# DC CTSA Spring Regulatory Update & Hot Topics in **Clinical and Translational Research**

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

# **Dissemination of Research During the Pandemic**

Moderator: Sarah Vittone, DBe, MA, MSN, RN

Doctor of Bioethics Assistant Professor, School of Nursing and Health Studies **Georgetown University** 

11:30 AM - 12:25 PM EST









# **DC CTSA Spring Regulatory Update & Hot Topics in Clinical and Translational Research**

# Beyond COVID-19: Challenges & Lessons Learned during a Pandemic **Dissemination of Research During the Pandemic**





## Lars Berglund, M.D., Ph.D.

Editor Journal of Clinical and Translational Science

**Executive Editor** The BMJ

# Theodora Bloom, Ph.D.



# JCTS and COVID Lars Berglund MD PhD Editor-in-Chief



# JCTS in brief

- Journal started 2017, now in its 5<sup>th</sup> 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**

180 -2021 YTD Perspective Expedited Reports Special Communication Review Article Research Article Letters Editorial Brief Report Total 

Submissions

## JCTS new submissions 2020





# 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 26<sup>th</sup>, 2021.



Abstract Views

## 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

Article Title	Author(s)	Vol:Iss	Downloads
Safety of influenza vaccine during COVID-19	Zein et al.	5	9,805
The potential for antibody-dependent enhancement of SARS-CoV-2 infection: Translational implications for vaccine development	Wang & Zand	5	4,712
Clinical characteristics associated with COVID-19 severity in California	Rubin et al.	5	1,963
Leveraging community engaged research partnerships for crisis and emergency risk communication to vulnerable populations in the COVID-19 pandemic	Wieland et al.	5	1,760
Application of volumetric absorptive microsampling (VAMS) to measure multidimensional anti-influenza IgG antibodies by the mPlex-Flu assay	Wang et al.	3:6	1,606
Safety of ACE-I and ARB medications in COVID-19: A retrospective cohort study of inpatients and outpatients in California	Rubin et al.	5	1,383
Effect of various decontamination procedures on disposable N95 mask integrity and SARS-CoV-2 infectivity	Smith et al.	5	1,318
COVID-19 and public health efforts in Mongolia: A lesson maybe learned?	Bayasgalan et al.	5	1,283
Mapping the evolving definitions of translational research	Fort et al.	1:1	1,207
Equipoise and research in the current COVID-19 pandemic	Pulley et al.	5	1,165
Immediate impact of the COVID-19 pandemic on CTSA TL1 and KL2 training and career development	McCormack et al.	4:6	1,078
Optimizing sampling rate of wrist-worn optical sensors for physiologic monitoring	Bent & Dunn	5	1,066
A REDCap-based model for electronic consent (eConsent): Moving toward a more personalized consent	Lawrence et al.	4:4	1,058
Mentoring in crisis does not need to put mentorship in crisis: Realigning expectations	Cameron et al.	5	999
Research on COVID-19 through patient-reported data: a survey for observational studies in the COVID-19 pandemic	Verma et al.	5	965
The digital biomarker discovery pipeline: An open-source software platform for the development of digital biomarkers using mHealth and wearables data	Bent et al.	5	803
Education and training of clinical and translational study investigators and research coordinators: A competency-based approach	Calvin-Naylor et al.	1:1	749
Advancing health equity through CTSA programs: Opportunities for interaction between health equity, dissemination and implementation, and translational science	Yousefi Nooraie et al.	4:3	631
Comorbidities and health care systems differences among states as it relates to COVID-19	Anderson et al.		596
Building bridges between a community and an academic medical center via community tours	Irby et al.	4:4	571
Career orientation and perceived professional competence among clinical research coordinators	Rojewski et al.	3:5	562
An exploratory study of Clinical and Translational Science Award community-engaged research training programs	Ziegahn et al.	2:2	529
Situating dissemination and implementation sciences within and across the translational research spectrum	Leppin et al.	4:3	525
Pilot study of an intervention to increase cultural awareness in research mentoring: Implications for diversifying the scientific workforce	Byars-Winston et al.	2:2	511
Assessing clinical research coordinator knowledge of good clinical practice: An evaluation of the state of the art and a test validation study	DuBois et al.	4:2	505

# 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

# 8-

## **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

# BMJ

# 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







International Congress on Peer Review and Scientific Publication Enhancing the quality and credibility of science









## How it worked for 150 years



https://commons.wikimedia.org/wiki/File:Faraday\_ Michael\_Christmas\_lecture.jpg

#### 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<sup>1</sup>. 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 phosphate diester groups joining  $\beta$ -D-deoxyribofuranose residues with 3',5' linkages. The two chains (but

No. 4356 April 25, 1953













## 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

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Allergy and Immunology	HIV/AIDS	Pallistive Medicine
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Cardiovascular Medicine	HIV/AIDS)	Padatrics
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Dermatology	Madical Education	Therapeutics
Emergency Medicine	Medical Ethics	Primary Care Research Psychiatry and Clinical
Endocrinology (including Diabetes Mellinus and	Nephrology	Psychology
Metabolic Disease)	Neurology	Public and Global Health
Epidemiology	Nursing	Radiology and Imaging
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Fonensic Medicine	Obstetrics and Gynecology	Physical Thorapy
Gastroenterology		Respiratory Medicine
	Occupational and	
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Gastroenterology Genetic and Genomic Medicine	Environmental Health Oncology	Rheumatology Sexual and Reproductive Health
Gastroenterology Genetic and Genomic Medicine Genistric Medicine	Environmental Health Oncology Ophthalmology	Sexual and Reproductive
Gastroenterology Genetic and Genomic Medicine Genetic Medicine Health Economics	Environmental Health Oncology Ophthalmology Orthopedics	Sexual and Reproductive Health
Gastroenterology Genetic and Genomic Medicine Gerlatric Medicine Health Inconomics Health Informatics	Environmental Health Oncology Ophthalmology	Sexual and Reproductive Health Sports Medicine

- 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?





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

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CSH) Spring Harbor Harbor Harbor

THE PREPRINT SERVER FOR HEALTH SCIENCES

#### What is an unrefereed preprint?

Before formal publication in a scholarly journal, scientific and medical articles are traditionally "peer reviewed." In this process, the journal's editors take advice from various experts—called "referees"—who have assessed the paper and may identify weaknesses in its assumptions, methods, and conclusions. Typically a journal will only publish an article once the editors are satisfied that the authors have addressed referees' concerns and that the data presented support the conclusions drawn in the paper.

Because this process can be lengthy, authors use the medRxiv service to make their manuscripts available as "preprints" before peer review, allowing

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other scientists to see, discuss, and comment on the findings immediately. Readers should therefore be aware that articles on medRxiv have not been finalized by authors, might contain errors, and report information that has not yet been accepted or endorsed in any way by the scientific or medical community.

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 preprints and emphasize it has yet to be evaluated by the medical community and the information presented may be erroneous.

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occurring cancer in American men. The existing treatment approaches and surgical	Addiction Medicine		

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> 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.





THE PREPRINT SERVER FOR HEALTH SCIENCES

medRxiv is receiving many new papers on coronavirus SARS-CoV-2. A reminder: these are preliminary reports that have not been peer-reviewed. They should not be regarded as conclusive, guide clinical practice/health-related behavior, or be reported in news media as established information.

### COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv

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

Most recent first

Page I: Articles I-10 | Next 🕄

#### Forecast of the covid19 epidemic in France

Pottier, L. 10.1101/2021.04.13.21255418 — Posted: 2021-04-20

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

Santana-Cibrian, M., Acuna-Zegarra, M.A., Rodriguez Hernandez-Vela, C. E., Velasco-Hernandez, J. X., Mena, R. H.

10.1101/2021.04.14.21255436 --- Posted: 2021-04-20

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

Shattock, A. J., Le Rutte, E. A., Duenner, R. P., Sen, S., Kelly, S. L., Chitnis, N., Penny, M.A. 10.1101/2021.04.14.21255503 — Posted: 2021-04-20

Subje	ect Areas
All Ar	rticles
	Addiction Medicine
	Allergy and Immunology
	Anesthesia
	Cardiovascular Medicine
	Dentistry and Oral Medicine
	Dermatology
	Emergency Medicine
	Endocrinology (including Diabetes Mellitus and Metabolic Disease)
	Epidemiology
	Forensic Medicine
	Gastroenterology



## medRxiv Usage by Month



## Widespread recognition of the value of preprints...



## nature briefing Age is the biggest predictor of who will die

## Europe PMC: unlocking the potenti COVID-19 preprints

Four studies (three of which have not yet been peer-reviewed) from Spain, England, Italy and Geneva, Switzerland, pinpoint the infection fatality ratio (IFR), which is the proportion of people infected with the virus, including those who didn't get tested or show symptoms, who will die as a result. All found that the IFR was close to zero in younger

Tuesday 1 September 2020

#### Summarv

BM

30 Jul 2020 - 10:40

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

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 <u>eligible preprint servers</u>. PMC already makes available more than one million peer-reviewed papers resulting from NIH-supported research collected under the <u>NIH Public Access Policy</u>. This pilot builds on PMC's NIH repository role as well as 2017 NIH guidance (<u>NOT-OD-17-050</u>) that encourages investigators to use interim research products, such as preprints, to speed the dissemination and enhance the rigor of their work.

## but also worries about their misuse

### Covid-19

## Scientific research on the coronavirus is being **Mother Jones** released in a torrent POLITICS

### Will that change how science is published?

All that's fit to preprint

COVID-19 has reinforced the importance of preprints as an indispensable means for rapid research dissemination

Bloomberg Opinion

one reason why the medical community was Med last year (30,627 ,413 papers), Thus, so cautious about preprints in the first place. A case in point is bioRxiv's most arger proportion of

Check for update

editoria

#### **Technology & Ideas**

## A Pandemic Moves Peer Review to Twitter

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

#### APRIL 1, 2020



Strong caveats are lacking as news stories trumpet preliminary COVID-19 research

## CORONAVIRUS APRIL 28, 2020 Science Has an Ugly, Complicated Dark Side. And the

#### Coronavirus Is Bringing It Out.

Experts say the pandemic is letting bad science slip through the cracks.

CRIME AND JUSTICE

JACKIE FLYNN MOGENSEN Assistant Editor **Bio | Follow** 

ENVIRONMENT

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FOOD

MEDIA

INVESTIGATIONS

Date: Tue, 16 Jun 2020 at 15:51

Subject: FOR IMMEDIATE RELEASE: WORLD FIRST CORONAVIRUS TREATMENT APPROVED FOR NHS USE BY GOVERNMENT To:

#### \*\*FOR IMMEDIATE RELEASE\*\*

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Abstract

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Background: Coronavirus

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Info/History



Dexamethasone in Hospitalized Patients with Covid-19 — Preliminary Report The RECOVERY Collaborative Group\* Figures/Media July 17, 2020 Article Metrics DOI: 10.1056/NEJMoa2021436 39 References 89 Citing Articles **Related Articles** Abstract EDITORIAL JUL 17, 2020 Research in the Context of a Pandemic BACKGROUND H.C. Lane and A.S. Fauci Coronavirus disease 2019 (Covid-19) is associated with diffuse lung damage. Glucocorticoids may modulate inflammation-mediated lung injury and thereby reduce

O Comments (17)

**ORIGINAL ARTICLE** 

EDITORIAL JUL 21, 2020

G Previous

Posted June 22, 2020.



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BACKGROUND: Despite limited and conflicting data on the use of hydroxychioroquine 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 inteasible. Hydroxychioroquine, 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

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## 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.

9:34 AM · Dec 31, 2020 · Twitter for Android

# The BMJ: print magazine, online journal

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## **BMJ** journals portfolio





















## Outline of the**bmj** review process







# the**bmj**

Is primary care forever changed? p12 Clinical traits of covid-19 deaths p 22 GP guide to remote assessment p 32 How to cope with redeployment p 40 1 CPD hour in the education section



## Are we doing enough to protect doctors?





BMJ Learning offers online courses directly related to

(24 courses)

#### Information for patients

Information for patients from BMJ Best Practice

#### Latest issue

# Speeding up journal 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.



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

#### PRODUCTION TIME

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



## Rapid Recommendations and Living Systematic Reviews



## Covid: the first preprinted epidemic. Will it help?

Waste in covid-19 research: how do we make the outpouring of research more effective?



Waste in covid-19 research A deluge of poor quality research is sabotaging an effective evidence based response The medical research world is responding to the covid-19 pandemic...  $\mathscr{S}$  bmj.com

BM

Paul Glasziou, Sharon Sanders, Tammy Hoffmann, BMJ 2020;369:m1847 doi: 10.1136/bmj.m1847



Brierley L. Lessons from the influx of preprints during the early COVID-19 pandemic. Lancet Planet Health 2021; 5: e115–17.

Thank you!Web:bmj.comEmail:tbloom@bmj.comTwitter:@TheoBloom

## medrxiv.org

## @medrxivpreprint

