



C O P E

THE ETHICS OF DATA SHARING

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publicationethics.org



THE ETHICS OF DATA SHARING

Agenda

- Some data problems
- COPE Core Practice: *Data & reproducibility*
- Data stewardship & Responsible data sharing
- Challenges & opportunities
- ***Interactive cases:*** Case 1 & Case 2

SOME DATA PROBLEMS

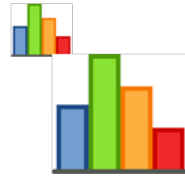
FFP



Fabrication



Falsification



Plagiarism

- Screen, detect, verify raw/original data
- Respond to allegations, investigate with institution*
- Correct/retract, train/prevent

*[CLUE Guidelines](#)
*[COPE Guidelines](#)
*[RePAIR Guidelines](#)

SOME DATA PROBLEMS

Questionable
Research Practices

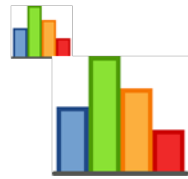
FFP



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Falsification



Plagiarism

QRP



Unauthorized data collection / use



Underpowered, faulty methods



Sampling / confounder bias



Extending, ending early, censoring



Cherry picking



Fishing



Trawling, dredging



P hacking



HARK

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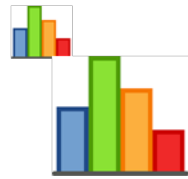
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HARK

Questionable Publishing Practices

QPP



Poor record keeping / reporting



Image distortion, exaggeration



Misinterpretation, spin



Unauthorized publication / sharing



Hiding, withholding data / info



Supporting predatory journals



Salami slicing



Redundant / duplicate publication



Selective publication, file drawer problem



Not correcting errors

COPE CORE PRACTICE

Data and reproducibility

“ Journals should include policies on **data availability** and encourage the use of **reporting guidelines** and **registration** of clinical trials and other study designs according to standard practice in their discipline ”



<https://cope.onl/data>

Example COPE Forum cases

- [Case 15-17](#): Researcher who provided a database wants to be named an author post publication
- [Case 17-02](#): Reader suspects image manipulation; author/institution says originals are lost
- [Case 11-04](#): Journal editor proposes raw data should be deposited in database owned by editor
- [Case 12-31](#): Journal asks author to supply sensitive data to reader, who then gets different results

COPE CORE PRACTICES

Policies and practices required to reach the highest standards in publication ethics:



Allegations of misconduct



Authorship and contributorship



Complaints and appeals



Conflicts of interest/ Competing interests



Data and reproducibility



Ethical oversight



Intellectual property



Journal management



Peer review processes



Post-publication discussions and corrections

DATA STEWARDSHIP

- **Laws & regulations:**
 - Research governance, study registration, data / metadata sharing
 - Individuals' **right to privacy**; exclusions for anonymized data
- **Ethics approval; Participant consent to participate** & for researcher to
 - **Collect, process, store confidential data**;
 - **Publish** certain data/images;
 - **Share** irreversibly **anonymized, deidentified data**, including future purposes (meta-analyses)
- **Ethical / legal use** of (others') datasets, illustrations
- Registered reports **+ results reported later** (www.cos.io/initiatives/registered-reports)
- Register clinical trial protocols **+ summary results** (eg, www.clinicaltrials.gov)
- Data management plan, (Statistical) Analysis plan, **Data publishing / sharing plan**; Standard operating procedures (secure data system, data entry/changes, data lock, archive)
- **Data for journal inspection; Complete reporting:** Equator Network Reporting guidelines (www.equator-network.org)



RESPONSIBLE DATA SHARING

- **Journal / funder data sharing policies** (inc. metadata, protocol, codebook, code, software,...)
- **Repositories** (*Registry of Research Data Repositories*, www.re3data.org)
- **DOIs / persistent identifiers, Data citation** ([FORCE11 Citation Principles](#))
- **FAIR** (Findable, Accessible, Interoperable, Reusable) principles for digital data (www.go-fair.org/fair-principles/)
- **CARE** (Collective benefit, Authority to control, Responsibility, Ethics) principles for indigenous data (www.gida-global.org/care)
- **Data journals, (Meta)Data articles**, Protocol papers, Online protocols; [STAR](#), [MDAR](#) checklists
- **Open Science / Research / Scholarship; Open Access / Data / Innovation;**
 - appropriate governance, infrastructure & standards (not allow re-identification or discrimination);
 - free access if public funding (eg, OECD [Recommendation of the Council concerning Access to Research Data from Public Funding](#))

Publish & share data

- Replication
- Data integrity
- Data preservation
- Scientific progress
- Public trust
- Human rights

<https://academic.oup.com/bioscience/article/63/6/483/226339>

RESPONSIBLE DATA SHARING

Global Alliance for Genomics and Health



- **Principles:**

- **Respect** individuals, families, and communities
- **Advance** research and scientific knowledge
- **Promote** health, well-being, fair distribution of benefits
- **Foster** trust, integrity, and reciprocity

- **Core elements:**

- **Transparency**
(eg, purposes, processes, procedures, governance)
- **Accountability**
(eg, systems, access, conflicts of interest, complaints/sanctions)
- **Engagement** with stakeholders
- **Data quality & security**
(eg, storage, processing, risks, lawful requests)
- **Privacy, data protection & confidentiality**
(eg, relevant regulations, no re-identification)
- **Risk-benefit analysis**
- **Recognition & attribution**
- **Sustainability**
- **Education & training**
- **Data accessibility & dissemination**

RESPONSIBLE DATA SHARING

ICMJE (International Committee of Medical Journal Editors) (www.icmje.org)

- *From 1 July 2018: **data sharing statement*** (eg, will deidentified individual-participant data, codebook, protocol, analysis plan be shared? How & for how long?)
- Advance online clinical trial registration;
*From 1 January 2019: **include data sharing plan***
- Editors may request all authors to declare they had **full access to data**
- Permission & acknowledgment to reuse or publish **others' data**
- Declare similar papers; encouraged to use **reporting guidelines**

Declaration of Helsinki

(www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/)

- **Public registration** of human studies
- Complete, accurate **public access to results** (negative, inconclusive, or positive)
- **Ethical** reporting

RESPONSIBLE DATA SHARING

TOP (Transparency & Openness Promotion) (www.cos.io/initiatives/top-guidelines)



- **TOP Factor & TOP Guidelines:**
 - *8 standards:* Data citation, **data / code / materials transparency/sharing**, design/analysis transparency, study preregistration, analysis plan preregistration, replication
 - *3 levels:* (1) **Whether data are available & where**
→ (2) **Must be posted to repository**
→ (3) **Must be posted to repository & analyses reproduced independently**

FORCE11 (Future of research communications and e-scholarship) (www.force11.org)

- **Research Data Publishing Ethics** working group (in collaboration with COPE)



CHALLENGES & OPPORTUNITIES IN DATA SHARING

Publishing

- **Guidelines & definitions:**
 - Type of data policy/statement; conditions?
 - Data types & formats?
 - Timing? Extent of “underlying data”; no more “(data not shown)”?
- **Repositories** or Journal / Supplementary materials
 - Assign DOIs / persistent identifiers?
 - File access, license (according to funder)?
 - Link to context (protocol, ethics, funding, COIs)?
 - Embargoes? Versions / copies?
- **Citation**, linking to data, permissions (even if **CC0**; no © for raw research data but © for compilations / selections / arrangements)
- **Exceptions / exemptions or controlled access:** legal, ethical, (commercial) sensitivity, safety reasons? *Did the authors have access to raw data?*
- **Processes:**
 - Check repository, FAIR/CARE, citation, ethical / legal, permissions, anonymity / deidentification (eg, [BMJ checklist](#); [US Safe Harbor Method](#))?
 - Data / statistics peer review?
 - Check appropriate reuse/publication of 2^o data
- **Investigations:** Data specialists? Check for misconduct/QRPs/QPPs? Corrections? Retractions?
- **Training** of editors, reviewers, journal staff, authors?

CHALLENGES & OPPORTUNITIES IN DATA SHARING

Institutions / Funders (see [Sherpa Juliet](#))

- **Mandated** data registration, sharing, venue, access, license; OA journal?
 - Level of data & timing?
 - Also for preprints / books / conferences?
 - Checking? Sanctions?
- **Data management plan**, analysis plan, publishing/sharing plan; approvals, amendments?
- **Data ownership**, authorship/contributorship
 - Author attitudes, knowledge, data literacy, digital skills? Credit / incentives for sharing?
 - Embargoes to allow author first-use, patents & prevent scooping?
 - Derivative datasets?
- **Institutional repositories**
 - Technical aspects, costs, time? Quality control, preservation, backups? DOIs?
 - Legacy format, versions, security, access levels (*closed – mediated – open*), curation, duration & continued participant protection?
 - Responsibilities or data transfer when authors leave? Ethics committee approval?
- **Investigations***:
 - Data protection / access / integrity personnel?
 - Misconduct investigations? If authors leave? Check whole portfolio? Data Corrections / Retractions?

*[CLUE Guidelines](#) *[COPE Guidelines](#) *[RePAIR Guidelines](#)

CHALLENGES & OPPORTUNITIES IN DATA SHARING

Progress

- *Adrian Ziderman, Michal Tal-Socher, [Prometheus 2020;36:116-134](#)*: Data sharing policy for 150 journals, 15 disciplines: **Biomedical (67%) > physical , social > formal > arts & humanities (27%)**
- *Charles Piller, [Science 13 Jan 2020](#)*: 2 y after 2018 FDA / NIH final rule on clinical trial + data registration: **Only ~45% of 4768 trials posted results on time, 24% posted late, 32% still not posted**
- *Valentin Danchev et al. [JAMA Netw Open. 2021;4:e2033972](#)*: 2 y after 2018 ICMJE required data sharing statement: Of clinical trials in JAMA, Lancet, NEJM, only **17 / 89 (19%) declaring posting of individual-participant data did post data**
- **[COVID-19 Clinical Research Coalition](#) & [Data Sharing Working Group](#)**



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|---|---|--|
| • FORCE11 (Future of research communications and e-scholarship) (www.force11.org) | • STM Research Data (www.stm-researchdata.org/) | • Consortium (www.cdisc.org) |
| • RDA , Research Data Alliance (www.rd-alliance.org) | • GA4GH , Global Alliance for Genomics and Health (www.ga4gh.org) | • TranspariMED (www.transparimed.org) |
| | • CDISC , Clinical Data Interchange Standards | • AllTrials (www.alltrials.net) |
| | | • OpenAIRE (www.openaire.eu) |
| | | • OpenPharma (www.openpharma.blog) |

INTERACTIVE CASE 1

Based on [Case 10-09](#)

- **Reader notices data problems in a published article & asks author for dataset**
- **Author refuses; reader complains to Editor**
- **Editor refuses to mediate & advises the two to talk directly**

Was the Editor's action appropriate?

1. Yes; editors are not responsible for postpublication data sharing
2. No; editors should ensure that authors keep promises of data sharing
3. No; editor should ask author to check data & publish correction / retraction if needed

INTERACTIVE CASE 2

Based on [Case 06-25](#)

- **Journal receives submission of clinical trial results**
- **Authors want to share anonymized raw data as an appendix**
- **Data were collected several years ago; consent was not obtained for data publication / sharing**

Should the Editor allow data sharing?

1. No; there was no consent or specific ethics committee approval
2. Yes, as long as data are anonymized & deidentified
3. Yes, but only after retrospective ethics committee approval

COPE Guidance for Editors: Research, Audit & Service Evaluations: <https://publicationethics.org/node/19876>
Journals' Best Practices for Ensuring Consent for Publishing Medical Case Reports: Guidance from COPE: <https://doi.org/10.24318/cope.2019.1.6>
Iain Hrynaszkiewicz et al, [Trials, 2020;11:9](#)

THANK YOU

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PROMOTING INTEGRITY IN SCHOLARLY
RESEARCH AND ITS PUBLICATION