Is it time to embrace preprints?

A conversation about the first 18 months of medRxiv

NIH Collaboratory Grand Rounds

January 22, 2021



Harlan M. Krumholz, MD, SM Joseph S. Ross, MD, MHS @hmkyale @jsross119

Department of Internal Medicine, Yale School of Medicine Center for Outcomes Research and Evaluation, Yale-New Haven Hospital

Potential Conflicts of Interest

 medRxiv funded by Chan-Zuckerberg Initiative via a grant to CSHL

Preprint (n):

a research manuscript yet to be certified by peer review and accepted for publication by a journal

Preprint server (n):

an online platform dedicated to the distribution of preprints

Preprint servers are proliferating



medRxiv: a server for health science preprints

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Gastronianology	Obsceptics and Gynecology	Physical Thurspy
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Health Economics	Ophthamology	Pleature
Health Milormanica	Orthopedics	Sporta Medicine
Health Palicy	Ossisryngelugy	Surgery
Health Systems and Quality		Testcology
Improvement		

- Conceptually and technologically similar to bioRxiv
- 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

Preprints in medicine: potential benefits

Rapid, early sharing of new information

- Establishes provenance of ideas while papers peer reviewed
- Facilitates awareness, prompts scientific feedback
- Enhances collaboration among scientists
- Demonstrates scientific productivity

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Make less "publishable" studies more readily available

- Medical education and qualitative research
- Quality improvement & healthcare delivery innovations
- Confirmatory or contradictory results
- Negative or inconclusive research findings

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Foster more "complete" results reporting

- Promotes research transparency, particularly for abstract presentations, complements trial registry results reporting
- Links protocols, sensitivity analyses and supplementary materials (not all journals publish)

Preprints in medicine: concerns and perceived risks

Editors worry about:

- Harm to the public from wrong information, magnified by media reporting
- 'Persistent preprints' with results/conclusion that changed after peer review
- Manipulation by commercial interests
- Undermining established medical communication norms
 - Peer-reviewed journals
 - Conferences
 - ClinicalTrials.gov

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Authors worry about:

• Journals won't publish their paper if it's preprinted

medRxiv: mitigating concerns and risks

- Submission requirements for authors
- Clear posting criteria research articles only!
- Established screening process
- Signaling the need for caution when scientists and non-scientists read and review preprints

medRxiv: submission requirements

- Follow ICMJE guidance, including author names, contact info, affiliation
- Funding and competing interest statements
- Statement of IRB / ethics committee oversight
- Study registration when applicable

(ClinicalTrials.gov or other ICMJE approved registry for trials, PROSPERO for reviews)

- Study protocol *
- Data sharing / availability statement *
- EQUATOR Network reporting guidelines checklist(s) *

medRxiv: allowed article types

- Original research in the biomedical sciences, including clinical trials, observational research, surveys, qualitative research, quality improvement and implementation science, policy studies, and medical education
- Systematic reviews and meta-analytic research
- Methodological research
- Data publications
- Protocols (to accompany study preprints)

Not Allowed: commentaries, editorials, opinion pieces or essays, letters to editors, narrative reviews, medical-legal research, case reports

1. Author submits manuscript to medRxiv

- Automated checks ensure all required information (e.g. author contact, etc.) is submitted.
- PDF is generated, identifying the work as a preprint

2. CSHL staff review for:

- General structure and organization as a research article
- Plagiarism, obscenity
- Statements confirming authorship, affiliation, contributions, and consent to submit
- Statements on funding, competing interests, trial registration, data sharing, and research checklists
- Statements confirming IRB review and patient consent
- Any other general concerns: flag for oversight

3. medRxiv Affiliate (community researcher) reviews for:

- Allowed article type
- Meets reasonable criteria for a scientific report in this area
- No patient identifiable information or other ethical concerns
- Any other concerns: flag for oversight

4. Precautionary Step: BMJ editor reviews for:

- Meets reasonable criteria for a scientific report
- Any concerns: flag for oversight

5. (Flagged Submissions) medRxiv oversight review for:

• Posting is in best interests of patients and clinicians, public health - post/don't post

Article posted to medRxiv (or not)

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	Allergy and Immunology	HIV/AIDS	Palliative Medicine
	Anesthesia Cardiovascular Medicine	Infectious Diseases (except HIV/AIDS)	Pathology Pediatrics

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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 health-related behaviors and should not be reported in news media as established information.

All Articles			
Addiction Medicine	Hematology	Pain Medicine	
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Polo like kinase (Plk) I: A novel target for the treatment of prostate cancer Marlene Graveland Tox C Donnen, rony Greogo oky doi: https://doi.org/10.1101/01001552 This article is a preprint and has not been peer-reviewed [what does this mean?]. It reports new medical research that has yet to be evaluated and so should not be used to guide clinical practice.	 Previous Posted January 22, 2019. Download PDF Data/Code Citation Tools 	Next <section-header></section-header>
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Abstract	Subject Areas	
Cancer of the Prostate gland (CaP), next only to skin cancer, is the most commonly	All Articles	
occurring cancer in American men. The existing treatment approaches and surgical	Addiction Medicine	
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medRxiv: urging caution in reporting on preprints

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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 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 sciencific 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.

medRxiv: urging caution in reporting on preprints

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Weekly submissions (06/05/19 – 12/31/19)



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>8000 Institutions Represented Top 10 University of Oxford University College London Imperial College London Stanford University King's College London University of Cambridge University of Bristol University of Pennsylvania Icahn School of Medicine at Mount Sinai London School of Hygiene and Tropical Medicine

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Factors associated with hospitalization with COVID-19 disease in New York Ci	• /	patients	Posted April 11, 2020.	
Christopher M. Petrilli, ⁽¹⁾ Simon A. Jones, Jie Yang, F Katie Tobin, Robert J. Cerfolio, Fritz Francois, ⁽²⁾ Lec doi: https://doi.org/10.1101/2020.04.08.20057794	' Iarish Rajagopalan, Luke F. O'Donnell, Yele	na Chernyak,	Download PDF	 ✓ Email ← Share ② Citation Tools
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system in New York City between March through April 7, 2020. Primary outcomes			All Articles	
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	Booster Shots - latimes.com, 15 Apr 2020 This may help explain why the coronavirus has hit the U.S. so hard: Obesity appears to be a risk factor for serious cases of			
	ConscienHealth, 14 Apr 2020 We are in the midst of an intense learning experience. We're learning how to live in physical isolation. At the same time, we're			
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	Well - New York Times, 16 Apr 2020 Young adults with obesity are more likely to be hospitalized, even if they have no other health problems, studies show.		Obesity, diabetes, and hypertension are clearly the major factors in hospitalizations and deaths from Covid-19.
	«Life.rus — информационный портал, 15 Арг 2020 Они также подтвердити более ранние исследования о связи заболевания с окирением. Интать далее		Northwell Health just released a study of over 5000 Covid-19 patients that revealed 94 percent
	Booster Shots - latimes.com, IS Apr 2020 This may help explain why the coronavirus has hit the U.S. so hard: Obesity appears to be a risk factor for serious cases of		
	ConscientHealth, 14 Apr 2020 We are in the midst of an intense learning experience. We're learning how to live in physical isolation. At the same time, we're		~10% have comments,
	FOAMcast, 13 Apr 2020 Apple Podcasts or Listen		
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mul max	Wake Up To The Truth, 25 Apr 2020 HARApril 25, 2020 The traggedy of the COVID-19 pandemic appears to be entering the containment phase. Tens of thousands of Research - The S Vord, 16 Apr 2020	mes, ai olitters.	Abstract	Info/History	Metrics		C P	review PDF
Res	More men die of covid-19 than women. Reasons for this may include differences in smoking, general health, immune defences TekCrings, 16 Apr 2020 E estudio de mis de 3.000 pacientes con coronavirus reveló que la obesidad aumenta el riesgo de complicaciones en el cursto de Vella I-New York Times, 16 Apr 2020 Young adults with obesity are more likely to be hospitalized, even if they have no other health problems, studies show. differum — информационный портал, 15 Apr 2020 Они также подтвердили более ранние исследования о связи заболевания о сокорением.Читата далее Booster Shots - Laimescom, 15 Apr 2020 This may help explain why the coronavirus has hit the U.S. so hard: Obesity appears to be a risk factor for	<u>t of w</u> l		SAGE lifetime ge: April 2020 to	Last 6 months	This month		
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Neeltje van Doremalen, Trenton Bushmaker, Dylan Morris, Myndi Holbrook, Amandi Brandi Williamson, Azaibi Tamin, Jennifer Harcourt, Natalie Thornburg, Susan Gerber Emmie de Wit, Vincent Munster doi: https://doi.org/10.1101/2020.03.09.20033217 Now published in The New England Journal of Medicine doi: 10.1056/NEJMc2004973		 Download PDF Supplementary Material Data/Code 	 Email Share Citation Tools 	
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Abstract		COVID-19 SARS-CoV-2 preprints from medRxiv and bioRxiv		
A novel human coronavirus, now named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, referred to as HCoV-19 here) that emerged in Wuhan,		Subject Area		
China in late 2019 is now causing a pandemic. Here, we analyze the aerosol and		Infectious Diseases (except HIV/AIDS)		
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Aerosol and surface

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Abstract

A novel human co coronavirus 2 (SAF China in late 2019 surface stability of human coronaviru aerosols and on di regression model

The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE



Aerosol and Surface Stability of SARS-CoV-2 as Compared with SARS-CoV-1

is now named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (formerly called HCoV-19) emerged in Wuhan, China, in late 2019 and is now causing a pandemic.1 We analyzed the aerosol and surface stability of SARS-CoV-2 from the upper and lower respiratory tract in and compared it with SARS-CoV-1, the most humans. closely related human coronavirus.2

We evaluated the stability of SARS-CoV-2 and SARS-CoV-1 in aerosols and on various surfaces and estimated their decay rates using a Bayesian regression model (see the Methods section in the Supplementary Appendix, available with the full text of this letter at NEJM.org). SARS-CoV-2 nCoV-WA1-2020 (MN985325.1) and SARS-CoV-1 Tor2 (AY274119.3) were the strains used. Aerosols (<5 µm) containing SARS-CoV-2 (105.25 50%) tissue-culture infectious dose [TCID₅₀] per milliliter) or SARS-CoV-1 (106.75-7.00 TCID 50 per milliliter)

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	THIS WEEK'S LETTERS	
_	64 Aerosol and Surface Stability of SARS-CoV-2	

TO THE EDITOR: A novel human coronavirus that were generated with the use of a three-jet Collison nebulizer and fed into a Goldberg drum to create an aerosolized environment. The inoculum resulted in cycle-threshold values between 20 and 22, similar to those observed in samples obtained

Our data consisted of 10 experimental conditions involving two viruses (SARS-CoV-2 and SARS-CoV-1) in five environmental conditions (aerosols, plastic, stainless steel, copper, and cardboard). All experimental measurements are reported as means across three replicates.

SARS-CoV-2 remained viable in aerosols throughout the duration of our experiment (3 hours), with a reduction in infectious titer from 103.5 to 102.7 TCID per liter of air. This reduction was similar to that observed with SARS-CoV-1, from 1043 to 1035 TCID 50 per milliliter (Fig. 1A).

SARS-CoV-2 was more stable on plastic and stainless steel than on copper and cardboard, and viable virus was detected up to 72 hours month als ...



Covid-19

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

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POLITICS

All that's fit to preprint

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

he uptake of preprints during the COVID-19 pandemic has been nothing short of remarkable. In April, papers indexed in PubMed last year (30,627 one reason why the medical community was preprints versus 1,401,413 papers). Thus, preprints represent a larger proportion of A case in point is bioRxiv's most

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

APRIL 1, 2020



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

NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19

Hospitalized patients with advanced COVID-19 and lung involvement who received remdesivir recovered faster than similar patients who received placebo, according to a preliminary data analysis from a randomized, controlled trial involving 1063 patients, which began on February 21. The trial (known as the <u>Adaptive COVID-19 Treatment Trial</u>, or ACTT), sponsored by the <u>National Institute of Allergy and Infectious Diseases (NIAID)</u>, part of the National Institutes of Health, is the first clinical trial launched in the United States to evaluate an experimental treatment for COVID-19.

An independent data and safety monitoring board (DSMB) overseeing the trial met on April 27 to review data and shared their interim analysis with the study team. Based upon their review of the data, they noted that remdesivir was better than placebo from the perspective of the primary endpoint, time to recovery, a metric often used in influenza trials. Recovery in this study was defined as being well enough for hospital discharge or returning to normal activity level.

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Preliminary results indicate that patients who received remdesivir had a 31% faster time to recovery than those who received placebo (p<0.001). Specifically, the median time to recovery was 11 days for patients treated with remdesivir compared with 15 days for those who received placebo. Results also suggested a survival benefit, with a mortality rate of 8.0% for the group receiving remdesivir versus 11.6% for the placebo group (p=0.059).

More detailed information about the trial results, including more comprehensive data, will be available in a forthcoming report. As part of the U.S. Food and Drug Administration's commitment to expediting the development and availability of potential COVID-19 treatments, the agency has been engaged in sustained and ongoing discussions with Gilead Sciences regarding making remdesivir available to patients as quickly as possible, as appropriate. The trial closed to new enrollments on April 19. NIAID will also provide an update on the plans for the ACTT trial moving forward. This trial was an adaptive trial designed to incorporate additional investigative treatments.

The first trial participant in the ACTT trial was an American who was repatriated after being quarantined on the Diamond Princess cruise ship that docked in Yokohama, Japan, and volunteered to participate in the study at the first study site, the University of Nebraska Medical Center/Nebraska Medicine, in February 2020. A total of 68 sites ultimately joined the study–47 in the United States and 21 in countries in Europe and Asia.

Remdesivir, developed by Gilead Sciences Inc., is an investigational broad-spectrum antiviral treatment administered via daily infusion for 10 days. It has shown promise in animal models for treating SARS-CoV-2 (the virus that causes COVID-19) infection and has been examined in various clinical trials.

Contact

To schedule interviews, contact NIAID Office of Communications (301) 402-1663 NIAIDNews@niaid.nih.gov ⊠

NIH Clinical Trial Shows Remdesivir Accelerates Recovery from Advanced COVID-19

April 29, 2020

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