

# The carnage of substandard research during the COVID-19 pandemic: a call for quality

Katrina A Bramstedt  <sup>1,2</sup>

<sup>1</sup>Luxembourg Agency for Research Integrity, Esch-sur-Alzette, Luxembourg

<sup>2</sup>Bond University Faculty of Health Sciences and Medicine, Gold Coast, Queensland, Australia

## Correspondence to

Professor Katrina A Bramstedt, Bond University Faculty of Health Sciences and Medicine, Gold Coast, Queensland, Australia; [tbioethics@yahoo.com](mailto:tbioethics@yahoo.com)

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## ABSTRACT

Worldwide there are currently over 1200 research studies being performed on the topic of COVID-19. Many of these involve children and adults over age 65 years. There are also numerous studies testing investigational vaccines on healthy volunteers. No research team is exempt from the pressures and speed at which COVID-19 research is occurring. And this can increase the risk of honest error as well as misconduct. To date, 33 papers have been identified as unsuitable for public use and either retracted, withdrawn, or noted with concern. Asia is the source of most of these manuscripts (n=19; 57.6%) with China the largest Asian subgroup (n=11; 57.9%). This paper explores these findings and offers guidance for responsible research practice during pandemics.

## INTRODUCTION

As of 7 May 2020, the international clinical trial registry site, ClinicalTrials.gov, reported 1221 registered studies focused on COVID-19 (table 1).<sup>1</sup> Of these, 214 (17.5%) include children as research participants, and 1155 (94.6%) include adults age 65 years and older. Healthy volunteers are the cohort for 243 (19.9%) studies, and of these, 13 (5.4%) are vaccine clinical trials. Most studies are being performed in Europe and North America where research ethics regulations are robust; however, no location is exempt from the pressures and speed at which COVID-19 research is occurring. This can increase the risk of honest error as well as misconduct.<sup>1</sup>

According to WHO, the first cases of COVID-19 occurred in China in December 2019.<sup>2</sup> Other sources indicate the first case could have been in November 2019.<sup>3</sup> As the virus rapidly spread from an epidemic to a pandemic, researchers worldwide began the search for treatments and vaccines. Journals have been flooded with manuscript submissions<sup>4</sup> and more journals are providing open access,<sup>5</sup> allowing the research to be readily viewed by clinicians who can potentially then use the research for clinical decision-making.

## PROBLEMATIC PANDEMIC RESEARCH PUBLICATIONS

As of 31 July 2020, 19 published articles and 14 preprints about COVID-19 have been retracted, withdrawn, or an expression of concern has been

issued (tables 2 and 3).<sup>ii</sup> The source of most of these incidents is Asia (n=19; 57.6%), with China the largest Asian subgroup (n=11; 57.9%). For three papers, the reason for the removal is unknown; however, for the others, a range of problems exist, including data falsification, methodological concerns, and concerns about interpretation of data and conclusions, as well as authorship and research participant privacy issues (table 4). To date, there have been no identified reports of plagiarism or data fabrication. Another paper, a preprint from the USA about COVID-19 antibody seroprevalence, has come under scrutiny for an undisclosed conflict of interest, but no official findings have been issued.<sup>6,7</sup>

## COMPLICATIONS OF PUBLISHING PROBLEMATIC RESEARCH

There has been a surge of almost 4000 papers related to COVID-19 placed on preprint servers recently.<sup>8</sup> These platforms provide a lower level of quality checks compared with a full peer review process by journals. Accordingly, preprint platforms do routinely advise their readers not to use their content for clinical decision-making, but the latter cannot be ruled out, especially in the situation of a pandemic with high rates of morbidity and mortality. Patient harm that is significant, permanent and irreversible could result from using faulty research results from preprints as well as published papers. Published papers are interpreted as vetted via peer review, with an inference of quality and accuracy and clinicians are likely to refer to them for guidance.

The act of retraction follows a thorough investigation and concern about a paper's integrity (eg, methods, data analysis, data interpretation, data reporting). While not as severe as a retraction, an expression of concern announces to potential readers that a paper should be read with caution due to potential integrity issues. Both retraction and expression of concern are markers of integrity issues that reflect on the authors and their institutional affiliation. Retracted research can have direct funding costs due to waste and payback requirements, as well as decreased future funding.<sup>9</sup> Sometimes, the integrity of the journal can also be implicated if the matter is associated with a less

<sup>ii</sup>Retraction Watch (<https://retractionwatch.com/retracted-coronavirus-covid-19-papers>) was used as the source of these articles as they catalogue articles from numerous journal indexing databases beyond MEDLINE, as well as preprint servers. The source also mentioned one COVID-19-related conference paper that was withdrawn before presentation with unclear explanation.

<sup>i</sup>Search terms COVID-19, SARS-CoV-2, severe acute respiratory syndrome coronavirus 2, 2019-nCoV, 2019 novel coronavirus, Wuhan coronavirus



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**Table 1** COVID-19 clinical trials summary (data from ClinicalTrials.gov, 7 May 2020), n=1221

Study characteristic	No of studies
<b>Study type</b>	
Patient registry	84
Observational	485
Interventional	736
<b>Phase</b>	
Early phase I	15
Phase I	66
Phase II	290
Phase III	200
Phase IV	47
<b>Funding</b>	
US Federal Government	3
NIH*	11
Industry	138
Other†	585
<b>Location (study site)‡</b>	
Europe	459
North America	294
East Asia	87
Middle East	55
Africa	36
South America	34
South Asia	16
Southeast Asia	11
North Asia	6
Pacifica	6
Central America	2

\*US National Institutes of Health.

†Individuals, universities, organisations.

‡Some studies have more than one study site within and across countries.

than robust peer review process or a deficient conflict of interest assessment.

Even if only one author’s behaviour is confirmed as the source of an article’s retraction or concern, the author’s collaborators

can potentially be harmed by a colleague’s misconduct. Research has shown that in such situations, the citations of prior collaborators can fall by 8–9%.<sup>10</sup> There can be additional harm to personal relationships amid and across teams as well, and unhappiness can negatively impact productivity.<sup>11</sup>

**PREVENTING SUBSTANDARD RESEARCH**

Research normally occurs at the speed of a marathon, but during a pandemic, the pace is more like a sprint.<sup>1</sup> The prior slower pace gave space for reflection on quality, as well as time for researchers to rest their minds and bodies. During the pandemic there is the potential for the race of research to occur with fewer reflective and rest periods. Less reflection can facilitate missed opportunities for quality checks such as robust reviews of study applications by research ethics committees (RECs) and quality checks by researchers and their supervisors. Less rest can facilitate fatigue and mistakes of human error or judgement (eg, taking short cuts rather than performing standard practice).<sup>12</sup> During a pandemic, research teams should build in time for reflection such as scheduled spot-checking of data.<sup>13</sup> Rejuvenation time can also be scheduled such as a team exercise break for a brisk walk around the campus (respecting social distancing) or even a fun musical tune blasted across the public announcement system signalling a 3 min brain break.

RECs cannot be expected to routinely have membership of immunologists, microbiologists and pulmonologists, for example, yet these are key topic experts for research protocols dealing with COVID-19. In an effort to provide high-quality reviews of these protocols, RECs should create a list of go-to experts who can be retained as consultants for these reviews. These experts can be readily found through a search of PubMed or international scientific professional societies. Some universities also provide experts collated by topic on their websites. It is not enough to have a fast-track review process that speeds the protocol submissions through the REC; a robust review process that reflects on both science and ethics is needed. Considering that many COVID-19 projects involve epidemiology and contact tracing, reviewers should also pay special attention to the privacy protection of human participants.

Research ethics and integrity training should be mandatory for all researchers so that they have a foundational understanding of

**Table 2** Problematic COVID-19 preprint articles

Source	Issue	Location of corresponding author’s institution	Finding
SSRN <sup>21</sup>	Dataset is linked to two other retracted papers <sup>22 23</sup>	USA	Retracted
SSRN <sup>24</sup>	Dataset is linked to two other retracted papers <sup>22 23</sup>	USA	Retracted
SSRN <sup>25 26</sup>	Numerous concerns including authorship, statistical analysis, findings	Indonesia	Retracted
bioRxiv <sup>27</sup>	Article lacked the full consent for publication by all authors	China	Withdrawn
bioRxiv <sup>28</sup>	Authors’ desire to perform additional research to validate their work	China	Withdrawn
medRxiv <sup>29</sup>	Authors’ desire to update their dataset to enlarge it	China	Withdrawn
medRxiv <sup>30</sup>	Authors’ desire to perform additional research to validate their work	China	Withdrawn
bioRxiv <sup>31</sup>	Consent was not obtained for use of the study dataset	Bangladesh	Withdrawn
medRxiv <sup>32</sup>	Controversy about hydroxychloroquine and a retrospective study design	France	Withdrawn
bioRxiv <sup>33</sup>	Concerns regarding technical approach and data interpretation	India	Withdrawn
medRxiv <sup>34</sup>	Study performed beyond scope of the research ethics committee approval	Italy	Withdrawn
medRxiv <sup>35</sup>	Study performed beyond scope of the research ethics committee approval	Italy	Withdrawn
medRxiv <sup>36</sup>	Controversy about hydroxychloroquine; results potentially different after peer review.	South Korea	Withdrawn
medRxiv <sup>37</sup>	Privacy concerns regarding research participants	USA	Withdrawn

**Table 3** Problematic COVID-19 published articles

Journal	Indexing	Issue	Location of corresponding author's institution	Finding
<i>International Journal of Antimicrobial Agents</i> <sup>38 39</sup>	MEDLINE	Concern regarding method, ethics review, and peer review	France	Expression of concern
<i>Lancet Global Health</i> <sup>40</sup>	MEDLINE	Data falsification	China	Retracted
<i>Zhonghua Er Ke Za Zhi Chinese Journal of Pediatrics</i> <sup>41</sup>	MEDLINE	Unknown	China	Retracted
<i>Cellular &amp; Molecular Immunology</i> <sup>42</sup>	MEDLINE	Invalid conclusions due to flawed test methodology and incorrect biological material for study	China and USA	Retracted
<i>Lancet</i> <sup>22</sup>	MEDLINE	Authors unable to arrange an independent audit of the data foundational to the study due to blocked data access	USA	Retracted
<i>New England Journal of Medicine</i> <sup>23</sup>	MEDLINE	Authors unable to arrange an independent audit of the data foundational to the study due to blocked data access	USA	Retracted
<i>Bulletin de la Dialyse à Domicile</i> <sup>43</sup>	DOAJ	Data erroneous	France	Retracted
<i>Lancet</i> <sup>44</sup>	MEDLINE	Article is a commentary on a paper that subsequently was retracted <sup>22</sup>	France	Retracted
<i>Journal of Molecular Pharmaceuticals and Regulatory Affairs</i> <sup>45</sup>	DRJI*	'The information pertaining in this paper is misleading the readers and creating massive conflicts amid the scientific community' <sup>45</sup>	India	Retracted
<i>Journal of Biological Regulators &amp; Homeostatic Agents</i> <sup>46</sup>	MEDLINE	Corrupted peer review process	Italy	Retracted
<i>Annals of Internal Medicine</i> <sup>47</sup>	MEDLINE	Findings below the limit of detection thus unreliable	South Korea	Retracted
<i>Chinese Journal of Epidemiology</i> <sup>48</sup>	China Academic Literature Database	Concern regarding results and conclusions	China	Withdrawn
<i>Practical Preventive Medicine</i> <sup>49</sup>	China Academic Literature Database	Unknown	China	Withdrawn
<i>Journal of the American Pharmacists Association</i> <sup>50</sup>	MEDLINE	Publisher's accidental duplication of another publication in the same journal	USA	Withdrawn
<i>Journal of the American Pharmacists Association</i> <sup>51</sup>	MEDLINE	Publisher's accidental duplication of another publication in the same journal	USA	Withdrawn
<i>Travel Medicine and Infectious Disease</i> <sup>52 53</sup>	MEDLINE	Another research team submitted the same case report to another journal	Iran	Withdrawn
<i>Engineering</i> <sup>54</sup>	DOAJ; Scopus	Language editing required to improve paper's clarity	China	Temporarily retracted but returned online
<i>Journal of the American Academy of Dermatology</i> <sup>55</sup>	MEDLINE	Unknown	China	Temporarily retracted but returned online
<i>American Journal of Obstetrics and Gynaecology</i> <sup>56</sup>	MEDLINE	Journal production error in title of manuscript (delete word 'effective') <sup>57</sup>	Turkey	Temporary removal from journal but returned after correction

\*DRJI (Directory of Research Journal Indexing) is noted to be a 'misleading metric' index per <https://predatoryjournals.com/metrics/#D>.

DOAJ, Directory of Open Access Journals.

both good research practice, ethical sensitivities, types of research misconduct and substandard practice, as well as the consequences of the latter. These courses are essential to fostering a research culture that embraces both ethics and quality, and they can potentially deter research misconduct and help researchers feel prepared to manage dilemmas pertaining to research ethics and research integrity.<sup>14 15</sup> Many of these courses are offered online.

Researchers should have ready access to services which can provide timely, expert advice to research dilemmas involving topics such as authorship disputes, image manipulation, citations and referencing, informed consent, participant recruitment, and so on. These services could include an online FAQ, an ethics consult service or video tutorials. Another option is on-site research coaches who are an adjunct to the research supervisor, available for quick advice.<sup>16</sup> 'Publish or perish' is a harmful mindset and the pandemic's 'need for speed' needs calibration which can be

aided by coaching, supervision and mentoring that recognises the humanness of the research process. Researchers need advice, support, rest and tools.<sup>17</sup>

Robust peer review of manuscripts is vital, especially when open access publishing makes them easy to find and view in full text. The pandemic has created a surge of manuscripts, yet the fleet of journal peer reviewers is a voluntary service to the research community in the setting of concurrent commitments which often include employment and family. The research topics are often complex and highly specialised and thus the peer review assignment must be thoughtful, and include avoiding conflict of interest (eg, research competitor, sponsor funding). Journals must also mitigate time when manuscripts age with long peer review times when reviewers cannot be secured. Rapid review should not compromise the quality of the review, but rather the efficiency of the process should be improved by identifying bottlenecks, removing steps that do not add value, and

**Table 4** Research ethics and integrity concerns

Issue	No of papers*
Methodology (eg, wrong method; wrong specimen; need more experiments; study design)	8
Consent (ie, study participants; data sharing partners)	6
Deception (eg, data interpretation)	6
Other (eg, sensitive topic; peer review feedback)	4
Research Ethics Committee	3
Unknown	3
Authorship	2
Peer review	2
Falsification	1
Duplicate manuscript submission	1
Privacy	1
Statistics	1

\*Preprints and published papers; some papers evidenced multiple concerns.

increasing staff and tools for the administrative/document handling tasks.<sup>18 19</sup>

When research integrity problems are found, they should be dealt with in a professional manner that includes whistle-blower protection. Confirmed infractions of policies and standards<sup>20</sup> should have meaningful consequences that reflect on root cause in order to deter repeat offences. Also, by publishing the results of investigations, these can be used for training purposes, and routine trending for areas of organisational concern can be identified (eg, supervision issues). It is also important to announce when investigations do not confirm misconduct or research quality issues so that accused personnel can be vindicated. There may be regional regulations that restrict the personal details of publishing integrity investigations (eg, European Union General Data Protection Regulation); however, there is value to the publishing of anonymised case summaries for both institutional transparency and training purposes. National research integrity offices can be sources of investigation summaries, training and consultation for researchers of all levels, and their continued support and funding is vital to fostering ethical and robust research.

**Twitter** Katrina A Bramstedt @AskTheEthicist

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#### ORCID iD

Katrina A Bramstedt <http://orcid.org/0000-0001-5446-0123>

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### COVID-19 pandemic has created flood of potentially substandard research

- *Rush to publish is testing research integrity process*
- *33 papers retracted, withdrawn, or had serious doubts raised as of end of July*
- *Thousands of COVID papers on pre-print servers where fewer quality checks made*

The COVID-19 pandemic has created a flood of potentially substandard research amid the rush to publish, with a string of papers retracted or under a cloud and a surge in submissions to pre-print servers where fewer quality checks are made, a leading ethicist has warned in the *Journal of Medical Ethics*.

This has implications for patients, clinicians, and potentially government policy, says Adjunct Professor Katrina Bramstedt, Bond University, Queensland, Australia and Secretary General at Luxembourg Agency for Research Integrity.

The rapid spread of COVID-19 and its transition into a global pandemic propelled researchers to begin the search for treatments and vaccines in earnest.

Scientific and medical Journals have since been flooded with submissions, while thousands of papers, which have not undergone thorough quality checks, have been posted on preprint servers.

As of 7 May 2020, 1221 studies on COVID-19 were registered on the international clinical trial registry site, ClinicalTrials.gov.

And as of 31 July 2020, 19 published articles and 14 preprints about COVID-19 have been retracted, withdrawn, or had serious doubts raised about the integrity of their data, formally known as an expression of concern.

Most of these papers came from Asia (n=19; 57.5%), with over half coming from China (n=11; 58%).

But as the author points out: “No research team is exempt from the pressures and speed at which COVID-19 research is occurring. And this can increase the risk of honest error as well as deliberate misconduct.”

The reason for the removal of the 33 papers isn't known in 3 cases, but data falsification, methodological issues, and concerns about interpretation of data and conclusions, as well as authorship and participant privacy issues were among the reasons in the other papers.

Two preprints (SSRN preprint server) and two research papers in *The Lancet* and *New England Journal of Medicine* were retracted because of unverifiable data common to all four.

And a preprint from the USA about COVID-19 antibody seroprevalence has come under scrutiny for an undisclosed conflict of interest.

There are obvious implications for the journal and the researchers involved, even if they are innocent of any research misconduct, points out the author. The evidence suggests that in such cases, the citations of prior collaborators can take a hit and fall by 8–9%.

But there are also implications for patients. “Patient harm that is significant, permanent and irreversible could result from using faulty research results from preprints as well as published papers,” she says.

The rush to publish means there is less time for quality checks by researchers and their supervisors and for thorough reviews of study applications by research ethics committees, says Professor Bramstedt.

Added to which, these committees can’t be expected to routinely include the key experts needed for COVID-19 research, such as immunologists, microbiologists and lung disease specialists.

Journals, too, rely on a fleet of peer reviewers, all of whom work on a voluntary basis and have competing demands on their time.

To counter these issues, the author suggests that the efficiency of the submission process is tightened up and that research ethics and integrity training be mandated for all researchers.

They should also have timely access to ethical advice on research dilemmas involving topics such as authorship disputes, image manipulation, citations and referencing, informed consent, ethical participant recruitment, etc.

Any infractions of policies and standards should have meaningful consequences to ward off repeat offences, she suggests, adding that it’s important to publicise the results of any investigations, whatever the outcome.

In a personal comment, not found in the text, Professor Bramstedt emphasizes: “Research has the potential to enter the public domain and be used by many stakeholders, including governments and policy makers, so the data must be robust.”

***Journal of Medical Ethics*** editor, Professor John McMillan, adds: “Researchers face powerful headwinds against their efforts to further knowledge about COVID-19. The urgency for evidence, the rewards from finding a successful therapy or vaccine, and the prevalence of disinformation mean scientific integrity is critically important.

“Professor Bramstedt’s report is an early warning for journals and preprint servers to be proactive and maintain rigour when assessing research.”