Faculty Information Exchange Series
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Navigating the publication process

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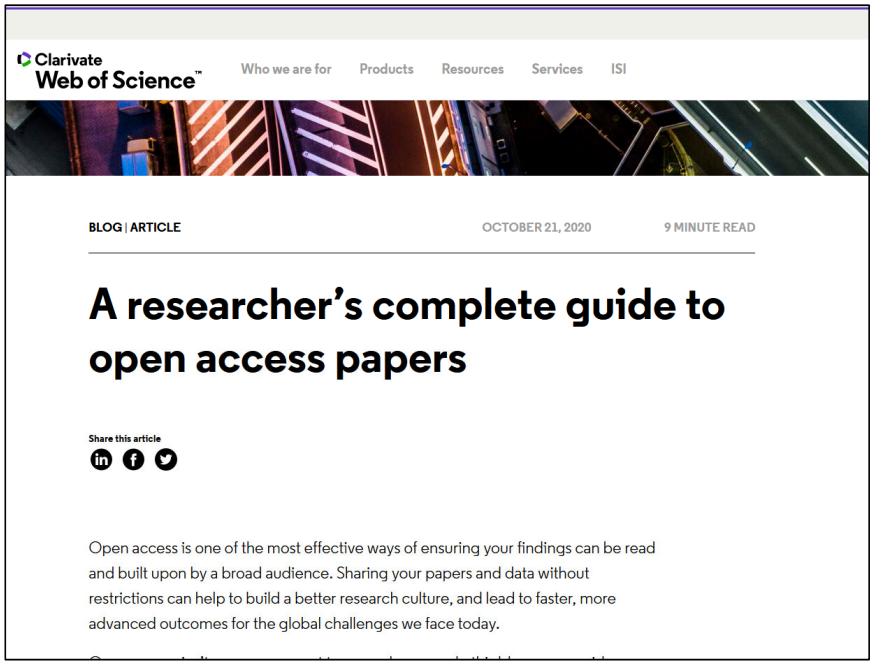
Open Access (OA) publication

- Good news:
  - Broader accessibility
  - Increased citation
- Bad news:
  - Various definitions (Gold OA vs. hybrid and 12-month models)
  - Costs more
- Build into budgets
- Not the same as
  - Open peer review
  - Data repository/sharing requirement
  - Pre-print servers
  - ResearchGate



https://clarivate.com/webofsciencegroup/article/a-researchers-complete-guide-to-open-access-papers/?utm_campaign=EM_1_Newsletter_Oct_Research_Smarter_SAR_Global_2020_Researchers_Non_US&utm_medium=email&utm_source=Eloqua

The funders, under an umbrella called **cOAlition S** that includes the Wellcome Trust and the Bill and Melinda Gates Foundation, have rowed back on one of the most controversial aspects of the plan — a ban on 'hybrid journals', which are outlets that allow researchers to make their work free to read if they pay a fee, but that keep other studies behind a paywall. Many publishers have expressed concerns about this aspect of the initiative.

Instead of an outright ban, **Plan S** funders now simply say that they will not cover the costs of publishing for authors who choose non-compliant hybrid journals, but that papers in these journals will still be regarded as compliant if an open copy is posted on a repository in tandem with publication. This means that it will be possible to publish open-access articles in any hybrid journal and, by posting those articles online, be compliant with Plan S.

Additionally, Plan S funders will actively support paying fees for publishing in particular hybrid journals that intend to become fully open-access.

NEWS · 20 OCTOBER 2020

Nature journals announce first open-access agreement

The arrangement will allow some researchers in Germany to publish openly – but critics say it comes with a high price.

Richard Van Noorden

The publisher of *Nature* has agreed its first deal to allow some researchers to publish in the journal, and in 33 other Nature-branded titles, under open-access (OA) terms.

Research published in *Nature* and its sister journals is behind a paywall, although the journals have sometimes chosen to make articles OA. But in April, publisher Springer Nature announced that it would offer open-accessing publishing routes for its most selective journals that would comply

RELATED ARTICLES

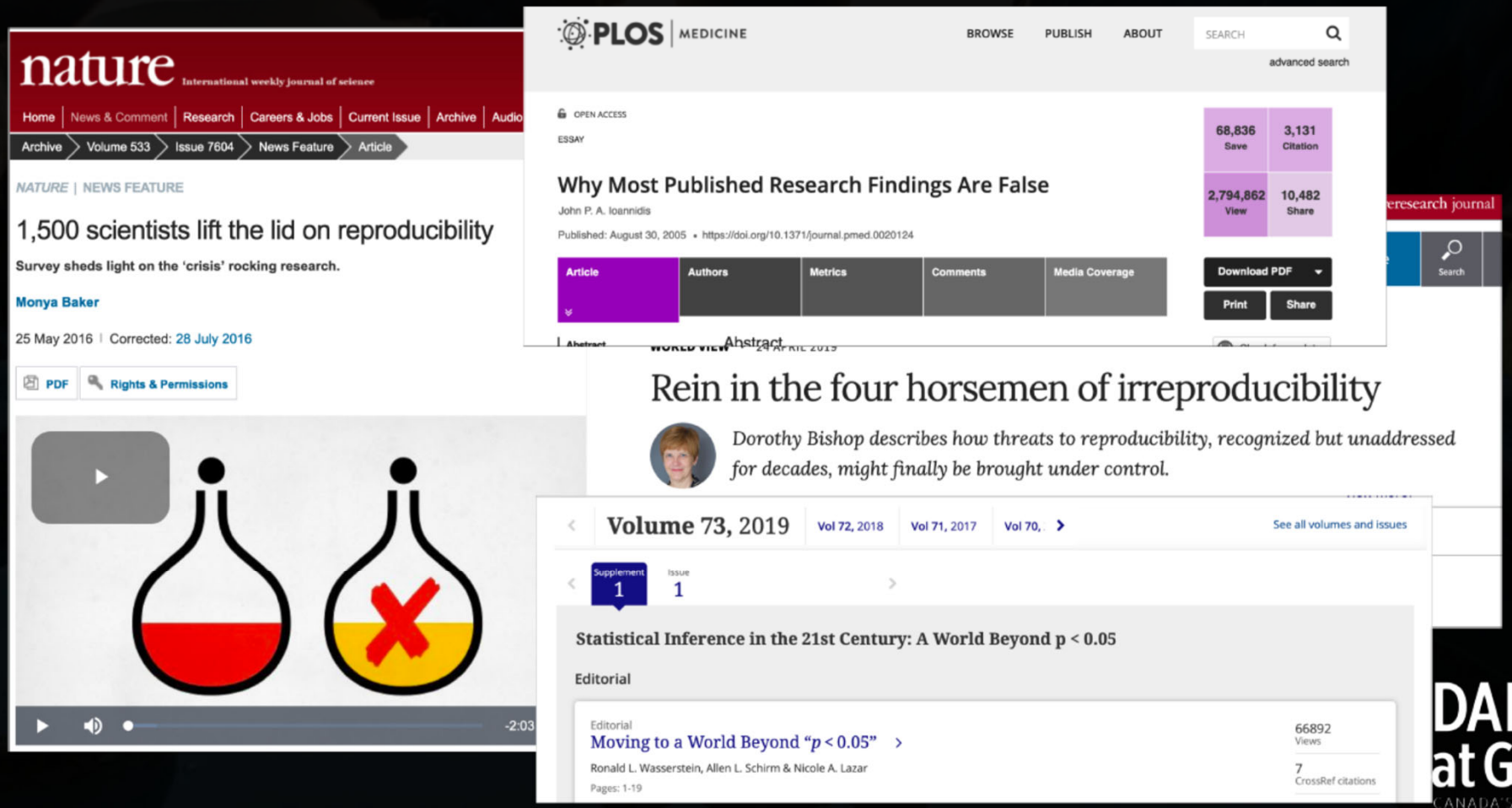
Open-access Plan S to allow publishing in any journal

Nature to join open-access Plan S, publisher says

Reporting Guidelines
Principles and background

- Scientific research should be reported so as to allow reproduction/replication of the study
- Readers can only judge quality and weigh inferences and application from what is reported
- Reporting guidelines do not prescribe design or analysis, but should help to improve them
- Poor reporting precludes inclusion in systematic reviews and meta-analyses

Replication and reproducibility



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Why is reporting often incomplete or poor?

- Lack of clarity at the planning or design stage
- Lack of awareness of correct methods
- Lack of perspective or awareness of reporting
- Preference for significant differences
- Wish for novelty
- Pressure to publish

Common substantial issues

- Lack of (description of):
  - Definition of primary outcome(s)
    - Consistent with the (stated) objective and hypothesis
  - Basis of the sample size
  - Method of randomization
  - Blinding of evaluators
  - Nature of grouping of subjects; contextual data
  - Statistical methods
    - Inclusion and exclusion criteria, especially for (unplanned) subgroup analyses
    - Losses to follow-up
    - Accounting for experimental unit and clustering
  - Candid and complete discussion of strengths and limitations

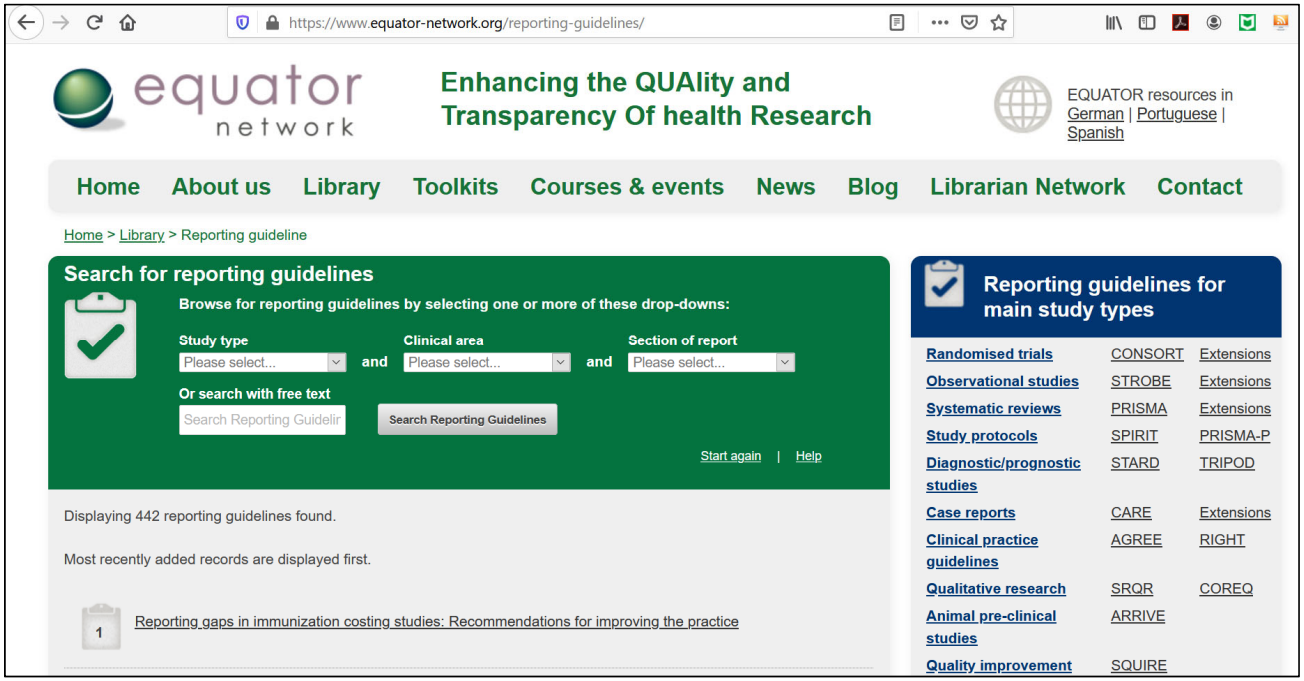
Quality of reporting is related to bias

- Randomly selected sample of trials in livestock health and production (Sargeant et al *Preventive Veterinary Medicine* 2009) and in pre-harvest food safety (Sargeant et al *Foodborne Pathogens and Disease* 2009):

- Poorer reporting (randomization; exclusion criteria; lack of details on subjects, interventions, and measurements) was associated with reporting positive treatment effects

Why use reporting guidelines?

- Adoption and use of CONSORT was associated with improved quality of reporting of trials
- Transparency is stronger than trust
  - Is incomplete reporting just sloppy or selective?



Completeness of reporting of experiments: REFLECTing on a year of animal trials in the *Journal of Dairy Science*

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Invited review: Completeness of reporting of experiments: REFLECTing on a year of animal trials in the *Journal of Dairy Science*

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REFLECT

Checklist for REFLECT statement: Reporting guidelines For randomized control trials in livestock and food safety. Bold text are modifications from the CONSORT statement description (Altman DG et al . Ann Intern Med 2001; 134(8):663-694).

Paper section and topic	Item	Descriptor of REFLECT statement item	Reported on Page #
Title & Abstract	1	How **study units** were allocated to interventions (eg, "random allocation," "randomized," or "randomly assigned"). **Clearly state whether the outcome was the result of natural exposure or was the result of a deliberate agent challenge.**	
Introduction Background	2	Scientific background and explanation of rationale.	
Methods Participants	3	Eligibility criteria **for owner/managers and study units at each level of the organizational structure,** and the settings and locations where the data were collected.	
Interventions	4	Precise details of the interventions intended for each group, **the level at which the intervention was allocated,** and how and when interventions were actually administered.	
	4b	**Precise details of the agent and the challenge model, if a challenge study design was used.**	
Objectives	5	Specific objectives and hypotheses. **Clearly state primary and secondary objectives (if applicable).**	
Outcomes	6	Clearly defined primary and secondary outcome measures and the levels at which they were measured, and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors).	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules. **Sample-size considerations should include sample-size determinations at each level of the organizational structure and the assumptions used to account for any non-independence among groups or individuals within a group.**	
Randomization -- Sequence generation	8	Method used to generate the random allocation sequence **at the relevant level of the organizational structure**, including details of any restrictions (eg, blocking, stratification)	
Randomization -- Allocation concealment	9	Method used to implement the random allocation sequence **at the relevant level of the organizational structure**, (eg, numbered containers ~~**or central telephone**~~**),** clarifying whether the sequence was concealed until interventions were assigned.	
Randomization -- Implementation	10	Who generated the allocation sequence, who enrolled **study units,** and who assigned **study units** to their groups **at the relevant level of the organizational structure**.	
Blinding (masking)	11	Whether or not ~~**participants**~~ those administering the interventions, **caregivers** and those assessing the outcomes were blinded to group assignment. If done, how the success of blinding was evaluated**. Provide justification for not using blinding if it was not used.**	
Statistical methods	12	Statistical methods used to compare groups for all outcome(s); Clearly state the level of statistical analysis **and methods used to account for the organizational structure, where applicable;** methods for additional analyses, such as subgroup analyses and adjusted analyses.	
Results **Study** flow	13	Flow **of study units** through each stage **for each level of the organization structure of the study** (a diagram is strongly recommended). Specifically, for each group, report the numbers of **study units** randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.	
Recruitment	14	Dates defining the periods of recruitment and follow-up.	
Baseline data	15	Baseline demographic and clinical characteristics of each group, **explicitly providing information for each relevant level of the organizational structure. Data should be reported in such a way that secondary analysis, such as risk assessment, is possible.**	
Numbers analyzed	16	Number **of study units** (denominator) in each group included in each analysis and whether the analysis was by "intention-to-treat." State the results in absolute numbers when feasible (eg, 10/20, not 50%).	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group, **accounting for each relevant level of the organizational structure**, and the estimated effect size and its precision (e.g., 95% confidence interval)	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those pre-specified and those exploratory.	
Adverse events	19	All important adverse events or side effects in each intervention group.	
Discussion Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes. **Where relevant, a discussion of herd immunity should be included. If applicable, a discussion of the relevance of the disease challenge should be included.**	
Generalizability	21	Generalizability (external validity) of the trial findings.	
Overall evidence	22	General interpretation of the results in the context of current evidence.	

Methods

Sample of 120 papers published in JDS in 2017

- REFLECT items without subjective interpretation (excluded 2,20,21,22)
- Yes/no questions on presence or absence of information[1]
- Some questions subdivided to gain more information
  - *e.g.* randomization
- Additional question on washout period for cross-over trials
- Assessed by two authors, independently in duplicate
- Conflicts resolved by consensus

[1]Totton *et al.*, 2018

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Results

- Description of study settings: 126/137 (92%)
- Precise details of intended interventions: 134/137 (98%)
- Study objectives: 127/137 (93%)
- Level of outcome measurement: 127/137 (93%)
- Description of statistical methods: 135/137 (99%)

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Results

- Stated hypothesis: 97/137 (71%)
- Study unit eligibility: 75/137 (55%)
- Random allocation to treatment group: 104/137 (76%)
- Blocking factors reported: 51/104 (49%)
- Denominator for each group in analysis: 78/137 (57%)
- Summary results presented for each group: 89/137 (65%)

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Results

- Farm level eligibility: 6/137 (4%)
- Sample size justification provided: 22/137 (16%)
- Method to generate random allocation: 7/104 (7%)
- Allocation concealment: 3/104 (3%)
- Blinding of caregiver and/or outcome assessor: 17/137 (12%)
- Multiplicity of analyses: 1/137 (1%)

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Responding to reviewers

- Be brief
- Don’t thank them for every comment
- Accept that you may have to re-analyze some things
- Put important information in the text, not just the response
- Make it easy for them
  - Correct line numbers
- Choose your battles