reviews	Total protocols	Total reviews and protocols
Issue 9 '17	7415	2572	9987
Issue 8 '17	7399	2470	9869
Issue 7 '17	7380	2452	9832
Issue 6 '17	7352	2538	9890
Issue 5 '17	7316	2539	9855
Issue 4 '17	7284	2548	9832
Issue 3 '17	7258	2543	9801
Issue 2 '17	7201	2542	9743
Issue 1 '17	7169	2526	9695
Issue12'16	7133	2525	9658
Issue11'16	7104	2520	9624
Issue10'16	7066	2523	9589



# **Impact Factor** for the CDSR

Year	

# Impact factor (IF)

2016

6.264

2015

6.103

2014

6.035

2013

5.939

2012 5.785

5.912



2011

2010

6.186



### WHAT'S BAD FOR SYSTEMATIC REVIEWS?

Contamination of "publish or perish" virus to SRs →
epidemic production of useless, incomplete,
outdated, methodologically flawed SRs



- Slow growth of Cochrane reviews and protocols
- Impact factor of CDSR substantially unchanged
- DARE, that collected high quality SRs, has no more been updated from March 2015



### WHAT'S BAD FOR CLINICAL PRACTICE GUIDELINES?

- Too many CPGs on the same disease
- Low quality, outdated CPGs
- Influence of COIs
- Most of CPGs do not take account of multimorbidity
- Low usability of CPGs
- Lack of a central CPGs database searchable for quality criteria





# **WHAT'S GOOD?**



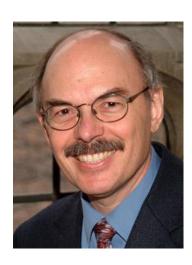


### EDITORIAL

# The paths from research to improved health outcomes



Paul Glasziou, MBBS, PhD University of Oxford Oxford, England, UK



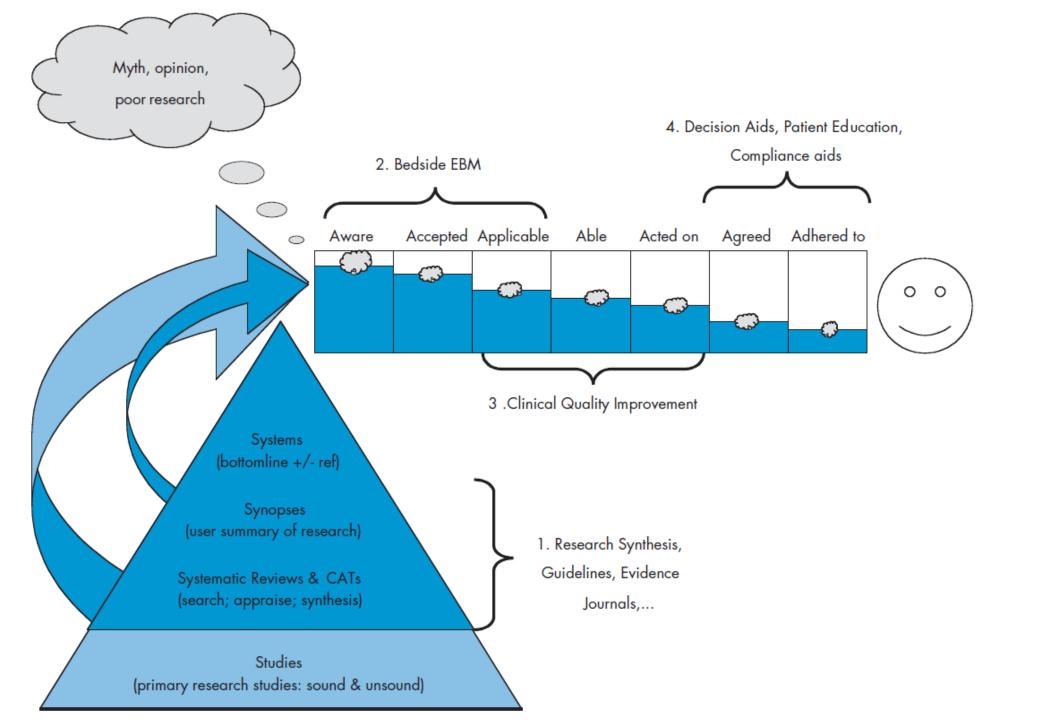
Brian Haynes, MD, PhD McMaster University Hamilton, Ontario, Canada

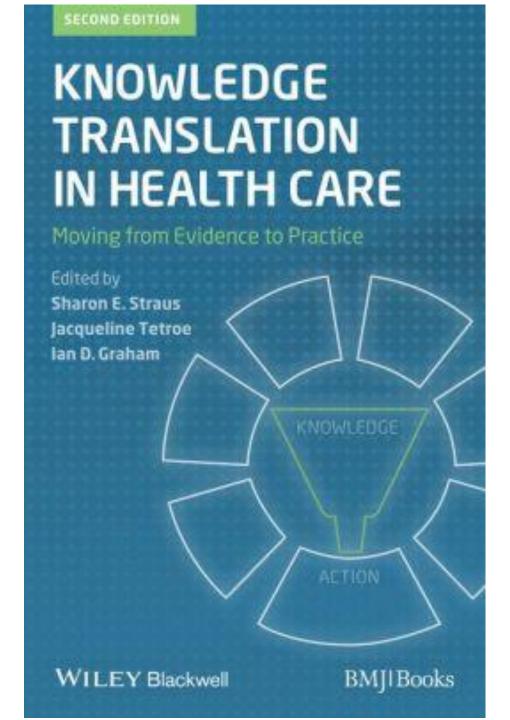
**ACP J Club** 2005;142:A8-10

**Evid Based Med** 2005;10:4-7

**Evid Based Nurs** 2005;8:36-8

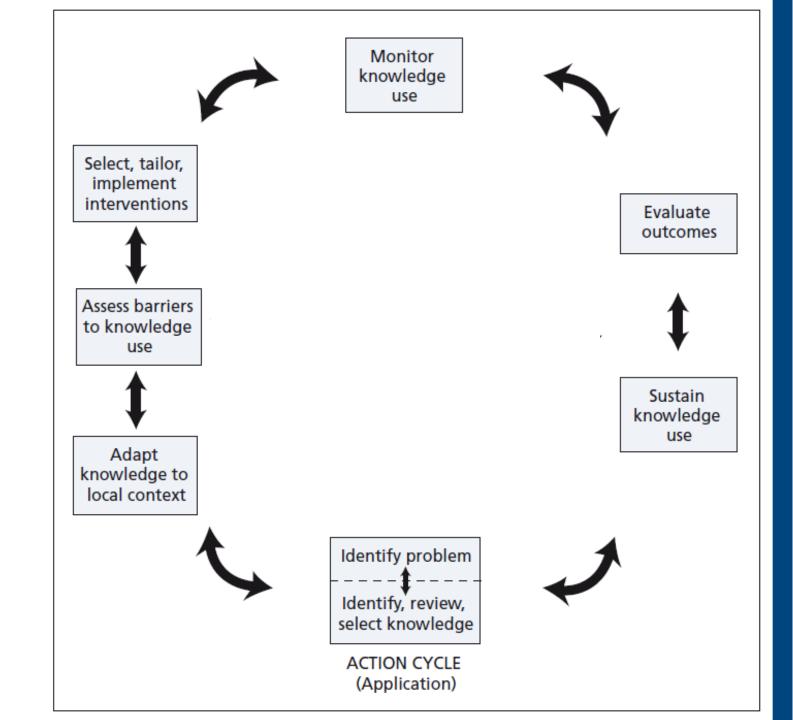








### 2. ACTION CYCLE





### **WHAT'S GOOD?**

 Excellent frameworks available, including all determinants, methods and tools for:



- individual KT
- systemic KT
- •
- •
- •



# WHAT'S BAD?





### **WHAT'S BAD?**

- KT evidence too context-related → low applicability
- KT is a young science, not included in academic curricula
- Professional behaviors areinfluenced by habits and COIs, more than evidence
- Fragmented and not well-connected information systems





# **Evidence Generation**

### THE WAY FORWARD

- More guidelines for reporting protocols: observational studies, diagnostic studies...
- More evidence about the impact of reporting guidelines
- Extending both WHO statement and ICMJE policies concerning clinical trials to register observational studies
- Exploring ways to reduce the extreme fragmentation of regulation issues
- Exploiting all opportunities to increase the reproducibility of biomedical research



# Evidence Generation

### THE WAY FORWARD

- We need less publications and more high quality evidence
  - Changing the ways to measure the impact biomedical research and to fund it
  - To increase the efficiency of basic research
  - To reach good balance among basic, translational, clinical and health service research





### **VIEWPOINT**

# Assessing Value in Biomedical Research The PQRST of Appraisal and Reward

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### Table. PQRST Index for Appraising and Rewarding Research

Item in PQRST Index	Example	
P (productivity)	Number of publications in the top tier % of citations for the scientific field and year	
	Proportion of funded proposals that have resulted in ≥1 published reports of the main results	
	Proportion of registered protocols that have been published 2 y after the completion of the studies	
Q (quality of scientific work)	Proportion of publications that fulfill ≥1 quality standards	
R (reproducibility of scientific work)	Proportion of publications that are reproducible	
S (sharing of data and other resources)	Proportion of publications that share their data, materials, and/or protocols (whichever items are relevant)	
T (translational influence of research)	Proportion of publications that have resulted in successful accomplishment of a distal translational milestone, eg, getting promising results in human trials for intervention tested in animals or cell cultures, or licensing of intervention for clinical trials	



RESEARCH ARTICLE

# Assessing the impact of healthcare research: A systematic review of methodological frameworks

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Primary research related impact

Influence on policy-making

Health & health systems impact Health-related & societal impact

Broader economic impacts

### Short-term

Research and

innovation outcomes\*

Publications

Peer-reviewed

articles (journal

impact factor)

Citation rates

Dissemination and

seminars.

Teaching

knowledge transfer\*

Conferences.

workshops and

presentations

### Level of policy-making

Presentations to

decision-makers

Information base

for political and

making

policy debate

Influence on public

Mid-term

### Evidence-based

- Improving response
- Fulfilling previously unmet clinical

### Type and nature of policy impact

executive decision-

- Changes to legislations, regulations and government policy
- Influence and involvement in the decision-making process
- Changes to clinical or healthcare training, practice or quidelines

### Policy networks

Collaborative research with industry

### practice

- diagnostics and prediction
- needs

### Quality of care and service delivery

- Improved health outcomes (QALYs)
- Patient satisfaction (PROMS)
- Making services more accessible for local communities
- Reduction in waiting times

### Cost containment and effectiveness

- Cost savings
- Increased service effectiveness

### Resource allocation

### Health literacy

Long-term

Activities to change health-risk behaviours such as strategies and campaigns

### Health knowledge. attitudes and behaviours

- Increased levels of public engagement with science and research
- Outcomes from focus groups to assess changes in attitudes. behaviours and attitudes

### Improved social equity, inclusion or cohesion

- United Nations Millennium Development Goals
- Human rights

### **Economic impacts**

- Attracting R&D investment from NHS, medical charities and overseas
- Income from intellectual property
- Spill over effects
- Patents ۰ granted/licenses awarded and brought to the market
- Spin-out companies
- Research contracts and income from industry

# Mass media

- Capacity building. training and leadership\*
- PhD and post-doc studentships
- Academic careers advancement
- Subsequent grants received

Academic collaborations, research networks and

### THE WAY FORWARD FOR SYSTEMATIC REVIEWS

- International policies to converge efforts on Cochrane reviews
- New ICMJE Statement:
  - PROSPERO registration number mandatory for publication
  - Encourage Cochrane reviews → publication of a synthesis on affiliated ICMJE journals
- Centralized database for (non Cochrane) high-quality systematic reviews



### THE WAY FORWARD FOR CLINICAL PRACTICE GUIDELINES

- International governance to avoid proliferation of low quality CPGs
- Better management of COIs according to G-I-N standards
- Exploring ways to include multimorbidity in CPGs recommendations
- Central CPGs database searchable for quality criteria (AGREE II, G-I-N, IOM)
- Improve usability: e.g. CDSS



### THE WAY FORWARD

- More good quality evidence about: knowledge translation (KT), shared decision making, patient adherence
- Set standards for:
  - defining KT priorities at local level
  - developing care pathways, through local adapting of CPGs
  - assessing barriers and facilitating factors



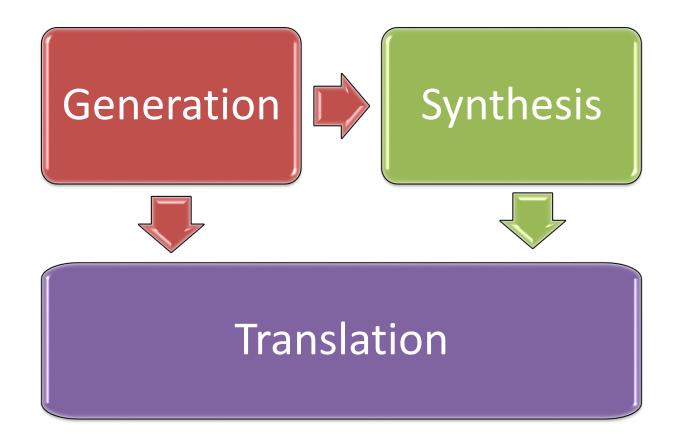


### THE WAY FORWARD

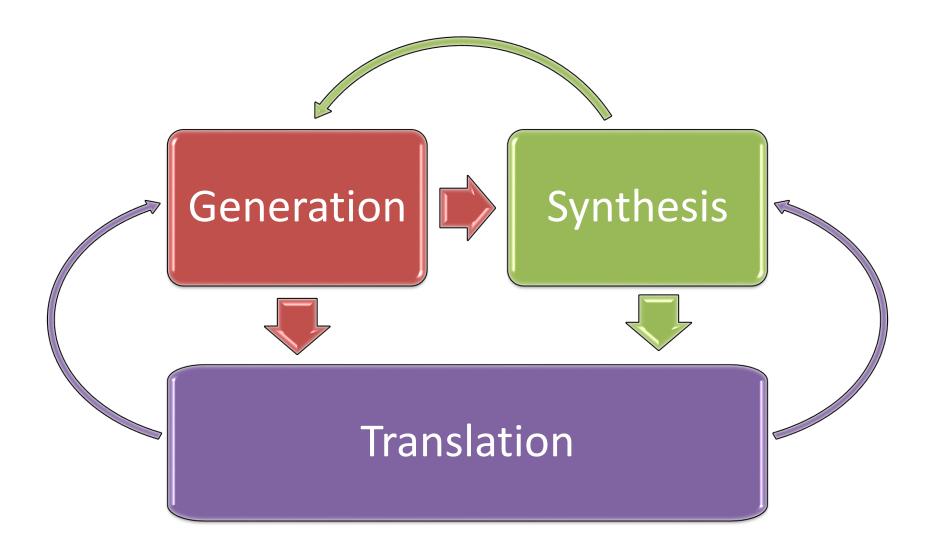
- Measuring performance
  - Using reliable process and outcome measures
  - Align performance measures and reward systems across
     different levels: professional → team → health organization
    - → health care system

















# The ecosystem of evidence

# An ecosystem influenced by:

- **Living organisms**: stakeholders, with their competition, collaboration and conflicts of interest
- Environment: social, cultural, economic, political context
- Non living component: evidence





