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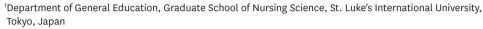


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Fundamental Shifts in Research, Ethics and Peer Review in the Era of the COVID-19 Pandemic

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ABSTRACT

The era of the coronavirus disease 2019 (COVID-19) pandemic has led to fundamental shifts in research, ethics, and peer review including reframing of the research design, adapting methodologies to the study type, transitioning of research mechanics, changing research methodologies, overcoming data collection and standardization constraints, upholding research standards and ethics, maintaining informativeness and social value, and providing guarded peer review flexibility. Indeed, the COVID-19 crisis, despite disrupting research worldwide to an unprecedented degree, has also become a catalyst to develop strategies of adaptation to this disruption. As the COVID-19 pandemic continuous to evolve, new, cost-effective, and highly flexible research models need to be developed. Planning is crucial for ensuring short-term and long-term contingency funds to support research logistics and personnel. A mental shift must accompany changes in methodologies to mentor and support researchers who are vital to the continuity of high-caliber research in the long term. A global research perspective through interinstitutional and interprofessional collaboration will sustain adherence to the highest standards of data collection and research reporting.

Keywords: COVID-19; Data Collection; Ethics; Peer Review; Research Design; Research Methodology

INTRODUCTION

Many academic and research institutions across the globe were caught off guard by the outset of the coronavirus disease 2019 (COVID-19) global pandemic caused by severe acute respiratory syndrome coronavirus 2.1,2 Scientists were unprepared and had few options but to go virtual.3 Most basic science research and clinical studies were curtailed by the pandemic.4 Many academic educators and researchers without prior training and mental preparation had to shift to innovative ways of maintaining their scholarly work, academic careers, and research networks.3,5 Specialized fields such as rheumatology have moved towards online education by switching to digital platforms and online scholarly activities to enrich education.6

Vital research activities, including participant recruitment, study visits, and outcome assessments, have taken an unpredictable detour towards remote platforms.⁷ Most clinical



trials have been paused, enrollment to continuing trials closed, and ongoing clinical trials modified to home therapy and virtual monitoring. Undeniably, COVID-19 has caused distinct shifts in research in terms of research design, study type, mechanics, methodology, data collection and standardization, standards and ethics, informativeness and social value, and scholarly peer review among others. This article aims to provide an overview of the fundamental shifts in research, ethics, and peer review in the era of the COVID-19 pandemic.

REFRAMING THE RESEARCH DESIGN

Researchers have found themselves unable to conduct their research freely owing to the unforeseen inaccessibility of research fields and the limitations imposed on forms of knowledge production. Countless studies have come to a halt. In particular, participatory research in communities has been curtailed by the partial to total lockdowns imposed in various countries. To overcome these constraints and challenges, Hussain correctly postulated the need for researchers to reframe their research questions and objectives; rethink and rearticulate forms of knowledge production; reassess modes of conducting research; evaluate partnerships; and revisit how the world is framed through research inquiries.

Non-Anglophone researchers must also become skilled in the use of scientific English to clearly articulate their research questions, hypotheses, and objectives. ¹⁰ To be able to effectively contribute to the growth of science during the COVID-19 pandemic, they must become cognizant of the main features of English research writing. This involves the use of appropriate collocations, simple and readable sentences, logically developed ideas, convincing argumentation, reader-friendly text, hedges, and writing techniques (e.g., "jigsaw"), as well as the avoidance of contracted forms, informal vocabulary, inadvertently placed adverbs, unintentional plagiarism, redundancy, and nominalization. ¹¹ Thus, during the COVID-19 pandemic or future pandemics, studies must be carefully written and designed in view of the available channels for establishing field and network connections, and for collecting adequate and reliable data.

ADAPTING METHODOLOGIES TO STUDY TYPE

There are new realities in research due to the pandemic, specifically limitations on the conduct of qualitative and quantitative studies. These new constraints have initiated adaptable methodologies for conducting these types of studies. For qualitative studies, innovative methods have been adopted, such as online interviews and focus groups, mobile methods for capturing social life and interactions, questionnaire diaries for obtaining reflections, photo/video/voice data collection using smartphones, and video work documentation.¹² For semiquantitative or quantitative studies, online and phone surveys utilizing free or paid online survey tools have been used. Digitization of traditional research methods and 'Big data' methods through text mining, social media analysis, content analysis, or spatial analysis have also been considered.¹² Therefore, adaptable but ethical methodologies should be actively devised to avert paralysis of qualitative and quantitative studies.



TRANSITIONING RESEARCH MECHANICS

Increasingly, researchers have transitioned to working online owing to the restraints posed by the pandemic. The normal mechanics of conducting research has been upended, prompting researchers to ramp up their technological literacy and skills. They need to discover new online resources and enhance their digital proficiency and competence in computers and its peripherals (e.g., laptops, webcams, audiovisual devices). They need to master teleconferencing and educational applications for online learning or research (e.g., Skype, Zoom, Google Meet, Microsoft Teams, Cisco WebEx, Moodle, Facebook, Telegram, Yammer, Google classroom, WhatsApp, WebEx). The mechanics of working online also requires creative planning, involving revisions in methodology, modifications of the institutional review board evaluation, and updates of consent approvals to sustain research continuity. Effective communication must also be maintained positively and productively with advisees, research teams, supervisors, and research networks through regular remote meetings and alternative networking mechanisms. Going virtual with research work therefore entails enhancing digital proficiency, formulating creative plans, and maintaining effective communication.

CHANGING RESEARCH METHODOLOGIES

With no quick end in sight to the COVID-19 pandemic, researchers must mitigate growing ethical concerns arising from the need to conduct research remotely. The realities of the pandemic has made it imperative to change research design and methodologies such as reducing study time and budget, promoting participation, strengthening generalizability, and accelerating publication. Other shifts include developing evidence gap maps, investing in multidisciplinary evaluations, and relying on local consultant expertise. 15 One of the significant innovations is the use of social media which affords opportunities for continuing medical education, professional development, and scholarly collaboration through online social networking. However, attention is also called to drawbacks related to misinformation, unethical promotion, and unprofessional behavior, emphasizing the need to filter credible and expert-proven information by skilled users. 16 Other innovations include network-based online referral strategies, web forms for screening and enrollment, videochat platforms for telehealth, self-reported outcomes, and remote focus group platforms. Shifts in data collection may include virtual interviews, review of repository data, and use of social media data. 15 Thus, methodological shifts are crucial for lessening the impact of the pandemic on operational and participatory research. However, efforts must be made to allay concerns about research quality brought about by these changes. By maintaining the highest standards and rigor of the study, these concerns can be lessened despite the changes in methodologies.

OVERCOMING DATA COLLECTION AND STANDARDIZATION CONSTRAINTS

The continuity of operational or participatory research has become uncertain with physical distancing and indirect social interactions owing to quarantines. Limited direct interactions have led to the use of online and remote tools for data collection. Particularly, empirical data collection methods including interviews, focus groups, and direct observations have shifted to online interactions and remote research. In evitably, data collection and analysis have been impacted by shifting priorities and constraints in capacity and resources. In addition



to concerns about maintaining research productivity,¹⁷ researchers also need to be vigilant about their physical and mental health,^{18,19} adding another layer of stress in the coexistence with COVID-19. Limitations in collecting information, specifically primary data, has raised the need to use methodology or study designs that guide the focus and objectives of the study. Realistically, more time may be required in collecting qualitative primary data through local networks.²⁰

Other collection approaches have pivoted to data sampling from traditional or social media or conducting observational studies. A recent cross-sectional study highlights the role of social media as a double-edged sword, serving as the most important sources of information and misinformation on COVID-19, which may affect research in the time of the pandemic. The ubiquity and popularity of social media platforms reportedly suggested non-passive subscribers actively engaged in creating, modifying, and disseminating misinformation that magnify the infodemic. 22

What has been missing is the appreciation of the role of standardized data collection and sharing that follow internationally recognized terminology and health concepts to realize effective responses through global research effort.²³ Thus, despite the practical and ethical constraints in the capacity to collect information, various remote tools, research methodologies, study designs, and traditional data sampling approaches have been augmenting the continuity of operational or participatory research. Standardized data collection and sharing must be aimed to facilitate global effort in collecting, sharing, aggregating, and interpreting data for an effective response.

UPHOLDING RESEARCH STANDARDS AND ETHICS

Upholding research standards has become a major challenge under the COVID-19 pandemic. Research standards may be compromised by using smaller sample sizes, employing unvalidated surrogate end points, disregarding randomization, using partial evidence, and altering prespecified research organization and design. A Recently, the top scientific journals *The Lancet* and *The New England Journal of Medicine (NEJM)* had to retract two high-profile papers as the validity of the raw data could not be confirmed independently. These papers relied on hospital records of COVID-19 patients. Since massive and rapid data generation can undermine the moral mission of research, London and Kimmelman emphasized the need for initiatives that combine efforts, divide labor, and triage out low-value and duplicative research to meet core scientific and ethical requirements. Thus, during pandemics, operational and participatory research may be adjusted, but research standards and ethics must not be compromised.

MAINTAINING INFORMATIVENESS AND SOCIAL VALUE

The COVID-19 pandemic has also caused limitations in conducting a thoroughly verified research owing to the need to produce quick results under time constraints. This scenario potentially compromises the informativeness and social value of research. Indeed, as Campbell emphasized, hasty research produces wasteful and inadequately confirmed results. 26 This pandemic-induced rush for data has resulted in numerous published articles with insufficient scientifically robust data, or with trials that do not meet published clinical



standards, or without any peer review.²⁴ London and Kimmelman²⁴ called serious attention to this issue and emphasized five conditions of informativeness and social value that research should embody: 1) importance; 2) rigorous design; 3) analytical integrity; 4) complete, prompt and consistent reporting of trials; and 5) feasibility. They emphasized the need to maintain study rigor even during pandemics.

Another angle of growing interest related to informativeness and the social value of research is the credibility of information made available online. The numbers of online academic publications (i.e., case reports and letters) and preprint publications (i.e., randomized controlled trials and systematic reviews) have increased significantly, with preprints being more slightly prevalent as a source of empirical but not peer-reviewed findings.²⁷ Perhaps prompted by the need to disseminate data rapidly, preprints involve less robust interpretation and critical evaluation of a scientific report. Their conclusions are often drawn from data without assessment of the full context of the experiment. Many preprints have also disregarded research reporting standards.^{24,25} An example of a recently retracted preprint reported that ivermectin dramatically reduces mortality in COVID-19 patients.²⁵

Female scientists may have also been sidetracked by the pandemic more so than their male colleagues. In a recent evaluation of the preprint archiving services medRxiv and bioRxiv, there appears to be a growing gender gap of corresponding authors in health sciences, implying the need to address pandemic-related gender disparities. ²⁸ The rush to publish owing to a perceived need for data during the COVID-19 crisis may cause researchers to cut corners and sacrifice the quality of research. However, resulting retractions emphasize the need to maintain study rigor even during pandemics. It cannot be overstated that research standards, including thorough vetting by the peer review process, cannot be compromised even during challenging times. Thus, crucial research informativeness and social value will be maintained.

PROVIDING GUARDED PEER REVIEW FLEXIBILITY

Due to the constraints posed by the pandemic, some open access journals have adopted a more flexible approach to the peer review process. Many researchers have found it a challenge to meet additional experiments or components required by peer review. In response, journals have given authors more time to respond at any stage of the peer review process. However, caution must be exercised when lowering peer review standards as flawed studies have slipped through this gatekeeping mechanism.

As examples, Servick²⁹ and Piller and Servick²⁵ have recently reported the retractions of two dubious papers on coronavirus that used "large, real-word datasets" and slipped past peer review in two top scientific journals, *The Lancet* and *NEJM*. *The Lancet* retracted a paper on the risks of hydroxychloroquine because of questionable details regarding its large sample size and patient demographics and dosing.²⁹ Afterwards, *The Lancet* revised its review process and implemented stricter standards on the expertise of peer reviewers. In addition, the journal now requires all authors to vouch for the validity of their data and explain in detail their data-sharing plans.^{29,30} *NEJM* retracted a paper which concluded that taking certain blood pressure drugs, including angiotensin-converting enzyme inhibitors, did not appear to increase the risk of death among COVID-19 patients.²⁵



These retractions show that even top-tier scientific journals can publish flawed studies when peer review standards are eased in the rush to publish a hot research topic. Innovative changes in peer review³¹ or flexibilities in the peer review process such as the proposed 'rapid response peer-review process'³² may be inevitable, even advantageous during pandemics, but the integrity of peer review and reporting standards should not be compromised so faulty studies can be rooted out. Looking to the future, high-quality peer review as well as full and immediate open access and post-publication social media promotion have been identified by scholars as key anticipated features of scholarly publishing.³³

CONCLUSION

In conclusion, the COVID-19 pandemic remains a major global crisis and continues to disrupt basic science research and clinical studies. Thus, fundamental shifts in research, publishing ethics, and the dynamics of the peer reviewing process have become "a new normal". From a broader perspective, these shifts have become pivotal in the strategic use of available data collection channels, adaptable but ethical methodologies, and virtual methods for augmenting operational or participatory research. Utmost caution, however, must be exercised when lowering ethical standards that accompany these shifts. Mechanisms must be in place for maintaining study rigor as well as the informativeness, integrity, and social value of research. Adaptable innovations of research tools, study designs, and clinical research safety should be actively pursued without compromising research quality and integrity.

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