Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

Dissemination of Research During the Pandemic

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Georgetown University

11:30 AM - 12:25 PM EST
Beyond COVID-19: Challenges & Lessons Learned during a Pandemic

Dissemination of Research During the Pandemic

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Editor
Journal of Clinical and Translational Science

Theodora Bloom, Ph.D.
Executive Editor
The BMJ
JCTS and COVID

Lars Berglund MD PhD
Editor-in-Chief
JCTS in brief

• Journal started 2017, now in its 5th year
• Major focus area: Clinical research; Education; Implementation, Policy and Community Engagement; Translational Research Design and Analysis
• Switched from 6 issues/year to continuous publication in 2021
• Editorial Board largely recruited from CTSA and CTR center institutions
• Junior editors – APSA and KL2 trainees
• In 2020 initiated thematic issues: 3 published, 3 under way including one focused on COVID-19, and several in planning stage
Original Submissions Received – last 5 years

<table>
<thead>
<tr>
<th>Submissions</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020</th>
<th>2021 YTD</th>
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<tr>
<td>Perspective</td>
<td>7</td>
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<td>Expedited Reports</td>
<td>70</td>
<td>63</td>
<td>135</td>
<td>165</td>
<td>68</td>
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<tr>
<td>Special Communication</td>
<td>24</td>
<td>18</td>
<td>38</td>
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<td>Review Article</td>
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<td>Research Article</td>
<td>28</td>
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<tr>
<td>Letters</td>
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<td>1</td>
<td>1</td>
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<td></td>
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<tr>
<td>Editorial</td>
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<td>1</td>
<td>5</td>
<td>6</td>
<td>1</td>
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<td>Brief Report</td>
<td>12</td>
<td>8</td>
<td>16</td>
<td>16</td>
<td>14</td>
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<td>Total</td>
<td>70</td>
<td>63</td>
<td>135</td>
<td>165</td>
<td>68</td>
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JCTS new submissions 2020

- Reviews
- Perspectives
- Special Comm
- Research Articles
- Brief Reports
- Editorials
- Expedited reports
- Letters
JCTS – changes made due to COVID-19

• In April 2020, initiated a rapid review pathway for COVID-related submissions – goal to review within 7 days
• Engaged Editorial Board to be onboard with rapid turnaround
• No major change regarding review process beyond the shorter timeline – criteria same as for regular submissions
• After discussions with Cambridge University Press (publisher) offered waiving submission fees for COVID-related submissions
• Waiver initially lasting until September, continued until end of December 2020
• In the fall of 2020, due to volume, we reverted back to a single review process for all submissions
JCTS – COVID vs non-COVID submissions

• Between April 2020 – March 2021 we received 203 submissions, of which 50 were COVID manuscripts (25%).
• COVID submissions to date – 33 accepted and 10 rejected – rejection rate 23%
• Non-COVID submissions to date – 72 accepted and 22 rejected – rejection rate 23%
• Under review or in revision – 7 COVID paper and 59 non-COVID papers
• COVID papers had shorter timeline – 30 vs 46 days to first decision and 46 vs 74 days to final decision
The chart below shows the number of full-text downloads and abstract views annually from January 2017 – March 26th, 2021.
Of top 10 downloaded papers – 7 addressed COVID

Popular papers on Cambridge Core – Top 25 articles by number of fulltext downloads, 1 January 2020 to 31 December 2020

<table>
<thead>
<tr>
<th>Article Title</th>
<th>Author(s)</th>
<th>Vol:Iss</th>
<th>Downloads</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety of influenza vaccine during COVID-19</td>
<td>Zeln et al.</td>
<td>5</td>
<td>9,805</td>
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<tr>
<td>The potential for antibody-dependent enhancement of SARS-CoV-2 infection: Translational implications for vaccine development</td>
<td>Wang &amp; Zand</td>
<td>5</td>
<td>4,712</td>
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<tr>
<td>Clinical characteristics associated with COVID-19 severity in California</td>
<td>Rubin et al.</td>
<td>5</td>
<td>1,963</td>
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<tr>
<td>Leveraging community engaged research partnerships for crisis and emergency risk communication to vulnerable populations in the COVID-19 pandemic</td>
<td>Wu et al.</td>
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<td>1,760</td>
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<tr>
<td>Application of volumetric absorptive microsampling (VAMS) to measure multidimensional anti-influenza IgG antibodies by the mPlex-Flu assay</td>
<td>Wang et al.</td>
<td>3:6</td>
<td>1,606</td>
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<tr>
<td>Safety of ACE-I and ARB medications in COVID-19: A retrospective cohort study of inpatients and outpatients in California</td>
<td>Rubin et al.</td>
<td>5</td>
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<tr>
<td>Effect of various decontamination procedures on disposable N95 mask integrity and SARS-CoV-2 infectivity</td>
<td>Smith et al.</td>
<td>5</td>
<td>1,218</td>
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<td>COVID-19 and public health efforts in Mongolia: A lesson maybe learned?</td>
<td>Bayasgalan et al.</td>
<td>5</td>
<td>1,207</td>
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<td>Mapping the evolving definitions of translational research</td>
<td>Fort et al.</td>
<td>1:1</td>
<td>1,207</td>
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<tr>
<td>Equipoise and research in the current COVID-19 pandemic</td>
<td>Pulley et al.</td>
<td>5</td>
<td>1,165</td>
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<tr>
<td>Immediate impact of the COVID-19 pandemic on CCTA TI1 and KL2 training and career development</td>
<td>McCormack et al.</td>
<td>4:6</td>
<td>1,078</td>
</tr>
<tr>
<td>Optimizing sampling rate of wrist-worn optical sensors for physiologic monitoring</td>
<td>Bent &amp; Dunn</td>
<td>5</td>
<td>1,066</td>
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<tr>
<td>A REDCap-based model for electronic consent (eConsent): Moving toward a more personalized consent</td>
<td>Lawrence et al.</td>
<td>4:4</td>
<td>1,058</td>
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<tr>
<td>Mentoring in crisis does not need to put mentorship in crisis: Realigning expectations</td>
<td>Cameron et al.</td>
<td>5</td>
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<tr>
<td>Research on COVID-19 through patient-reported data: a survey for observational studies in the COVID-19 pandemic</td>
<td>Verma et al.</td>
<td>5</td>
<td>965</td>
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<tr>
<td>The digital biomarker discovery pipeline: An open-source software platform for the development of digital biomarkers using mHealth and wearables data</td>
<td>Bent et al.</td>
<td>5</td>
<td>803</td>
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<tr>
<td>Education and training of clinical and translational study investigators and research coordinators: A competency-based approach</td>
<td>Calvín-Naylor et al.</td>
<td>1:1</td>
<td>749</td>
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<tr>
<td>Advancing health equity through CTSA programs: Opportunities for interaction between health equity, dissemination and implementation, and translational science</td>
<td>Yousefi Nooraei et al.</td>
<td>4:3</td>
<td>631</td>
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<tr>
<td>Comorbidities and health care systems differences among states as it relates to COVID-19</td>
<td>Anderson et al.</td>
<td>4:4</td>
<td>596</td>
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<td>Building bridges between a community and an academic medical center via community tours</td>
<td>Irby et al.</td>
<td>4:4</td>
<td>571</td>
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<tr>
<td>Career orientation and perceived professional competence among clinical research coordinators</td>
<td>Rojewski et al.</td>
<td>3:5</td>
<td>562</td>
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<tr>
<td>An exploratory study of Clinical and Translational Science Award community-engaged research training programs</td>
<td>Ziegahn et al.</td>
<td>2:2</td>
<td>529</td>
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<tr>
<td>Situating dissemination and implementation sciences within and across the translational research spectrum</td>
<td>Leppin et al.</td>
<td>4:3</td>
<td>525</td>
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<tr>
<td>Pilot study of an intervention to increase cultural awareness in research mentoring: Implications for diversifying the scientific workforce</td>
<td>Byars-Winston et al.</td>
<td>2:2</td>
<td>511</td>
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<td>Assessing clinical research coordinator knowledge of good clinical practice: An evaluation of the state of the art and a test validation study</td>
<td>Dubois et al.</td>
<td>4:2</td>
<td>505</td>
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JCTS – COVID thematic issue under way

- Prioritization – COVID vs non-COVID studies
- Virtual visits
- Role of Biorepositories
- Risk/Benefit related to personnel risk and re-opening studies
- Informed consent processes
- Modifying laboratory testing
- IRB procedures
- Role of Informatics
- FDA interactions
Lessons learned

• Important to offer flexibility
• Engagement of Editorial Board members and Reviewers critical – important stakeholders in process
• Maintaining focus on quality and content in spite of need for speed
• Working with publisher on communication and marketing
Dissemination of Research in the Pandemic

2021 DC CTSA Spring Regulatory Update & Hot Topics in Clinical and Translational Research Agenda

Dr Theodora Bloom, Executive Editor, The BMJ
Competing interests

- I’m Executive Editor of The BMJ. It is published by BMJ, a wholly owned subsidiary of the British Medical Association.
- BMJ (the company) receives 8.7% of revenues from drug & device companies through advertising, reprint sales, & sponsorship. For The BMJ it’s 12%. The BMJ is an open access journal that charges article-processing fees for Research Articles.
- I chair the Advisory Board of Europe PubMed Central.
- I am a founder of the MedRxiv clinical preprint server.
- I am European Coordinator for the quadrennial Peer Review Congress.
- I am on the Board of AIP Publishing
In an ideal world

- Do some research
- Prepare it for public sharing
- Share it with the world
- Read / use other people's work
- Discuss ideas
How it worked for 150 years


MOLECULAR STRUCTURE OF NUCLEIC ACIDS

A Structure for Deoxyribose Nucleic Acid

We wish to suggest a structure for the salt of deoxyribose nucleic acid (D.N.A.). This structure has novel features which are of considerable biological interest.

A structure for nucleic acid has already been proposed by Pauling and Corey. They kindly made their manuscript available to us in advance of publication. Their model consists of three intertwined chains, with the phosphates near the fibre axis, and the bases on the outside. In our opinion, this structure is unsatisfactory for two reasons: (1) We believe that the material which gives the X-ray diagrams is the salt, not the free acid. Without the acidic hydrogen atoms it is not clear what forces would hold the structure together, especially as the negatively charged phosphates near the axis will repel each other. (2) Some of the van der Waals distances appear to be too small.

Another three-chain structure has also been suggested by Fraser (in the press). In his model the phosphates are on the outside and the bases on the inside, linked together by hydrogen bonds. This structure as described is rather ill-defined, and for this reason we shall not comment on it.

We wish to put forward a radically different structure for the salt of deoxyribose nucleic acid. This structure has two helical chains each coiled round the same axis (see diagram). We have made the usual chemical assumptions, namely, that each chain consists of phosphoester groups joining D-deoxyribofuranose residues with 3',5'-linkages. The two chains (but
But now*...

But now*...

Discuss ideas

Do some research

Write a description

Submit to a journal

Rejection: try elsewhere

Do more work as requested

Resubmit

Publication

Be judged by publications

Get grants

Promotion

Read / use other people's work

* I think I first showed a slide like this in 2010.

Bias by Nick Youngson CC BY-SA 3.0 Alpha Stock Images
Do some research
Write a description
Submit to a journal
Do more work as requested
Resubmit
Publication
Be judged by publications
Get funding
Success
Read / use other people's work
Discuss ideas
Rejection: try elsewhere
Bias by Nick Youngson CC BY-SA 3.0 Alpha Stock Images
The case for preprints

- **Speed up science: faster dissemination** within the research community
- Allow pre-publication peer review and feedback, making ‘better’ articles
- Give authors precedence
- Freely available (but not always fully ‘open’)
- Surface data that may not survive peer review
- Risk of surfacing incorrect information, conclusions or assumptions that could be harmful to the health of individuals or whole populations

http://asapbio.org/
medRxiv: a server for health science preprints

- Conceptually and technologically similar to bioRxiv (basic science, biology)
- Not-for-profit
- A service not a product
- Publisher-neutral
- Operated by CSH Laboratory
- Managed in partnership with BMJ and Yale University
- Launched Q2 2019
- Now supported by CZI
medRxiv submission requirements:

Original research articles

- Original clinical/health research, including clinical trials, observational or qualitative research, quality improvement and implementation, policy studies, and medical education
- Systematic reviews and meta-analyses
- Methodological research
- Clinical study Protocols
- Not commentaries, editorials, opinion pieces, essays, letters to editors, narrative reviews, case reports

Following community norms

- Follow ICMJE guidance
- Funding and competing interests statements
- Statement of IRB / ethics committee oversight
- Study registration when applicable (e.g. ClinicalTrials.gov; PROSPERO)
- Data availability statement
- EQUATOR Network reporting guidelines checklists
medRxiv: risk mitigation

Is it nonsense?
Is it non-science?
Is it a paper?
Is it research?
Is it plagiarized?
Is it a health threat?
Is there a benefit to sharing now vs. after peer review?

BMJ
Caution: Preprints are preliminary reports of work that have not been peer-reviewed. They should not be relied on to guide clinical practice or health-related behaviors and should not be reported in news media as established information.

This article is a preprint and has not been peer-reviewed. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.

We also urge journalists and other individuals who report on medical research to the general public to consider this when discussing work that appears on medRxiv and emphasize it has yet to be evaluated by the medical community and the information presented may be erroneous.
COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

15,186 Articles (11,736 medRxiv, 3,450 bioRxiv)

Forecast of the COVID-19 epidemic in France
Pottier, L.

COVID-19 epidemic scenarios into 2021 based on observed key superdispersion events

Impact of vaccination and non-pharmaceutical interventions on SARS-CoV-2 dynamics in Switzerland
Monthly posted:

Daily submitted:

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<th>Jan</th>
<th>Feb</th>
<th>Mar</th>
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<td>77</td>
<td>59</td>
<td>57</td>
<td>51</td>
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Widespread recognition of the value of preprints...

Europe PMC: unlocking the potential of COVID-19 preprints

30 Jul 2020 - 10:40

**Summary**

- Europe PMC is now indexing full-text preprints related to the COVID-19 pandemic and the SARS-CoV-2 virus, as well as the underlying data.
- The project will make COVID-19 scientific literature available in a format that allows text mining.
- Researchers and healthcare professionals will be able to access the literature easily, accelerating research into better treatments or a vaccine.

| Reference: | medRxiv preprint 1, medRxiv preprint 2, medRxiv preprint 3 & The Lancet Infectious Diseases paper |

**NIH Preprint Pilot**

The NIH Preprint Pilot is a project of the National Library of Medicine (NLM). During the pilot, NLM will make preprints resulting from research funded by the National Institutes of Health (NIH) available via PubMed Central (PMC) and, by extension, PubMed. The pilot aims to explore approaches to increasing the discoverability of early NIH research results posted to eligible preprint servers. PMC already makes available more than one million peer-reviewed papers resulting from NIH-supported research collected under the NIH Public Access Policy. This pilot builds on PMC’s NIH repository role as well as 2017 NIH guidance (NOT-OD-17-050) that encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work.
Scientific research on the coronavirus is being released in a torrent

Will that change how science is published?

A Pandemic Moves Peer Review to Twitter

The coronavirus has transformed how scientific research findings are communicated. Is that good? Will the changes stick?

Strong caveats are lacking as news stories trumpet preliminary COVID-19 research
**FOR IMMEDIATE RELEASE**

Effect of Dexamethasone in Hospitalized Patients with COVID-19: Preliminary Report

The RECOVERY Collaborative Group*

Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report

The RECOVERY Collaborative Group*

**BACKGROUND**

President calls negative hydroxychloroquine study 'a Trump enemy statement' - as it happened

Outcomes of hydroxychloroquine usage in United States veterans hospitalized with Covid-19

BACKGROUND: Despite limited and conflicting data on the use of hydroxychloroquine in patients with Covid-19, the U.S. Food and Drug Administration has authorized the emergency use of this drug when clinical trials are unavailable or infeasible. Hydroxychloroquine, alone or in combination with azithromycin, is being widely used in Covid-19 therapy based on anecdotal
Where is the sweet spot for dissemination?

Joseph LIM @joseph11lim

Replying to @bmj_latest and @TheoBloom

Preprints should be let loose only among professionals and peers of researchers, not to the general public. This would still serve to hasten scientific discovery but could help reduce the problems of public mis-understanding or mis-handling of research yet to be peer-reviewed.
The BMJ: print magazine, online journal

- News
- Features
- Investigations
- Education
- Campaigns
- Opinions
- Guidelines
- Commentary
- Analysis
- And Open Access Research

Articles supported by article-processing charges
BMJ journals portfolio
Are we doing enough to protect doctors?
BMJ's covid-19 hub supports health professionals and researchers with practical guidance, online CPD courses, as well as the latest news, comment, and research from BMJ. The content is free and updated daily.

Guidance

Education

Testing for SARS-CoV-2 antibodies
How might antibody testing be used?

A living WHO guideline on drugs for covid-19
A rapid recommendation on corticosteroids

Training

Covid-19 related courses
(24 courses)
BMJ Learning offers online courses directly related to

Management

Covid-19 diagnosis and management
The latest practical guidance from BMJ Best Practice on diagnosis and management of patients with covid-19

Clinical decision support
Diagnosis and management of related conditions, with patient information to support shared decision making

Patient information

Information for patients
Information for patients from BMJ Best Practice

Infographics

Covid-19 antibody tests
Updated: 8 Sept

Covid-19: Long covid
Updated: 11 August

Remote consultation of covid-19
Updated: 25 Mar

Latest issue

All information is freely available
Speeding up journal publication

PRE-PANDEMIC:

Peer review 100 days + production 24 days = median > 4 months from submission to publication.

REVIEW TIME

An analysis of all papers in PubMed up to 2015 with listed submission and acceptance dates suggests that the median time from submission to acceptance has hovered at around 100 days, although it has gone up at some journals.

A few journals with quick review times started in 2000, lowering the median.

2015: 9,045 journals in the PubMed database.

PRODUCTION TIME

The same analysis of Pubmed papers suggests that the time between acceptance and publication has dropped, probably because technology has improved.

Nature 530, 148–151 (11 February 2016) doi:10.1038/530148a
Rapid Recommendations and Living Systematic Reviews

Rapid Recommendations process step by step (with target times)

1. Monitor and identify potentially practice changing evidence (day 1)
2. Executive + chair triggers process and RapidRecs panel (day 7)
3. Systematic reviews created by separate teams (day 45)
4. RapidRecs created in MAGICapp and as synopsis paper (day 60)
5. RapidRecs + reviews submitted for peer review (day 60)
6. RapidRecs and reviews disseminated globally (day 90)
Covid: the first preprinted epidemic. Will it help?


Paul Glasziou, Sharon Sanders, Tammy Hoffmann, BMJ 2020;369:m1847 doi: 10.1136/bmj.m1847
Thank you! Web: bmj.com
Email: tbloom@bmj.com
Twitter: @TheoBloom

medrxiv.org
@medrxivpreprint