The REWARD campaign: reducing waste (and increasing value) in research is an integrity issue

10-year anniversary of
Österreichische Agentur
für Wissenschaftliche Integrität
Vienna, Sept 10, 2018

Sabine Kleinert
Senior Executive Editor, *The Lancet*
Member of the Governing Board of the
World Research Integrity Conferences Foundatio

THE LANCET

Research: increasing value, reducing waste - January, 2014 www.thelancet.com

"By ensuring that efforts are infused with rigour from start to finish, the research community might protect itself from the sophistry of politicians, disentangle the conflicted motivations of capital and science, and secure real value for money for charitable givers and taxpayers through increased value and reduced waste."

Research: increasing value, reducing waste

How journals like Nature, Cell and Science are damaging science

Randy Schekman

The incentives offered by top journals distort science, just as big bonuses distort banking

Research environment/ Reward system

Research Integrity

Research productivity/waste

Research and publications as career progression/personal monetary gain?

or

The right research question (curiosity, added value)

+

Responsible conduct of research with highest standard of integrity

+

Transparent and full publication

=

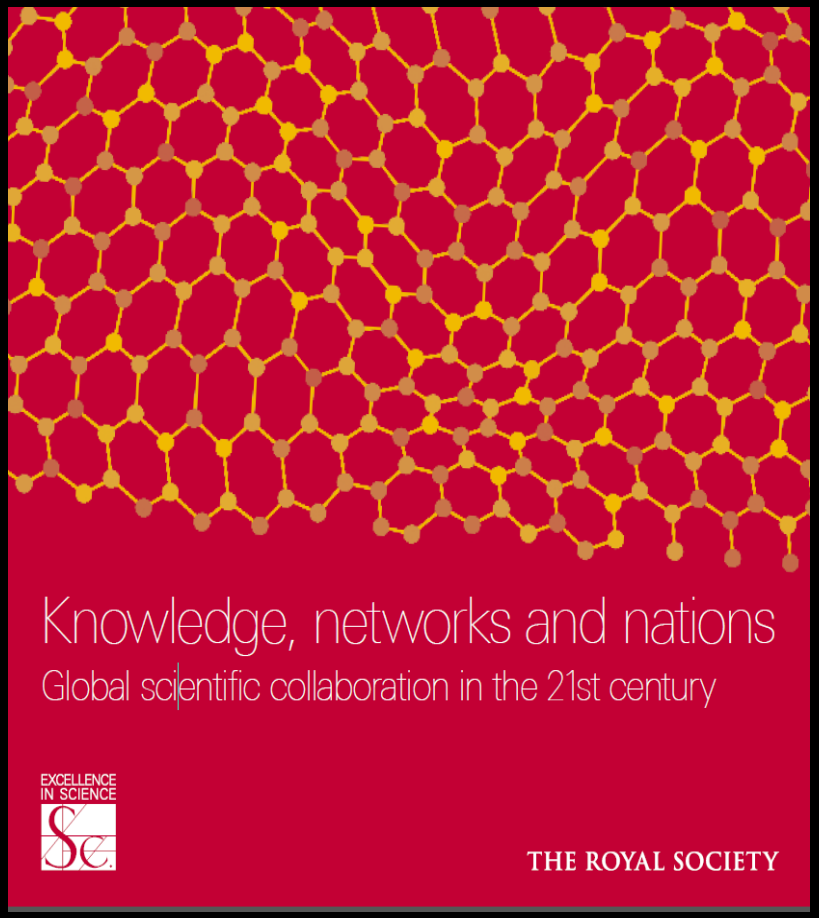
Trust, validity, innovation, and scientific progress

Research for the benefit of society

The many levels of (Research) Integrity

Individual values and integrity
Immediate lab/work environment
Institutional environment
Societal/cultural norms
National/political environment
International collaboration/global

Science in the 21st century

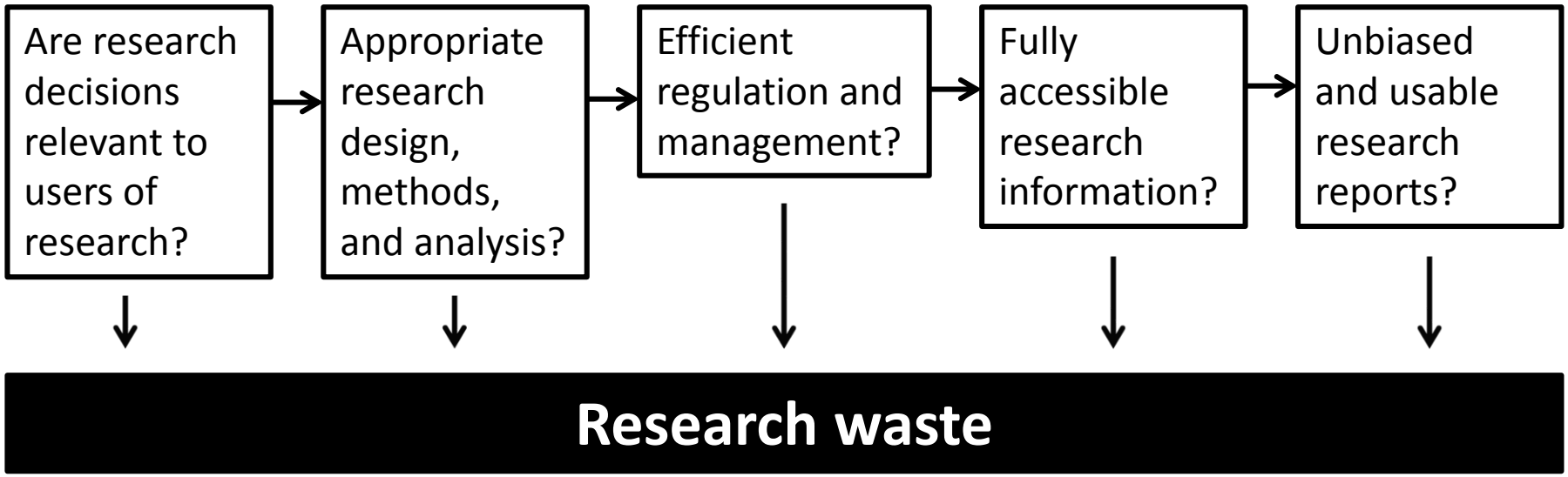


- Where science is done is changing
- Science growth is changing
- Research is becoming more international
- Research is becoming more collaborative
- Research environment is becoming more competitive
- Research reward system has false incentives
- Distorted purpose of research?

Comment

Series

Avoidable waste or inefficiency in biomedical research



Research: increasing value, reducing waste

Lancet 2014;383:101–4

1. Setting research priorities

Involve stakeholders

Panel: Top ten research priorities relating to life after stroke

1 What are the best ways to improve cognition after stroke?
2 What are the best ways to help people come to terms with the long-term consequences of stroke?
3 What are the best ways to help people recover from aphasia?
4 What are the best treatments for arm recovery and function, including visual feedback, virtual reality, bilateral training, repetitive task training, imagery or mental practice, splinting, electromechanical and robot-assisted arm training, and botulinum toxin?
5 What are the best ways to treat visual problems after stroke?
6 What are the best ways to manage or prevent fatigue?
7 What are the best treatments to improve balance, gait, and mobility, including physiotherapy, gait rehabilitation, visual and auditory feedback, electrical stimulation, different types of ankle foot orthoses, and electromechanical assisted gait training?
8 How can stroke survivors and families be helped to cope with speech problems?
9 What are the best ways to improve confidence after stroke, including stroke clubs or groups, offering support, one-to-one input, and re-skilling?
10 Are exercise and fitness programmes beneficial at improving function and quality of life and avoiding subsequent stroke?

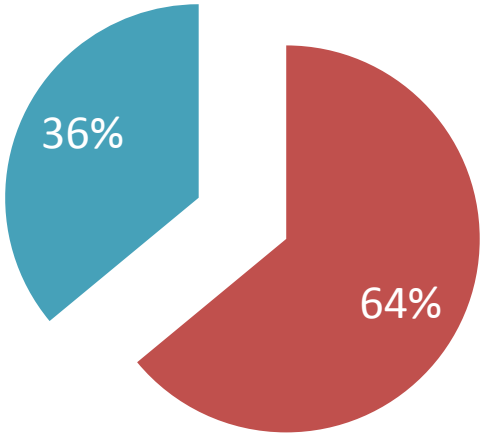
Lancet Neurol 2012;11:209

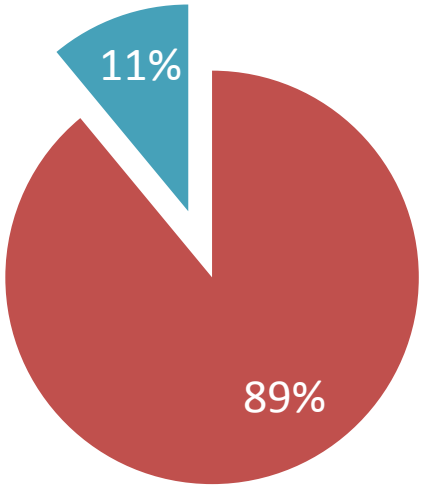
1. Recommendations

- More research on research should be done to identify factors associated with successful replication of basic research and translation to application in health care
- Funders should make information available about how they decide what research to support, and fund initiatives to engage potential users of research in research prioritisation
- Research funders and regulators should demand that proposals for additional primary research are justified by systematic reviews showing what is already known, and increase funding for the required syntheses of existing evidence
- Research funders and regulators should strengthen and develop sources of information about research that is in progress

2. Design, conduct and analysis

Failure to replicate published pre-clinical academic results





Lancet 2014;383:166–75

Reproducibility and reliability of biomedical research: improving research practice

Symposium report, October 2015

The Academy of Medical Sciences · BBSRC · MRC · wellcome trust

What are the main issues?

- Conflicts of interest and introduction of bias
- Incentives to publish novel findings in high impact journals
- Current scientific culture

How do we talk publicly about reproducibility?

- Open discussion about irreproducible research, its causes and methods to tackle it
- Joint responsibility of researchers, journalists, science writers and press officers to ensure accurate reporting

2. Recommendations

- Make publicly available the full protocols, analysis plans or sequence of analytical choices, and raw data for all designed and undertaken biomedical research

- Maximise the effect-to-bias ratio in research through defensible design and conduct standards, a well trained methodological research workforce, continuing professional development, and involvement of non-conflicted stakeholders

- Reward (with funding, and academic or other recognition) reproducibility practices and reproducible research, and enable an efficient culture for replication of research

4. Accessible reporting

Proportion of funded/completed research that is reported

50%

HTA 2010;14(8):iii, ix-xi, 1-193

4. Recommendations

- Institutions and funders should adopt performance metrics that recognise full dissemination of research and reuse of original datasets by external researchers

- Investigators, funders, sponsors, regulators, research ethics committees, and journals should systematically develop and adopt standards for the content of study protocols and full study reports, and for data sharing practices

- Funders, sponsors, regulators, research ethics committees, journals, and legislators should endorse and enforce study registration policies, wide availability of full study information, and sharing of participant-level data for all health research

The *Lancet* REWARD (**RE**duce research **W**aste **A**nd **R**eward **D**iligence) Campaign invites everyone involved in (biomedical) research to critically examine the way they work to reduce waste and maximise efficiency.

Read the REWARD statement

The REWARD Statement

We recognise that, while we strive for excellence in research, there is much that needs to be done to reduce waste and increase the value of our contributions. We maximise our research potential when:

we set the right research priorities;
we use robust research design, conduct and analysis;
regulation and management are proportionate to risks;
all information on research methods and findings are accessible;
reports of research are complete and usable.

We believe we have a responsibility not just to seek to advance knowledge, but also to advance the practice of research itself. This will contribute to improvement in the health and lives of all peoples, everywhere. As funders, regulators, commercial organisations, publishers, editors, researchers, research users and others – we commit to playing our part in increasing value and reducing waste in research."

http://www.thelancet.com/campaigns/efficiency

The *Lancet* REWARD (REduce research Waste And Reward Diligence) Campaign invites everyone involved in biomedical research to critically examine the way they work to reduce waste and maximise efficiency.

Read the REWARD statement

Updates

The first REWARD conference, held jointly with EQUATOR Network, in Edinburgh 28-30 September 2015, was an unmitigated success! Full details of the programme and abstracts are available; the PowerPoint slide presentations and video content will be posted online soon. There were 236 delegates from 28 countries.

More…

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The Lancet Neurology
The Lancet Neurology, Vol. 14, No. 11, p1065
Published in issue: November, 2015
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How should medical science change?
Sabine Kleinert, Richard Horton
The Lancet, Vol. 383, No. 9913, p197–198
Published online: January 8, 2014
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COMMENT
Biomedical research: increasing value, reducing waste
Malcolm R Macleod, Susan Michie, Ian Roberts, Ulrich Dirnagl, Iain Chalmers, John P A Ioannidis, Rustam Al-Shahi Salman, An-Wen Chan, Paul Glasziou

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- **How can we improve decisions on which research papers we should publish?**
- **How can we better ensure accurate, transparent, and full reporting of research findings?**
- **How can we improve the accessibility and usability of research findings, and data availability?**
- **How can we further raise awareness and continue discussions on the topic of research productivity?**

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.

Research in context

Evidence before this study

Snakebite envenoming is a category A neglected tropical disease of particular public health importance in tropical areas of Africa, Asia, Latin America, and Papua New Guinea. It is estimated that up to 1·2 million people are envenomed annually, resulting in 81 000–138 000 fatalities. Although effective therapies exist to treat envenoming by some snakes of highest medical importance, there are many species without such treatments. The global distribution of venomous snakes and vulnerable populations remains inadequately characterised; therefore, the lack of knowledge of subnational disease burden might impede production of antivenom supplies and distribution efforts among populations currently at risk. To investigate this further, we searched for articles on PubMed published before March 1, 2017, using the search terms "snakebite", "distribution", and "burden". Contemporary studies have investigated venomous snake distributions and snakebite risk at national levels (several countries in Latin America) or subnational levels (India, Nigeria, and Sri Lanka), but these studies did not encompass all medically important snake species and are limited in both geographical extent and spatial resolution. A more recent analysis mapped the distribution of venomous snakes in Central America and Latin America but was restricted to widely studied species with ample occurrence data. Although an important start, no study has coupled global ecological information about snake distributions with measures relating to public health capabilities to hone in on populations most vulnerable to this cause of mortality and morbidity.

Added value of this study

We identified populations most vulnerable to 278 medically important snake species by using expert opinion, species' ranges refined by publicly available occurrence data and multivariate analyses, information about effective therapies, and metrics of health-care quality and accessibility. Although a large proportion of the world's population live in areas where such snakes could be present, proxy metrics such as the Healthcare Access and Quality Index and urban accessibility paired with broad-scale information about market antivenom availability provide a subnationally resolved yet globally comprehensive picture of vulnerability, highlighting populations that could be most affected.

Implications of all the available evidence

We highlight locations where the combination of the presence of a variety of venomous snakes, inequalities in health care and accessibility, and possible absence of effective therapy might contribute toward increased vulnerability of snakebite envenoming. Our analyses can be used to inform the positioning of local-scale household surveys to assess the true risk of snakebite in areas where such estimates are currently inadequate. This study highlights the importance of continuing to iterate, improve, and re-evaluate existing geographical assessments of snake distributions, and the need to incorporate spatially heterogeneous risk within future burden estimation efforts. This work is a first step in trying to identify and assist the most neglected populations of this newly designated neglected tropical disease.

Data sharing statements for clinical trials: a requirement of the International Committee of Medical Journal Editors

The International Committee of Medical Journal Editors (ICMJE) believes there is an ethical obligation to responsibly share data generated by interventional clinical trials because trial participants have put themselves at risk. In January, 2016, we published a proposal aimed at helping to create an environment in which the sharing of de-identified individual participant data becomes the norm.[1] In response to

It is encouraging that data sharing is already occurring in some settings. Over the past year, however, we have learned that the challenges are substantial and the requisite mechanisms are not in place to mandate universal data sharing at this time. Although many issues must be addressed for data sharing to become the norm, we remain committed to this goal.

Therefore, the ICMJE will require the following as

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For **ICMJE's website** see www.icmje.org

For **ICMJE's policy regarding trial registration** see www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after de-identification	Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices)	Individual participant data that underlie the results reported in this article, after de-identification (text, tables, figures, and appendices)	Not available
What other documents will be available?	Study protocol, statistical analysis plan, informed consent form, clinical study report, analytic code	Study protocol, statistical analysis plan, analytic code	Study protocol	Not available
When will data be available (start and end dates)?	Immediately following publication; no end date	Beginning 3 months and ending 5 years following article publication	Beginning 9 months and ending 36 months following article publication	Not applicable
With whom?	Anyone who wishes to access the data	Researchers who provide a methodologically sound proposal	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose	Not applicable
For what types of analyses?	Any purpose	To achieve aims in the approved proposal	For individual participant data meta-analysis	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (link to be included)	Proposals should be directed to xxx@yyy; to gain access, data requestors will need to sign a data access agreement Data are available for 5 years at a third party website (link to be included)	Proposals may be submitted up to 36 months following article publication After 36 months the data will be available in our university's data warehouse but without investigator support other than deposited metadata Information regarding submitting proposals and accessing data may be found at (link to be provided)	Not applicable

*These examples are meant to illustrate a range of, but not all, data sharing options.

Table: **Examples of data sharing statements that fulfil the ICMJE requirements***

Data sharing (example)

"The High-STEACS trial makes use of several routine electronic health care data sources that are linked, de-identified, and held in our national safe haven, which is accessible by approved individuals who have undertaken the necessary governance training. Summary data can be made available upon request to the corresponding author."

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
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Introduction

More than 30 years ago, the adverse clinical consequences of biased under-reporting of research were clearly documented[1] and non-publication of research remains hugely problematic.[2–5] Non-publication is bad value for funders, who could double research output by ensuring all the funded studies are published, and this situation puts patients and clinicians at a substantial disadvantage in making informed decisions about health care.[6] Trial registration, supported by the International Committee of Medical Journal Editors (ICMJE),[7] has helped to address this problem[8,9] although this solution is clearly not a panacea.[10,11] Other related initiatives, such as the Alltrials initiative and the Institute of Medicine's report on data sharing[12] are working to ensure that the results of all trials are reported and that their data are made available.

Chalmers and Glasziou[13] estimated in 2009 that 85% of research funding was being avoidably wasted across the entire biomedical research range (eg, clinical, health services, and basic science). Evidence of the extent and avoidability of waste in research production at each stage

five stages to identify common themes and examples of good practice across their programmes. For example, since 2013, NIHR has required applicants for support of new primary research to reference an existing systematic review "as well as including reference to any relevant literature published subsequent to that systematic review" or when no such systematic review exists, applicants should review the relevant evidence (with a method that systematically identifies, critically appraises, and combines the evidence), which "must also include reference to relevant on-going studies, eg, from trial registries".[22]

In 2014 *The Lancet* published a Series ("Increasing value: reducing waste")[23–27] extending the 2009 analysis from 4 to 50 journal pages, with more than 40 authors focused on the five NIHR stages. As the Commissioning Editors noted: "Our belief is that research funders, scientific societies, school and university teachers, professional medical associations, and scientific publishers (and their editors) can use this Series as an opportunity to examine more forensically why they are doing what they do…and whether they are getting the most value for the time and

Academic institutions

“We assessed the extent to which academic institutions have policies to make study materials publically available, a recommendation from the Series. Deans and directors of research of the medical schools of the top 100 universities from the *Times Higher Education* World University Rankings 2013–14 (ordered by clinical, preclinical, and health) were invited to participate in a five-question email survey.”

"We received complete responses from only 26 of the 100 invited universities. We noted that most of these schools (n=20) have a policy to register clinical trials in a publicly accessible trial registry and to make full study reports available (n=19), but such policies are rare for protocols (n=5), analytical algorithms (n=5), and raw data (n=5). Two of 26 universities did not have an institutional policy for any of these five elements".

How can research institutions become partners to increase value in research through strong integrity measures ??


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