La valutazione della ricerca in un panorama in evoluzione

Antonio Addis

Unità di Epidemiologia del Farmaco Dipartimento di epidemiologia della Regione Lazio









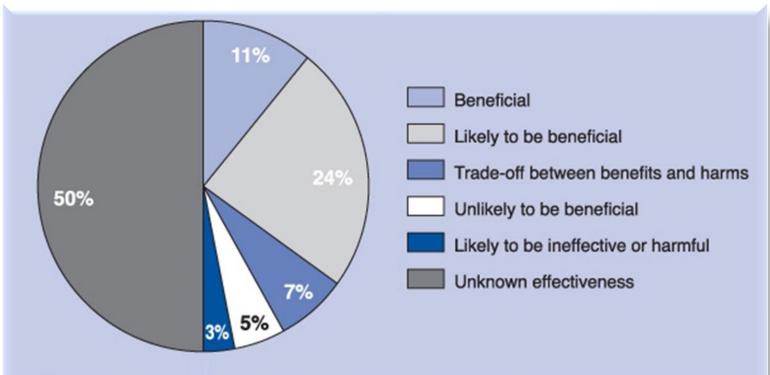
How to evaluate results form any new research finding?



- **✓** Quality
- **√** Impact
- ✓ Relevance







Effectiveness of 3000 treatments as reported in randomised controlled trials selected by Clinical Evidence. This does **not** indicate how oftentreatments are used in healthcare settings or their effectiveness in individual patients.



Ask to an expert



- ✓ Subjective point of view
- ✓ (In)Competence
- **✓** Conflict of interests



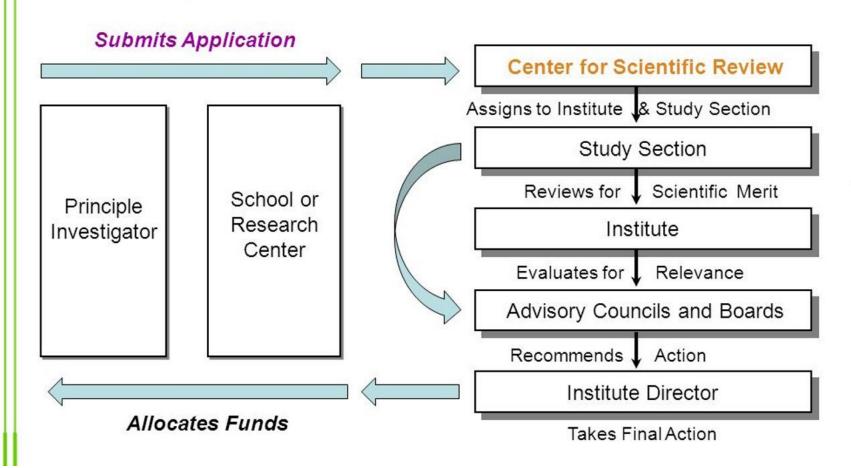
Peer review Process



- ✓ Time consuming
- **✓** Open/Blind
- ✓ Transparency
- √ Bias (?)



Review Process for an NIH Research Grant





Principles of Peer Review

Peer review is the central pillar of trust for researchers 84%

of researchers believe that without peer review there would be no control in scientific communication.



Peer review means better research

9 out of 10 researchers feel that peer review improves the quality of their published paper.

Good reviewers attract good authors

Reviewer quality and speed

are the top 2 contributing factors that lead to a pleasant publishing experience and attract authors to publish in a journal.



Publishers are key to good peer review

Researchers believe organizing and managing peer review is the crucial role of publishers.

Sources

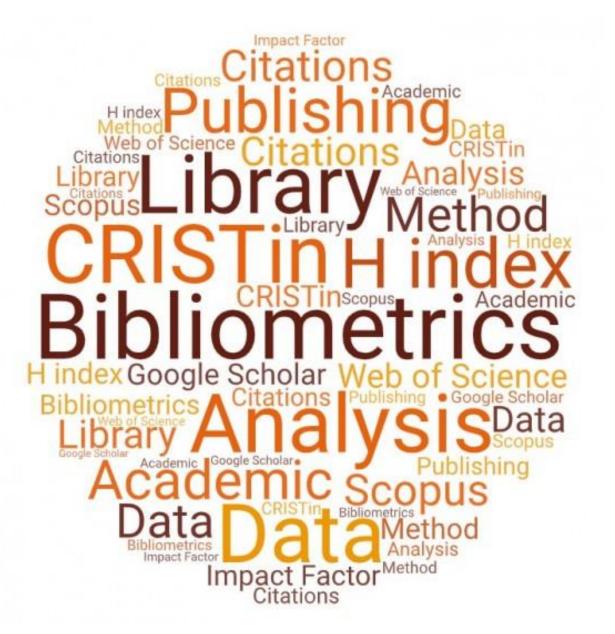
Wiley RANO survey, 2013

Mabe & Mulligan, "What journal Authors Want", New Review of Information Networking, 2011

Trust and Authority in Scholarly Communications in the Light of the Digital Transition, University of Tennessee & CBBR Research Ltd, 2013.









The impact factor

"

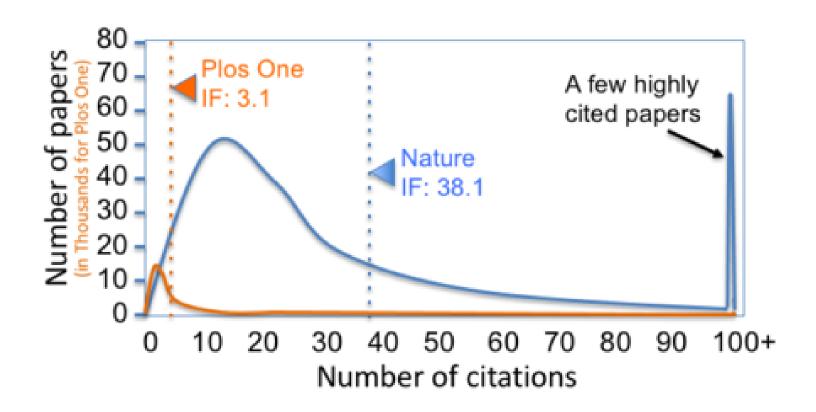
The impact factor is a measure of the frequency in which the average <u>article in a</u> <u>journal</u> is cited in a particular year. Impact factors measure the impact of a journal, not the impact of individual articles.



The Citation Index

Citation Analysis: Is the process whereby the impact or "quality" of an article is assessed by counting the number of times other authors mention it in their work.







The h-index

"

The h-index is an index to quantify an individual's scientific research output
The h-index is an index that attempts to measure both the scientific productivity and the apparent scientific impact of a scientist.

The index is based on the set of the researcher's most cited papers and the number of citations that they have received in other people's publications

A scientist has index h if h of [his/her] Np papers have at least h citations each, and the other (Np – h) papers have at most h citations each.

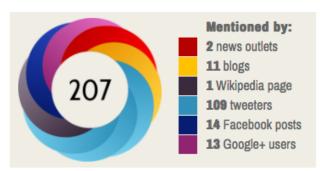


The Altmetrics

Altmetrics is a quantitative measure of the quality and quantity of attention that a scholarly work is receiving through social media, citations, and article downloads.

The Altmetric Donut

A Framework for K-12 Science Education: Practices, Crosscutting Concepts, and Core Ideas

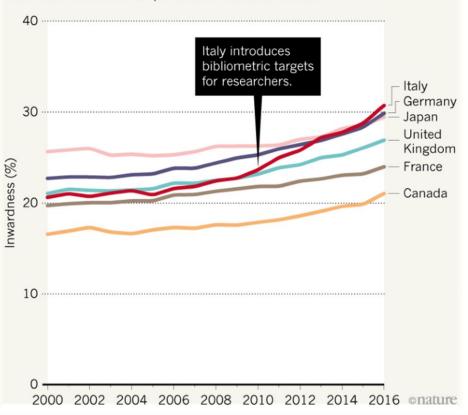




Citation Doping

STRATEGIC CITATIONS

Italy's inwardness — the share of its citations that come from papers with at least one Italian co-author — has risen disproportionately since the country introduced thresholds for promotions based on metrics.





How we evaluate research proposals?

"It is a scandal that billions of dollars are spent on research without knowing the best way to distribute that money."



Fund people not projects

John P. A. Ioannidis proposes ways to save scientists from spending all their time writing grants.



How we evaluate research proposals?

OPTIONS FOR REVAMPING THE FUNDING SYSTEM							
Option	Pros	Cons	Example	Who would be funded?			
Egalitarian (fund everybody)	Avoids peer-review biases Gives sufficient amounts to scientists doing low-cost research Small administrative burden	Does not support large research efforts Does not recognize exceptional scientists	Some universities fund the salaries of all their faculty	All			
Aleatoric (fund at random)	Avoids peer-review biases Small administrative burden	Will not capture all deserving scientists	Foundational Questions Institute	Flexible			
Assessment of career	Captures career trajectory Has gold-standard status	Is vulnerable to favouritism Inappropriate for young researchers Is labour-intensive	MacArthur Fellows Program	Few elite scientists (or else administratively burdensome)			
Automated impact indices	Eliminates favouritism Evaluates many applicants with ease Approaches objectivity	There are many indices, all with flaws; no consensus about best one to use Indices can be gamed Databases have shortcomings (such as imperfect citation coverage, entry errors, name disambiguation problems)	UK Research Excellence Framework	Flexible			
Scientific citizenship	May improve science, if good practices are rewarded and bad ones penalized	Automation is not yet possible for data gathering, and is difficult for some citizenship practices Has peer-review biases	Financial incentives to peer reviewers	Could be extended to many scientists only for aspects that can be automated			
Projects with broad goals	Proposals are easy to write and review Formulating work can be flexible Permits targeted innovation	Does not eliminate project proposals Is vulnerable to favouritism Holds potential for exaggerated promises and claims	NIH Director's Pioneer Awards Howard Hughes Medical Institute	Few elite scientists			

Two or more options can also be combined (for example, automated impact indices plus evaluation of scientific citizenship).



Biomedical research: increasing value, reducing waste

W^a

Of 1575 reports about cancer prognostic markers published in 2005, 1509 (96%) detailed at least one significant prognostic variable. However, few identified biomarkers have been confirmed by subsequent research and few have entered routine clinical practice. This pattern—initially promising findings not leading to improvements in health care—has been recorded across biomedical research. So why is research that might transform health care and reduce health problems not being successfully produced?

Global biomedical and public health research involves billions of dollars and millions of people. In 2010, expenditure on life sciences (mostly biomedical) research was US\$240 billion.³ The USA is the largest funder, with about \$70 billion in commercial and \$40 billion in governmental and non-profit funding annually,⁴ representing slightly more than 5% of US health-care expenditure. Although this vast enterprise has led to substantial health improvements, many more gains are possible if the waste and inefficiency in the ways that biomedical research is chosen, designed, done, analysed, regulated, managed, disseminated, and reported can be addressed.

In 2009, Chalmers and Glasziou⁵ identified some key sources of avoidable waste in biomedical research. They estimated that the cumulative effect was that about 85% of research investment—equating to \$200 billion of the investment in 2010—is wasted. This amount was calculated without consideration of the inefficiencies in the regulation and management of research. Although some real progress with the issues they identified has been made ⁶⁻¹⁵ at the present

others (table). Through consideration of these drivers, the economic, social, cultural, and political conditions that have shaped the research environment can be understood.⁸

Economic forces are important. Industry seeks to maximise profit by bringing new products to market and by protecting and expanding market share. In industry-funded clinical research, commercial motives can control the study design and comparators, and so-called seeding trials (in which the purpose is to promote familiarity with a new drug rather than generate knowledge) can be done for marketing purposes. The economic motivations of industry do much to characterise health as a commodity that can be bought, which informs and distorts the motivations of other actors. The profit motive is central to everything with which industry is involved, including its interactions with seemingly independent researchers and clinicians. To

Equally, advertising, publication charges, and charges for reprints make journal publication a highly profitable business, and attempts to maximise income are not always consistent with an ambition to publish only reports about research of the highest quality and relevance. Although peer review is supposed to uphold the quality of publications and grants awarded, the costs of the system are substantial, 11 raising questions about its cost-effectiveness. 12

Governments and politicians have an important role. Funding is needed for research in areas important for the protection and restoration of human health even when the prospects for commercial profit are poor or non-existent. For example, the LIK Health Technology.

Published Online January 8, 2014 http://dx.doi.org/10.1016/ S0140-6736(13)62329-6

See Series pages 156, 166, and 176

See Online/Comment http://dx.doi.org/10.1016/ S0140-6736(13)62678-1

See Online/Series http://dx.doi.org/10.1016/ S0140-6736(13)62296-5, and http://dx.doi.org/10.1016/ S0140-6736(13)62228-X



Biomedical research Increasing value reducing waste

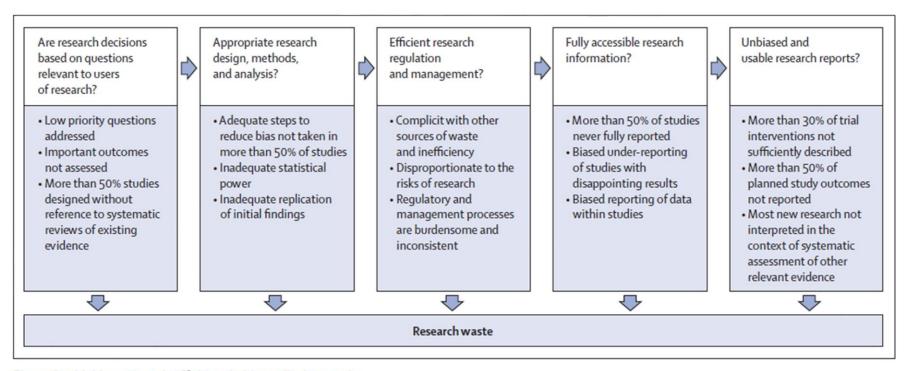


Figure: Avoidable waste or inefficiency in biomedical research

Priority Setting

Are research decisions based on questions relevant to users of research?

- Low priority questions addressed
- Important outcomes not assessed
- More than 50% studies designed without reference to systematic reviews of existing evidence

- ✓ Scientific Questions
- ✓ Research' epidemiology
- ✓ Reaearch and knowledge gaaps
- Duplication of research funds aims



Promoting research quality

Appropriate research design, methods, and analysis?

- Adequate steps to reduce bias not taken in more than 50% of studies
- Inadequate statistical power
- Inadequate replication of initial findings

- Selecting methodological approaches according to research aims
- ✓ Selecting kind of studies according to research grant objectives
- Process of evaluation transparent and with less burocracy



Reseach Management

Efficient research regulation and management?

- Complicit with other sources of waste and inefficiency
- Disproportionate to the risks of research
- Regulatory and management processes are burdensome and inconsistent

- ✓ Supporting research facilities
- ✓ Supporting activities of ethical committee
- ✓ Taking care of Good Clincal Practices

Accesso alla conoscenza

Fully accessible research information?

- More than 50% of studies never fully reported
- Biased under-reporting of studies with disappointing results
- Biased reporting of data within studies

- ✓ Promoting the open access
- Promoting educational programme
- ✓ Promoting international and local collaborations



La ricerca utile

Unbiased and usable research reports?

- More than 30% of trial interventions not sufficiently described
- More than 50% of planned study outcomes not reported
- Most new research not interpreted in the context of systematic assessment of other relevant evidence

- ✓ Etica della ricerca
- ✓ Riconoscimento della ricerca come percorso di formazione
- ✓ Disinvestire nella ricerca ridondante



Research funders primarily rely on peer review,

They often use a combination of independent written review and discussion in a peer review panel, to inform their funding decisions.

Peer review panels have the difficult task of integrating and balancing the various assessment criteria to select and rank the eligible proposals.

Rebecca Abma-Schouten, Joey Gijbels, Wendy Reijmerink, Ingeborg Meijer, Evaluation of research proposals by peer review panels: broader panels for broader assessments?, *Science and Public Policy*, Volume 50, Issue 4, August 2023, Pages 619–632



Serve uno sguardo più ampio?

"The assessment of research proposals ought to include broader assessment criteria, including both scientific quality and societal relevance, and a broader perspective on relevant peers."





Cosa premiare in una ricerca? Rilevanza sociale e possibile impatto?



Contents lists available at ScienceDirect

Research Policy

journal homepage: www.elsevier.com/locate/respol





Evaluating impact from research: A methodological framework

M.S. Reed ^{a,g,*}, M. Ferré ^{b,f}, J. Martin-Ortega ^b, R. Blanche ^c, R. Lawford-Rolfe ^d, M. Dallimer ^b, J. Holden ^e

- * Thriving Natural Capital Challenge Centre, Department of Rural Economies, Environment & Society, Scotland's Rural College (SRUC), Peter Wilson Building, Kings Buildings, West Mains Road, Edinburgh E119 3JG
- ^b School of Earth & Environment, University of Leeds, Leeds, LS2 9JT, United Kingdom
- ^c Division of Media, Communication and Performing Arts, School of Arts, Social Sciences and Management, Queen Margaret University, Queen Margaret University Way, Musselburgh EH21 6UU, United Kingdom
- ^d School of Earth & Environment, University of Leeds, Leeds, LS2 9JT, United Kingdom
- 6 School of Geography, University of Leeds, Leeds, LS2 9JT, United Kingdom
- ⁴ Agricultural Research Centre for International Development (CIRAD), 42 Rue Scheffer, 75116 Paris, France
- 8 Centre for Rural Economy and Institute for Agri-Food Research and Innovation, School of Natural and Environmental Sciences, Newcastle University, Agriculture Building, Newcastle upon Tyne NEI 7RU, United Kingdom

ABSTRACT

Background: Interest in impact evaluation has grown rapidly as research funders increasingly demand evidence that their investments lead to public benefits.

Aims: This paper analyses literature to provide a new definition of research impact and impact evaluation, develops a typology of research impact evaluation designs, and proposes a methodological framework to guide evaluations of the significance and reach of impact that can be attributed to research.

Method: An adapted Grounded Theory Analysis of research impact evaluation frameworks drawn from cross-disciplinary peer-reviewed and grey literature.

Results: Recognizing the subjective nature of impacts as they are perceived by different groups in different times, places and cultures, we define research impact evaluation as the process of assessing the significance and reach of both positive and negative effects of research.

Five types of impact evaluation design are identified encompassing a range of evaluation methods and approaches: i) experimental and statistical methods; ii) textual, oral and arts-based methods; iii) systems analysis methods; iv) indicator-based approaches; and v) evidence synthesis approaches.

Our guidance enables impact evaluation design to be tailored to the aims and context of the evaluation, for example choosing a design to establish a body of research as a necessary (e.g. a significant contributing factor amongst many) or sufficient (e.g. sole, direct) cause of impact, and choosing the most appropriate evaluation design for the type of impact being evaluated.

Conclusion: Using the proposed definitions, typology and methodological framework, researchers, funders and other stakeholders working across multiple disciplines can select a suitable evaluation design and methods to evidence the impact of research from any discipline.

1. Introduction

Interest is growing rapidly in the evaluation of non-academic benefits or "impacts" (see Section 3 for definition) arising from research, as funders and Governments around the world increasingly seek evidence of the value of their research investments to society (Edler et al., 2012; Oancea, 2019). The growth of research over the past few decades has outstripped available public funding in many countries, leading to discussions about how to get best value from research, particularly basic research which may not have immediate application (Boreman, 2012). The Global Financial Crisis of 2007/8, further intensified discussions about how to measure the quality of research and how to evaluate its

evidence to justify budgetary requests to governments. The drive to evaluate the societal impact of research is exemplified by the assessment of non-academic impact by the UK's Research Excellence Framework in 2014 and 2021 (REF; the system for assessing the quality of research in UK higher education institutions), and the growing trend to evaluate research impact at national scales around the world (Box 1).

In this paper, we refer to evaluation as the process of collecting and interpreting data to assess the significance, reach and attribution of impacts from research. We refer to evidence as the communication or "demonstration" of impact based on robust evaluation. However, defining the benefits of research is a highly subjective process, and a benefit for one group in one place, time and culture, may be perceived as



Cosa premiare in una ricerca?

La potenzialità di far crescere le sinergie tra pubblico, diversi stakeholder e privato?





La qualità formale di una *application* è indicatore di qualità sostanziale?

"Quality is seen as not only a rich concept but also a complex concept in which excellence and innovativeness, methodological aspects, engagement of stakeholders, multidisciplinary collaboration, and societal relevance all play a role."

Roumbanis L. Academic judgments under uncertainty: A study of collective anchoring effects in Swedish Research Council panel groups. Social studies of science. 2017 Feb;47(1):95-116.





La componente etica e l'attenzione allo spreco può essere un criterio di valutazione di una proposta di ricerca?

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.

Introduction

More than 30 years ago, the adverse clinical consequences of biased under-reporting of research were clearly

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 original distance.

Lancet 2016; 387: 1573-86

Published Online September 28, 2015 http://dx.doi.org/10.1016/ S0140-6736(15)00307-4

Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, ON, Canada (D Moher PhD, Prof I D Graham PhD); School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, ON, Ottawa, Canada (D Moher, Prof I D Graham); Centre for Research in Evidence Based Practice, Bond University, Robina, QLD, Australia

La componente etica e l'attenzione allo spreco può essere un criterio di valutazione di una proposta di ricerca?

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.

Introduction

More than 30 years ago, the adverse clinical consequences of biased under-reporting of research were clearly

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 original distance.

Lancet 2016; 387: 1573-86

Published Online September 28, 2015 http://dx.doi.org/10.1016/ S0140-6736(15)00307-4

Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, ON, Canada (D Moher PhD, Prof I D Graham PhD); School of Epidemiology, Public Health and Preventive Medicine, University of Ottawa, ON, Ottawa, Canada (D Moher, Prof I D Graham); Centre for Research in Evidence Based Practice, Bond University, Robina, QLD, Australia

Latest Issues

SCIENTIFIC AMERICAN

Sign In | Newsletters

POLICY

Science Funding Is Broken

The way we pay for science does not encourage the best results

By John P. A. Ioannidis on October 1, 2018





READ THIS NEXT

CLIMATE CHANGE

Journey to the Thawing Edge of Climate Change

Jocie Bentley

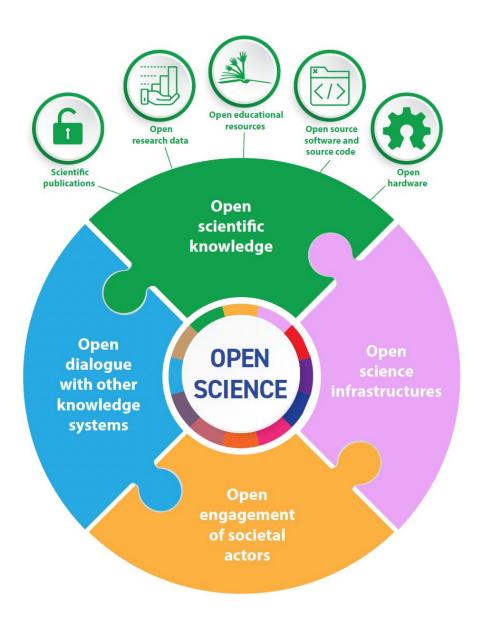
PSYCHOLOGY

Know Yourself Better by Writing What Pops into Your Head

Christiane Gelitz

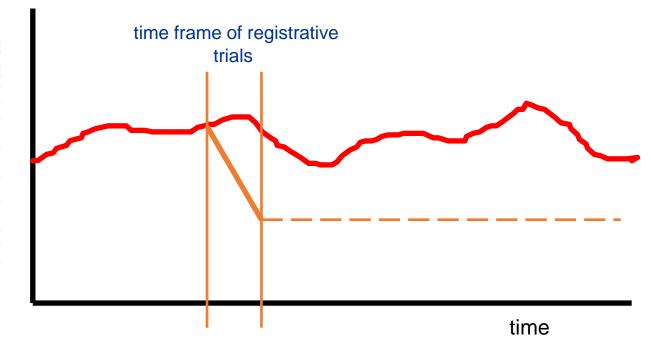
CONSERVATION

5'33' C3.5



Encourage and value open science practices, such as data sharing and transparent methodologies. Collaboration and open communication facilitate a quicker dissemination of knowledge.

Collaborative efforts and interdisciplinary research become increasingly important in addressing complex and evolving scientific questions.



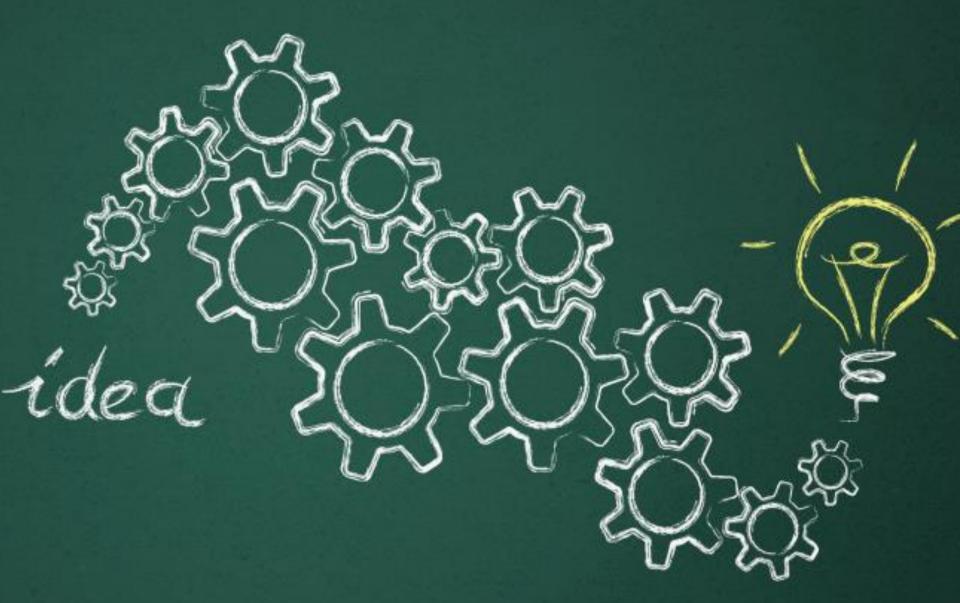
- ✓ Consider the potential long-term impact of research rather than immediate results. In rapidly changing fields, the true significance of a study may take time to unfold.
- ✓ Evaluate whether the research contributes to foundational knowledge or has practical implications for future studies and applications.

Ethical Considerations:

As new technologies and methodologies emerge, ethical considerations become paramount.

Evaluate research not only based on scientific merit but also on ethical practices and implications

Liberati principles



FARE EPIDEMIOLOGIA DELLA RICERCA PER NON DISPERDERE LE RISORSE DEL SERVIZIO SANITARIO NAZIONALE

AN EPIDEMIOLOGY OF RESEARCH TO AVOID DISSIPATION OF RESOURCES OF THE ITALIAN NATIONAL HEALTH SERVICE

Antonio Addis, Marina Davoli

Dipartimento di epidemiologia del Servizio sanitario regionale, Regione Lazio, ASL Roma 1 **Corrispondenza:** Antonio Addis; a.addis@deplazio.it



Epidemiol Prev 2018; 42 (1):96-97. doi:10.19191/EP18.1.P096.027

CRITERI	RILEVANZA DEL PROGETTO	ADEGUATEZZA DEL PROGETTO	FATTIBILITÀ DEL PROGETTO E RISPETTO DELLE NORME REGOLATORIE	ACCESSIBILITÀ DEL DATO	UTILIZZABILITÀ DEL DATO
Indicatori di	 bisogno di conoscenza rilevanza delle patologie assenza di terapie disponibili 	 produzione scientifica collaborazione, partnership e networking 	attività scientifica coerenza normativa	 disseminazione scientifica disponibilità del dato 	 servizio e disseminazione capacità di trasferire il dato accessibilità e riutilizzo dei dati
Strumenti	 analisi dei bisogni di ricerca effettuati da agenzie internazionali revisioni sistematiche della letteratura analisi degli obiettivi finanziati nei programmi di ricerca sanitaria 	 misurazione produzione scientifica misurazione della coerenza nella produzione scientifica (per esempio, H index, bibliometria) misurazione collaborazione e networking (nazionale e internazionale) valutazione degli esiti degli interventi sanitari 	classificazione attività scientifica esame del rispetto GCP, GMP consultazione con la rete dei comitati etici	 pubblicazione dei protocolli su database internazionali e nazionali misurazione del piano di pubblicazione del dato prodotto messa a disposizione dei dati originali 	misurazione delle attività di servizio e di formazione misurazione del trasferimento nella pratica clinica (per esempio, linee guida)
Fonti e Database	 sistema informativo sanitario Cochrane database Programma nazionale esiti documenti di priority setting internazionali (WHO, AHRQ eccetera) 	SCIVAL Medline Embase CORE (Core Outcome Measures in Effectiveness Trials)	EUDRACT Clinicaltrial.gov Osservatorio sperimentazioni cliniche Comitati etici	• riviste open source	ECM Piano nazionale linee guida

Italian Medicine Agency criteria for drug's innovation



Medical Need	Add Therapeutical Value	Quality of evidence	
Maximum	Maximum	High	
Important	Important	Moderate	
Moderate	MOderate	Low	
Poor	Poor	Low	
Absent	Absent	Very Low	

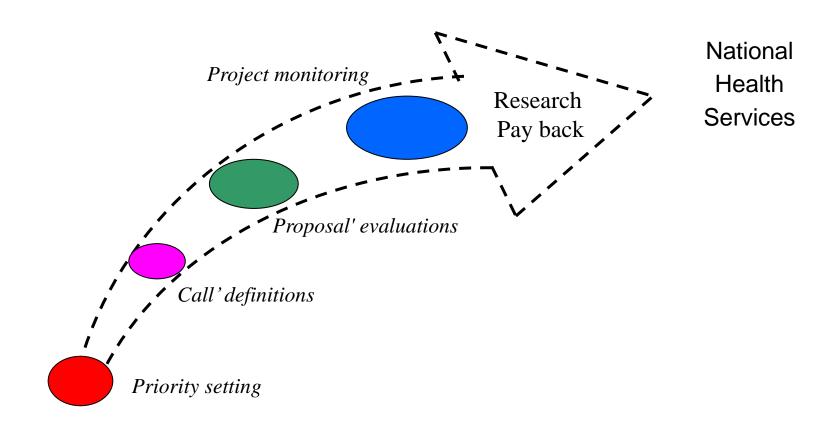
Innovativity

Full

Conditional

Absent

Better research for better health



Grazie per l'attenzione

Antonio Addis | a.addis@deplazio.it

