Methods: Mind the Gap
Webinar Series

Transparent, Open, and Reproducible Prevention Science

Presented by:
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HEDCO Institute for Evidence-Based Educational Practice
College of Education
University of Oregon

NIH National Institutes of Health
Office of Disease Prevention

Webinar Outline

- Factors Motivating Interest in Open Science
- Open Science Practices
- Open Science and Prevention Science
- Stakeholders and the Open Science Movement

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Prevention Science and Open Science

Effective Programs

Promising Programs

No Effects Program

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Images: https://www.cos.io/initiatives/badges, https://crimesolutions.ojp.gov/media/image/46

Growing Support for Open Science

AUGUST 25, 2022

OSTP Issues Guidance to Make Federally Funded Research Freely Available Without Delay

OSTP › BRIEFING ROOM › PRESS RELEASES

JANUARY 11, 2023

FACT SHEET: Biden-Harris Administration Announces New Actions to Advance Open and Equitable Research

OSTP › BRIEFING ROOM › PRESS RELEASES

Open Science Announcements from Federal Agencies

Open Science is the principle and practice of making research products and processes available to all, while respecting diverse cultures, maintaining security and privacy, and fostering collaborations, reproducibility, and equity.

Federal agencies are celebrating 2023 as a Year of Open Science, a multi-agency initiative across the federal government to spark change and inspire open science engagement through events and activities that will advance adoption of open, equitable, and secure science.

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Image: WhiteHouse.gov , OpenScience.gov

Prevention Science Special Issue on Open Science

Prevention Science (2022) 23:697–700
https://doi.org/10.1007/s11121-022-01393-1

Check for updates

Moving Toward Transparent, Open, and Reproducible Prevention Science: Introduction to the Special Issue

Sean Grant[1] · Frances Gardner[2] · Catherine P. Bradshaw[3]

Accepted: 2 June 2022 / Published online: 13 June 2022

"Open science" refers to a transdisciplinary movement to make scholarly activities more transparent, reproducible, and accessible (Framework for Open & Reproducible Research Teaching, 2022). While open science involves various principles and practices, proponents of this movement share an underlying aspiration to improve the credibility, utility, and inclusiveness of academic scholarship (Vicente-Saez & Martinez-Fuentes, 2018). Once a fringe concept, open science is now a focal point on the agendas of influential scientific organizations. In the USA, the National Academies of Sciences, Engineering, and Medicine has released a report related to open science each year for the last several years. Examples include open science as the default approach for twenty-first century science (National Academies of Sciences, Engineering, and Medicine, 2018), reproducibility and replicability in science (National Academies of Sciences, 2019), stakeholder perspectives on advancing open science (National Academies of Sciences, Engineering, and

To this end, this editorial serves as a brief introduction to this special issue of *Prevention Science*, entitled "Transparency, Openness, and Reproducibility: Implications for the Field of Prevention Science." The overall goal of this special issue is to facilitate the engagement of prevention science with the open science movement. Its specific aims are to introduce prevention scientists to transparent and reproducible research practices, provide prevention scientists with worked examples of using these practices, and discuss how prevention scientists can contribute their expertise to advancing the wider open science movement. The manuscripts included in this special issue aspire to stimulate this discourse through a primer on open science for prevention scientists, followed by examinations of replication in prevention and implementation science, study registration and null results in preventive intervention trials, open science and translational prevention research, and applications to prevention research methods.

Volume 23, issue 5, July 2022

Special Issue: Transparency, Openness, and Reproducibility: Implications for the Field of Prevention Science

Issue editors

Sean Grant, Frances Gardner & Catherine Bradshaw

13 articles in this issue

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Aligns Scientific Practice with Scientific Ideals

Norm	Counter-Norm
Communality: Scientists openly share new findings with colleagues. **Norm and Counter-Norm data. Norms include Communality, Universalism, Disinterestedness, and Organized Skepticism. Counter-Norms include Secrecy, Particularism, Self-Interestedness, and Organized Dogmatism.**	***Secrecy***: Scientists protect their newest findings to ensure priority in publishing, patenting, or applications.
Organized Dogmatism: Scientists evaluate research only on its merit, i.e., according to accepted standards of the field.	***Particularism***: Scientists assess new knowledge and its applications based on the reputation and past productivity of the individual or research group.
Disinterestedness: Scientists are motivated by the desire for knowledge and discovery, and not by the possibility of personal gain.	***Self-Interestedness***: Scientists compete with others in the same field for funding and recognition of their achievements.
Organized Skepticism: Scientists consider all new evidence, hypotheses, theories, and innovations, even those that challenge or contradict their own work.	***Organized Dogmatism***: Scientists invest their careers in promoting their own most important findings, theories, or innovations.

https://www.tandfonline.com/doi/abs/10.1080/00221546.2010.11779057

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Accelerate Scientific Discovery and Progress

Psychological Science Accelerator

A Distributed Laboratory Network

https://psysciacc.org/

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Broadening Access to Scientific Knowledge

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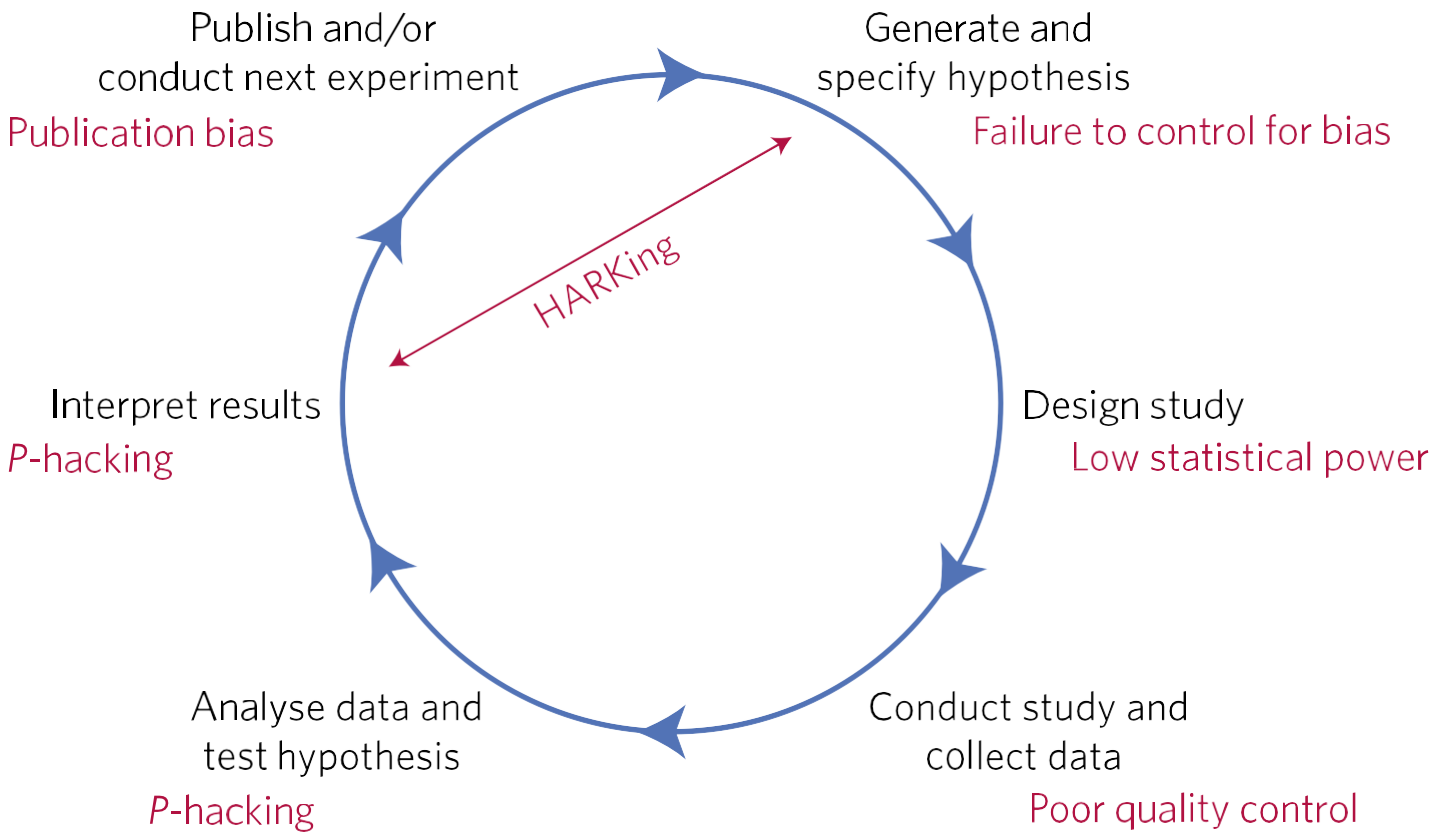
Undisclosed Flexibility Across the Research Lifecycle: Researcher Degrees of Freedom



https://www.nature.com/articles/s41562-016-0021

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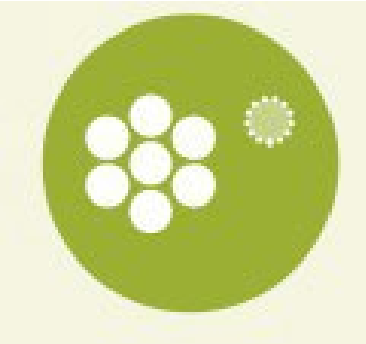
The "Reproducibility Crisis"

Study	Discipline	Objective	Replication Findings
Camerer et al. (2016)	Economics	Attempt to replicate 18 studies from AER and QJE in 2011-2014	- 61% significant effect, same direction as original - Replicated effect size 66% of original on average
Camerer et al. (2018)	Social Sciences	Attempt to replicate 21 experimental studies in Nature and Science	- 62% significant effect, same direction as original - Replicated effect size 50% of original on average
Chang and Li (2015)	Economics	Attempt to reproduce findings from 67 papers using original data and code	- 33% replication of key qualitative result - 49% replication with original author assistance
Klein et al. (2014)	Psychology	Attempt to replicate 13 psychological effects using 36 independent samples	- 10 effects replicated consistently - Effects did not differ by setting or country
Open Science Collaboration (2015)	Psychology	Attempt to replicate 100 studies from three high-ranking journals	- 36% were statistically significant - 47% had 95% CI containing original effect size

Detrimental Research Practices

Underspecified Methods
Methods and analytic plan are not shared with other scientists in sufficient detail.



Reporting Bias
When scientists or journals decide not to publish analyses, outcomes, or entire studies (e.g., results are not statistically significant).

Human Error
Technical errors may exist within a study, (e.g., computational errors, copy/paste mistakes).

Data dredging (p-hacking)
Repeatedly searching a dataset or trying alternative analyses until a (significant) result is found.

https://acmedsci.ac.uk/policy/policy-projects/reproducibility-and-reliability-of-biomedical-research

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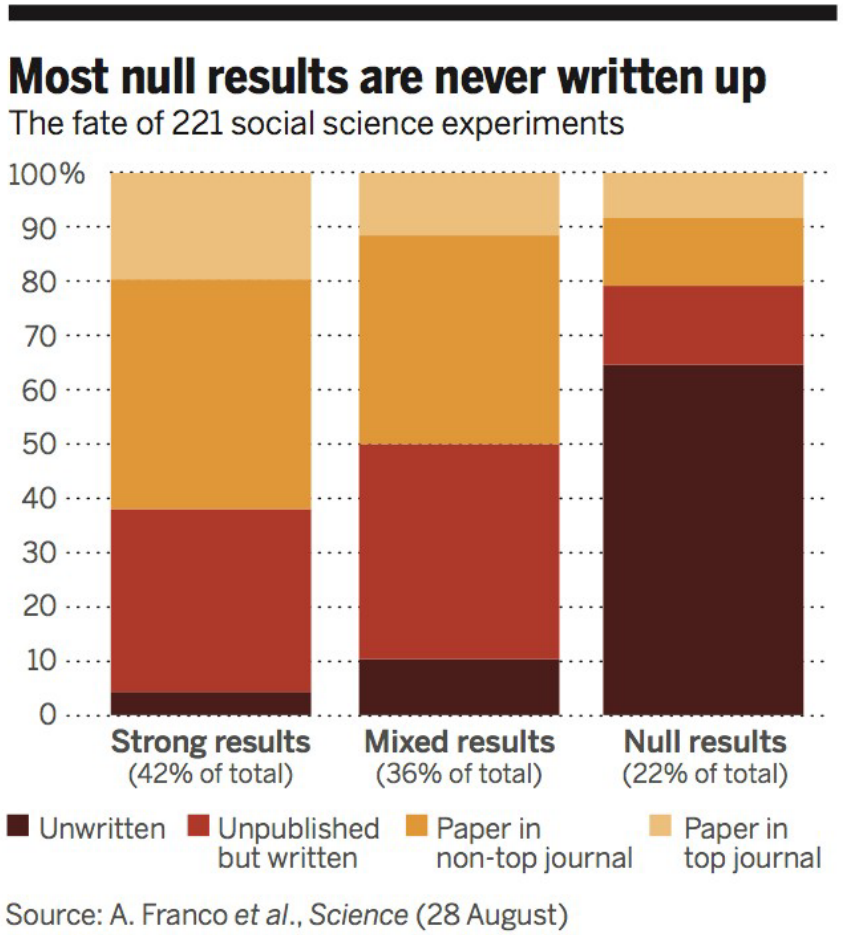
Publication Bias



https://www.science.org/doi/10.1126/science.1255484

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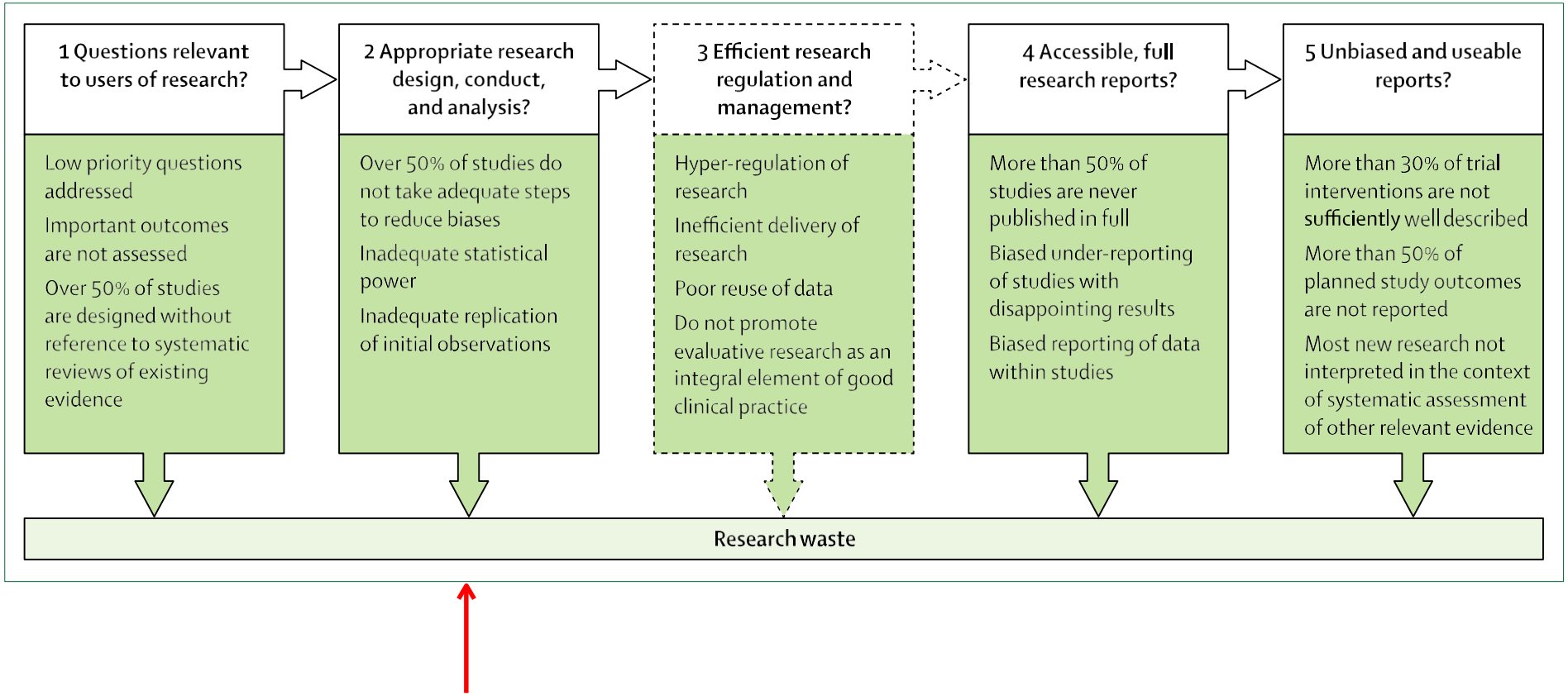
Closed Workflows Enable Other Detrimental Practices



https://www.sciencedirect.com/science/article/pii/S0140673615003074

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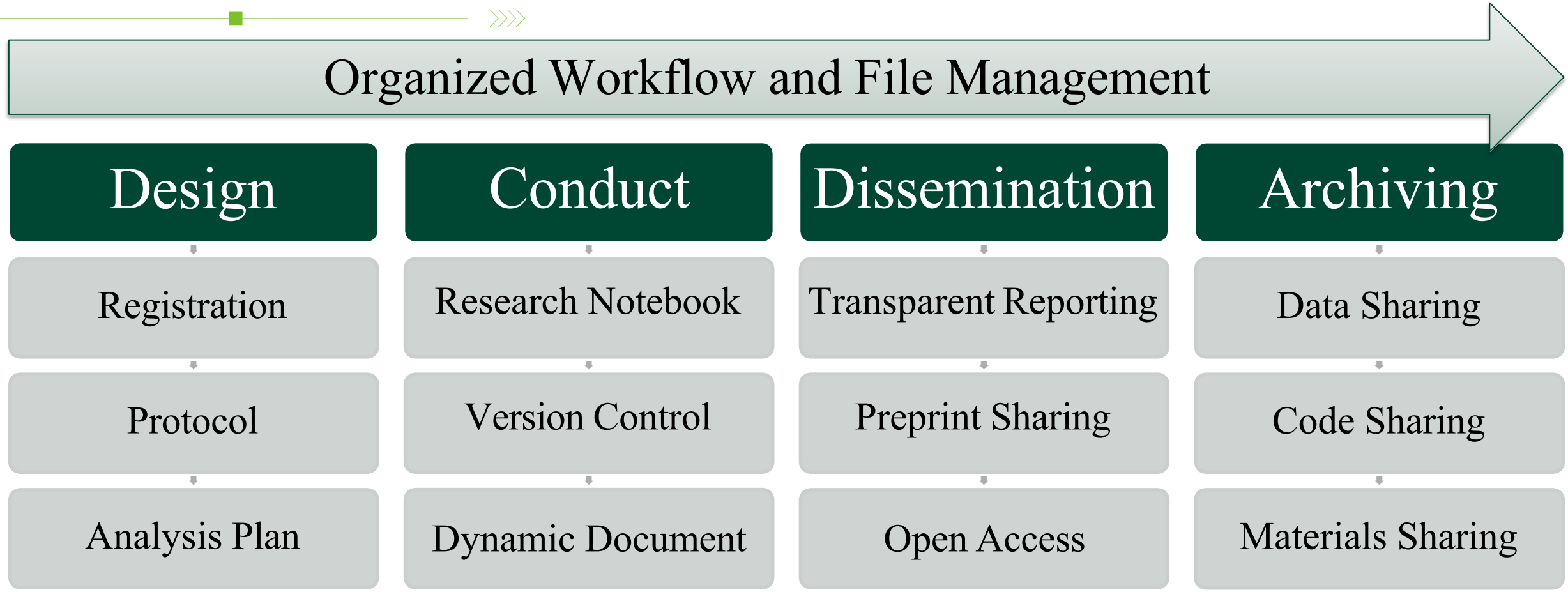
An Overview of Core Open Science Practices



https://link.springer.com/article/10.1007/s11121-022-01336-w

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Study Registration

NIH GRANTS & FUNDING
NIH Central Resource for Grants and Funding Information

NIH U.S. National Library of Medicine
ClinicalTrials.gov

Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov

All NIH-funded clinical trials are expected to register and submit results information to Clinicaltrials.gov, as per the "NIH Policy on Dissemination of NIH-Funded Clinical Trial Information" for competing applications and contract proposals submitted on or after January 18, 2017 . This website provides resources for understanding and complying with this NIH policy and the federal regulations in Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) as implemented by 42 CFR Part 11 (Final Rule).

https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

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Study Protocols and Analysis Plans

National Institutes of Health
Office of Behavioral and Social Sciences Research

Clinical Trials Protocol Template for the Behavioral and Social Sciences

The Clinical Trials Protocol Template for the Behavioral and Social Sciences is a resource for communicating the science, methods, and operations of a clinical trial. This template is a suggested format for clinical trials that are testing a behavioral or social intervention or experimental manipulation. Use of the protocol template is encouraged but not required.

The Behavioral and Social Clinical Trials Template was derived from the successful NIH-FDA Phase 2/3 IND-IDE Clinical Trial Template but was adapted to include terminology and approaches used by behavioral and social scientists.

While the template is a suggested format for clinical trials that are testing a behavioral or social intervention or manipulation for which a stand-alone clinical protocol is required, the template can also be a useful tool for those trials funded by NIH Institutes or Centers that do not require stand-alone clinical protocols. Using the template to anticipate decision points and potential challenges before a study launches can help avoid subsequent delays and problems.

https://obssr.od.nih.gov/research-resources/bssr-clinical-trials

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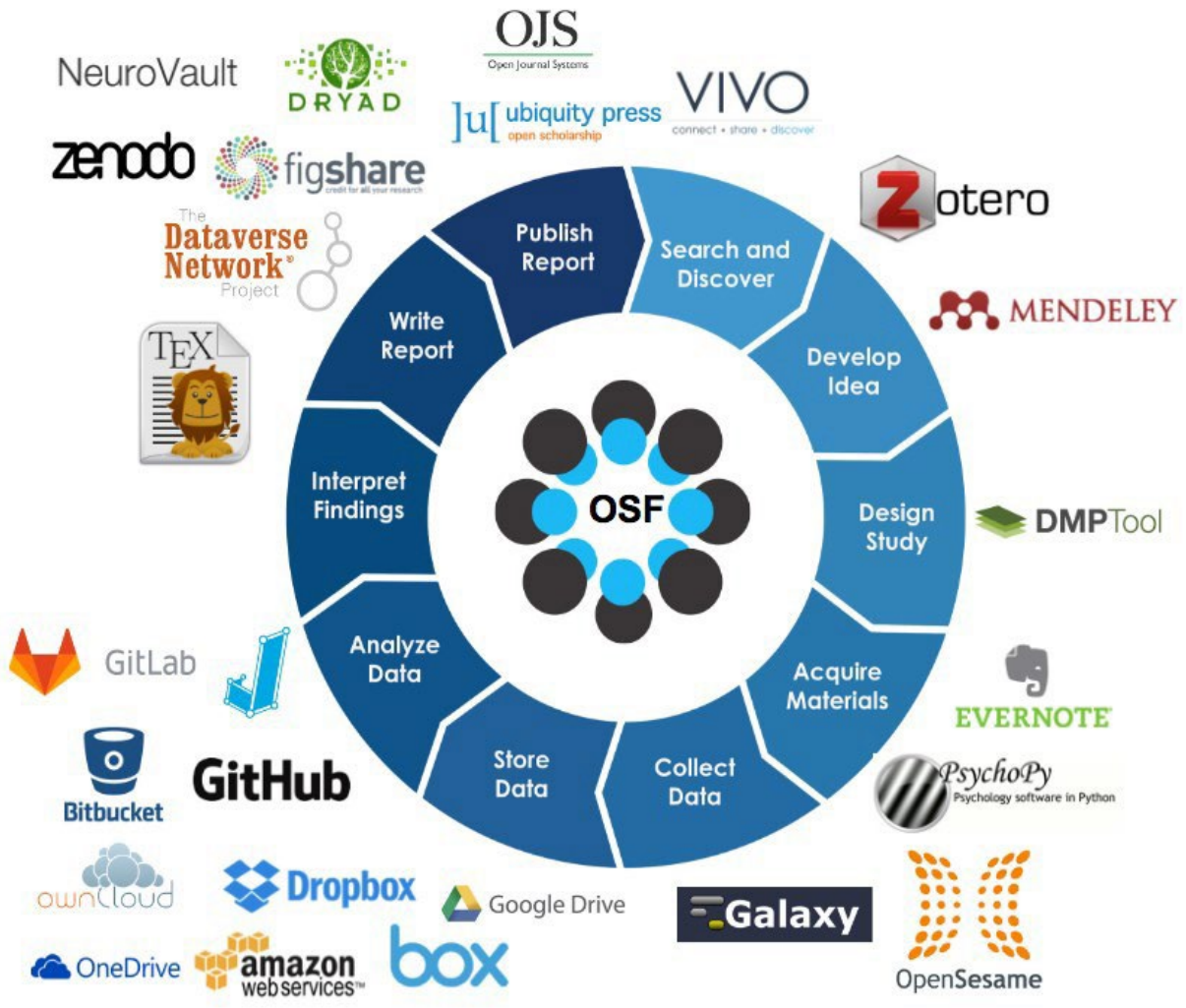
Organized Workflows



https://osf.io/

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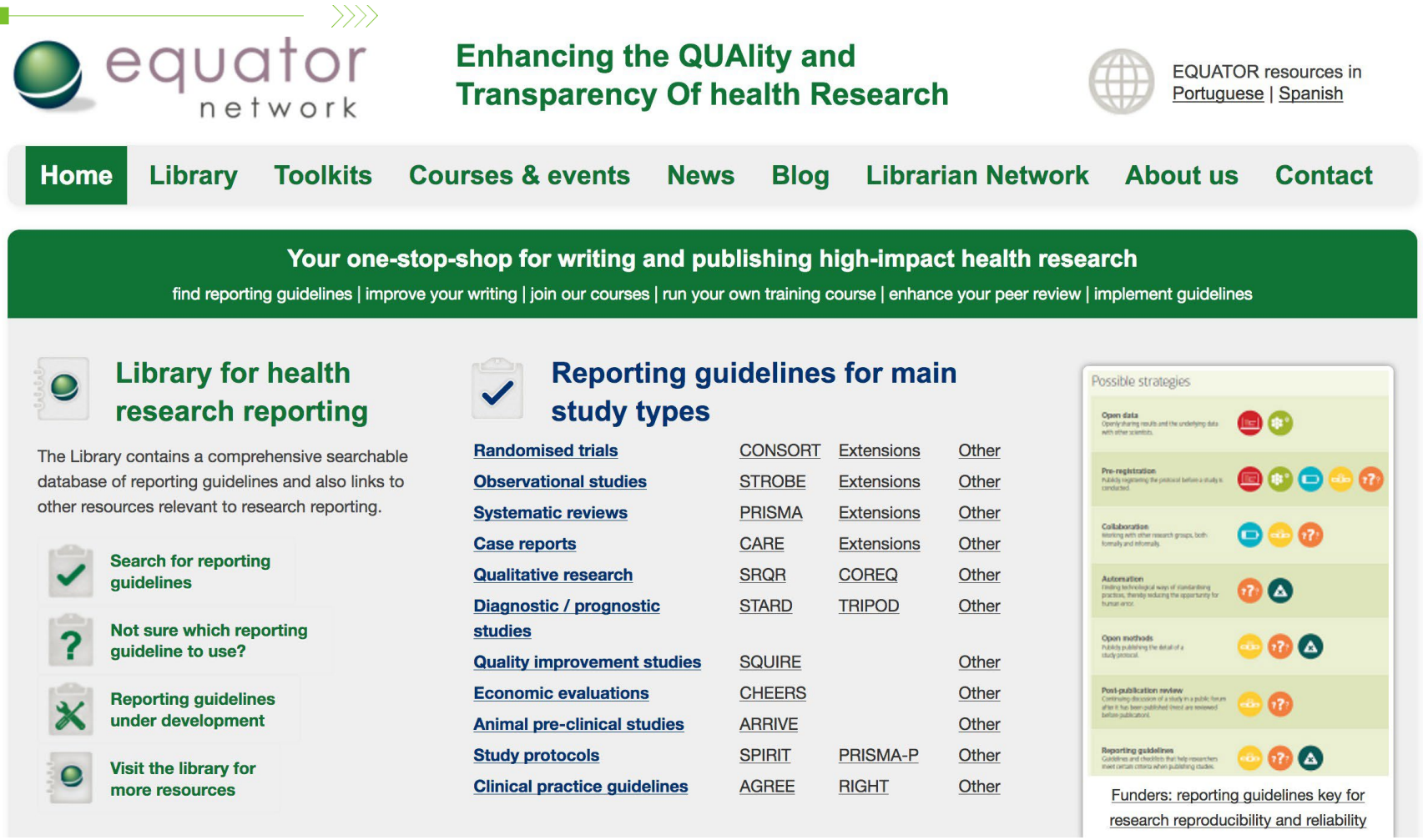
Transparent Reporting



http://www.equator-network.org/

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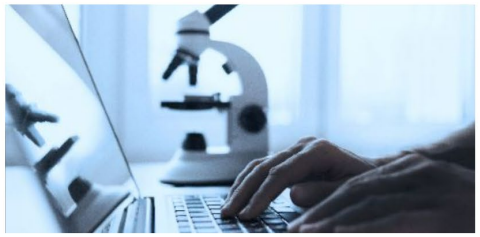
Data, Code, and Materials Sharing

SCIENTIFIC DATA SHARING

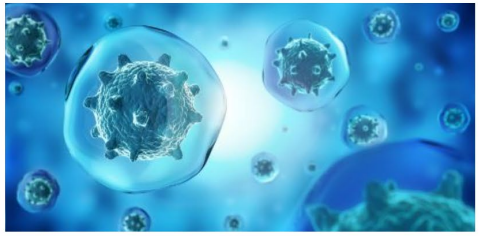
Explore the areas in which NIH has sharing policies.



Scientific Data

Genomic Data

Research Tools



Model Organisms

Clinical Trials

Research Publications

https://sharing.nih.gov/

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Applying Open Science in Prevention Science: Epidemiological Research

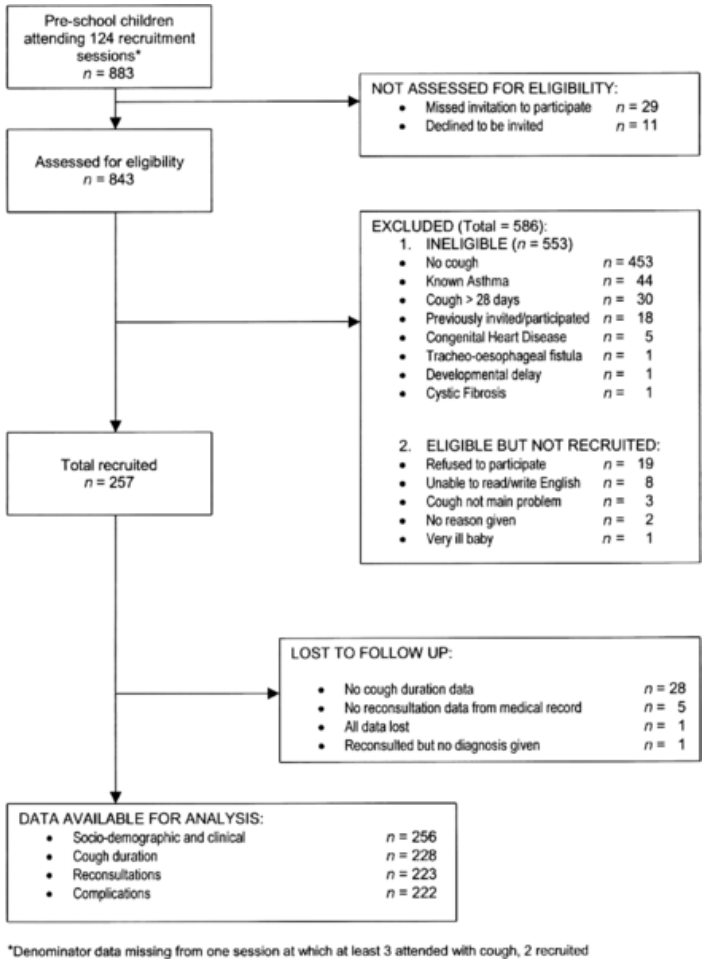
Image: https://www.strobe-statement.org/

Table. **The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: Checklist of Items That Should Be Addressed in Reports of Observational Studies**

Item	Item Number	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract. (b) Provide in the abstract an informative and balanced summary of what was done and what was found.
Introduction		
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported.
Objectives	3	State specific objectives, including any prespecified hypotheses.
Methods		
Study design	4	Present key elements of study design early in the paper.
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection.
Participants	6	(a) Cohort study: Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up. Case–control study: Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls. Cross-sectional study: Give the eligibility criteria, and the sources and methods of selection of participants. (b) Cohort study: For matched studies, give matching criteria and number of exposed and unexposed. Case–control study: For matched studies, give matching criteria and the number of controls per case.
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable.
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group.
Bias	9	Describe any efforts to address potential sources of bias.
Study size	10	Explain how the study size was arrived at.
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen, and why.
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding. (b) Describe any methods used to examine subgroups and interactions. (c) Explain how missing data were addressed. (d) Cohort study: If applicable, explain how loss to follow-up was addressed. Case–control study: If applicable, explain how matching of cases and controls was addressed. Cross-sectional study: If applicable, describe analytical methods taking account of sampling strategy. (e) Describe any sensitivity analyses.
Results		
Participants	13*	(a) Report the numbers of individuals at each stage of the study—e.g., numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analyzed. (b) Give reasons for nonparticipation at each stage. (c) Consider use of a flow diagram.
Descriptive data	14*	(a) Give characteristics of study participants (e.g., demographic, clinical, social) and information on exposures and potential confounders. (b) Indicate the number of participants with missing data for each variable of interest. (c) Cohort study: Summarize follow-up time—e.g., average and total amount.
Outcome data	15*	Cohort study: Report numbers of outcome events or summary measures over time. Case–control study: Report numbers in each exposure category or summary measures of exposure. Cross-sectional study: Report numbers of outcome events or summary measures.
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (e.g., 95% confidence intervals). Make clear which confounders were adjusted for and why they were included. (b) Report category boundaries when continuous variables were categorized. (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period.
Other analyses	17	Report other analyses done—e.g., analyses of subgroups and interactions and sensitivity analyses.
Discussion		
Key results	18	Summarize key results with reference to study objectives.
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias.
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence.
Generalizability	21	Discuss the generalizability (external validity) of the study results.
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based.

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

An Explanation and Elaboration article (18–20) discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available at www.annals.org and on the Web sites of *PLoS Medicine* [www.plosmedicine.org] and *Epidemiology* [www.epidem.com]). Separate versions of the checklist for cohort, case–control, and cross-sectional studies are available on the STROBE Web site (www.strobe-statement.org).



*Denominator data missing from one session at which at least 3 attended with cough, 2 recruited

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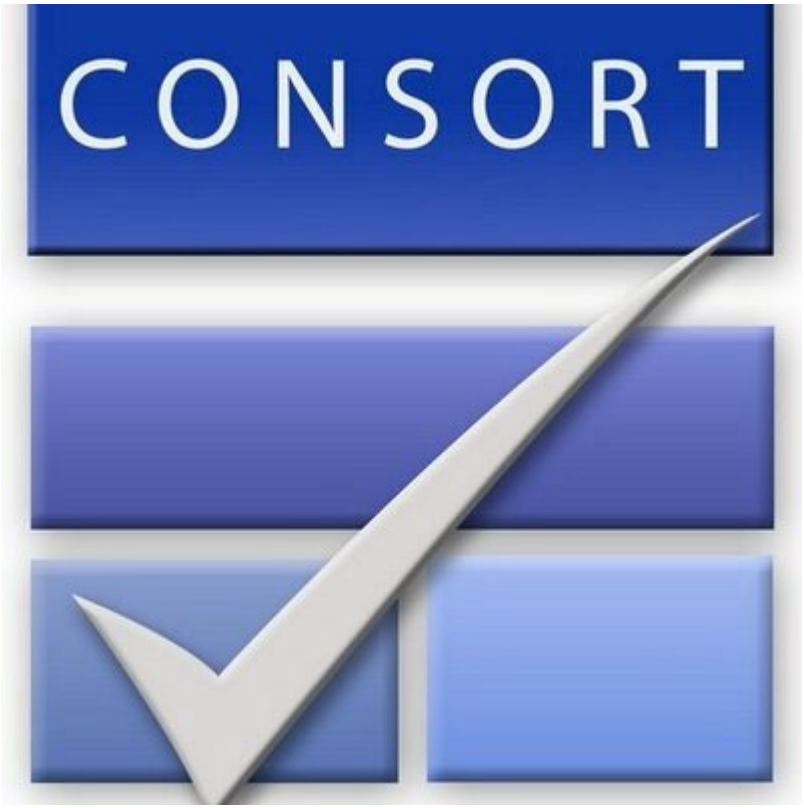
Intervention Research



Grant *et al. Trials* (2018) 19:406
https://doi.org/10.1186/s13063-018-2735-z

Trials

METHODOLOGY Open Access

CONSORT-SPI 2018 Explanation and Elaboration: guidance for reporting social and psychological intervention trials

Sean Grant[1*], Evan Mayo-Wilson[2], Paul Montgomery[3], Geraldine Macdonald[4], Susan Michie[5], Sally Hopewell[6], David Moher[7], on behalf of the CONSORT-SPI Group

Abstract

Background: The CONSORT (Consolidated Standards of Reporting Trials) Statement was developed to help biomedical researchers report randomised controlled trials (RCTs) transparently. We have developed an extension to the CONSORT 2010 Statement for social and psychological interventions (CONSORT-SPI 2018) to help behavioural and social scientists report these studies transparently.

Methods: Following a systematic review of existing reporting guidelines, we conducted an online Delphi process to prioritise the list of potential items for the CONSORT-SPI 2018 checklist identified from the systematic review. Of 384 international participants, 321 (84%) participated in both rating rounds. We then held a consensus meeting of 31 scientists, journal editors, and research funders (March 2014) to finalise the content of the CONSORT-SPI 2018 checklist and flow diagram.

Results: CONSORT-SPI 2018 extends 9 items (14 including sub-items) from the CONSORT 2010 checklist, adds a new item (with 3 sub-items) related to stakeholder involvement in trials, and modifies the CONSORT 2010 flow diagram. This Explanation and Elaboration (E&E) document is a user manual to enhance understanding of CONSORT-SPI 2018. It discusses the meaning and rationale for each checklist item and provides examples of complete and transparent reporting.

Conclusions: The CONSORT-SPI 2018 Extension, this E&E document, and the CONSORT website (www.consort-statement.org) are helpful resources for improving the reporting of social and psychological intervention RCTs.

Keywords: CONSORT, Randomised controlled trial, Reporting guideline, Reporting standards, Transparency

Background

CONSORT-SPI 2018 explanation and elaboration

The CONSORT (Consolidated Standards of Reporting Trials) Statement was developed to help authors report randomised controlled trials (RCTs) [1]. It has improved the quality of reports in medicine [2–5], and has been officially endorsed by over 600 journals and prominent editorial groups [6]. A smaller number of journals have implemented CONSORT—particularly its extension statements—as a requirement for the manuscript submission, peer-review, and editorial decision-making process [6, 7].

There are extensions of the CONSORT Statement (http://www.consort-statement.org/extensions) for specific trial designs [8–11], types of data (e.g. patient-reported outcomes, harms, and information in abstracts) [12–14], and interventions [15–17].

Several reviews have shown that RCTs of social and psychological interventions are often not reported with sufficient accuracy, comprehensiveness, and transparency to replicate these studies, assess their quality, and understand for whom and under what circumstances the evaluated intervention should be delivered [18–22]. Moreover, behavioural and social scientists may be prevented from reproducing or synthesising previous studies because trial protocols, outcome data, and the materials required to implement social and psychological interventions are often

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Full list of author information is available at the end of the article

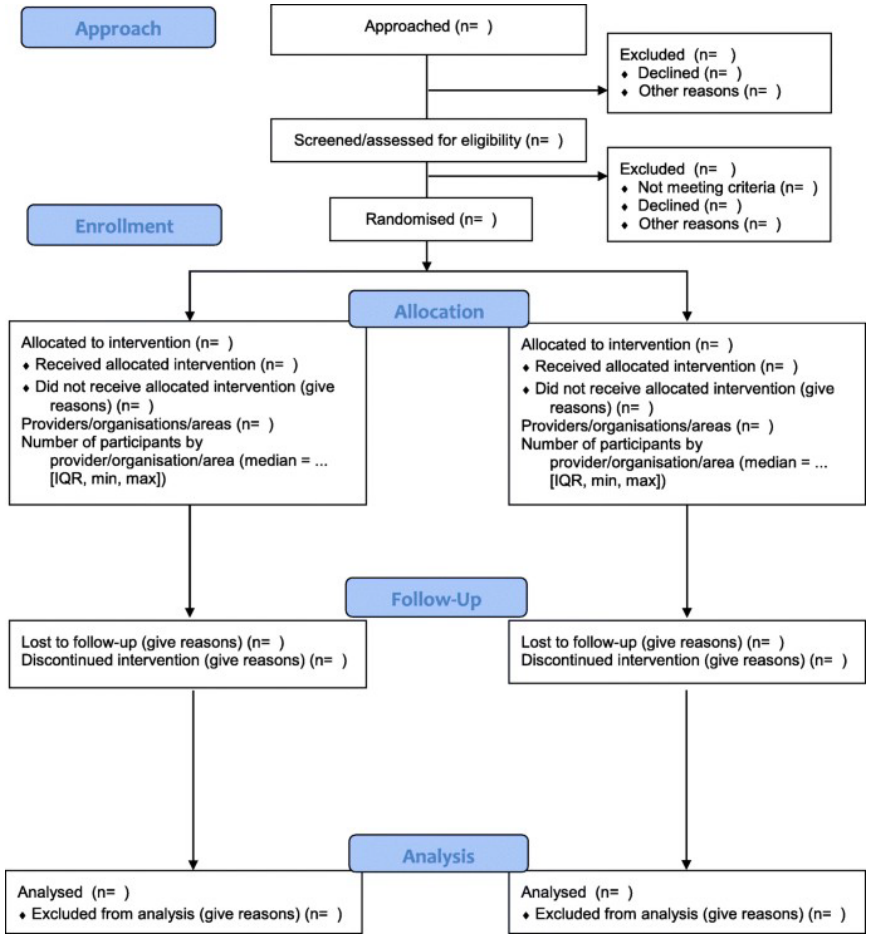

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Image: http://www.consort-statement.org/

Translational Research

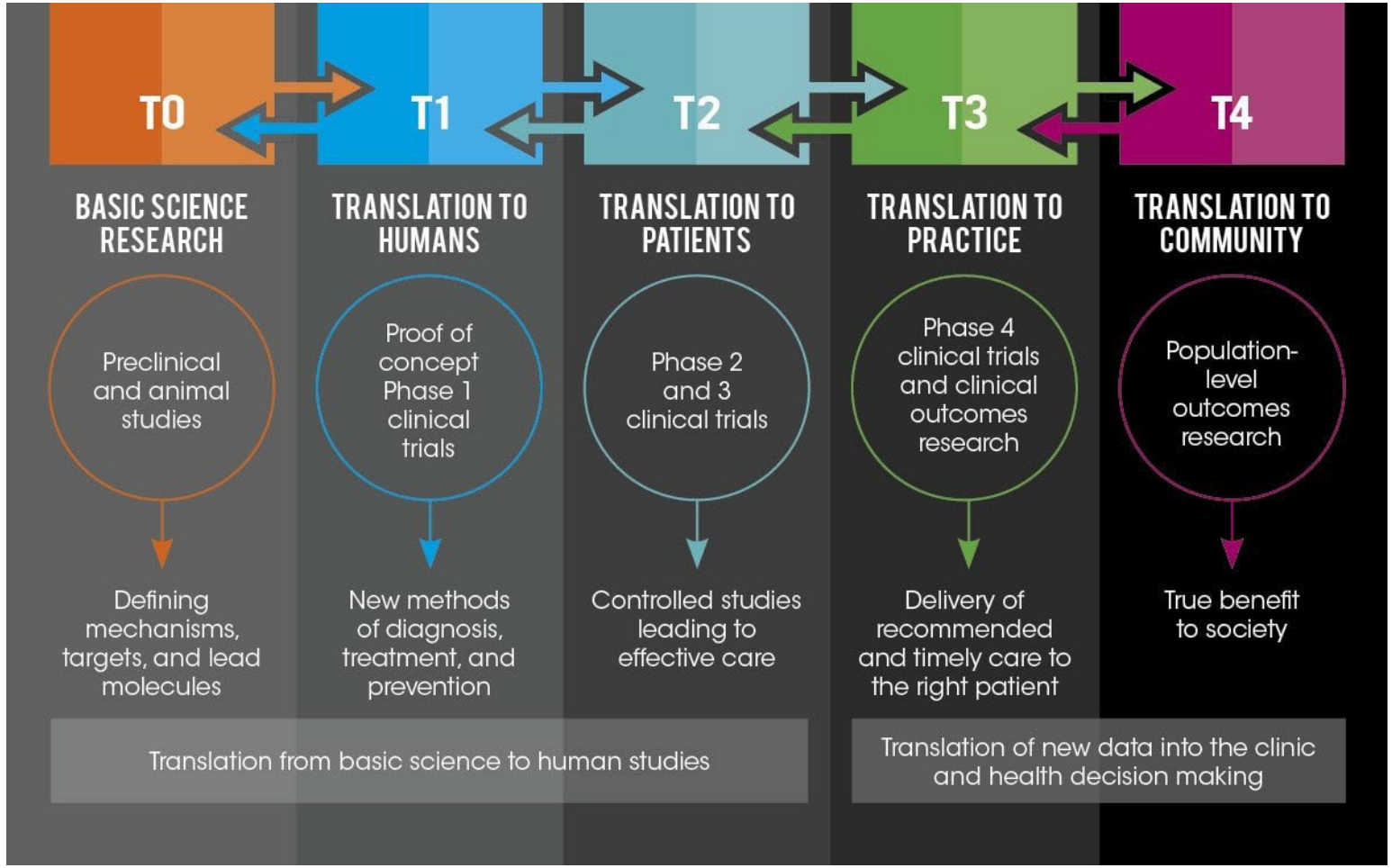

Image: https://tri.uams.edu/

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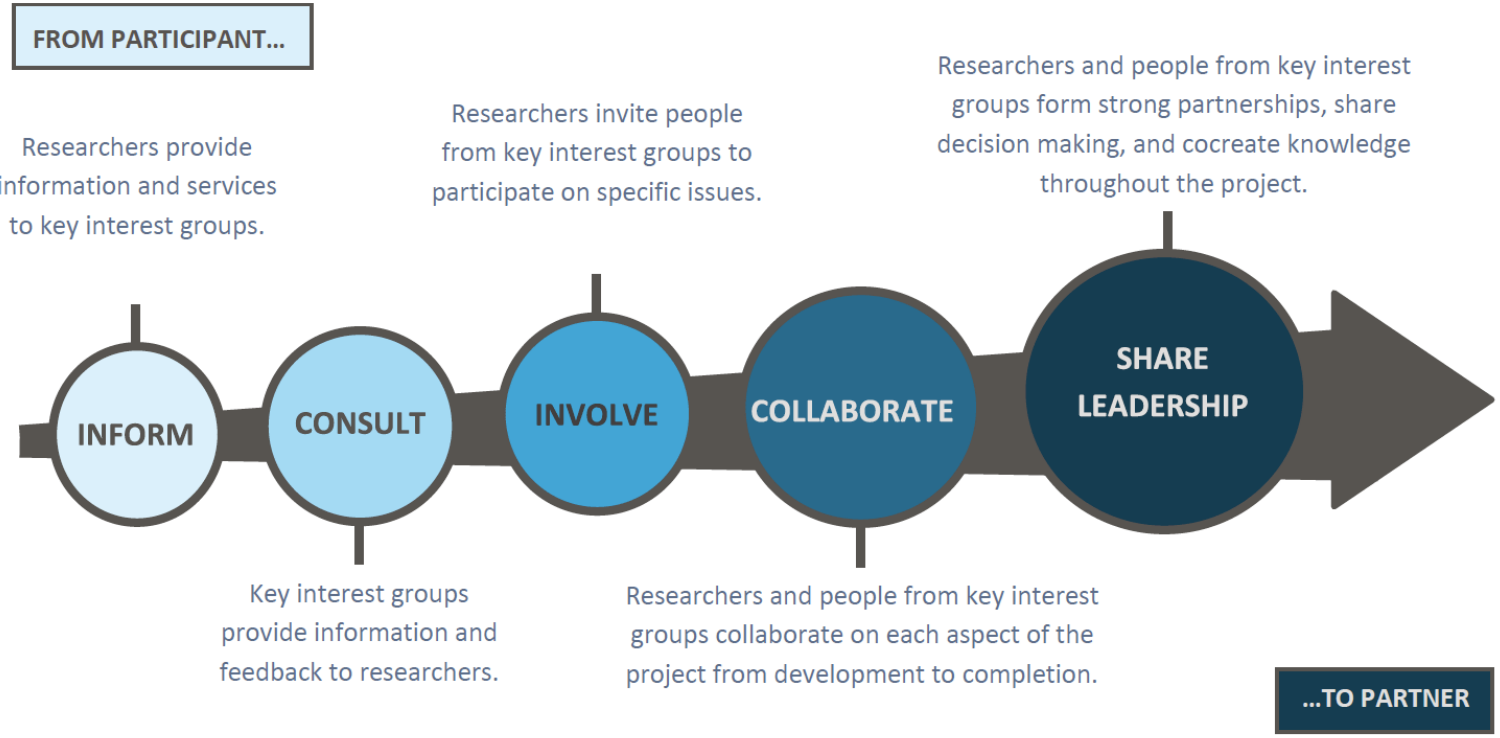
Community-Based Participatory Research

Exhibit 1. Continuum of engagement in research



Adapted from:
Balazs, C. L., & Morello-Frosch, R. (2013). The three R's: How community based participatory research strengthens the rigor, relevance and reach of science. *Environmental Justice, 6*(1).
National Institutes of Health. (2011). *Principles of community engagement second edition.* (NIH Publication No. 11-7782).

Image: https://www.hvresearch.org/

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Qualitative Research

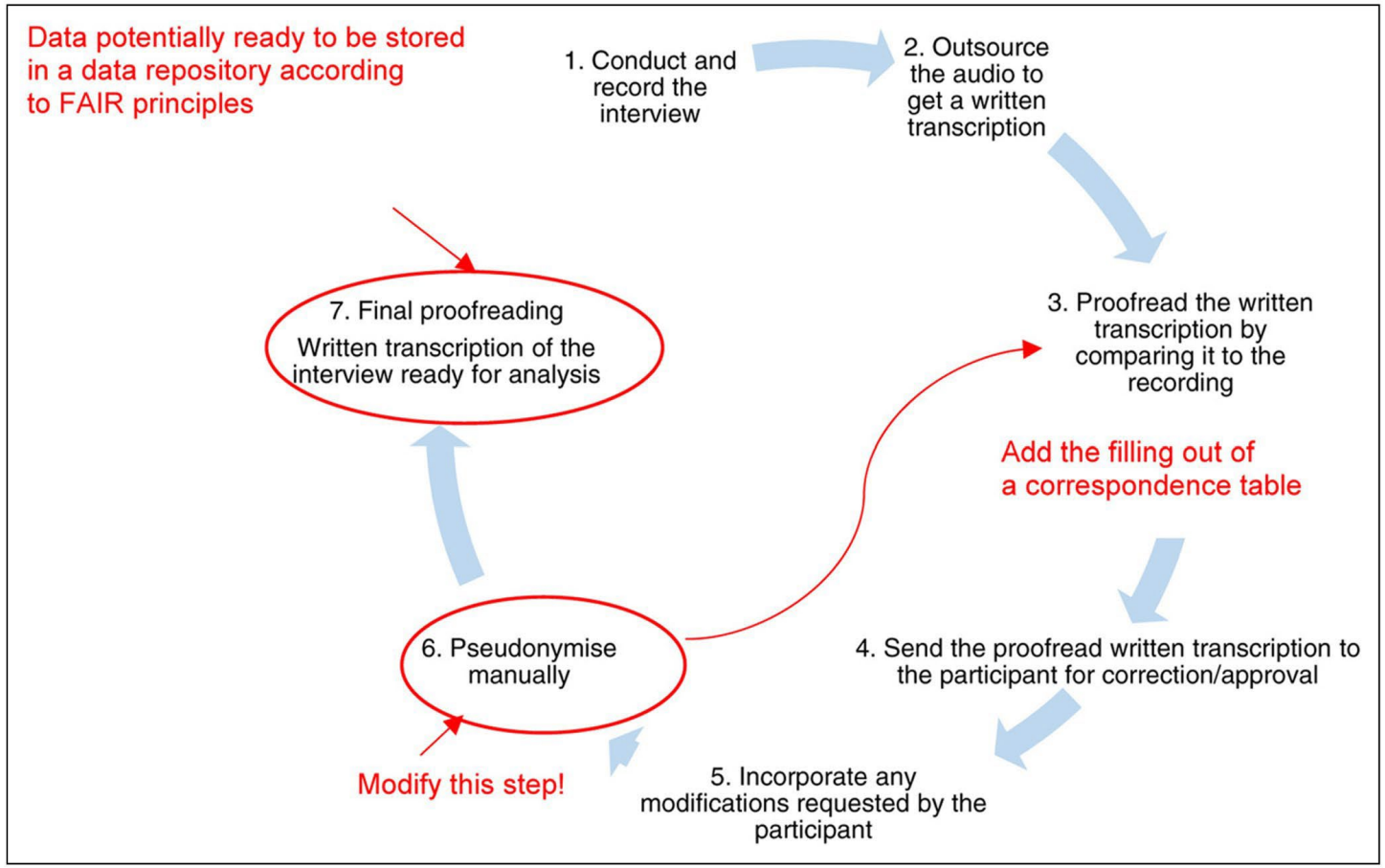

Figure 4. Process to prepare interview data for analysis.

Image: https://pubmed.ncbi.nlm.nih.gov/24979285/

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Research Using Administrative Data

Data Accelerator

The Data Accelerator provides leadership in the acquisition, linkage, use, and secure storage of sensitive human health and social science administrative data.

Learn More

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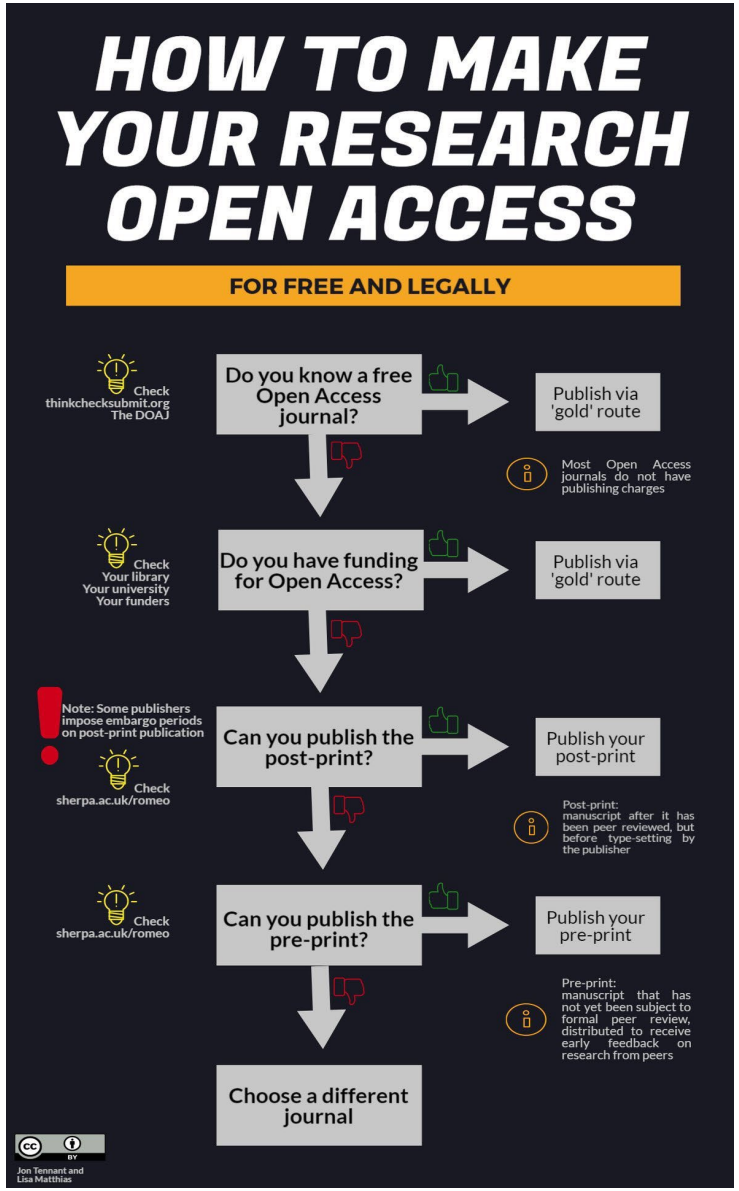
Image: https://evidence2impact.psu.edu/

Potential Challenges of an Open Prevention Science

- Tensions with intellectual property and sensitive personally identifiable information
- Scooping and excessive criticism
- Reinforcing inequitable power structures within science
- Additional bureaucracy and burdensome regulation
- Stifles creativity and nonexperimental work
- Potential to falsely signal quality

Stakeholders in the Scientific Ecosystem

Journals and Publishers



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Images: https://www.cos.io/;
https://figshare.com/articles/dataset/How_to_make_your_research_open_access_For_free_and_legally_/5285512?file=9052321

Funders

Image: https://www.orfg.org/

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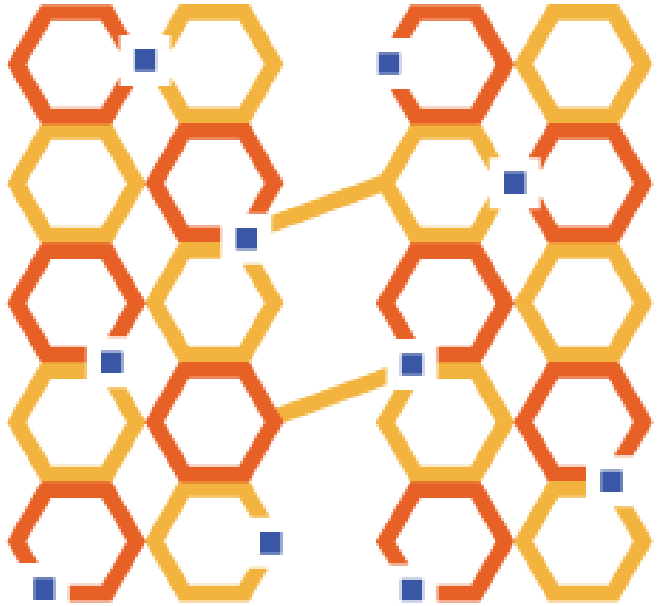
Universities and Research Institutions



HELIOS

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Image: https://www.heliosopen.org/

Key Stakeholders in the Scientific Ecosystem: Practice and Policy Decision-Making

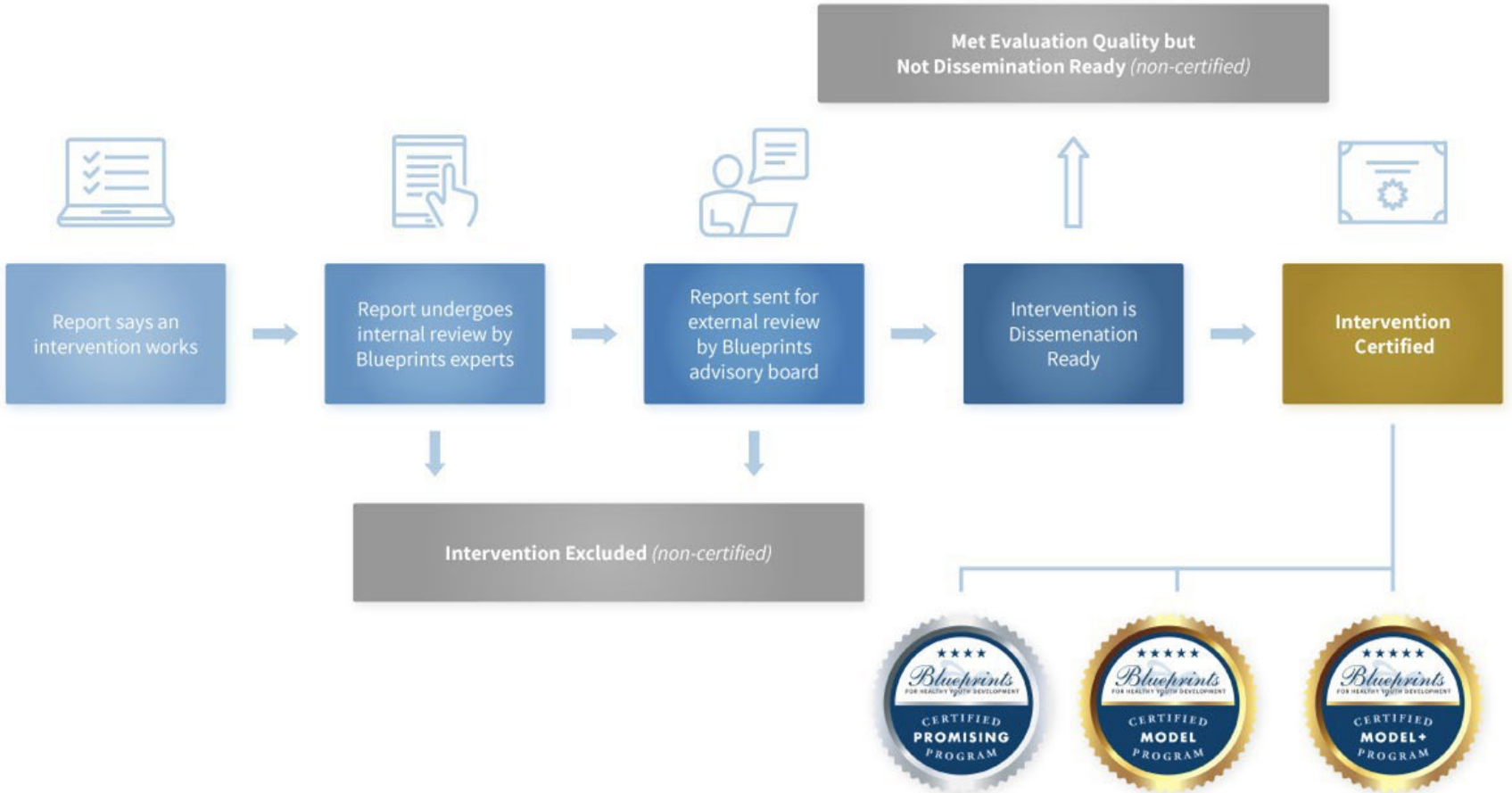

Image: Blueprints for Healthy Youth Development

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Public Engagement with Prevention Science

THE UNIVERSITY OF SYDNEY

The Australian Prevention Partnership Centre
Systems and solutions for better health

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Image: https://preventioncentre.org.au/, https://senseaboutscience.org/

Development of Evidence Base on Open Science Reform Efforts as “Interventions"

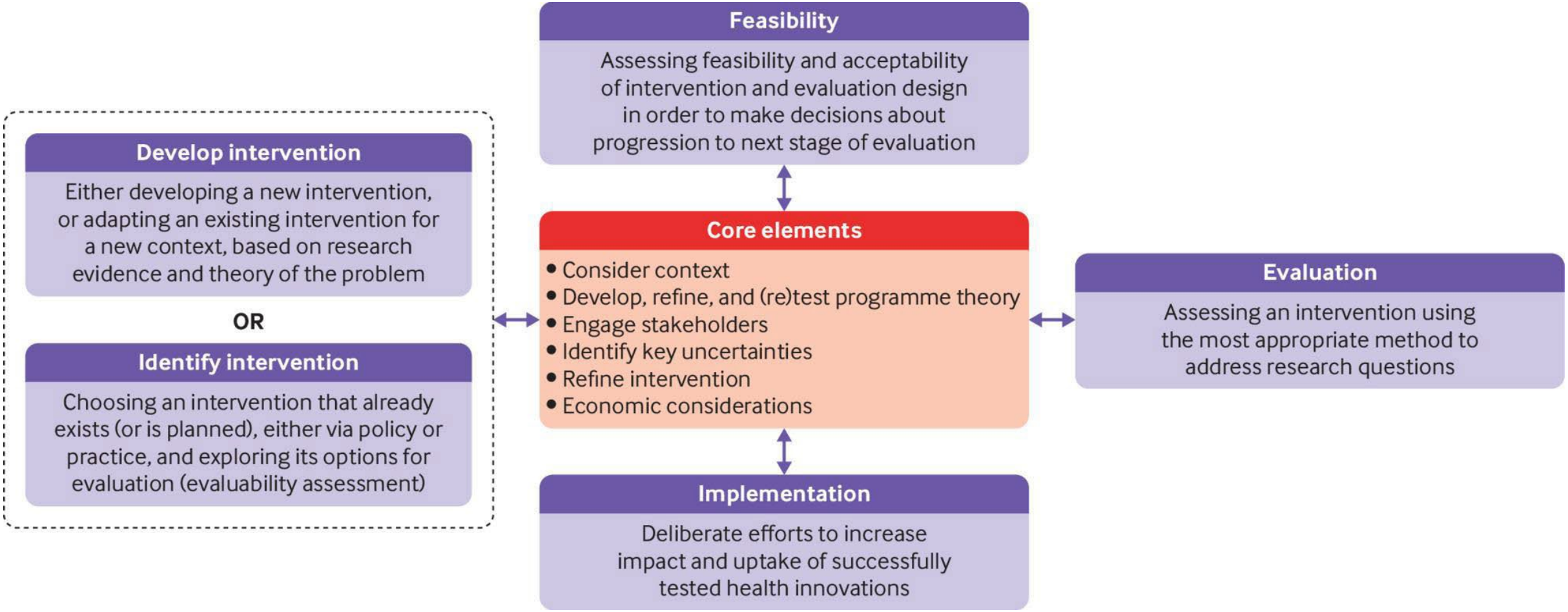

Image: https://doi.org/10.1136/bmj.n2061

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Leveraging Program Planning Models to Advance the Open Science Movement

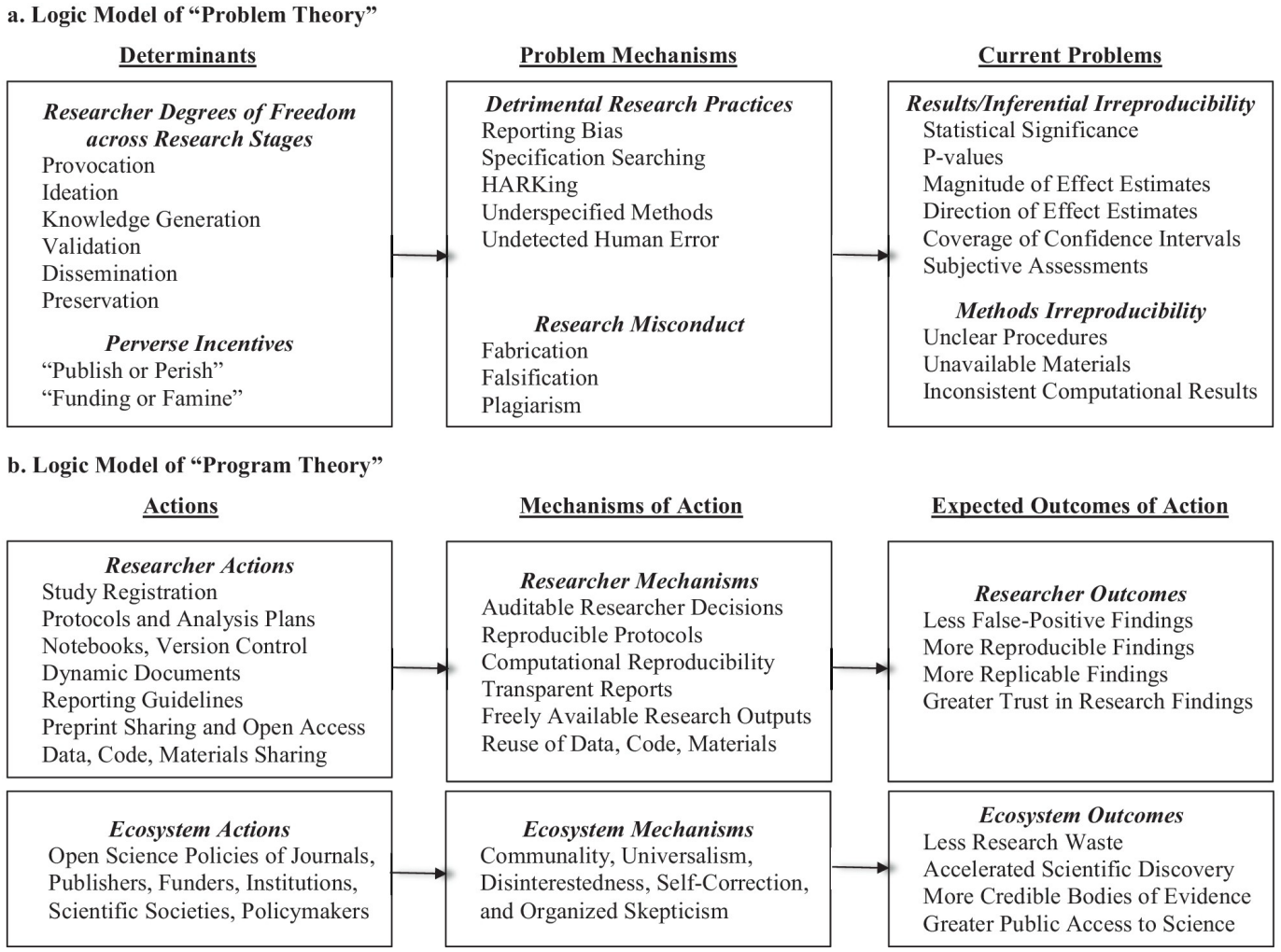

Image: https://doi.org/10.1007/s11121-022-01336-w

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Let’s Foster Prevention Science as an Open Science Community!

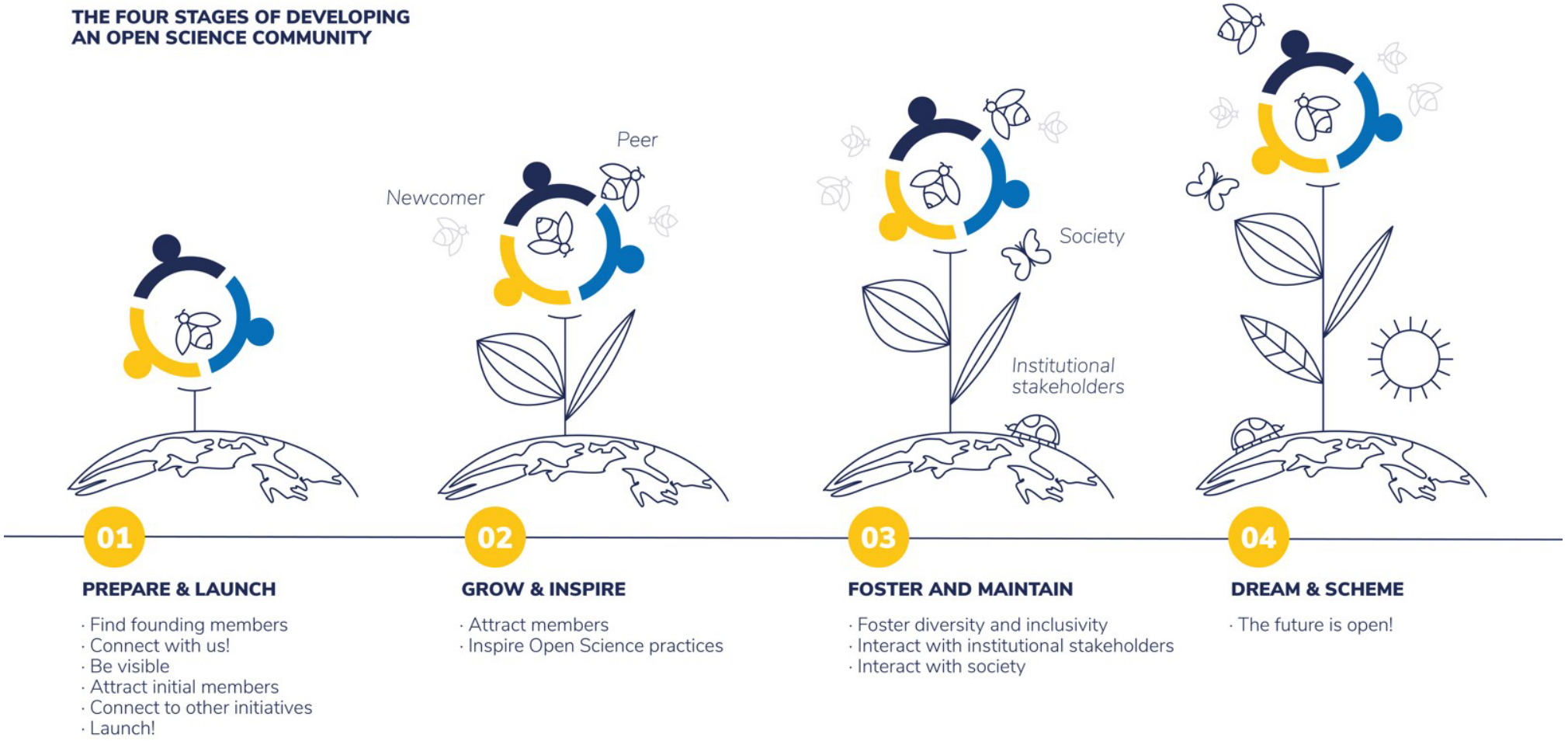

Image: https://www.startyourosc.com/

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Thank you!

Twitter: https://twitter.com/GrantSeanP

Email: spgrant@uoregon.edu

Website: https://education.uoregon.edu/directory/faculty/all/spgrant

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