Is it time to embrace preprints?

A conversation about the first 18 months of medRxiv

NIH Collaboratory Grand Rounds

January 22, 2021

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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

- 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)

medRxiv: urging caution in using preprints

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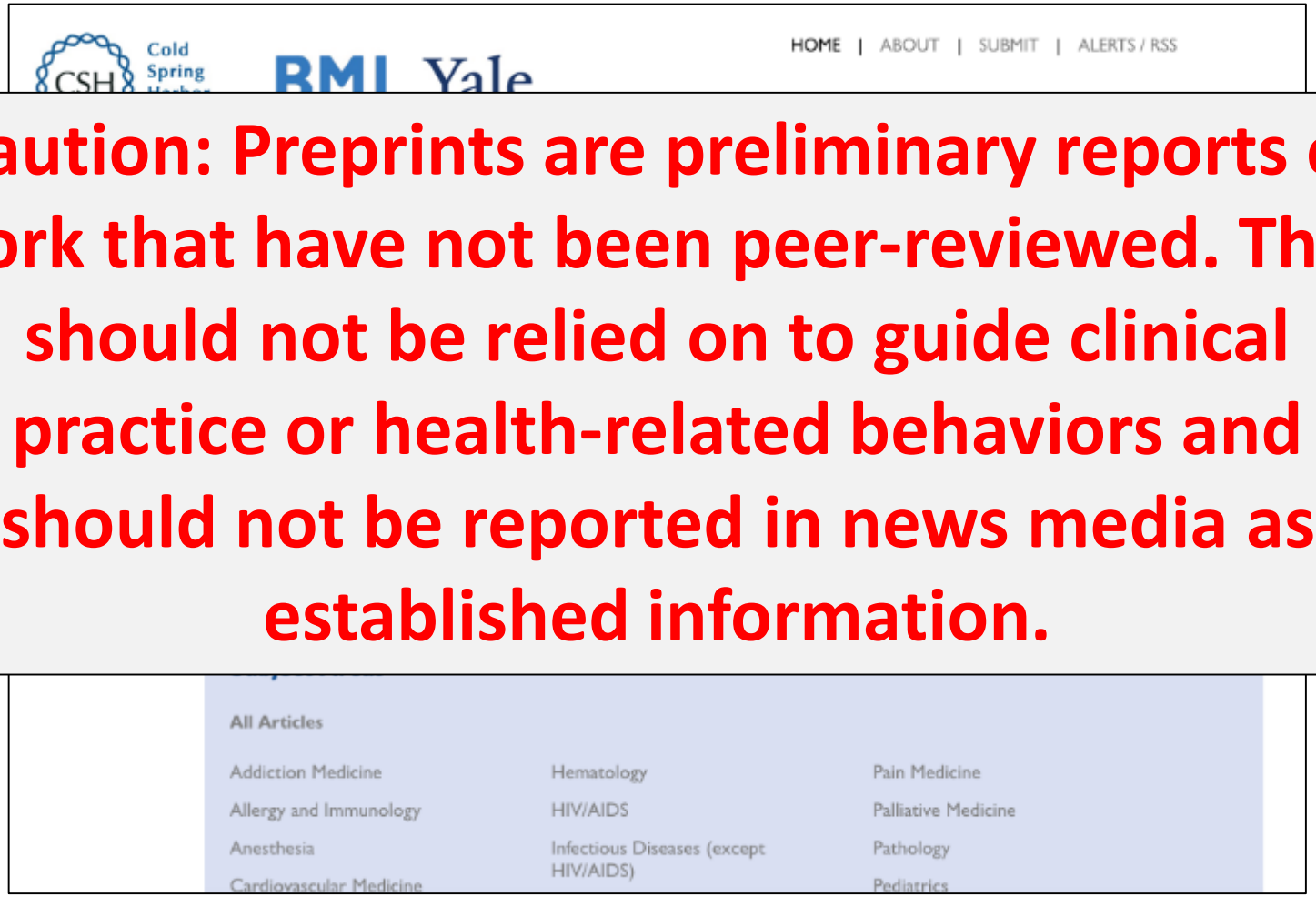

Caution: Preprints are preliminary reports of work that have not been peer-reviewed. They should not be relied on to guide clinical practice or health-related behaviors and should not be reported in news media as established information.

medRxiv: urging caution in using preprints

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Polo like kinase (Plk) 1: A novel target for the treatment of prostate cancer

Marlene Graveland, Tony Gregoroky

doi: https://doi.org/10.1101/01001552

Posted January 22, 2019.

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.

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Abstract

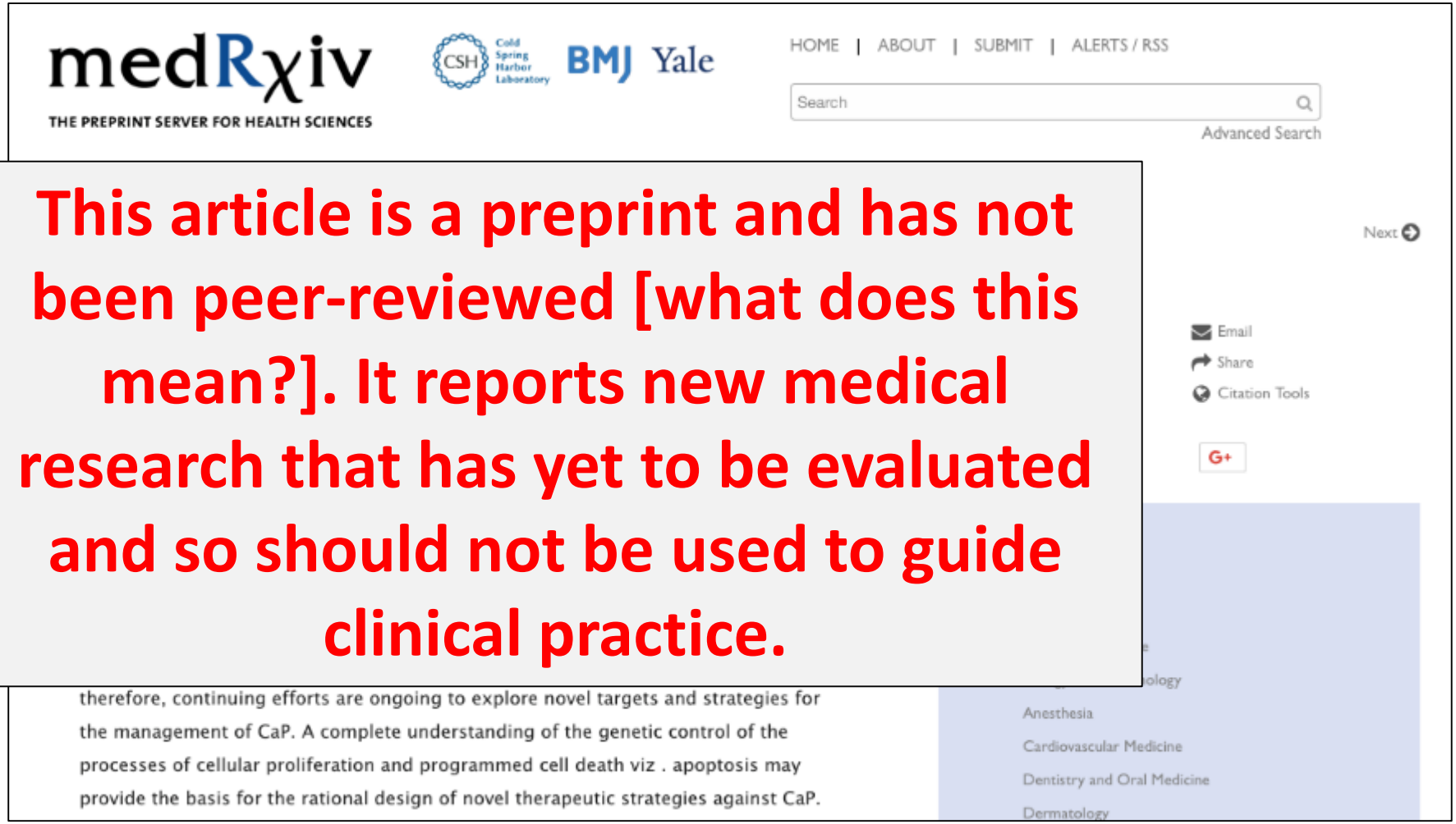
Cancer of the Prostate gland (CaP), next only to skin cancer, is the most commonly occurring cancer in American men. The existing treatment approaches and surgical intervention have not been able to effectively manage this dreaded cancer and, therefore, continuing efforts are ongoing to explore novel targets and strategies for the management of CaP. A complete understanding of the genetic control of the processes of cellular proliferation and programmed cell death viz . apoptosis may provide the basis for the rational design of novel therapeutic strategies against CaP.

Subject Areas

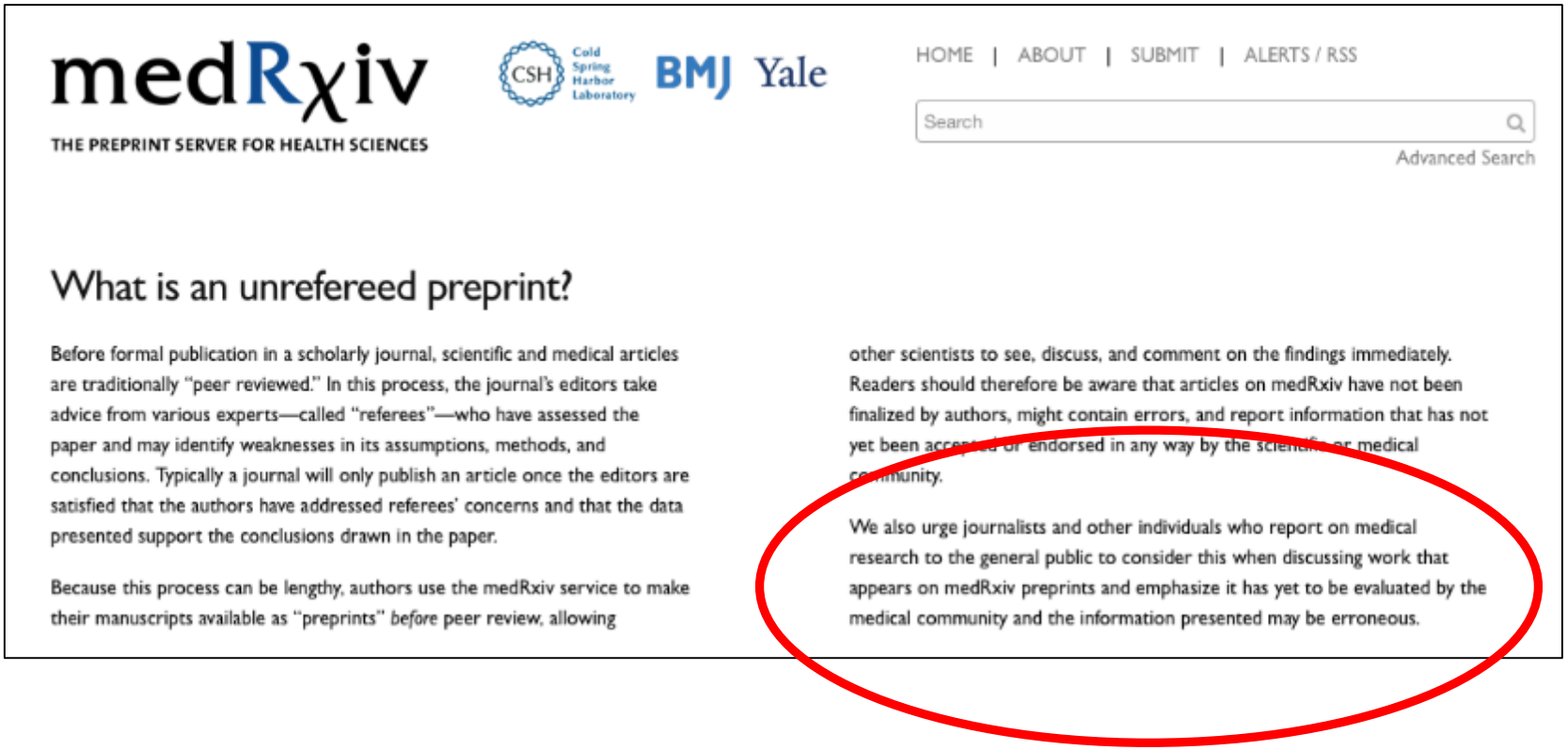
All Articles

Addiction Medicine
Allergy and Immunology
Anesthesia
Cardiovascular Medicine
Dentistry and Oral Medicine
Dermatology

medRxiv: urging caution in using preprints



medRxiv: urging caution in reporting on preprints



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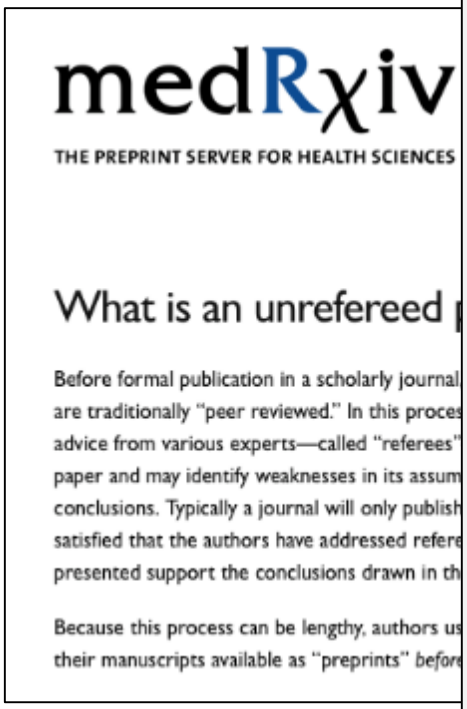
What is an unrefereed preprint?

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 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.

medRxiv: urging caution in reporting on preprints



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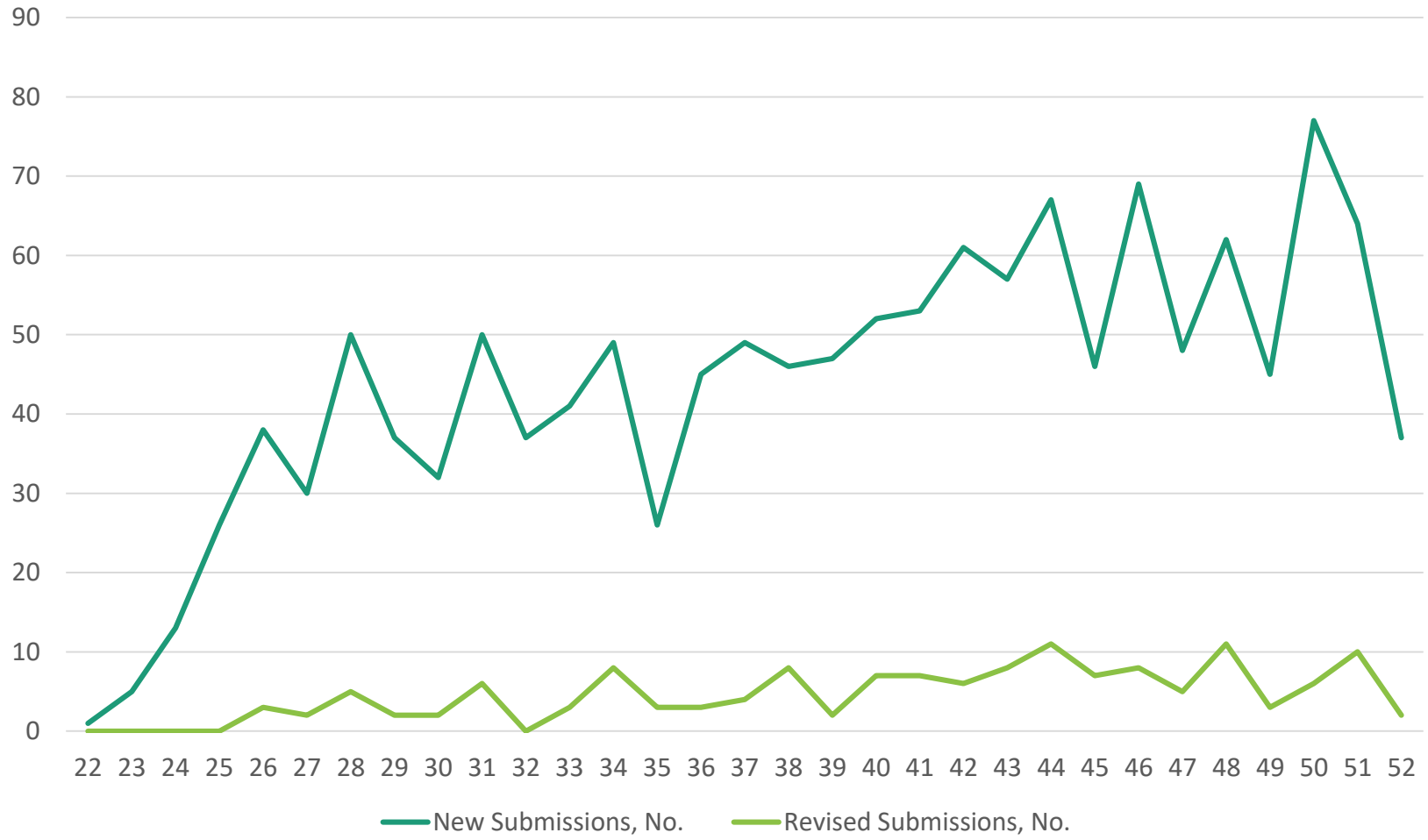
Weekly submissions (06/05/19 – 12/31/19)



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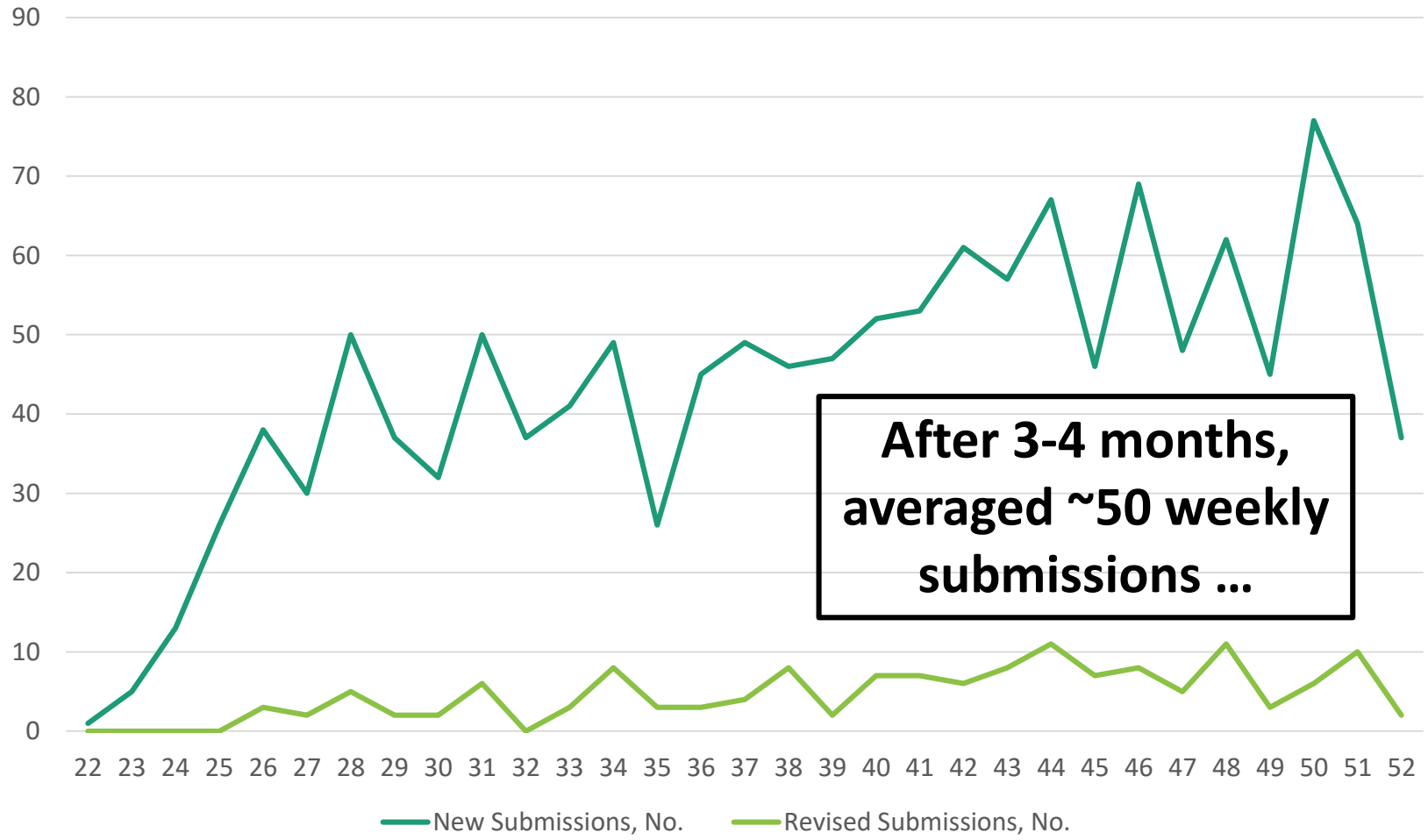
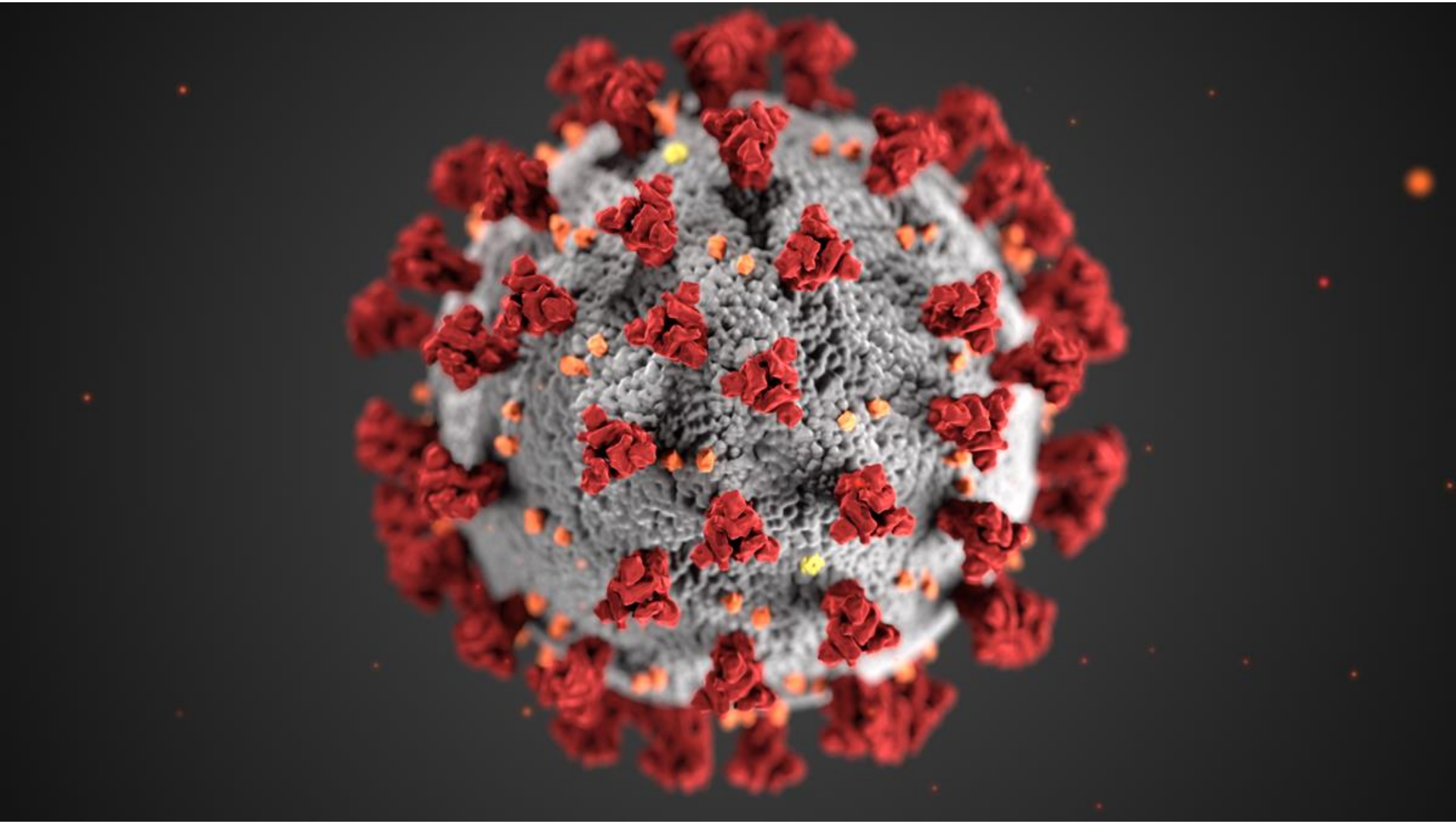
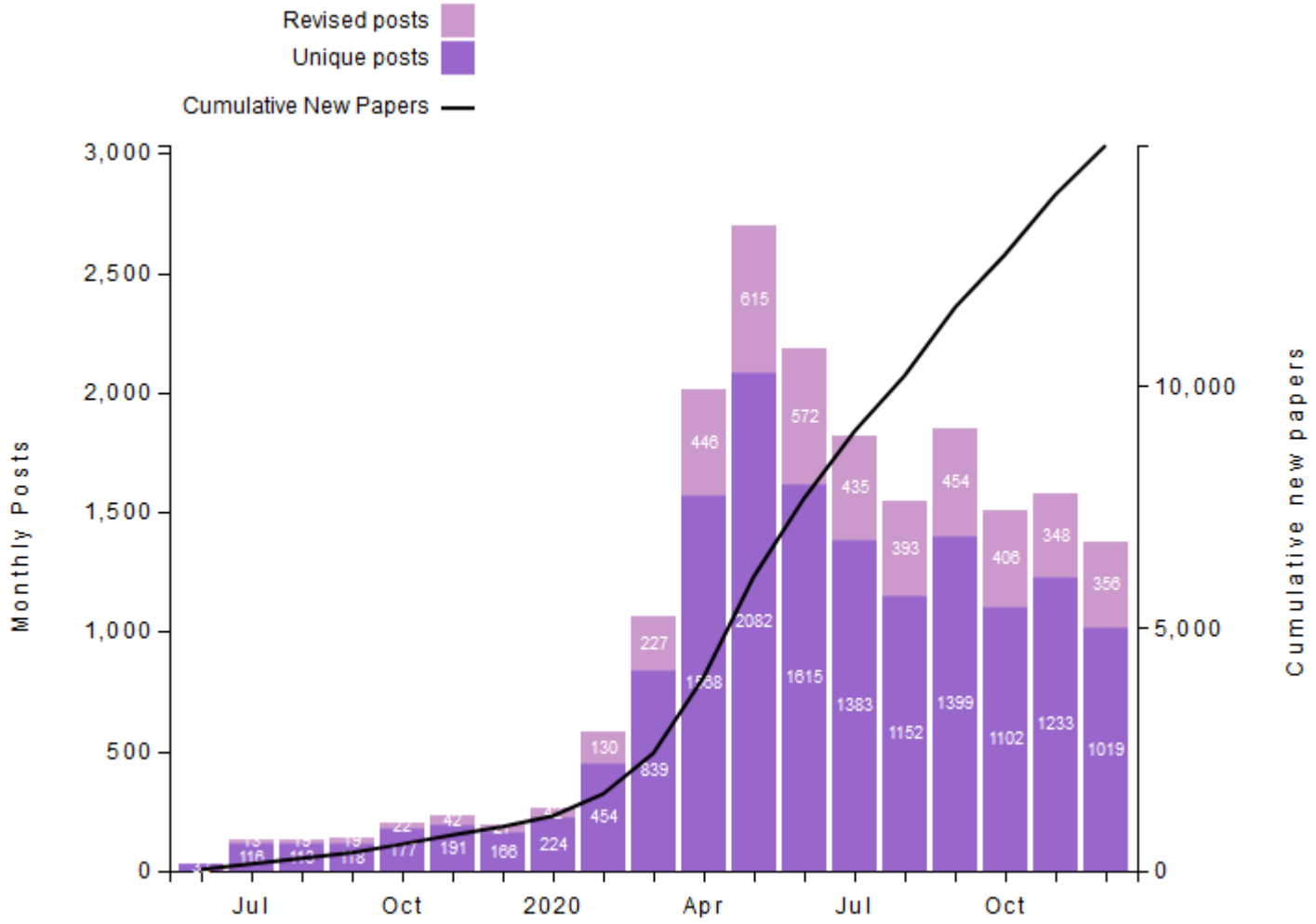




	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
Average **DAILY** Submissions, No.	7.2	16.2	27.1	52.3	77.1	65.1	58.6	49.5	61.8	48.6	52.7	44.4



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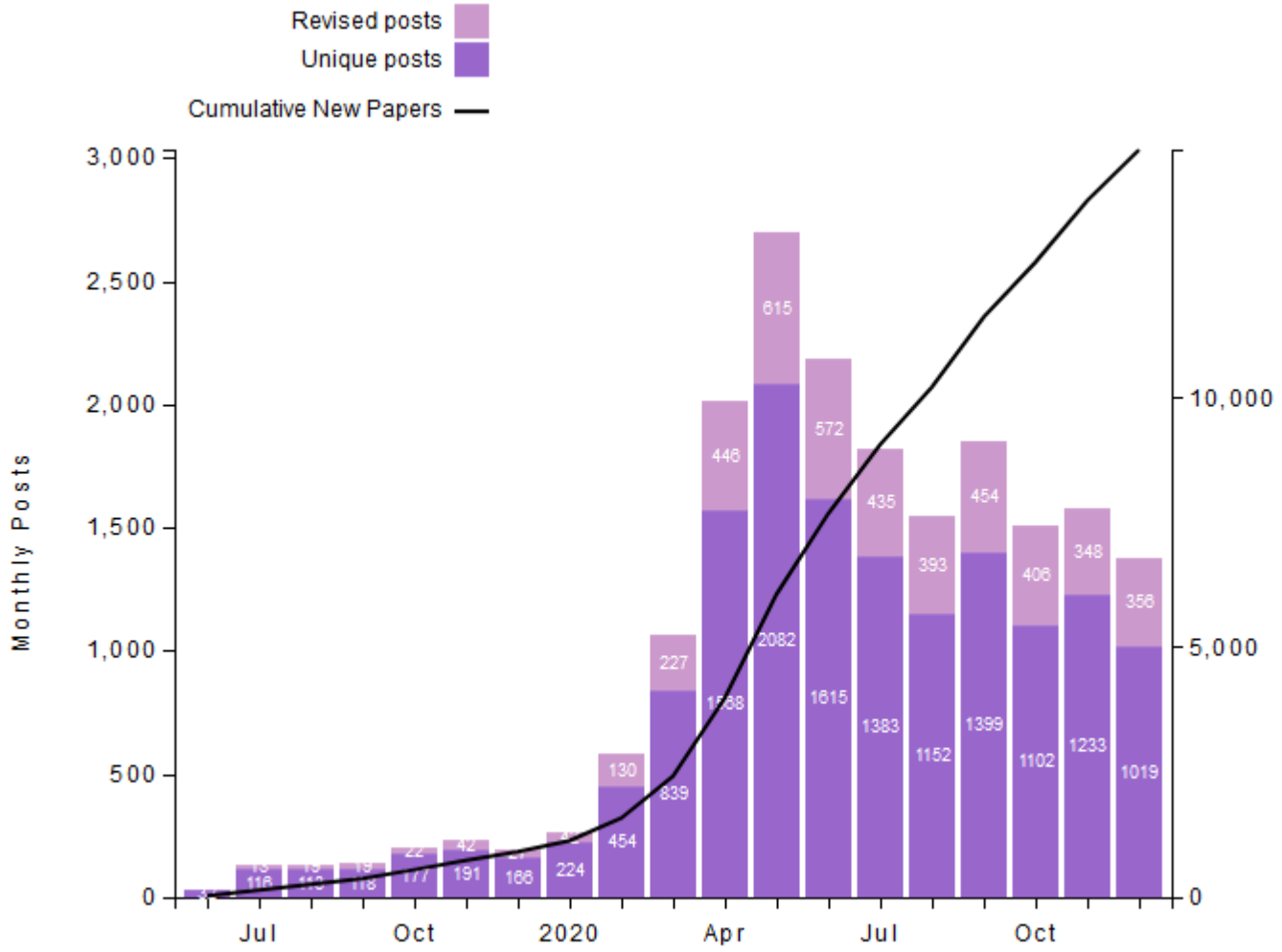

~15000 total papers

~4600 revised

~15% rejected

>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 and critical illness among 4,103 patients with COVID-19 disease in New York City

Posted April 11, 2020.

Christopher M. Petrilli, Simon A. Jones, Jie Yang, Harish Rajagopalan, Luke F. O'Donnell, Yelena Chernyak, Katie Tobin, Robert J. Cerfolio, Fritz Francois, Leora I. Horwitz

doi: https://doi.org/10.1101/2020.04.08.20057794

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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.

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Abstract Info/History Metrics Preview PDF

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

Subject Area

Intensive Care and Critical Care Medicine

Abstract

Background: Little is known about factors associated with hospitalization and critical illness in Covid-19 positive patients. Methods: We conducted a cross-sectional analysis of all patients with laboratory-confirmed Covid-19 treated at a single academic health system in New York City between March 1, 2020 and April 2, 2020, with follow up through April 7, 2020. Primary outcomes were hospitalization and critical illness (intensive care, mechanical ventilation, hospice and/or death). We conducted multivariable logistic regression to identify risk factors for adverse outcomes, and maximum information gain decision tree classifications to identify key splitters. Results: Among 4,103 Covid-19 patients, 1,999 (48.7%) were hospitalized, of whom

Subject Areas

All Articles

Addiction Medicine
Allergy and Immunology
Anesthesia
Cardiovascular Medicine

Source: Petrilli et. al., https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.

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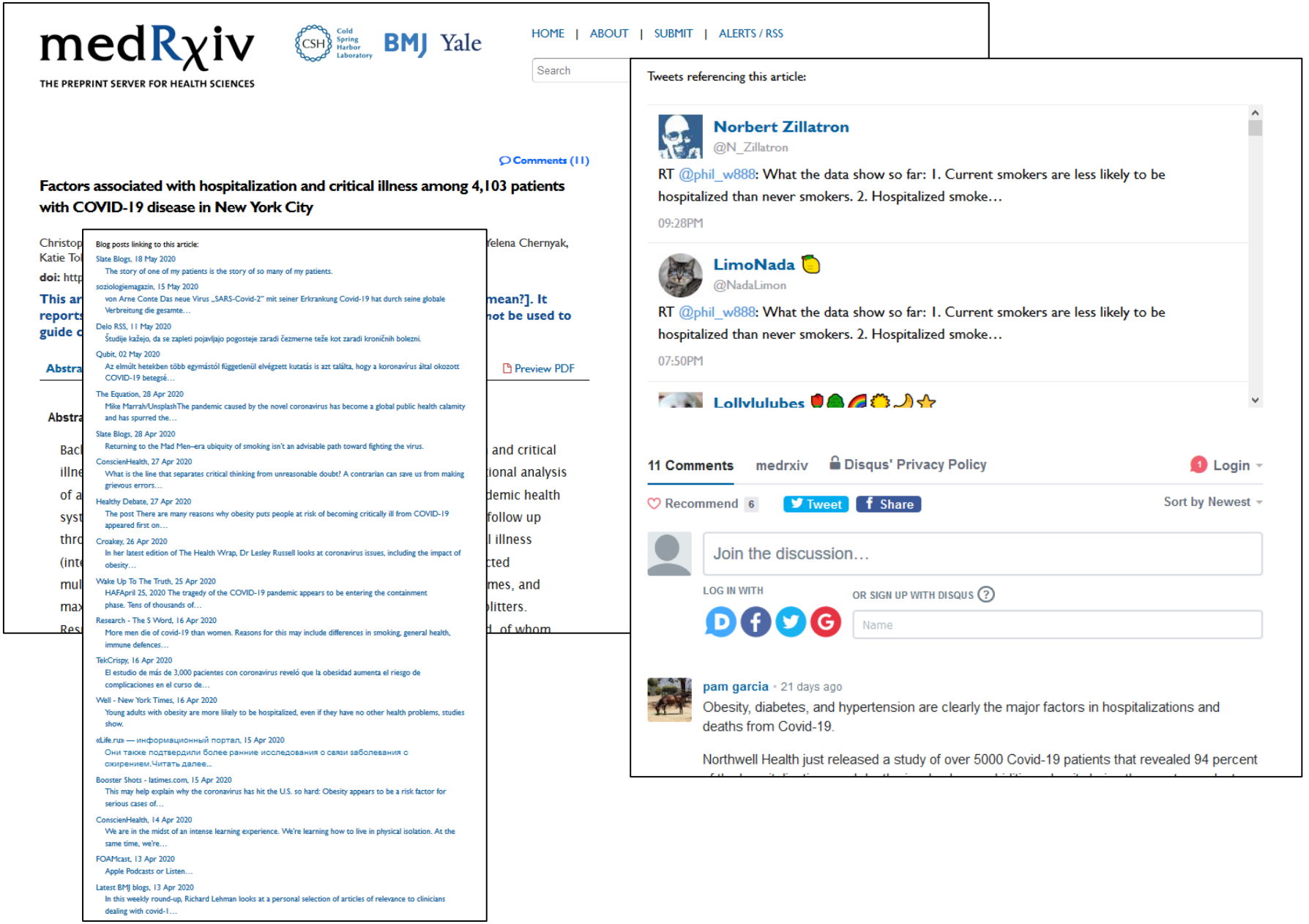

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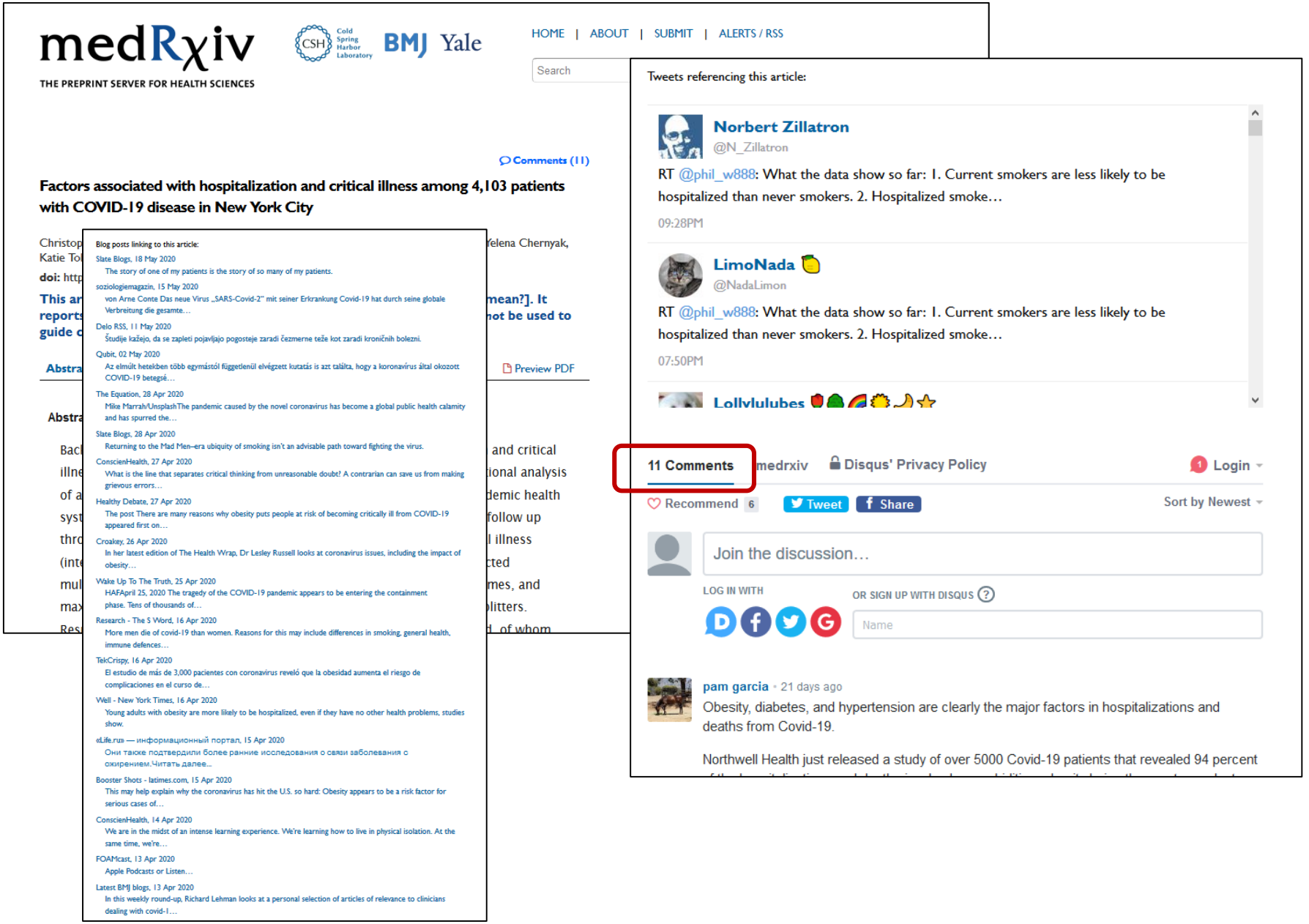

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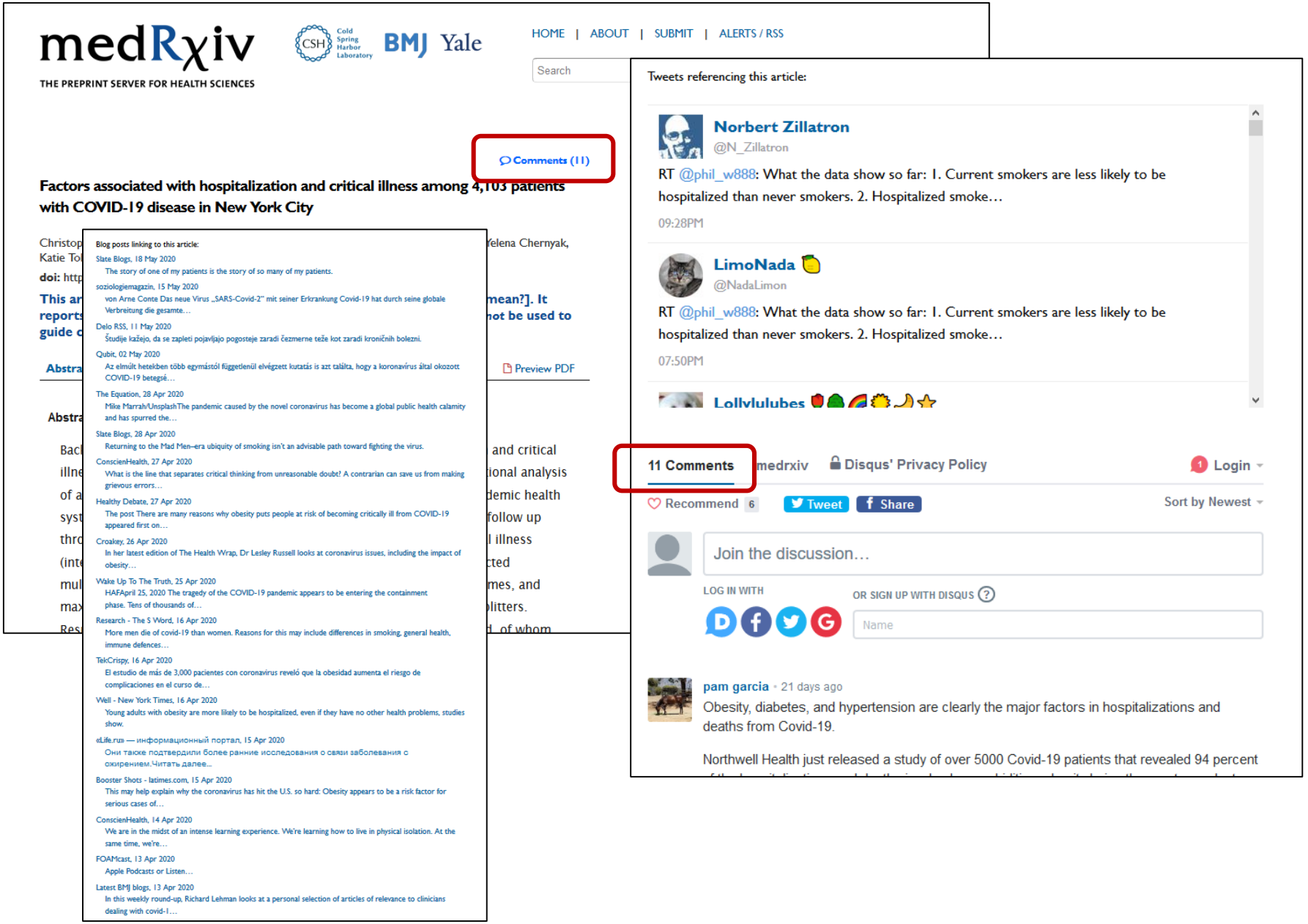

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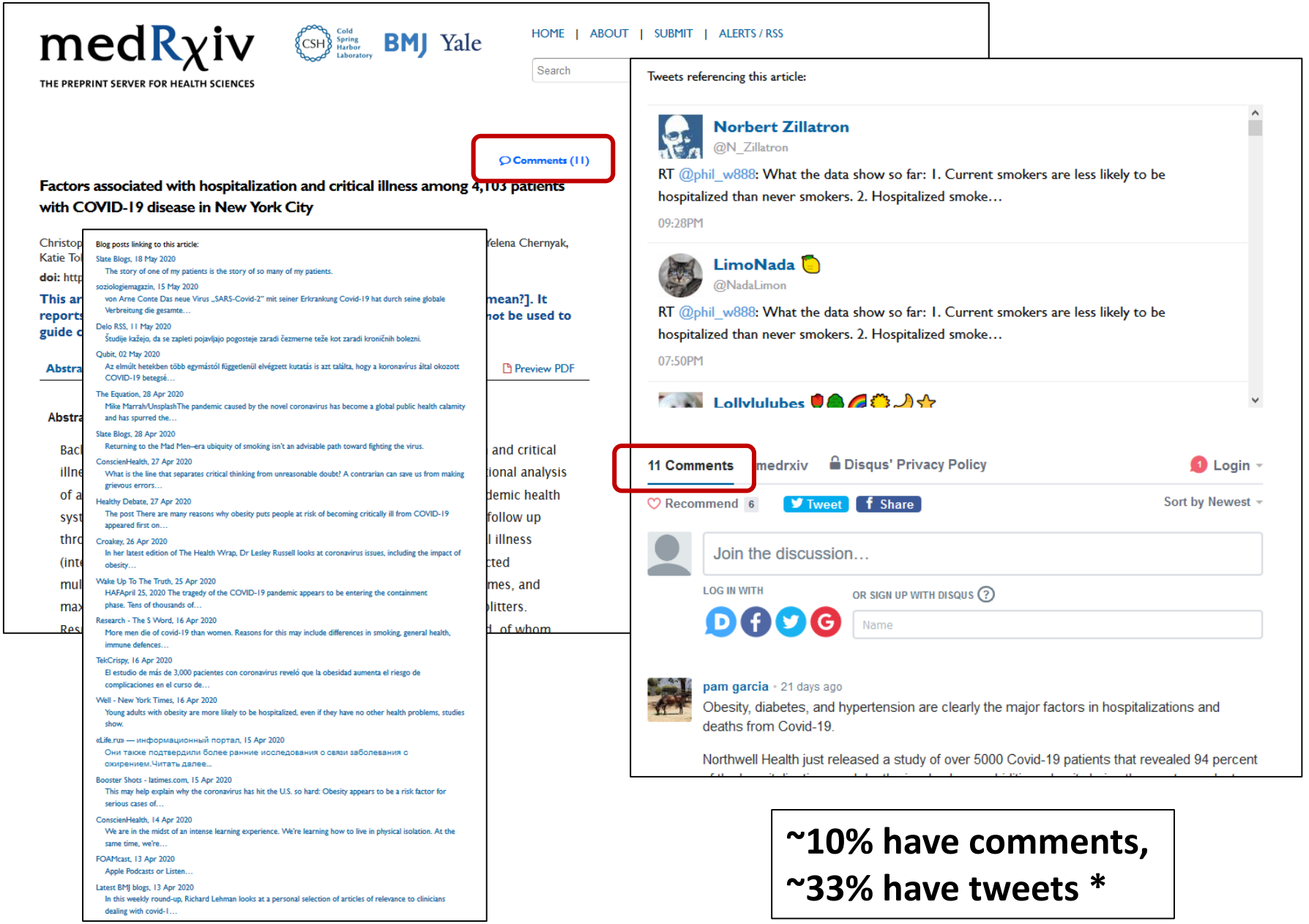

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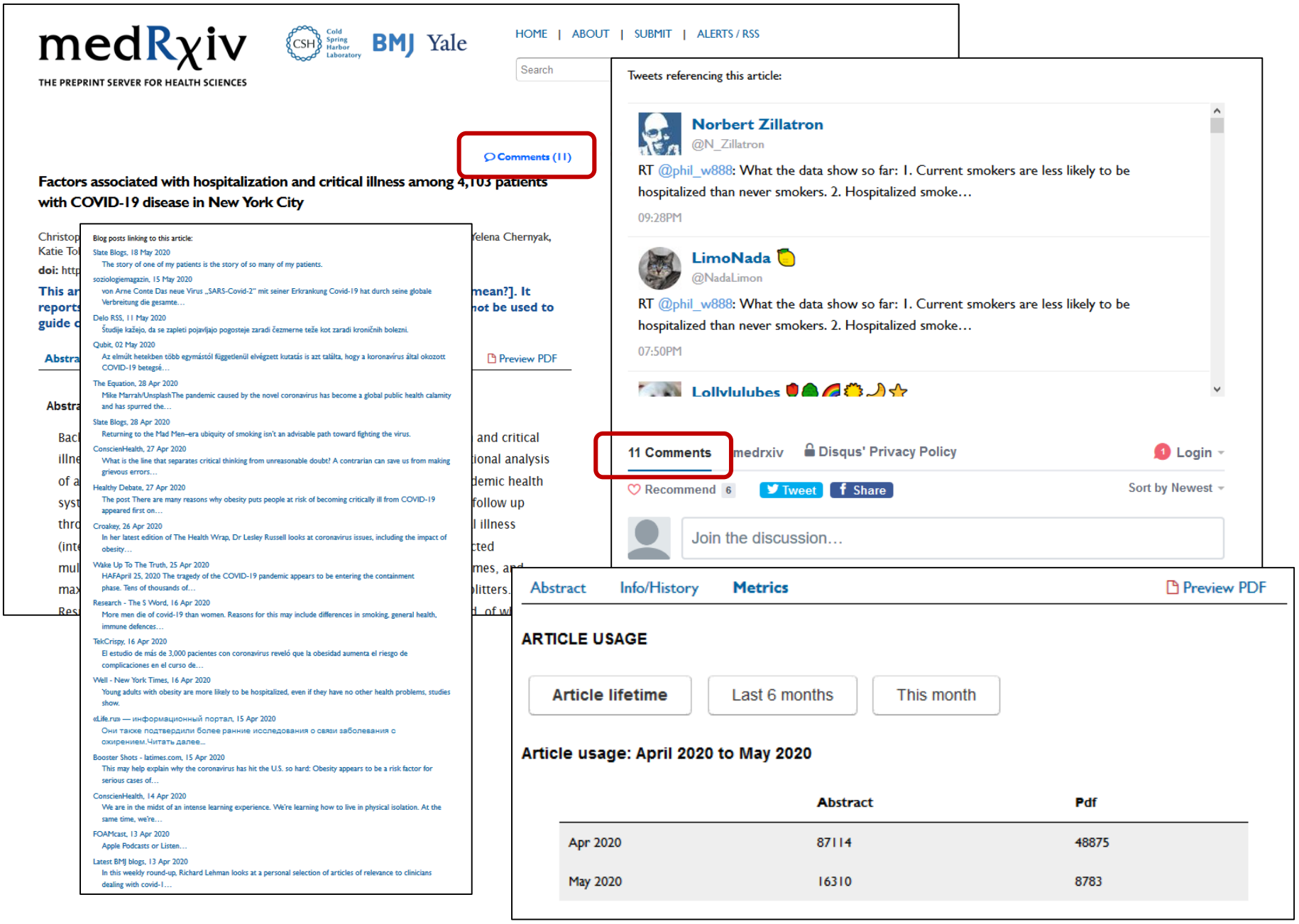
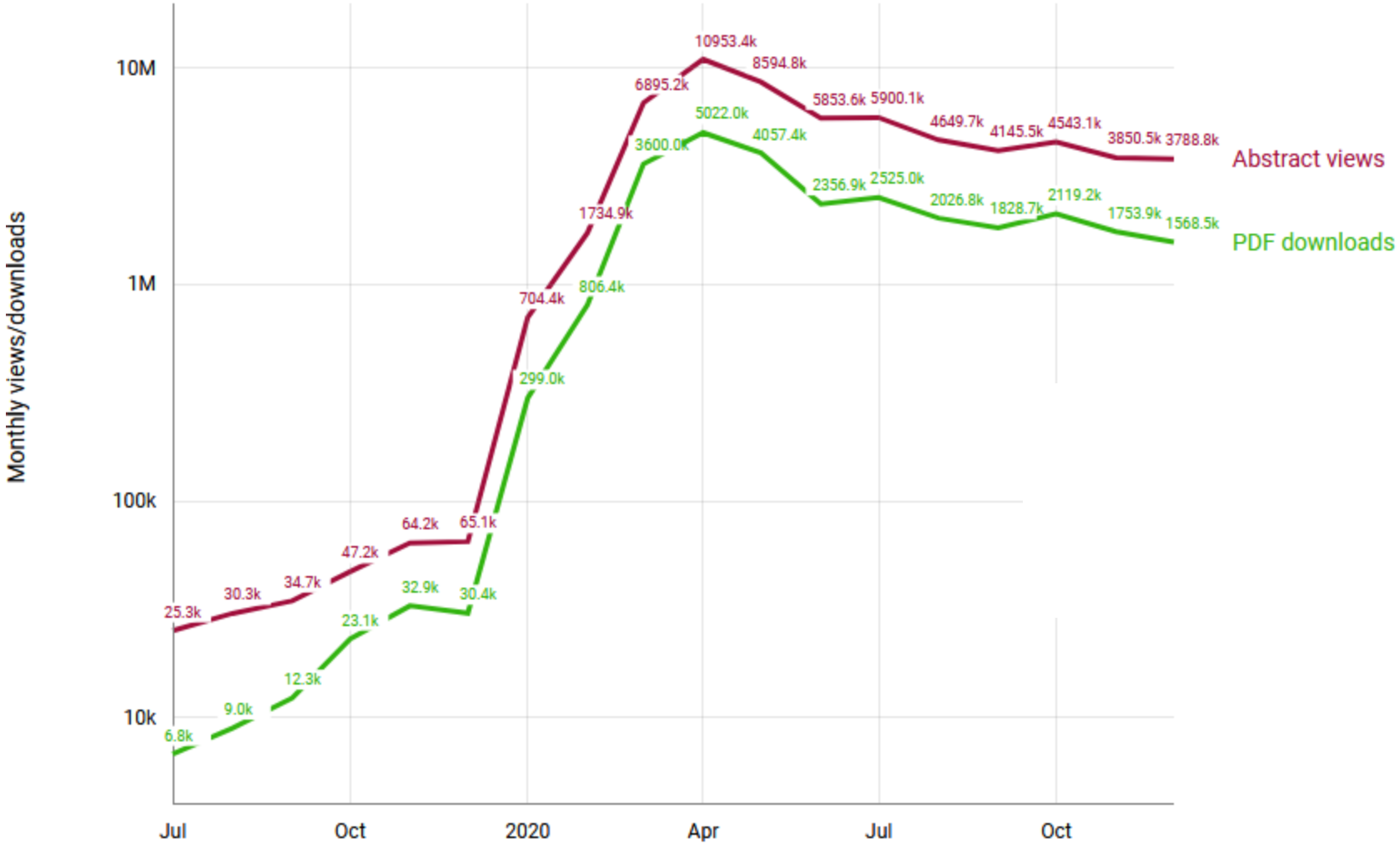


Source: Petrilli et. al., https://www.medrxiv.org/content/10.1101/2020.04.08.20057794v1.

Monthly Usage (excluding bots)



Thus far, ~25% of papers posted > 1 month have been published in ~1,600 journals …

Source: van Doremalen et. al., https://www.medrxiv.org/content/10.1101/2020.03.09.20033217v2.

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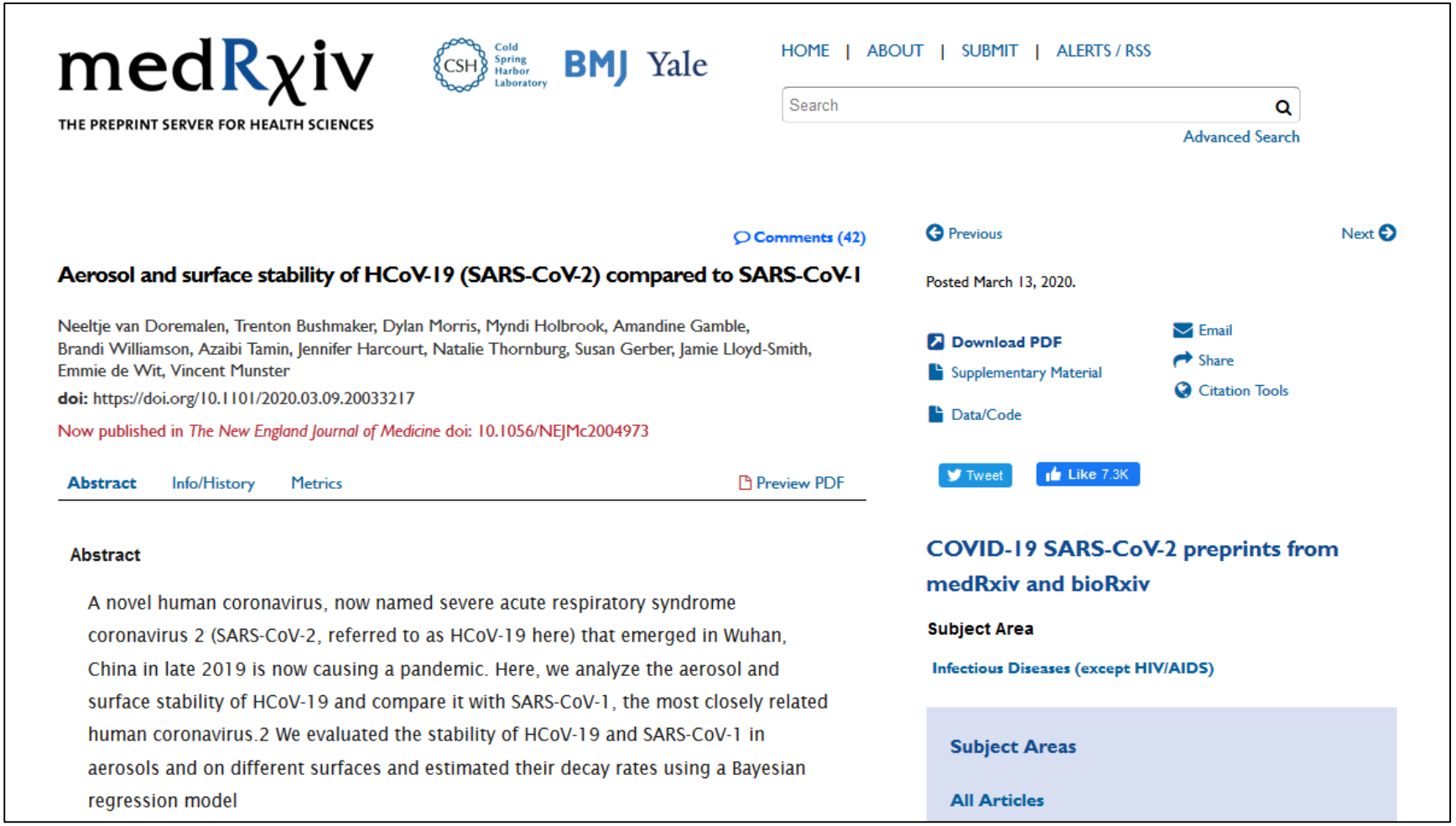

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Aerosol and surface stability of HCoV-19 (SARS-CoV-2) compared to SARS-CoV-1

Posted March 13, 2020.

Neeltje van Doremalen, Trenton Bushmaker, Dylan Morris, Myndi Holbrook, Amandine Gamble, Brandi Williamson, Azaibi Tamin, Jennifer Harcourt, Natalie Thornburg, Susan Gerber, Jamie Lloyd-Smith, 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

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Abstract

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, China in late 2019 is now causing a pandemic. Here, we analyze the aerosol and surface stability of HCoV-19 and compare it with SARS-CoV-1, the most closely related human coronavirus.2 We evaluated the stability of HCoV-19 and SARS-CoV-1 in aerosols and on different surfaces and estimated their decay rates using a Bayesian regression model

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

Subject Area

Infectious Diseases (except HIV/AIDS)

Subject Areas

All Articles

Source: van Doremalen et. al., https://www.medrxiv.org/content/10.1101/2020.03.09.20033217v2.

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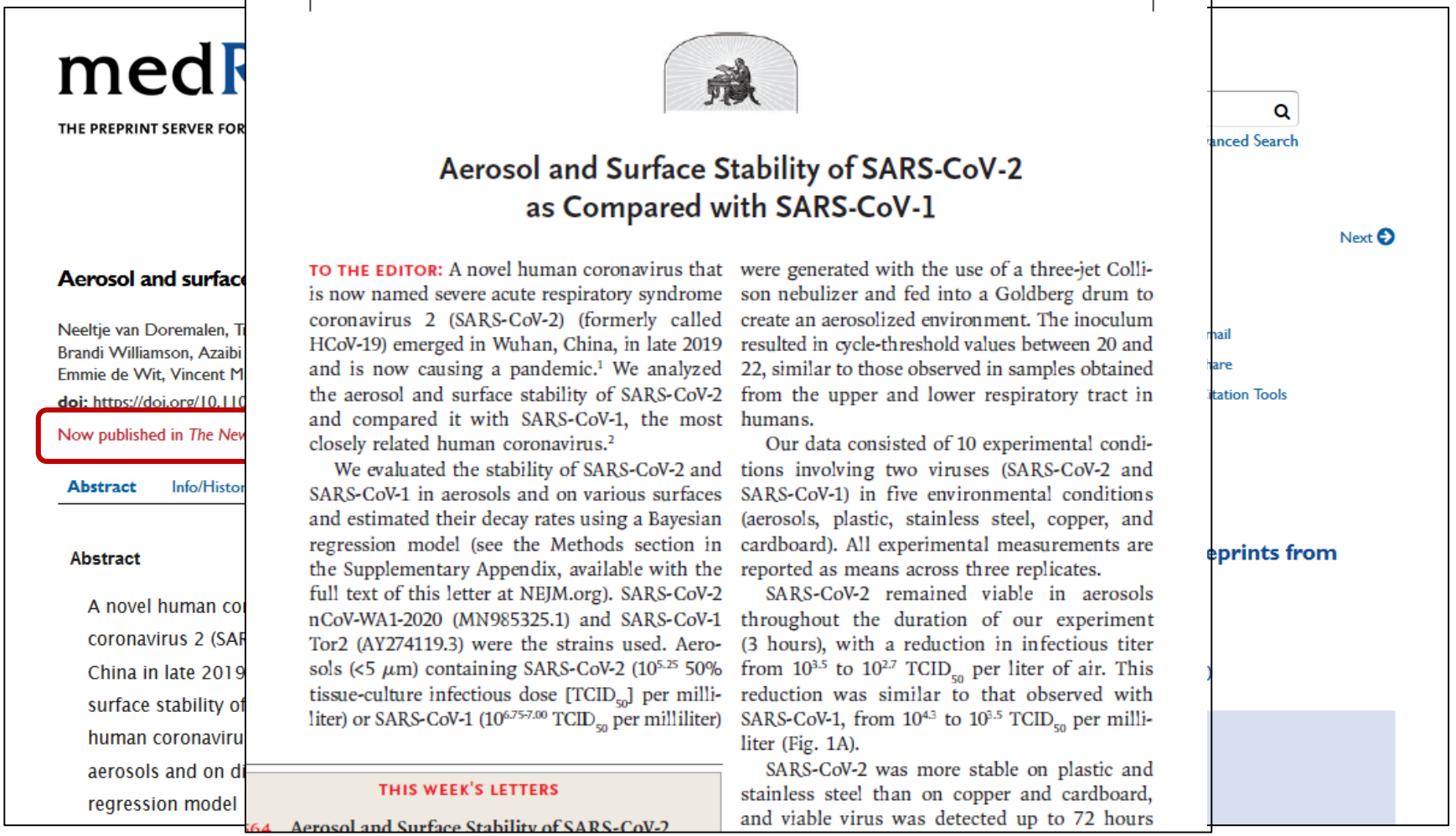

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Aerosol and surface

Neeltje van Doremalen, T…
Brandi Williamson, Azaibi…
Emmie de Wit, Vincent M…

doi: https://doi.org/10.11…

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Abstract

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The NEW ENGLAND JOURNAL of MEDICINE

CORRESPONDENCE

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

TO THE EDITOR: A novel human coronavirus that 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 and compared it with SARS-CoV-1, the most 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 ($10^{5.25}$ 50% tissue-culture infectious dose [$TCID_{50}$] per milliliter) or SARS-CoV-1 ($10^{6.75-7.00}$ $TCID_{50}$ per milliliter) 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 from the upper and lower respiratory tract in humans.

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 $10^{3.5}$ to $10^{2.7}$ $TCID_{50}$ per liter of air. This reduction was similar to that observed with SARS-CoV-1, from $10^{4.3}$ to $10^{3.5}$ $TCID_{50}$ 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

THIS WEEK'S LETTERS

…64 Aerosol and Surface Stability of SARS-CoV-2

Source: van Doremalen et. al., https://www.medrxiv.org/content/10.1101/2020.03.09.20033217v2.

Covid-19

Scientific research on the coronavirus is being released in a torrent

Will that change how science is published?

Mother Jones

POLITICS ENVIRONMENT CRIME AND JUSTICE FOOD MEDIA INVESTIGATIONS PH

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editorial

All that's fit to preprint

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

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

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.

JACKIE FLYNN MOGENSEN
Assistant Editor
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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

HEALTHNEWSREVIEW
YOUR HEALTH NEWS WATCHDOG

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

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

April 29, 2020

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 Adaptive COVID-19 Treatment Trial, or ACTT), sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), 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.

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

April 29, 2020

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 Adaptive COVID-19 Treatment Trial, or ACTT), sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), 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.

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 ($p=0.059$).

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WORLD VIEW · 11 MAY 2020

Pandemic researchers – recruit your own best critics

To guard against rushed and sloppy science, build pressure testing into your research.

Daniël Lakens

Source: https://medium.com/@jamesheathers/preprints-arent-the-problem-we-are-the-problem-75d29a317625

Preprints Aren't The Problem — WE Are The Problem

James Heathers Follow

May 20 · 9 min read

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3. **Deliberately engage experts in the appropriate areas to assess your information publicly**
4. **Admit that criticism of your work exists and then engage with it**
5. **Update your pre-print!**

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