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# The Path to Open Medicine: Driving Global Health Equity through Medical Research

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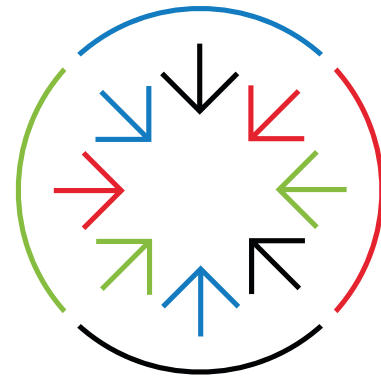
# Foreword

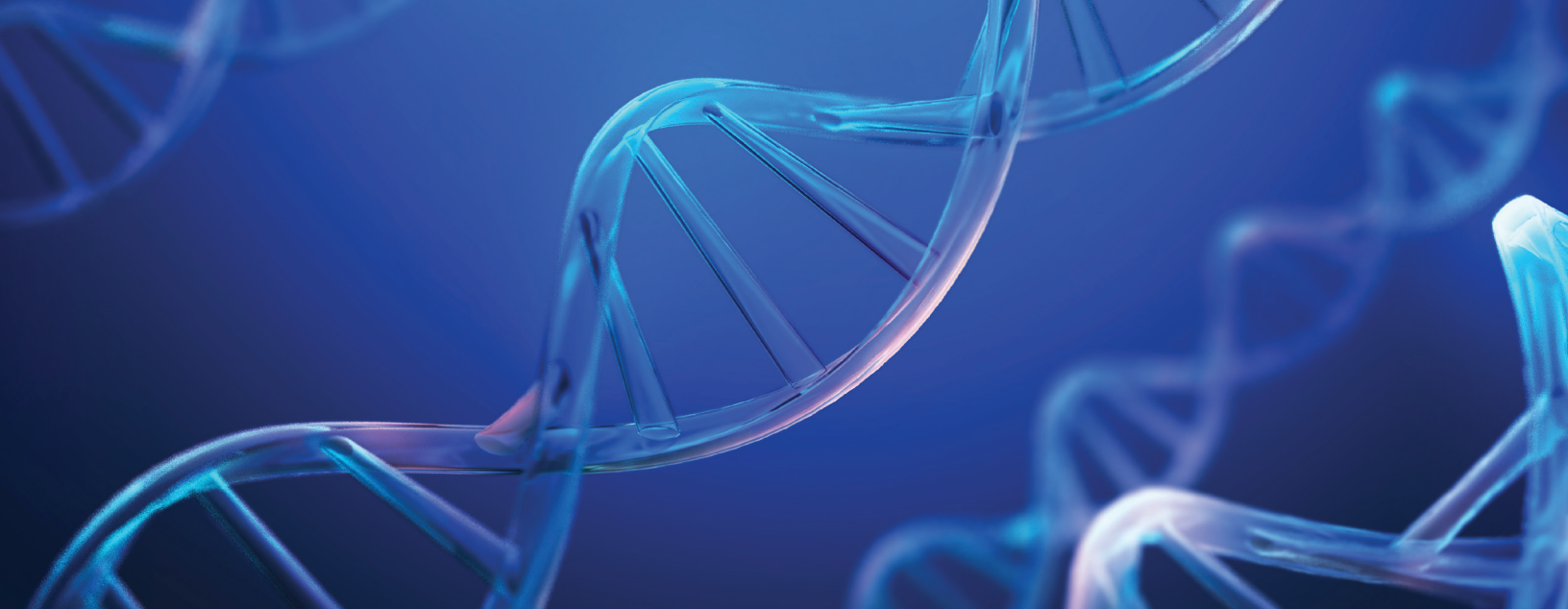
The rise of the Open Science movement embodied a set of values that were intended to move beyond their origins in mathematics and physics, and subsequently improve global healthcare. To date, that challenge remains largely unfulfilled. Thus, Wolters Kluwer has wholly committed itself to the concept of Open Medicine -- the idea that medical research should be fully shared, without the traditional barriers that hindered the access to research and the ability to fund its publication. Wolters Kluwer has undertaken this mandate to ensure that all researchers have access to the latest information, and patients are provided an opportunity for the best possible outcomes.

In embracing Open Medicine, we are committed to maintaining the highest quality and integrity in the scientific process, working for the collective benefit of humankind, advocating for equity and fairness in the research community, and embracing diversity and inclusion to support the global community.

This paper is but the first step in a journey toward a new collaborative environment, in which funders, publishers, institutions, and researchers work collectively to optimize the impact of our individual efforts.

We want to thank those who helped build the initial framework and we look forward to continuing the dialogue.





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# Introduction

In the wake of the COVID-19 pandemic, the urgency to achieve global health equity has reached a new level of intensity. The most recent World Bank data indicate that the gap in life expectancy between the lowest and the highest ranking nations in the world has widened to 30 years.<sup>1</sup> No longer can those working in healthcare worry only about regional, or national interests. The community's focus must be on addressing resource constraints, discrimination, biases, and other obstacles that lead to poorer health in poorer regions of the world. Global health equity will only be achieved when people across the globe can attain their full potential for health and well-being, regardless of geographic location or nationality. It takes little probing to know that we are far from this aspiration today.

As active participants in the global healthcare field, Wolters Kluwer's mission is to make a major impact on patient treatment through technology and research, thereby protecting people's health and prosperity and contributing to a safe and just society. As such, we embrace the challenge of contributing to the achievement of global health equity. While there are many paths of action involved in promoting this vision, we believe that our strong presence in the world of medical research publishing enables us to play a significant role in promoting and investing in Open Medicine, the subcategory of Open Science that pertains to biomedical and clinical research. Open Science embodies the core values of academic freedom and human rights for all; the gathering of diverse knowledge sources; and open, rigorous scrutiny of research methods, outputs, and evaluation processes by researchers from all parts of the world. Open Science asserts that the benefits of global health knowledge should be universally shared and that the scientific process should be inclusive, sustainable, and equitable. The vision of Open Science imagines that researchers from all countries will be empowered to be both producers and consumers of scientific knowledge, with opportunities for scientific education and capacity development for all.<sup>3</sup>

To further the mission of advancing global health equity, this position paper explores the concepts and values of the movement. The three main pillars of Open Medicine under discussion are:

- open access to scholarly publications (open access, OA),
- open data sharing (open data), and
- open sharing of procedures, methodologies, algorithms, and software (open source/open code).<sup>4</sup>



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While many aspects of Open Medicine reflect the broader characteristics of Open Science, some important particular characteristics of Open Medicine stem from the fact that the field of medicine directly and quickly affects human well-being to a greater degree than most fields of science. Thus, any discussion of Open Medicine must keep patient outcomes and risk to patients at front of mind. For example, misleading or erroneous data about the proper medications to treat COVID-19 might lead to near-immediate harm to thousands or millions of human lives. This potential imminent risk, which sets clinical research apart from other kinds of scientific research, must be kept in mind when envisioning the optimal state of Open Medicine.

In our view, much has been accomplished towards the vision of Open Medicine since the ideals of Open Science were first put forth more than 20 years ago by The Budapest Open Access Initiative Declaration, The Bethesda Statement on Open Access Publishing, and The Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities. However, the necessary infrastructure, policies, and practices to truly achieve the mission and goals that the scientific community set for itself are still not fully in place. Often publications and data are not shared openly in a way that can benefit all stakeholders. Institutions can remain siloed and continue to base career advancement, tenure, and other rewards on systems that will no longer be viable or useful in an Open Medicine landscape. Research funding frequently benefits high-income countries (HICs), while neglecting lower- and middle-income countries (LMICs), creating an imbalance of knowledge production and consumption.

For Open Medicine to move further towards the achievement of global health equity, we believe the global health community should embrace the following ideas:

1. There are many stakeholders in the Open Medicine landscape: funders, institutions, publishers, and researchers.
2. All stakeholders must make internal changes and collaborate to find a viable path forward that aligns with the values of Open Medicine. No stakeholder can achieve the goals of Open Medicine alone.
3. All stakeholders affirm that the future of Open Medicine must achieve equity in how biomedical knowledge is produced as well as consumed across the globe. The production of health and medical knowledge should no longer be siloed and privileged to only certain regions and countries

The paper is divided into three parts. Part 1 traces the historical events that led to the modern system of scientific research, funding, knowledge dissemination, and recognition, which largely confines health and medical knowledge production to those in HICs. By understanding our shared past and the rise of structural barriers to global health equity, we can better inform our shared path to dismantle them. Part 2 takes a clear-eyed look at where the scientific community is now. Are the ideals of Open Medicine playing out as envisioned? Are the benefits of Open Medicine shared amongst all of humanity, or with only a select few? Lastly, Part 3 offers ideas and recommendations for all stakeholders to chart a path to bring Open Medicine into alignment with its goals and aspirations.

As this paper will make clear, there is no simple panacea to bring the community into closer alignment with Open Medicine. We outline a balanced, complex approach that considers the responsibilities of all stakeholders. If there is anything approaching a panacea that we envision, it is collaboration between the stakeholders; we look for a bold, yet pragmatic, approach among publishers, funders, institutions, and researchers to tackle the issues before us. We remain committed to open dialogue and cooperation as, together, the biomedical research and development community shifts towards global health equity through Open Medicine.

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## UNESCO Definition of Open Science<sup>3</sup>

*In 2021, the 41st United Nations Educational, Scientific, and Cultural Organization (UNESCO) general conference defined Open Science as “... an inclusive construct that combines various movements and practices aiming to make multilingual scientific knowledge openly available, accessible and reusable for everyone, to increase scientific collaborations and sharing of information for the benefits of science and society, and to open the processes of scientific knowledge creation, evaluation and communication to societal actors beyond the traditional scientific community. It comprises all scientific disciplines and aspects of scholarly practices, including basic and applied sciences, natural and social sciences and the humanities, and it builds on the following key pillars: open scientific knowledge, open science infrastructures, science communication, open engagement of societal actors and open dialogue with other knowledge systems.”*



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# Part 1. Setting the stage: the origins of open science

Between the 16<sup>th</sup> and 18<sup>th</sup> centuries, an early version of Open Access to scientific and medical knowledge arose in the Western world via letters posted among educated men (and a few women). Observations, data, and procedures were openly exchanged across the globe through millions of missives.<sup>5,6</sup> This “Republic of Letters” was the social media network of the scientific and medical communities of the time and included about thirty thousand correspondents.<sup>7</sup> The landscape could be considered “Open Medicine 1.0”. Things shifted dramatically in 1660, when a dozen scientists and physicians founded The Royal Society of London for Improving Natural Knowledge.<sup>8</sup> Society Secretary Henry Oldenburg became the first journal editor and the inventor of the peer-reviewed scientific article when he released *Philosophical Transactions (PT)*, the first scientific journal, on a subscription basis in 1665.<sup>9</sup> *PT* was a scholarly success, as it helped curate an increasingly unwieldy amount of letters and replies for consumption by Society members and subscribers.

Based on the *PT* model, the number of subscription-based scholarly journals grew rapidly in the late 17<sup>th</sup> and 18<sup>th</sup> centuries, while the Republic of Letters dwindled. With the exponential growth of journals came the need to filter out those publishing unreliable or false data. So in 1879, US Surgeon General John Shaw Billings responded by establishing the *Index Medicus*, a monthly curated guide to the current medical literature.<sup>15,16</sup> Billings also produced the first series of the *Index-Catalogue*, a subject-heading guide to the Library of the Surgeon General’s holdings. It was eventually published in five series in 61 volumes from 1880–1961.<sup>15,16</sup>

This explosion in scholarly journals was not distributed across the globe equitably, in an organized effort to gather and distribute global medical knowledge and improve global health outcomes. Instead, biomedical journals quickly became concentrated

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## Timeline of First Biomedical Journal Launches, 1673-1880 <sup>8,10-14</sup>

### 1673

| *Acta Medica et Philosophica Hafniensia*, the first biomedical journal, launched in Denmark.

### 1684

| *Medicina Curiosa*, the first English-language medical journal, launched in England.

### 1797

| *Medical Repository*, the first North American medical journal, launched in the US.

### 1812

| *The New England Journal of Medicine and Surgery and the Collateral Branches of Science* launched in the US.

### 1900

| *The American Journal of Nursing*, the first nursing journal, launched in the US.

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in North America and Europe due to funding constraints. The main source of funding for journals came from a mixture of society/university sponsorship, advertising, and individual subscriptions,<sup>15</sup> which only those in higher-income countries could afford.

The funding sources and methods for biomedical knowledge production also shifted dramatically between the 16<sup>th</sup> and 20<sup>th</sup> centuries. During the time of the Republic of Letters, funding was provided by the scholar's family, by wealthy patrons, or by the scholar's earnings from professional duties.<sup>6,17</sup> The lack of competition for centralized funding sources and the method of generally funding the *scholar*, not a particular *project*, contributed to the free flow of information and the ability of researchers from many geographic regions to both produce and consume information.<sup>6</sup> In the 19<sup>th</sup> and early 20<sup>th</sup> centuries, funding for scientific and medical researchers and organizations continued to rely heavily upon patronage and philanthropy, although an increasing level of funding was provided by industry, institutions, and government.<sup>18</sup>

Funding methodology was altered when The Rockefeller Foundation pioneered the first fixed-term project grant in the 1930s. The US Public Health Service (PHS) followed suit with a small extramural research grant program, which was expanded following World War II.<sup>19,20</sup> Within a dozen years, the National Institutes of Health (NIH) was born. By 1946, it established a system of peer-reviewed, fixed-term, extramural grants to support medical research.<sup>20</sup> In the post-war period, several private voluntary associations in the United States, including the National Foundation for Infantile Paralysis and the American Cancer Society, followed the NIH's direction. While these organizations previously had engaged in public education campaigns and had directly funded patient care, now their missions expanded to support laboratory researchers through direct research grants.<sup>19</sup> This competitive, project-based funding model gained popularity in the United States and internationally. It is currently the most common method of medical research support utilized by government and private funding institutions around the world.<sup>21,22</sup>

The shift in funding sources and methodology, coupled with the rise of subscription journals during this time, completely altered the landscape of global health information production and consumption by the mid-1900s. While researchers in the original Republic of Letters acted as both producers and consumers of knowledge by open exchange across the globe, knowledge-producers in the age of scholarly journals sent letters or manuscripts to curated journals located in HICs, to which knowledge-consumers from across the globe subscribed. Because journals and funding were concentrated in HICs, knowledge-producers became increasingly concentrated in HICs, whereas researchers in LMICs increasingly became predominantly knowledge-consumers.

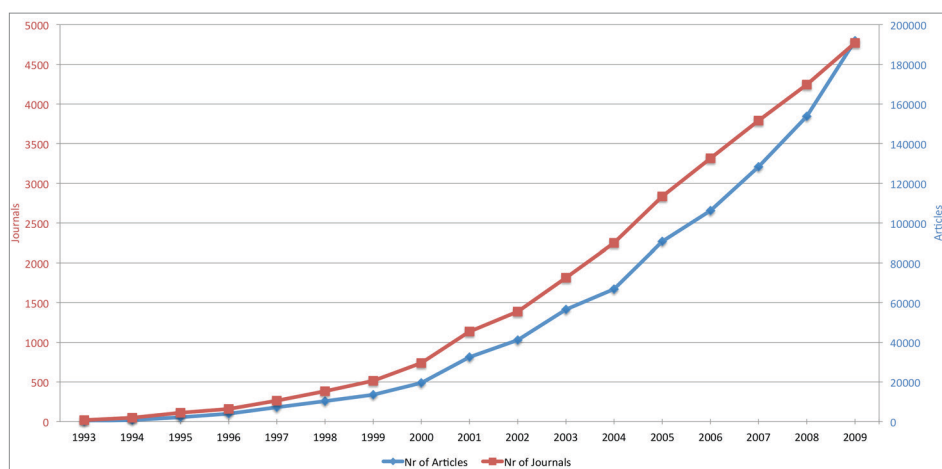
## From Paper to Digital Publications and The Growth of Open Access

The 20<sup>th</sup> century saw an explosion in number of paper-based scientific and medical journals, rising from approximately 10,000 titles in 1900 to 133,000 in 1991.<sup>23-25</sup> The paper-based model began to shift in 1971, when the National Library of Medicine (NLM) created an online version of the *Index Medicus* (MEDLARS onLINE [MEDLINE]) to provide access to medical journal citations published from 1966 onward. Researchers needed training in the command line syntax used to search the database, so access was limited, but this was a watershed moment.<sup>26</sup> In 1988, Mark Nelson developed an online interface to MEDLINE that allowed a high level of search precision without the need to master MEDLINE's command line syntax. By 1992, he had developed a Microsoft Windows interface for this product, which he successfully marketed under the name Ovid.<sup>27</sup> (Ovid Technologies, Inc., is now part of the Wolters Kluwer group of companies). In 1995, *The British Medical Journal* made headlines as the first general medical journal



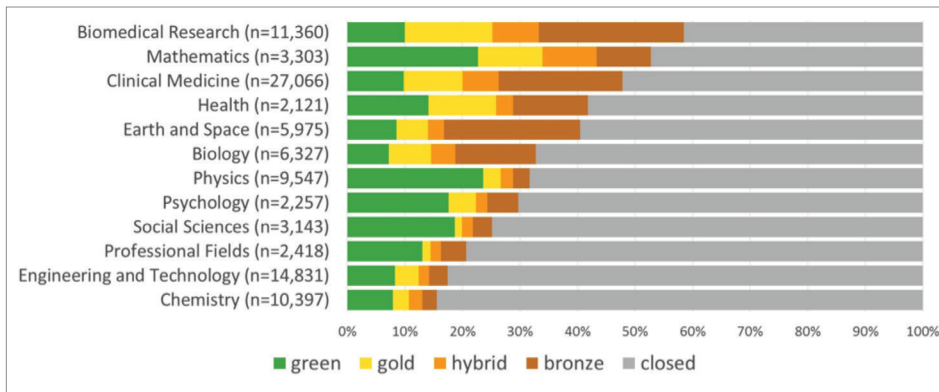
to make content available online. Just one year later, in 1996, a survey of science, technology, and medical journals tallied 83 journals published online.<sup>28</sup> In 1997, PubMed was launched and funded by the US government, providing open online search access to MEDLINE for researchers.<sup>26</sup>

The concept of OA was popularized contemporaneously with the movement from paper to digital journals between 1995 and 2010. One of the pioneers of biomedical OA publishing was Arthur Huntley of the University of California, Davis. He coded and published the first OA medical journal, *Dermatology Online Journal*, in 1995. One year later, *The New England Journal of Medicine (NEJM)* initiated Delayed OA, with articles freely available to read six months after publication. By 2003, *PLOS Biology* was launched, with *PLOS ONE*, *PLOS Medicine*, *PLOS Computational Biology*, and *PLOS Genetics* close behind. *The Journal of the American Medical Association (JAMA)* allowed Delayed OA starting in 2004.<sup>29</sup> Given this rapid-fire launch of OA biomedical journals, it is no surprise that the number of both journals and articles published OA grew significantly in this time period (**Figure 1**).<sup>30</sup>



**Figure 1. The growth in Open Access publishing between 1993 and 2009.**<sup>30</sup>

The biomedical field surged forward along with other fields in the prevalence of OA, particularly Gold OA (permanent and free online access to final published articles for anyone, anywhere), starting around 2009. A 2018 study by researchers in the US and Canada examined all citable Web of Science articles with digital object identifiers (DOIs) from 2009 to 2015 to determine the prevalence of types of OA publishing by discipline. They found that approximately 60% of publications were available under some type of OA in the biomedical field, compared with less than 20% in chemistry and engineering and technology. The biomedical field led the way in percentage of Gold OA articles (15%), compared with the health (12%), mathematics (11%), clinical medicine (10%), and chemistry (5%) fields (**Figure 2**).



**Figure 2. Percentage of different access types of a random sample of Web of Science articles and reviews with a DOI published between 2009 and 2015 per National Science Foundation (NSF) discipline (excluding Arts and Humanities).<sup>31</sup>**

Another service for authors, preprint posting began in the physics and mathematics research communities as early as the 1950s.<sup>32-34</sup> Articles posted on preprint servers are not peer-reviewed and have not yet been accepted for publication by a journal. Preprint servers provide researchers a rapid way to solicit real-time feedback on their work before publication, as readers can review articles and post comments. In addition, posting on preprint servers can help researchers solidify the primacy of their methods and results.<sup>29-31,35 32,36</sup>

The rise in modern preprint servers began in 1991, when physicist Paul Ginsparg at the Los Alamos National Laboratory in New Mexico, USA, created a central server for unpublished research article drafts. An explosion in uploads led to a relaunch of the server, dubbed arXiv, by Cornell University.<sup>37,38</sup> In 2013, Cold Spring Harbor Laboratory in New York, USA, launched bioRxiv, a server for unpublished preprints in the life sciences.<sup>39</sup> Six years later, Cold Spring Harbor Laboratory, Yale University, and *The BMJ* (formerly the *British Medical Journal*) launched medRxiv, a dedicated preprint archive for health sciences and medical research.<sup>40</sup>

## The Call for Universal Open Access and the Expansion to Open Science

By the early 2000s, frustrations were building over rising subscription costs, and the subscription model of academic publishing was seen by many as restricting access to science and medicine. Several international declarations were made in support of a universal OA model of publishing as well as a broader move towards Open Science. Universal OA was conceived as a way to drive costs down.<sup>24,41-44</sup> It was also hoped (and expected) that a move toward greater OA would stimulate education and research across the globe, to bridge the gap in research output and publications between HICs and LMICs that was obvious, problematic, and growing ever larger.<sup>10</sup>

In 2001, The Budapest Open Access Initiative Declaration stated, “An old tradition and a new technology have converged to make possible an unprecedented public good ... the world-wide electronic distribution of the peer-reviewed journal literature and completely free and unrestricted access to it by all. ... Removing access barriers to this literature will accelerate research, enrich education, and share the learning of the rich with the poor and the poor with the rich”.<sup>43</sup> In 2003, The Bethesda Statement on Open Access Publishing promoted a rapid transition to universal OA publishing: “The purpose of this document is to stimulate discussion within the biomedical research community on how to proceed, ... to the widely held goal of providing open access to the primary scientific literature.”<sup>44</sup>

*“Removing access barriers to this literature will accelerate research, enrich education, and share the learning of the rich with the poor and the poor with the rich”*

### The Budapest Open Access Initiative Declaration

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Later in 2003, The Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities broadened the call for openness beyond simply universal OA for publications: “Our mission of disseminating knowledge is only half complete if the information is not made widely and readily available to society. ... In order to realize the vision of a global and accessible representation of knowledge, the future Web has to be sustainable, interactive, and transparent. Content and software tools must be openly accessible and compatible.”<sup>45</sup>

In the ensuing decade, developments such as high-speed computer networks, data storage and data processing capabilities, virtual communications, multi-disciplinary and trans-disciplinary research teams, and artificial intelligence pushed the aspirations of Open Science even higher.<sup>46</sup> By 2012, The Royal Society report *Science as an Open Enterprise* asserted: “Rapid and pervasive technological change has created new ways of acquiring, storing, manipulating and transmitting vast data volumes, as well as stimulating new habits of communication and collaboration amongst scientists. ... Successful exploitation of these powerful new approaches will come from six changes: (1) a shift away from a research culture where data is viewed as a private preserve; (2) expanding the criteria used to evaluate research to give credit for useful data communication and novel ways of collaborating; (3) the development of common standards for communicating data; (4) mandating intelligent openness for data relevant to published scientific papers; (5) strengthening the cohort of data scientists needed to manage and support the use of digital data (which will also be crucial to the success of private sector data analysis and the government’s Open Data strategy); and (6) the development and use of new software tools to automate and simplify the creation and exploitation of datasets. The means to make these changes are available. But their realization needs an effective commitment to their use from scientists, their institutions and those who fund and support science.”<sup>47</sup>

In 2018, the US National Academies of Science, Engineering, and Medicine argued that openness is *the* linchpin to successful scientific advancement across the globe: “Openness and sharing of information are fundamental to the progress of science and to the effective functioning of the research enterprise. ... Open science aims to ensure the free availability and usability of scholarly publications, the data that result from scholarly research, and the methodologies, including code or algorithms, that were used to generate those data.”<sup>48</sup>

That same year, cOAlition S, an association of research institutions and funding organizations, launched Plan S. Its main goal is rapid transition to a universal OA publishing model by requiring recipients of research funding from cOAlition S organizations, including Science Europe and the European Commission, to make the resulting publications available immediately under open licenses either in OA journals or platforms, or through deposition in open repositories.<sup>49</sup> Further, Plan S stipulates that the author or the author’s institution must retain their copyright, and that licenses to publish that are granted to a publisher must allow the author or institution to make either the Version of Record (VoR), the Author’s Accepted Manuscript (AAM), or both versions available under an open license in an Open Access repository without embargo.<sup>50</sup>

As justification for these many requirements, cOAlition S stated: “As major public funders of research in Europe, we have a duty of care for the good functioning of the science system. ... Hence, driven by our duty of care for the proper functioning of the science system, we have developed Plan S whereby research funders will mandate that access to research publications that are generated through research grants that they allocate, must be fully and immediately open and cannot be monetised in any way.”<sup>51</sup>

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*“Openness and sharing of information are fundamental to the progress of science and to the effective functioning of the research enterprise. ... Open science aims to ensure the free availability and usability of scholarly publications, the data that result from scholarly research, and the methodologies, including code or algorithms, that were used to generate those data.”*

**US National Academies of Science, Engineering, and Medicine**

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In August 2022, the US Office of Science and Technology Policy (OSTP), a White House office that coordinates policy on behalf of the many agencies that fund scientific research including the NIH, released a memorandum entitled “Ensuring Free, Immediate, and Equitable Access to Federally Funded Research”.<sup>52</sup> It calls for federal agencies with research and development expenditures to implement a policy by the end of 2025 under which scientific articles reporting the results of research that these agencies have funded should be made openly available immediately upon publication in a scholarly journal. The memo states, “A federal public access policy consistent with our values of equal opportunity must allow for broad and expeditious sharing of federally funded research—and must allow all Americans to benefit from the returns on our research and development investments without delay. ... [This] public access policy also strengthens our ability to be a critical leader and partner on issues of open science around the world. ... [T]he rapid sharing of federally funded research data with appropriate protections and accountability measures will allow for greater validity of research results and more equitable access to data resources aligned with these ideals ... [and will] promote equity and advance the work of restoring the public’s trust in Government science and ... advance American scientific leadership. ... ”<sup>52</sup>

The underlying hope demonstrated by cOAlition S and the US OSTP is clear – that universal OA, open data, open source, and open code, taken together, will lead to public benefit, global health equity, and an environment in which knowledge is both produced and consumed in a balanced way by researchers in HICs and LMICs alike. We examine this idea further in Part 2.



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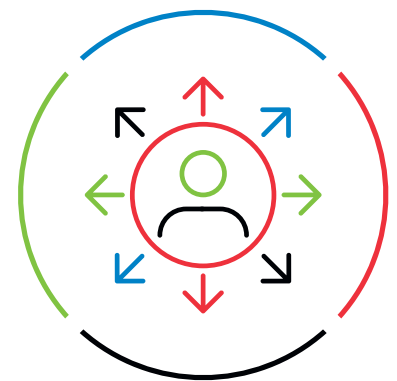
## Part 2. The aspirations of open medicine

### Knowledge Dissemination

In 2020, 36% of all scholarly articles were published as paid OA, a 25% increase from 2019, showing the very rapid growth of OA publishing in the current publication landscape.<sup>53</sup> Indeed, a very recent analysis of the growth of OA journals that were indexed in the Directory of Open Access Journals (DOAJ) between 2002 and 2021 found that the average annual growth rate was more than 50%, with a total of 16,589 OA journals indexed by July 2021.<sup>54</sup> In 2003, the aspirations of Open Science described by the Bethesda Statement included the idea that growth in OA publishing would, “... promote the creation and dissemination of new ideas and knowledge for the public benefit.”<sup>44</sup> Is this the case?

OA publishing does appear to increase the dissemination of new ideas and knowledge. Studies have compared the citation counts of OA articles and toll-access articles, and the majority have found higher citation counts with OA, christened the “open access citation advantage (OACA)”.<sup>31,55,56</sup> A recent systematic review reported that, of 134 studies identified for inclusion, 64 studies (47.8%) confirmed the existence of OACA, while 37 (27.6%) found no evidence for it, and 32 (23.9%) found OACA in certain fields of research. Among the studies that did confirm the existence of OACA, the degree of advantage varied widely, from 8% to 42%.<sup>31,55,57-60</sup> While more research will clarify the extent of OACA, the fact is that OACA is real.<sup>61</sup> Indeed, usage tracking confirms that providing practicing medical personnel and public health professionals with access to more OA publications increases their average weekly article consumption.<sup>62</sup>

Preprint servers also appear to increase the uptake of biomedical literature and provide broader access.<sup>4,63</sup> In times of a public health crisis, this can be especially pronounced. As seen during the COVID-19 pandemic, a rapid increase in the number of submissions to standard peer-review publication systems overloaded capacity and led to longer publication delays.<sup>64</sup> Preprints provided an alternative outlet, as was demonstrated in 2020 by medRxiv and bioRxiv when the number of preprints posted about COVID-19 surged.<sup>64</sup>



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## “The Public Benefit”

What about “... for the public benefit”? This concept can be difficult to assess, but one way to consider it in the setting of Open Medicine is to look at the conversion of research to demonstrable patient benefit (so-called “bench to bedside”). This has been termed “translational research.”<sup>65-68</sup>

### **Translational research**

The Institute of Medicine report *Crossing the Quality Chasm*, stated in 2001: “It now takes an average of 17 years for new knowledge generated by randomized controlled trials to be incorporated into practice, and even then application is highly uneven.”<sup>69</sup> This average time lag has been confirmed in a number of studies, but within it lies a wide range of time lag durations which vary not only by field but also by subtopic within field.<sup>65,66,68</sup> For example, Grant *et al.* examined decades of research relating to advances in neonatal care and found that the overall time lag ranged from 13 years for artificial surfactant to 21 years for parenteral nutrition.<sup>66</sup> Overcoming the translational time lag has been a major policy focus in different areas of the world, including the US, the EU, and China. The policy discourse around clinical translation, particularly in the EU, is often framed as “... constructing a model of economic growth centered around the idea of a more interconnected and cohesive knowledge-based economy, thereby connecting policy stimuli to translation with broader political imaginations.”<sup>70</sup>

Given the premise that an open knowledge-based economy will shorten the translational time lag and improve patient care, greater stakeholder participation in Open Medicine (open access, open data, and open source) has been widely promoted as a time-cutting solution.<sup>71-75</sup> Harlan Krumholz, MD, SM, the Harold H. Hines, Jr. Professor of Medicine (Cardiology) and the Director of the Center for Outcomes Research and Evaluation at Yale University, wrote: “Patients facing a decision deserve information that is based on all of the evidence. ... Now is the time to bring data sharing and open science into the mainstream of clinical research, particularly with respect to trials that contain information about the risks and benefits of treatments in current use.”<sup>76</sup>

Attila A. Seyhan, PhD, the Director of Translational Oncology Operations at the Cancer Center at Brown University, agreed: “Perhaps, to improve translational research, it may be even more prudent to improve first the quality of hypotheses before testing them ... therefore, there has to be trust (i.e., more transparency) in scientific research ... where the primary goal is to test and not support hypotheses. To accomplish this, we must make some changes in several research practices ... including the availability of detailed methods and protocols and results (even the raw data), software and codes in ways that are accessible and for those who may want to reanalyze or replicate their findings.”<sup>77</sup>

Has the move towards Open Medicine over the past 20 years led to a significant reduction in the translational time lag? The evidence suggests that this is not the case.<sup>77-80</sup> While the reasons for this are complex, most experts agree that the barriers in translational research exist across multiple domains and within the realm and responsibility of many stakeholders, including researchers, academic institutions, government, funders, and publishers.<sup>77-82</sup> Joseph Steven Fernandez-Moure, MD, MS, Assistant Professor of Surgery at Duke Medical School, noted: “The success of any translational research program lies in the elimination of silos segregating scientists, doctors, and industry professionals from each other ... the reality is that in most nations, revenue streams are strictly separated between the “hospital” and “research institute.” As the landscape of healthcare and reimbursement continues to evolve, clinicians will continue to be seen as earners with little to no incentive to spend any additional time pursuing innovative collaborative relationships in science. This has led to a deficiency in the development of clinician-scientists and translational science collaboration.”<sup>82</sup>

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*“Perhaps, to improve translational research, it may be even more prudent to improve first the quality of hypotheses before testing them ... therefore, there has to be trust (i.e., more transparency) in scientific research ... where the primary goal is to test and not support hypotheses. To accomplish this, we must make some changes in several research practices ... including the availability of detailed methods and protocols and results (even the raw data), software and codes in ways that are accessible and for those who may want to reanalyze or replicate their findings.”*

**Attila A. Seyhan, PhD,  
Director of Translational Oncology  
Operations, Cancer Center at  
Brown University**

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According to Heather Goodell, Vice President Scientific Publishing for the American Heart Association: “Researchers themselves are struggling with the steps required for greater transparency. When you ask researchers about it, they are overwhelmingly in favor of open science. However, the actual number of them that take the necessary steps, particularly in biomedical research, is not high. Why? Well, part of it is competition, proprietary concerns, and just confusion. Part of it is how institutions evaluate researchers; they are not rewarded for following open principles ... ”<sup>83</sup>

In sum, the shift toward universal OA publishing may be a necessary factor in reducing the translational time lag, but alone it is certainly not sufficient.

### **Preprint servers**

As described above, preprint servers do rapidly disseminate scientific knowledge; however, there are significant concerns about whether this is “in the public good.” A key problem occurs when preliminary results are accessed by the public and widely disseminated, only to be later amended by researchers. It is difficult to then correct the perception of the general public.<sup>84</sup> Further, medical discussions can and do become politicized, and preprints can become a tool of manipulation.<sup>85</sup>

One real-world example is the discourse surrounding the COVID-19 pandemic. Public interest in preprint articles soared during the first months of the pandemic. Preliminary findings published on preprint servers were used as arguments in politicized discussions on medical issues in certain countries, such as the US.<sup>86-88</sup> A comparison study of all Twitter messages containing a medRxiv URL that were posted either before (June 2019-January 2020) or during (January-June 2020) the pandemic found that, during the pandemic, six of the top ten most-tweeted preprints were focused on hydroxychloroquine treatment of COVID-19.<sup>89</sup> It is equally concerning that, prior to the COVID-19 pandemic, the term “preprint” was the most frequently mentioned term in tweets linking to medRxiv. During the pandemic, the term “study” was most frequently mentioned instead.<sup>89</sup>

Jason Miller, Chief Operating Officer at *The Journal of Bone & Joint Surgery*, commented, “At *JBJS* as an organization and as a leading journal in orthopedics, our core mission is to make sure everything we do is aimed at improving patient care. We feel strongly that allowing for unfettered openness to clinical information through preprint servers has been shown to have a great potential for danger and patient harm. There are those that knowingly disseminate false data. There are those that do not understand the nature of a preprint server and the type of information that is available, and these include many patients and some clinicians and members of the media. That is why we do not accept submissions from preprint servers. Preprint servers absolutely have good intentions, and they do serve a useful purpose in certain disciplines, such as basic science or mathematics. However, in terms of medical and clinical findings, the peer-review process is sacred to us.”<sup>90</sup>

Clearly, the impact of preprint servers is multivalent, and much thought must be applied by the community toward how best to extract the benefits, while minimizing the risks.

## **Increasing the Usefulness of the Research Literature**

In 2001, The Budapest Open Access Initiative Declaration stated: “Removing access barriers to this [scientific research] literature will ... make this literature as useful as it can be, and lay the foundation for uniting humanity in a common intellectual conversation and quest for knowledge.”<sup>43</sup> In 2022, has the increase in OA literature caused literature to be “as useful as it can be”?

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*“Researchers themselves are struggling with the steps required for greater transparency. When you ask researchers about it, they are overwhelmingly in favor of open science. However, the actual number of them that take the necessary steps, particularly in biomedical research, is not high. Why? Well, part of it is competition, proprietary concerns, and just confusion. Part of it is how institutions evaluate researchers; they are not rewarded for following open principles ... ”*

**Heather Goodell,  
Vice President Scientific Publishing,  
American Heart Association**

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## **Predatory and grey-area publishing**

Though increased openness has improved the dissemination of medical research knowledge, it also brought on the problem of predatory journals. The term was first coined by Jeffrey Beall, Scholarly Communications Librarian at the University of Colorado-Denver, who kept a blog from 2010 to 2017 listing journals he believed were predatory (Beall's List).<sup>91,92</sup> According to a current consensus definition published in *Nature*, "Predatory journals and publishers are entities that prioritize self-interest at the expense of scholarship and are characterized by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices."<sup>93</sup> Article processing charges in predatory journals are usually quite low, with a median APC of just \$100 USD (IQR, \$63-150 USD), to lure in authors, particularly those from LMICs.<sup>94</sup> There has been rapid growth in predatory publishing in the last decade. One sample of journals from Beall's List showed a publication volume increase from about 53,000 articles in 2010 to about 420,000 articles in 2014, published by approximately 8,000 active journals.<sup>95</sup> Then there is the additional problem of 'grey-area' journals. Such journals provide some degree of editorial services and perhaps some type of review but publish nearly everything that is submitted, including mediocre or poor content.<sup>96</sup>

Rick Anderson, University Librarian at Brigham Young University and a former President of the Society for Scholarly Publishing, pondered the question of what to do about predatory and grey-area journals: "There's always simple denial, which can take multiple forms: try the argument that predatory publishing has nothing to do with OA (and therefore isn't a problem that the OA community has any need to address), or that predatory publishers aren't really predatory but are merely "innovators," purveyors of "new wave" journals with lower acceptance standards and faster turnaround times, or that only an idiot would be fooled by them and therefore what's the big deal? Unfortunately, none of these arguments is particularly convincing, given that these journals are invariably OA publications, that they don't do anything especially innovative (selling fake scholarly credentials has a long and ugly history, after all), and that they demonstrably attract lots of authors, a significant number of whom don't seem to be idiots."<sup>97</sup>

The fallout experienced by Open Medicine from predatory and grey-area journals has been well-documented.<sup>98-100</sup> They provide an outlet for false, misleading, or incomplete methods and results that would not otherwise be published by a reputable peer-reviewed journal.<sup>101</sup> Using these methods and results, unaffiliated researchers may unintentionally craft new studies on shaky foundations, citing them in their own publications and further disseminating false information. Articles originally published in predatory journals are known to appear in hundreds of systematic reviews later published in reputable journals.<sup>99,100</sup> Indeed, a small number of predatory OA journals even regularly leak into indexing in PubMed, PubMed Central, MEDLINE, Scopus, and Web of Science.<sup>98,102</sup> Some researchers question the integrity of the body of medical research overall and look upon all OA journals with wariness, tainting the vision of Open Medicine.<sup>91,103</sup> The consequences of predatory journal content are particularly sobering in the context of clinical research, where bad data is a hazard to direct patient care. This is not an idle concern. Many predatory journals directly target practicing physicians, nurses, clinicians, and other allied health professionals.<sup>101,104-108</sup> Frighteningly, it has been reported that 30% to 60% of practicing clinicians, nearly 25% of medical school faculty, and over 90% of medical students are not aware predatory journals exist and/or do not know how to recognize them.<sup>109-112</sup>

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*"There's always simple denial, which can take multiple forms: try the argument that predatory publishing has nothing to do with OA (and therefore isn't a problem that the OA community has any need to address), or that predatory publishers aren't really predatory but are merely "innovators," purveyors of "new wave" journals with lower acceptance standards and faster turnaround times? ... "*

**Rick Anderson, University Librarian at Brigham Young University, and former President of the Society for Scholarly Publishing**



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## The Cost of Knowledge Dissemination

The Budapest Open Access Initiative asserted: “With such an opportunity to save money and expand the scope of dissemination at the same time, there is today a strong incentive for professional associations, universities, libraries, foundations, and others to embrace open access as a means of advancing their missions ... the significantly lower overall cost of dissemination is a reason to be confident that the goal is attainable and not merely preferable or utopian.”<sup>43</sup> But has the move to Open Medicine reduced the cost of knowledge dissemination today?

According to *The New England Journal of Medicine*, the answer is no. “Growth in the overall cost of publishing was predictable, because even if online dissemination is less expensive than printing on paper and distributing by mail, the Internet has also opened new ways of presenting content and interacting with researchers and readers that add value but cost money. Most importantly, the cost of producing high-quality content is independent of the dissemination method used. Electronic production and maintenance of high-quality content are at least as expensive as print production and maintenance. For example, with electronic publications, we have come to expect more dynamic papers with clickable references, active links to related articles, and supplemental information — all of which need to be maintained and kept current on the journal’s website and servers. Electronic editorial systems have numerous advantages, but they have also created more work checking the originality and validity of submissions: it has become easier to manipulate images and to plagiarize. Even authors’ and reviewers’ identities may have to be double-checked.”<sup>41</sup>

### **The true cost of digital OA publishing**

The main funding source for OA, the article-processing charge (APC) model, does not fully fund the true cost of OA publishing. According to Delta Think, a consulting and advisory firm focused on innovation and growth in scholarly communications, 36% of all scholarly articles were published as paid-for OA in 2020. This is a 25% increase over 2019, showing the very rapid growth of OA publishing. Yet, the market value of these OA articles represents only about 9% of the total journal publishing market value.<sup>53</sup> APCs for high-quality OA journals are expensive; the average APC was \$1,865 USD (IQR \$800-\$2,205) for high-quality OA journals and \$3,000 USD (IQR \$2,500-\$3,000) for high-quality subscription-based hybrid journals in 2017.<sup>94</sup> Another study has found that, among all the journals listed in the DOAJ, 41% charge more than \$1,000 USD. The average APCs are highest in the field of medicine, with around 50% of titles charging more than \$1,500 USD to publish an article.<sup>113</sup> Despite these high average APCs, they are still lower than the average cost to the publisher of producing an article, which was estimated in 2013 to be \$3,500 to \$4,000 USD, equivalent to \$4,263 to \$4,872 USD in 2022.<sup>42</sup> The 2018 *STM Report: An Overview of Scientific and Scholarly Publishing* noted that the intangible costs of publishing, including editorial activities such as peer review, are higher than the tangible ones, such as production or sales and distribution. Given that editorial activities generate the most value, some published “lowball” estimates of average publishing cost per article that do not take such activities into account may be misleading.<sup>114</sup>

Why are costs to publish online so high? The answer is that technology is neither free nor low cost. In order for a journal to meet Plan S compliance, for example, many requirements must be met, including the following:

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*“Growth in the overall cost of publishing was predictable, because even if online dissemination is less expensive than printing on paper and distributing by mail, the Internet has also opened new ways of presenting content and interacting with researchers and readers that add value but cost money. Most importantly, the cost of producing high-quality content is independent of the dissemination method used.”*

### **The New England Journal of Medicine**

- the use of persistent identifiers (DOIs),
- participation in a long-term digital preservation or archiving program (e.g., CLOCKSS, Portico, PubMed Central, etc.),
- the provision of high-quality article-level metadata, including the name of the funder and grant number, and
- machine readable information about OA status and license embedded in a standard format.<sup>115</sup>

Very few existing OA journals actually meet these requirements, as demonstrated in a 2019 study from Norway.<sup>116</sup> The authors used DOAJ metadata to assess journal compliance with 14 Plan S criteria and found that only 8.8% (1,085 of 12,350) of OA journals met all criteria. When analyzed by journals that charge APCs and those that do not, they found that 2.8% of non-APC journals met all criteria versus 25.6% of APC journals. The authors concluded that the current timeline and structure of Plan S will result in the disappearance of non-APC journals from the market, consolidating the publishing landscape into fewer publishing houses that charge higher APCs.

### **The consolidation of publishers and societies**

One perhaps unintended result of the push towards universal OA and the rising cost of knowledge dissemination has been the consolidation of smaller research societies and independent publishers with the largest, dominant players.<sup>41</sup>

David Crotty, Senior Consultant at Clarke & Esposito and former Editorial Director, Journals Policy for Oxford University Press, noted: “... if the goal was to shake things up and displace the dominant players, then that has not happened, and the net result to date of Plan S has been a massive consolidation of the market. The biggest publishers are growing bigger, and the smaller, independent publishers are abandoning their independence and signing on with the biggest houses.”

From the independent research society perspective, Goodell agreed: “There is going to be even more consolidation among societies and publishers than what we’ve already seen to date. I think that many of the small societies will look to align with larger societies, and if they’re self-published, they’re going to look for a publishing partner. I also think many small societies could dissolve.” She added, “Frankly, few societies will have the staff or funding to be able to execute all of the requirements of a universal OA future as modeled on the requirements of Plan S.”<sup>83</sup>

Crotty pointed out the role that APCs play into this consolidation: “[Societies] exist to instill rigor and drive excellence in research. As part of this, they’ve built highly selective journals to present the very best research results in their field. Unfortunately, these flagship journals don’t really work with an APC model. The more articles you reject, the more expenses you have that have no way of being covered ... [and] as the subscription revenues begin to wane, the APCs alone are not going to be enough to replace them and still maintain current earnings.”<sup>117</sup>

## **Global Diversity, Equity, and Inclusion in Biomedical Research**

One core value of Open Medicine has been to increase the global diversity, equity, and inclusion (DEI) in biomedical and clinical research. The Budapest Open Access Initiative stated: “Removing access barriers to this literature will ... share the learning of the rich with the poor and the poor with the rich ... ”<sup>43</sup> While the current state of Open Medicine does appear to share the learning of the rich with the poor, the reverse is still not the case. In other words, the current state of Open Medicine has not created global health equity and has not allowed researchers from all areas of the globe to participate equally in both biomedical knowledge production and consumption. Instead, it has

*“... if the goal was to shake things up and displace the dominant players, then that has not happened, and the net result to date of Plan S has been a massive consolidation of the market. The biggest publishers are growing bigger, and the smaller, independent publishers are abandoning their independence and signing on with the biggest houses.”*

**David Crotty, Senior Consultant, Clarke & Esposito, and former Editorial Director, Journals Policy, Oxford University Press**

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merely shifted the landscape such that those in LMICs have better access as consumers of knowledge but remain limited in their efforts to be equal players in producing knowledge. There are several reasons for this, including APCs acting as barriers to knowledge production by those in LMICs and funding inequities between researchers in HICs and those in LMICs.

### **APCs are a barrier to LMIC researchers despite waivers**

Bernd Pulverer, Head of Scientific Publications at *The EMBO Journal*, wrote in 2018: “Gold OA is not necessarily the most equitable system ... Since a much smaller number of authors than readers have to shoulder the whole cost of publishing, it accentuates imbalances in funding across nations, research disciplines, and laboratories.”<sup>118</sup> The high cost of publishing in high-quality OA journals limits access mainly to researchers from HICs and excludes those from LMICs. Researchers from LMICs are, knowingly or unknowingly, pushed towards publishing in predatory OA journals instead, thereby lowering the overall global DEI of the legitimate body of biomedical research literature.<sup>119,120</sup> A 2015 study of 8,000 predatory OA journals confirmed that the regional distribution of authorship is highly skewed, with three-quarters of authors hailing from Asia and Africa.<sup>95</sup>

According to Juliet Nabyonga-Orem, Team Leader Health Financing and Investment program, WHO Regional Office for Africa, and colleagues: “Where does this leave African researchers who earn too little (personal income or research grants) to publish in such top-tier open access journals? Already, Africa contributes much too little (1.3% in one estimate<sup>121</sup>) to research publication output globally, of which 52% are accounted for by just three middle-income countries—South Africa, Nigeria and Kenya.”<sup>122</sup>

There are partial or full APC waivers and programs to support researchers from LMICs. These are well-intentioned, but many researchers in LMICs receive such little funding that they are unable to afford even discounted APCs. In other instances, the waiver process lacks transparency or is poorly advertised to authors who may benefit. It is also common that researchers with limited funding are not eligible for waivers because they are based in a country with a per capita income that is too high. Nabyonga-Orem and her colleagues point out that per capita income numbers may not have any relevance to the actual level of funding received by many or most researchers within a given LMIC.<sup>122</sup>

Durga Prasanna Misra, Associate Professor of Clinical Immunology and Rheumatology at the Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, India, wrote: “Speaking from a regional standpoint, the present-day India is still a developing country. In such a scenario, where government funding for research and research publication is suboptimal ... it may be stretching too far to ask the government to cover OA publication charges. ... Indian scientists have to struggle for access to research services which may be considered routine in other parts of the globe, such as plagiarism checks and access to Scopus, Web of Science, and subscription-based aggregators of information. Therefore, it is highly unlikely that Indian scientists or their institutions will be able to afford OA publication fees in the majority of instances.”<sup>123</sup>

Lastly, researchers from LMICs may be ineligible for waivers because they have collaborated with a co-author from a HIC, even when they have received little or no financial support through that coauthor. Not only does this present a funding barrier, it disincentivizes global collaboration in medical research.<sup>122,123</sup>

### **Inequities in funding for biomedical and clinical research**

The DEI discussion must include funders, as they are a key stakeholder in the Open Medicine landscape. Currently, over 99% of biomedical research grant funding is directed towards researchers in HICs, in the US, UK, and the EU, according to the WHO’s Global Observatory on Health R&D in 2019 (**Figure 3**). Indeed, nearly 90% of all biomedical

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*“Where does this leave African researchers who earn too little (personal income or research grants) to publish in such top-tier open access journals? Already, Africa contributes much too little (1.3% in one estimate) to research publication output globally, of which 52% are accounted for by just three middle-income countries—South Africa, Nigeria and Kenya.”*

**Juliet Nabyonga-Orem, Team Leader Health Financing, and Investment program, WHO Regional Office for Africa**

research grants (worth approximately \$32 billion USD) are made to researchers in the USA alone.<sup>124</sup> In contrast, upper-middle income countries receive 0.4% of overall biomedical research grant funding, lower-middle income countries receive 0.3%, and low-income countries, most of which are in the WHO African region, receive just 0.2% of overall grant funding (worth approximately \$0.06 billion USD).

WHO region	High income	Upper middle income	Lower middle income	Low income	Grand Total
Africa		111.44	58.45	63.87	233.76
Americas	32,590.45	28.37	2.02		32,620.84
Eastern Medite..		0.46	5.41	1.08	6.96
Europe	2,377.20	0.61	0.58		2,378.39
South-East Asia		4.82	42.49		47.30
Western Pacific	79.93	11.60	2.78		94.31
Grand Total	35,047.58	157.30	111.73	64.95	35,381.55

**Figure 3. Annual grant amount for biomedical research in 2019 by recipient's WHO region and income group, in millions of USD.<sup>124</sup>**

In that year, the major funding stakeholders were the NIH, which awarded the highest total annual grant amount (approximately \$31 billion USD; 88%), followed by the Bill & Melinda Gates Foundation (BMGF) and the Wellcome Trust (each approximately \$1.08 billion USD; 3.1%). The UK Research and Innovation Medical Research Council (MRC) awarded approximately \$905 million USD (2.6%), and the Canadian Institutes of Health Research (CIHR) awarded approximately \$832 million USD (2.4%). Smaller percentages are awarded by the Semiconductor Research Corporation (SRC, 0.4%), the European & Developing Countries Clinical Trials Partnership (EDCTP, 0.3%), the United States Agency for International Development (USAID, 0.2%), the German Federal Ministry of Education and Research (BMBF, 0.1%), the Pasteur Foundation (0.02%), and the Japan Agency for Medical Research and Development (AMED, 0.007%).

Miranda Walker, President of the Society for Scholarly Publishing, commented: "With Open Medicine, we may be giving researchers and clinicians free access to information, including open source, open code, and open access publications, but fewer funding stakeholders are talking about giving LMIC researchers the tools to utilize the knowledge so they too can contribute to the global body of research. They don't have the materials and infrastructure to build upon previous work or, in many cases, even to implement it."

Science and medicine have long benefited from rigorous experimentalists at all levels of academia and industry.<sup>125</sup> The contributions of scientists working at smaller institutions or in underserved global regions are as vital as contributions made by those employed at the wealthiest and most powerful institutions. This is arguably even more true in medicine than in most fields of science. To draw a contrast of extremes, whereas research on hadrons can, perhaps, only be viable at multi-billion-dollar research sites in Europe or the United States, valuable clinical insights can be gleaned wherever doctors treat patients, which is to say, everywhere. In fact, some key medical insights are best addressed outside of HICs; research on dengue fever or other tropical diseases, for instance, can never be the priority for doctors in London or Boston that it is for clinicians in the parts of the world where patients are most at risk from those diseases. We believe that until biomedical researchers in every part of the world, including and especially LMICs, have access to the funding that they need to conduct and publish serious medical research, closing the global health equity gap will be an illusion, regardless of how freely published content from HICs flows. For the major funders in HICs, rethinking their model to direct more resources to LMICs must become central to the conversation about the future of Open Medicine.

*"With Open Medicine, we may be giving researchers and clinicians free access to information, including open source, open code, and open access publications, but fewer funding stakeholders are talking about giving LMIC researchers the tools to utilize the knowledge so they too can contribute to the global body of research. They don't have the materials and infrastructure to build upon previous work or, in many cases, even to implement it."*

**Miranda Walker, President of the Society for Scholarly Publishing**



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## Part 3: The path to open medicine

The current landscape of Open Medicine does not yet reflect the ideal of global health equity that was put forth more than 20 years ago. In considering a shared path forward, Angela Cochran, Vice President of Publishing at the American Society of Clinical Oncology (ASCO) and Associate Editor of *The Scholarly Kitchen* blog, stated, “There must be a model, not only for publishers, but for all stakeholders – publishers, institutions, funders, and researchers – that addresses the needs of researchers, clinicians, and patients in both HICs and LMICs. We must all understand and commit to the core values in Open Medicine. We must be brave enough and bold enough to try new things.”<sup>126</sup>

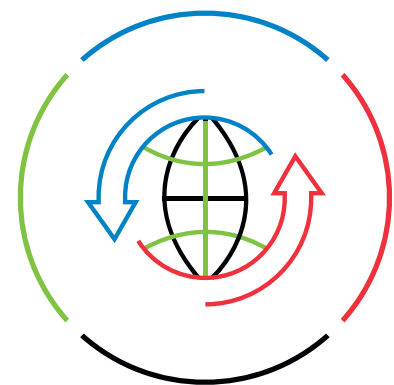
This section examines what “new things” might look like for each group of stakeholders: publishers, institutions, funders, and researchers, with the aim of taking a collaborative, nuanced approach that considers the needs and capabilities of all stakeholders.

### Publishers

#### **Open access**

While the role of publishers within the future of Open Medicine continues to be debated, it is clear that there is a great need for infrastructure development.<sup>127</sup> This would ensure that articles are easily accessible across the many different types, methods, and platforms of OA publishing. The existing OA infrastructures are supported and hosted by different publishers, academic societies, private funding organizations, governments, institutions, and research institutes. One publication can be related to various outputs, including a pre-print, different article versions, open data, and open source/code. Publishers are well-positioned to adapt to these changing requirements of the publishing process with new technologies, including artificial intelligence (AI)-based solutions, which can track and link all elements of publications across various platforms, instead of linking content only from a single organization.

Particularly in Open Medicine, where the consequences of misleading or poor data can have immediate and negative impacts upon patient care and human health, there



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is also a need for publishers to assist researchers and consumers in determining which content may be preliminary and which may be more mature and actionable in a clinical setting. This can be woven into the fabric of emerging technical solutions. One example of innovation in this context is seen in publishers' direct partnerships with preprint servers. About 200 journals, as well as the portable peer review service Review Commons, have partnered with bioRxiv in a streamlined submission process called "B2J", which allows authors to directly submit to participating peer-reviewed journals when they upload a manuscript to bioRxiv. In late 2021, BioRxiv announced a new pipeline for author services, called "B2X", enabling authors to send their manuscripts to a variety of third-party services, such as DataSeer, which scans articles for datasets and provides recommendations on how these can be shared to best navigate open data policies. Other planned services for the future of B2X include " ... groups that assess particular aspects of manuscripts, help authors improve them, or check for compliance with specific funder requirements."<sup>128</sup>

Infrastructure that can assist researchers in the navigation of various OA platforms, the open publication process, and its legal requirements is also urgently needed. The increasing variety of OA publication options and their associated policy and legal concerns is daunting to many researchers and is often cited as a major barrier to publishing scientific work in an OA format.<sup>130-132</sup> Therefore, publishers can provide value by developing tools to guide researchers across the Open Medicine landscape and by taking an active role in engaging researchers through the entire life span of a project.<sup>127</sup>

### **Open data, code, source**

Researchers consistently report that they desire recognition and credit as a facilitating factor for open data sharing, both from other researchers and from institutions and funders (the Reputation Economy).<sup>130,133-135</sup> A survey study of biomedical researchers found that 81% endorsed the statement that having formal data citations in journal articles would motivate them to share their datasets openly.<sup>133</sup> To recognize the value of open data and ensure credit to researchers who generate and archive open data, a variety of scientific policy organizations, such as CODATA<sup>136</sup>, the European Commission<sup>127</sup>, the US National Academy of Sciences<sup>48</sup>, and the Royal Society<sup>47</sup>, now recommend that scholarly publications treat primary data as first class research objects in line with the FAIR principles (Findable, Accessible, Interoperable, Reusable), which were first described in 2016.<sup>137</sup>

Many publishers are responding to the above recommendations by crafting data sharing policies, which may vary by specific publication title or may be unified across publications. It is important that policies indicate to researchers which datasets to cite, such as citing only underlying data or including relevant data not used in the analysis. Formatting should be specifically described; ideally, data citations should appear in the standard reference list in a format similar to standard literature references, which are both human and machine readable. The infrastructure policies should also provide guidance around Data Availability Statements. The trend is moving toward encouraging or requiring authors to deposit data in suitable publicly available repository, rather than simply stating that data are available on request or including data in supplementary information files, which are not machine readable.<sup>139</sup> Two key resources for finding suitable repositories are The Registry of Research Data Repositories<sup>140</sup> and the list of recommended repositories maintained by FAIRsharing.org.<sup>141</sup>

Jason Miller, Chief Operating Officer at *The Journal of Bone & Joint Surgery*, noted, "In scientific, technical and medical publishing, the next five to ten years will bring the next phase for data sharing. While human interaction with data and interpretation of that data will always be crucial through reading or listening to the narrative content of journal articles, machine readable, open data sharing is critical to really move Open

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### **A Preprint Server with Real-Time Feedback: Lippincott® Preprints<sup>129</sup>**

In an effort to reduce the risks often associated with preprint articles, Wolters Kluwer has recently launched Lippincott® Preprints, a server that allows readers to submit feedback and ratings on articles relevant to the medicine, nursing, and allied health communities. Comments and ratings are moderated and are displayed in such a way that readers can answer the question 'is this an article that would advance the science?' as well the flip side, 'is this an article that is a concern for patient safety?'. Before posting, all preprints submitted to Lippincott® Preprints undergo a moderation process (5–6-day turnaround time) to ensure that the paper is of a scholarly nature, is based in medicine, nursing or allied health, is written in English, and does not contain any inappropriate, confidential, harmful, or copyrighted materials used without permission.

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Medicine forward. Researchers will be more likely to buy in if they are given citation credit for being willing to take a risk and share data.”

He suggested that publishers may find it useful to increase awareness of the benefits of open data sharing among authors. For example, biomedical publications that contain a link to data in a repository receive approximately 25% more citations than those publications that indicate that data are available upon request or that present data in supplementary files.<sup>142</sup> Far from being inferior “parasitic studies”, studies that rely upon shared data are well-represented in moderate-to-high-impact journals. A 2018 *Nature* study utilizing open neuroimaging data demonstrated that openly shared data can increase the scale and sample size of scientific studies and can induce scientists from a broader range of disciplines to collaborate.<sup>143</sup>

### ***Global diversity, equity, and inclusion***

One of the most common publisher strategies to increase global DEI in the Open Medicine landscape is to offer APC waivers to authors and institutions in LMICs. As previously mentioned, significant variation exists in APC waiver policies, which may have the consequence of introducing or exacerbating disparities in global research. A recent analysis in the field of oncology revealed that the average cost of APCs is significantly higher in hybrid OA journals as compared to their full OA counterparts (\$3,161 v \$1,671 USD, respectively), and that hybrid journals are less likely to offer APC waivers for LMIC authors. Journals with the highest APCs (generally those with high impact factors) also offered waivers less frequently than those with lower APCs.<sup>144</sup> These trends are troubling, and may lead to the Open Medicine community losing high-impact knowledge from global colleagues. Publishers can take a proactive role by examining their portfolios from the perspective of increasing LMIC researcher access to APC waivers; this may include raising awareness of fee waivers, streamlining application processes, increasing waiver-eligible titles, and increasing the number of countries that have access to waivers.

Another common strategy to increase global DEI in the biomedical publishing landscape is to provide free or low-cost access to health-related academic literature to institutions and researchers in LMICs. For example, Research4Life’s Health Internetwork Access to Research Initiative (HINARI) program is a collaboration between the World Health Organization, other United Nations agencies, Cornell University, Yale University, the International Association of Scientific, Technical, and Medical Publishers, and nearly 200 publishers. Research4Life provides, at little or no cost, 10,500 institutions in over 125 LMICs with free or low-cost online access to some 154,000 leading journals and books in the fields of health, agriculture, environment, applied sciences and legal information.<sup>145</sup> Still, the program is limited by certain factors.<sup>146</sup> These include a lack of awareness, training, and reach in eligible countries; technical issues encountered by users; a language barrier with the vast majority of content in English; lack of regional and local content; and the limited number of OA publications included for Group B (low-cost) countries as opposed to those included for Group A (no-cost) countries. Further, institutions in Group B countries may still find the \$1,500 annual fee out of reach. Publishers can play a role in bolstering Research4Life by partnering with the program, contributing greater levels of OA content, and reducing costs.

Lastly, low- or no-cost read-and-publish agreements are increasingly being offered to institutions in LMICs, ensuring OA for readers and authors from those institutions. For example, Wiley recently announced a four-year agreement with the South African National Library and Information Consortium, a consortium of public South African universities and research institutions.<sup>147</sup> The agreement provides OA to all of Wiley’s journals and enables researchers to publish accepted articles OA in Wiley’s hybrid journals. From January 2023 onward, a pilot program will allow researchers to publish in Wiley’s gold OA journals, including journals published by Hindawi. Wiley has

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### **Lippincott® Data Repository<sup>138</sup>**

Wolters Kluwer is providing authors with the option to easily share the data supporting their findings through the Lippincott® Data Repository. All authors who submit research to Lippincott journals can also provide data to the Data Repository through an integrated submission process. The repository provides options to authors and directly addresses data availability needs and mandates.

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also agreed to work with SANLiC and its members to deliver additional support to researchers, including research publishing training workshops, online access to the Wiley Researcher Academy, and editorial resources.

Further work is needed to promote equity in the scientific publishing process, such as:

- journals and publishers can consider more nuanced tiered fee schedules and waivers not just for countries, but for different types of institutions or for various levels of funding that might be available to researchers in different local areas or career stages.<sup>148</sup>
- journals can update the demographic composition of their editorial boards, publication teams, and peer reviewers to increase representation from institutions and individuals in LMICs, people of color, women, and other underrepresented groups.
- editorial policies can reflect a commitment that any article submitted that reports results from research or experiences in specific LMICs should include authors from these countries.
- where English language barriers hinder publication opportunities, editorial teams can address these barriers with authors by offering editing or other services.
- publishers can commit to holding themselves accountable for meaningful follow-through on commitments to change.<sup>149</sup>

## Institutions

### Open access

Institutions and libraries can support OA in several ways, including providing education and information to researchers and students, creating institutional repositories, establishing OA publication funds, converting institution-based journals to OA, and negotiating Read and Publish agreements (also known as Transformative Agreements) with publishers that combine subscription spend with OA publication fees in complex deals. This would facilitate a higher rate of uptake of OA publishing options by the institution's researchers. Many institutions are now enacting institutional OA policies, which typically mandate and provide guidelines for open dissemination of publications, scholarly research tools, and data by institutional researchers. These policies help authors to navigate the publication process, and help preserve academic freedom, author choice, and consistency with copyright law.<sup>150</sup> Peter Suber, JD, PhD, Director of the Harvard Office for Scholarly Communication, has developed a widely consulted guidance document for institutions.<sup>151</sup> The document is based on the OA policy first adopted at Harvard, Stanford, and the Massachusetts Institute of Technology. It provides descriptions of six different types of OA policies and offers practical guidance in choosing, drafting, adopting, implementing, and marketing a policy. Other resources include the Coalition of Open Access Policy Institutions toolkit<sup>152</sup> and the Registry of Open Access Repository Mandates and Policies, a searchable international registry charting the growth of OA mandates and policies adopted by universities, research institutions and research funders.<sup>153</sup>

Another key factor in supporting open science in general, and Open Medicine in particular, is reducing reliance on impact factors when evaluating researchers for promotion or tenure, and instead rewarding Open Medicine practices more rigorously, such as OA publishing and the open sharing of data, source, code, and other materials.<sup>103,130,131,154</sup> According to Goodell, "Until institutions across the globe reduce competitive evaluation practices and give less consideration to the impact factor, their researchers have very little motivation to publish OA and to openly share their data and resources. The truth is that open science isn't just about publishers. We all have to work

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*"In scientific, technical and medical publishing, the next five to ten years will bring the next phase for data sharing. While human interaction with data and interpretation of that data will always be crucial through reading or listening to the narrative content of journal articles, machine readable, open data sharing is critical to really move Open Medicine forward."*

**Jason Miller, Chief Operating Officer,  
The Journal of Bone & Joint Surgery**



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together – publishers, funders, institutions, libraries, researchers – to make lasting, real changes to the way biomedical research is funded, conducted, disseminated, and validated.”<sup>83</sup>

One example of efforts to address this issue is the San Francisco Declaration on Research Assessment (DORA). A total of 22,165 individuals and organizations in 159 countries have signed DORA to date. The overarching general recommendation of DORA is that “... funders, institutions, publishers and researchers should avoid using journal-based metrics, such as impact factors, as a surrogate measure of the quality of individual research articles, to assess an individual scientist’s contributions, or in hiring, promotion, or funding decisions.”<sup>155</sup> DORA also recommends action items geared toward each stakeholder.

### **Open data, code, source**

Traditional institutional systems for evaluating researchers do not generally value or credit open data to the same degree that journal articles or books are valued. This acts as a barrier to researchers fully embracing open data.<sup>103,130,131,154</sup> Consider a recent research study that aggregated over 120,000 magnetic resonance imaging scans from more than 100 studies to craft brain development charts that are analogous to developmental height/weight growth charts.<sup>156</sup> Some of the data used in the study were open data, and some data were constrained by formal data-access agreements. As reported in an April 2022 *Nature* editorial, researchers whose data were constrained prior to the study start became active co-authors of the paper before sharing their data; however, those whose data were open from the start were credited in the citations and acknowledgements only. The editorialist commented, “Such a practice is neither new nor confined to a specific field. But the result tends to be the same: that authors of openly shared data sets are at risk of not being given credit in a way that counts towards promotion or tenure, whereas those who are named as authors on the publication are more likely to reap benefits that advance their careers. As long as authorship on a paper is significantly more valued than data generation, this will disincentivize making data sets open.”<sup>154</sup>

“Many researchers are afraid of being scooped,” said Walker. “Let’s say a researcher openly shares all the data they have worked years to collect and create. What happens to their tenure application when someone else analyzes that data and publishes something ahead of them? All they get is an acknowledgement in the publication. Right now, that tenure committee cares little for the fact that the researcher created a valuable dataset and shared it openly, nor do they care about that acknowledgement. But the committee could care. Open data could count.”

Another opportunity that institutions, specifically universities and medical schools, have to further the spread of open data is to teach data management and data sharing practices explicitly in the curricula, via departmental trainings, and/or through institutional library programs. To do so, institutions will need to fund data-science centers and academic data managers. The need is clear. The European Commission conducted a survey in 2018 and reported that only 28% of researchers believe that they had received sufficient training in data sharing.<sup>127</sup> This gap was starkly illustrated by a recent study that analyzed the content of data availability statements and the actual sharing of raw data in preprint articles about COVID-19 posted on medRxiv and bioRxiv from January 1, 2020 to March 30, 2020. Of the 283 preprints that reported that data were accessible, raw data/code were located for only 47%. The authors wrote, “Despite very clear descriptions about what is expected to be in the data availability field, some authors wrote strange information in that field, for example, information about competing interests, or information that is difficult to interpret, such as ‘All authors agree that all data submitted here are publicly available.’ Furthermore, many authors wrote that ‘all data’ are in the manuscript or accompanying files, but neither

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**Miranda Walker, President of the Society for Scholarly Publishing**

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the manuscript nor the associated files contained raw data; this implies that authors may not be aware ... that data sharing implies sharing of raw data collected within the study. ... Education of researchers about the meaning of data sharing is needed".<sup>157</sup>

In the future, institutions and researchers alike will be well-served by shifting data-sharing responsibilities to institutions. Barend Mons, a molecular biologist at Leiden University Medical Center in the Netherlands who advises the European Commission on open science, said: "The biggest mistake people are likely to make is trying to train every young researcher to be a half-baked data steward." He suggests that institutions should hire one open science specialist per 20 researchers to assist with data curation and sharing.<sup>134</sup>

### ***Global diversity, equity, and inclusion***

There are many strategies institutions can implement that will, collectively, work to increase global DEI in biomedical research conduct and dissemination. Institutions in LMICs can seek and provide stable funding for research and development activities, including Open Medicine infrastructure and training (see Funders, below). Once funding has been secured, there is more for institutions to do:

- establish incentives for scientific research and publications,
- promote and support training of young researchers,
- create tenure-track academic positions with significant research dedication,
- create PhD programs at the institutional and/or regional level,
- offer and advertise continuing education opportunities in biostatistics, biosafety, scientific writing, and navigation of Open Medicine methodologies and infrastructure, and
- advocate for stronger collaborations among institutions across various LMICs.<sup>158</sup>

Looking beyond academe, leveraging influence in government and policy may be a possible path for institutions in some LMICs to increase global DEI in biomedical research. Between 1996 and 2019, researchers from the US and China produced more than one-third of the global research publications, and researchers in Western European countries collectively produced nearly another third. Yet, researchers in the remaining 210 countries published at levels ranging from moderate to almost none.<sup>159</sup> Investment in science is the largest driver of these differences.<sup>160</sup> The US invests 2.83% and China invests 2.14% of their GDPs, respectively, in research and development. However, with the exception of Brazil (1.26% of GDP), most Central American countries invest between 0.024% of their GDP (Costa Rica) to 0.002% (El Salvador and Honduras) in research.<sup>159</sup>

Gustavo Fontecha, MQC, MSc, PhD, Professor of Microbiology at the National Autonomous University of Honduras, recently wrote an eloquent case study of the state of research investment that exists presently in his home country. He states, "Contemplating this post-COVID-19 grim scenario [for research support in LMICs], LMICs researchers as well as the institutions and governments that support them have two choices. The first, to accept what seems the inevitable fact of perpetual underdevelopment and dependence on international cooperation. The second and more difficult is to find opportunity in the challenge, to learn from the crisis and emerge stronger. This was the case ... after the 2009 H1N1 pandemic, [when] Mexico decided to build laboratories across the nation and invested in the modern Institute of Diagnostic and Epidemiologic Reference. ... Under proper leadership, with permanent governance and research structures, as well

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as with sustainable financial support, countries can advance their scientific productivity and make meaningful contributions to their own citizens in particular and to the rest of the world in general. The time to decide what choice to make is now.”<sup>158</sup>

Fontecha, along with his colleagues, suggest that, if LMICs wish to compete in a post-COVID biomedical research landscape, possible avenues forward may include:

- allocating at least 2% of the GDP to research and development,
- creating a national health research bureau and policy,
- crafting national standards for research ethics with human and animal subjects,
- creating national standards for biosafety and biosecurity,
- promoting collaboration with governments and institutions from HICs, and
- seeking guidance from international organizations such as the Pan American Health Organization’s Advisory Committee on Health Research<sup>161</sup> or the Council on Health Research for Development<sup>162</sup>, among others.<sup>158</sup>

Researchers and institutions in HICs may be tempted to believe that collaborations between themselves and researchers/institutions in LMICs can “solve the problem” of a lack of global DEI in biomedical research funding, conduct, and knowledge dissemination. Researchers in LMICs report considering pursuing collaborations with researchers in HICs if they feel that such collaborations will be equitable and beneficial. However, the truth is that most collaborations mainly benefit the researchers in HICs.<sup>163</sup> A large bibliometric analysis of scientific articles from the African region published between January 2014 and June 2016 in the four most prominent general medicine and five most prominent general global health journals based on impact factor revealed that corresponding authors with either exclusive or joint appointment to an LMIC institution were present in just 26.2% of all included articles, and 28.8% of publications did not list a local author at all.<sup>164</sup>

According to Mark Urassa, MA, MS, National Institute for Medical Research, Mwanza, Tanzania and colleagues:<sup>163</sup> “Recent months have witnessed a remarkable focus on racism and racial justice, along with global commitments to anti-racism ... Often missing from this discussion among high-income country (HIC)-based researchers, however, is the promotion of equitable collaboration in cross-cultural research with national universities and research centers in low and middle-income countries (LMICs).” In regard to collaborations between LMIC and HIC researchers, Urassa *et al.*<sup>163</sup> noted : “ ... where LMIC researcher contributions are made in HIC-led projects, they are often deemed unworthy of authorship status, and payment for services is rarely channeled through institutional overheads capable of fostering national research infrastructure and career development. These norms are extractive and woefully outdated, and until they are challenged and overturned, cross-cultural research on human behaviour will remain a robustly colonial enterprise.”

How can collaborations between HICs and LMICs provide benefits to all involved? Urassa *et al.*<sup>163</sup> provide useful suggestions for researchers in HICs. When planning research projects, HIC researchers can factor LMIC institutional overheads and capacity building activities into research at the planning stages and avoid ‘token’ LMIC co-authorship by collaborating genuinely in both intellectual and financial ways. When projects are ongoing, HIC researchers can provide training to LMIC universities and institutions when visiting to collect data or for other research activities, and can share unused field equipment with LMIC partners when not in active use for project data collection. When discussing research activities, it is critical that HIC researchers avoid possessive references to study communities (e.g., “my field site”), which propagate harmful

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**Mark Urassa, MA, MS, National Institute for Medical Research, Mwanza, Tanzania, and colleagues**

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connotations about ownership of access to a LMIC community. At the institutional level, HIC institutions can provide rewards for the time and effort required by HIC researchers to forge equitable collaborations with LMIC researchers.

In turn, researchers and institutions in LMICs can participate in the planning stage by proactively negotiating authorship, author position, and equitable data sharing practices with HIC researchers and institutions, and they can reject non-equitable proposals. When considering funding, LMICs can seek international grants and budget transparently within the institution to reduce financial dependence on HIC institutions. LMIC authors can negotiate to increase visibility through presenting collaborative and independent research at international conferences and taking advantage of OA publishing fee waivers to publish in international journals when feasible.<sup>163</sup>

Both HIC and LMIC institutions can work together to broadly and vocally acknowledge inequities in cross-cultural research norms, advocate for change, and campaign funders to facilitate equitable funding between HIC and LMIC institutions. HIC and LMIC researchers also can adopt flexible research agendas, explore shared priorities with collaborative partners, and embrace OA publishing and open data, source, and code practices. Institutions across the globe can strengthen teaching around the dangers of extractive research from LMICs to HICs and develop mentoring arrangements between HIC and LMIC researchers in the areas of project design, funding applications, English language proof-reading, publishing, and navigating the Open Medicine ecosystem. All countries can support LMIC-based journals and academic societies; and work to locate international society meetings in LMICs and/or virtually.<sup>163</sup>

## Funders

### ***Open access***

Funders are aware of the benefits of OA publishing and are powerful stakeholders for driving uptake. However, an equal awareness of the costs and time involved in OA publishing and the need for funders to take an active role are critical to the overall success of Open Medicine.<sup>42</sup> The Open Research Funders Group, a partnership of funding organizations committed to the open sharing of research outputs under the auspices of the Scholarly Publishing and Academic Resources Coalition, speaks directly to this issue: “Having funded the most expensive component of the research life cycle (the research itself), the incremental expense and effort required to ensure open sharing of the findings is modest by comparison. If you run a foundation committed to tackling a complex set of issues, ask yourself - Do I want more or fewer people to have access to the work we are funding? Do I want more or fewer researchers to be able to validate and build upon these findings? Do I want more or fewer practitioners and policy makers to be able to incorporate this work into their own activities? Do I want this access to happen more quickly or less quickly? The bottom line is that when a philanthropy commits to the open sharing of the research it funds, the audience for that work blossoms exponentially.”<sup>165</sup>

As discussed in Part 2, the cost of APCs in high-quality OA journals are commonly identified as an obstacle to OA publishing, particularly for researchers in LMICs. In a proactive response, more and more funders are releasing specific policies under which those costs are eligible for reimbursement from research grants — and are encouraging or requiring researchers to budget for them in funding applications. Indeed, the 2022 US OSTP memo “Ensuring Free, Immediate, and Equitable Access to Federally Funded Research” states, “ ... federal agencies should allow researchers to include reasonable

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publication costs and costs associated with submission, curation, management of data, and special handling instructions as allowable expenses in all research budgets.”<sup>52</sup> Other funders are stepping forward with grants specifically designed to fund OA costs for researchers who have fixed-term project grants that lack funds for OA cost reimbursement.<sup>127,166</sup> A recent *Nature* study confirms that when funders require OA publication as well as provide the funding for researchers to do so, nearly all researchers in the fields of biomedicine, clinical medicine and health research do comply.<sup>167</sup>

In addition to direct funding for APCs and other costs of OA publishing to researchers, there is a history of funder support for OA publishing infrastructures including:

- the Public Knowledge Project, which develops and maintains Open Journal Systems,
- the Collaborative Knowledge Foundation,
- many preprint servers hosted by the Center for Open Science and the Scientific Electronic Library Online,
- repositories, including PubMed Central and EuropePMC, and
- repository aggregators and abstracting/indexing services, including OpenAIRE, SHARE, LA Referencia, and the OAPEN Library.<sup>168</sup>

Another approach more recently taken by some funders is the development of OA publishing platforms commissioned by the funding organizations themselves, such as the Wellcome Open Research<sup>169</sup>, Gates Open Research<sup>170</sup>, and the European Commission’s Open Research Europe<sup>171</sup>, among others.<sup>168</sup> Many are contracted to the OA publishing platform F1000Research and follow its publishing model. Given the increasing success of these partnerships, in July 2017, F1000 announced Open Research Central, a centralized indexing service and portal through which researchers will be able to submit papers to any of the F1000-powered open research publishing platforms.<sup>172</sup>

Funders are demonstrating that they can accelerate OA via market interventions that encourage the development of new publishing models and prompt desirable innovation in the scholarly communication landscape. There is even more they can do moving forward, such as:

- increase researcher input around needs and attitudes,
- provide different options tailored to diverse global communities (including exploration of commercial models that move beyond the APC),
- ensure leadership independence by fostering a broad community of experts to govern all aspects of the platform, to ensure transparency around revenue-management and publishing processes, and
- embrace interoperability at all levels.<sup>168,173</sup>

### **Open data, code, source**

Funders are also well situated to be major drivers of Open Data. According to the Sherpa Juliet database, about 18% of research funders encourage and 30% require researchers to share data openly.<sup>174</sup> Examples include the NIH, the Wellcome Trust, the European Research Council, and the European Commission. Yet, many research funders worldwide (42%) still have no policy regarding open data, and 8% do not mention whether or not they have a policy.<sup>174</sup>

For funders considering implementation of open data policies, it should not be controversial to ask grantees to 1) ensure that any consent forms used for research projects involving human subjects allow for de-identified open data-sharing, 2) to acquire digital object identifiers for datasets to facilitate citations, 3) to cite datasets

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within any publications, 4) to clarify within publications where datasets can be accessed, and 5) to share metadata to facilitate machine readability.<sup>175</sup> Other possible requirements include asking researchers for data management plans with funding applications, for underlying publication data to be shared openly, for all data to be shared openly (when reasonable), for grantees to share data in a public repository, and to share data within a specific time frame (e.g., immediately upon publication, or after 6 to 12 months of receiving a grant, etc.).

Given the significant financial and time costs associated with data sharing that act as inhibiting factors,<sup>130</sup> funders might consider asking grantees to specify the anticipated costs for data sharing in their data management plans and then commit to covering those costs. Some funders offer professional incentives to reward and credit data sharing, such as asking grantees to list their shared data in funding applications, as is done at Wellcome Trust.<sup>176</sup> To reduce the burden of requiring data management plans, funders might offer workshops or trainings and provide example plans or templates.<sup>175</sup> Moving forward, increased awareness of their key role as stakeholders and drivers of Open Medicine may prompt research funders to stimulate and directly reward open data sharing and open collaboration. One example is The Dutch Research Council, which in 2020 launched a grant program for which proposals must directly promote innovative ways to increase open access, open data, open source/code, and open collaboration in scientific fields.<sup>177</sup>

### **Global diversity, equity, and inclusion**

Over the past two decades, a group of funders has stepped forward to prioritize increased global DEI in biomedical and health systems research by creating funding programs targeted to researchers in LMICs and to those in HICs that collaborate equitably with researchers in LMICs. These funders include the Fogarty International Center<sup>178</sup>, the Global Health Research Centres Programme<sup>179</sup>, the Bill and Melinda Gates Foundation<sup>180</sup>, and Wellcome<sup>181</sup>, among others. While this is a very welcome development, the level of impact achieved is still nascent, and more must be done. Walker noted: “Publishers can provide information and data to researchers, institutions, clinicians, and public health officials in LMICs for low or no cost through various Open Medicine initiatives. What we cannot do is provide the physical tools necessary for researchers and clinicians in LMICs to grow *new* research. What about microscopes, chemical compounds, hardware, pharmaceuticals, imaging technology, and all the other infrastructure necessary to implement new findings and to build on them? This is where funders step in and take the lead.”

Bridget Pratt, PhD, Bioethics Researcher at the Nossal Institute for Global Health and Centre for Health Equity at the School of Population and Global Health at the University of Melbourne, Australia, and Adnan A. Hyder, MD, MPH, PhD, Senior Associate Dean for Research and Professor of Global Health at the Milken Institute School of Public Health of George Washington University, USA, conducted an investigation of various funding strategies that carry the goal of incentivizing research that promotes health equity in LMICs. They interviewed grant officers working for 11 major funders of health research in LMICs, including Wellcome, the Rockefeller Foundation, and the European Commission. The authors pinpointed six features of funded projects that successfully advanced health equity in LMICs: 1) research being conducted with the worst-off countries and populations within them; 2) projects focusing on topics that advance equitable health systems; 3) projects being led or co-led by LMIC institutions and researchers rather than led by those from HICs; 4) researchers collaborating and/

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*“Publishers can provide information and data to researchers, institutions, clinicians, and public health officials in LMICs for low or no cost through various Open Medicine initiatives. What we cannot do is provide the physical tools necessary for researchers and clinicians in LMICs to grow new research. What about microscopes, chemical compounds, hardware, pharmaceuticals, imaging technology, and all the other infrastructure necessary to implement new findings and to build on them? This is where funders step in and take the lead.”*

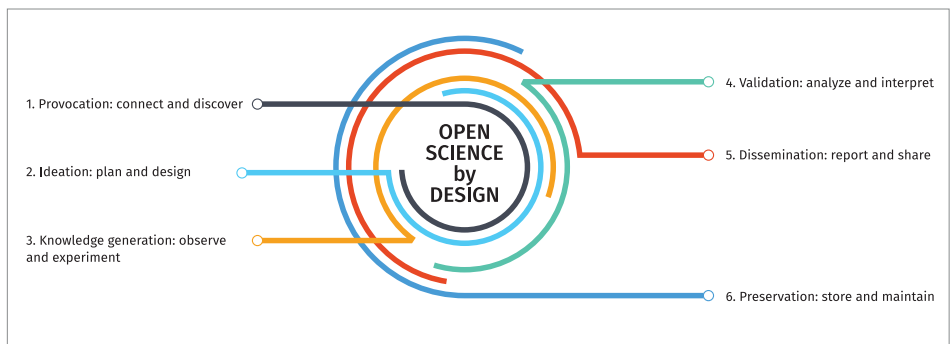
**Miranda Walker, President of the Society for Scholarly Publishing**

or consulting with policymakers and disadvantaged groups within LMICs; 5) projects committed to developing a critical mass of researchers and institutions in LMICs; and 6) work promoting lasting changes to health systems that benefits disadvantaged groups in LMICs.

Pratt and Hyder wrote: “Theories of justice from political philosophy establish obligations for parties in high-income countries to improve the health of parties in low and middle-income countries, with priority going to worst-off individuals ... [W]hile much attention can be focused on researchers’ role in generating knowledge to improve healthcare and systems for the worst-off, they operate within a larger structural context where funders set the rules for resource allocation to health research. The capacity of researchers to uphold their obligation of justice is fundamentally impacted by whether or not research funders uphold theirs. ... It is suggested that research funders ought to create and maintain funding schemes with strong incentives for the features identified above in order to more effectively help reduce global health disparities.”<sup>182</sup>

### Researchers

As academic publishers, institutions, and funders make fundamental shifts to their policies and reward structures to facilitate greater data sharing, researchers may find that historical barriers to open data are beginning to fall away. Yet, challenges remain that researchers themselves can ameliorate. Alexa McCray, a knowledge representation researcher at Harvard Medical School and co-chair of the National Academies of Sciences, Engineering and Medicine Board on Research Data and Information, suggests that researchers should work to practice “open science by design”.<sup>48</sup> As reported by the National Academies in their report by the same name, researchers can leverage open science technologies and principles at every stage of a research project (**Figure 4**).



**Figure 4. Open science by design at every stage of the research life cycle.**<sup>48</sup>

In the **provocation phase**, researchers search OA, open data, and open source/code archives. Database and text mining tools, including AI-based tools, can be used to identify new concepts, pinpoint gaps in the body of scientific knowledge, find unanswered research questions, and identify where novel contributions can be made. In the **ideation phase**, researchers prepare to apply for funding by creating a data management plan, and in some cases, preregistering research plans and protocols in an open repository. Researchers seek guidance on which open data repositories are favored by their discipline or required by their funder/institution. This will guide data storage and structuring throughout the project. During the **knowledge generation phase**, web-based electronic notebooks are used to store data and code, rather than paper notebooks or locally stored data files. These latter storage formats require significant time and energy for data curation and sharing at the end of a project, which should be avoided.

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In the **validation phase**, open data techniques are used to analyze, interpret, and confirm findings, which may then be presented at conferences and on preprint servers for open peer review and refinement. Next, researchers submit articles for OA publication. During the **dissemination phase**, researchers revise and improve their work based on formal and informal peer review. Upon acceptance of their work, they select a public copyright license. They adjust the metadata describing their data and code to improve machine and human readability and usability. Finally, in the **preservation phase**, researchers deposit final peer-reviewed articles into an open archive. They place research data, code, and sources into FAIR data archives, and they provide clear and persistent links from the article. The Center for Open Science, a non-profit organization in Charlottesville, Virginia, has created a set of web badges that researchers can affix to papers and data sets to highlight that their data are open, which have been shown to increase subsequent citations.

This may seem like a daunting vision for researchers who have not been trained in open science techniques. Researchers can take advantage of training programs offered by libraries or training projects such as OpenAIRE<sup>183</sup>, FOSTER<sup>184</sup>, or ORION<sup>185</sup> to learn the necessary skills. As described above, institutions would be well-served by hiring open science specialists to assist with data curation and stewardship.







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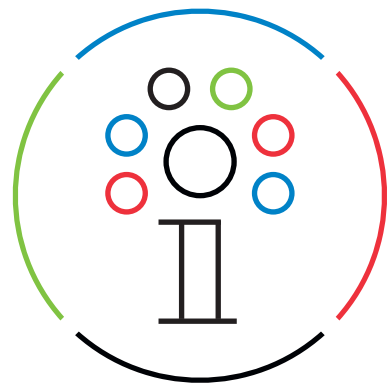
# Conclusion

When the early-modern era of openness in health research, known as the “Republic of Letters,” gave way to the rise of subscription journals and project-based funding sources and methodology by the mid-1900s, the landscape of global health information production and consumption shifted in ways that the global health community is still grappling with today. As scholarly journals and funding were highly concentrated in HICs, so too were those researchers who were elevated into the role of knowledge producers. Researchers in LMICs have endured centuries of being forced into a “knowledge consumer” role without regard to the essential contributions that they can (and do) make to the global health community. We are all, collectively, the poorer for it, both in the depth and breadth of knowledge left unshared and in the cost of human lives lost.

The rise of the Open Science movement in the early 2000s embodied a set of core values that were meant, among other things, to improve global health equity and ameliorate the historic injustices that had become entrenched in the global healthcare community. As the Budapest Open Access Initiative Declaration, The Bethesda Statement on Open Access Publishing, and The Berlin Declaration on Open Access to Knowledge in the Sciences and Humanities stated, these core values include:

- academic freedom and human rights for all,
- the bringing together of diverse knowledge sources, and
- open, rigorous scrutiny of research methods, outputs, and evaluation processes by researchers from all parts of the world.

Further, Open Science asserts that the benefits of global health knowledge should be universally shared, and the scientific process should be inclusive, sustainable, and equitable and include opportunities for scientific education and capacity development across nations. Open Science values the voices and expertise of Indigenous peoples, local communities, and underrepresented groups and empowers researchers from all countries to be both producers and consumers of knowledge.



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We, as a global health community, have not yet achieved these ideals. One of the main barriers in reaching these ideals has been the notion that global health equity can be attained through the actions of a single category of stakeholder. It has been argued by some that perhaps publishers are solely responsible for global health inequities in research production and consumption. At other times, it has been posited that perhaps the problem is institutions, or researchers, or funders.

Wolters Kluwer believes that global health equity can only be achieved if the global health community agrees to work collaboratively. All stakeholders, including publishers, institutions, funders, and researchers, have roles to play and commitments to keep. No single stakeholder can achieve the goals of Open Medicine when acting alone. In this position paper, we have articulated the challenges and opportunities for each of these stakeholder groups (summarized in **Tables 1-4**).

Although the current landscape of Open Medicine does not yet reflect the ideals and values that were put forth more than 20 years ago and that continue to be affirmed by the global scientific community, a shared path to improvement is visible. As an active participant in the evolving Open Medicine landscape, Wolters Kluwer is committed to quality and integrity in the scientific process, working toward the collective benefit of research for global humanity, advocating for equity and fairness among researchers and citizens from all countries, and embracing diversity and inclusiveness to support global needs, including those of indigenous peoples, local communities, and underrepresented groups. We are proud to work in concert with all stakeholders, including funders, publishers, institutions, and researchers, to engage in open dialogue and to strive together toward a better future. As Angela Cochran so eloquently framed it, we commit to being “brave enough and bold enough to try new things.”

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# Tables

Table 1. Recommendations for Publishers

<b>Publishers</b>
Develop infrastructure to ensure that articles are findable and accessible across the many different types, methods, and platforms of OA publishing.
Develop infrastructure that can assist researchers in the navigation of various OA platforms as well as the open publication process and its legal requirements.
Recognize the value of open data and ensure credit to researchers who generate and archive open data by treating primary data as first class research objects in line with the FAIR (Findable, Accessible, Interoperable, Reusable) principles.
Craft data sharing policies that indicate to researchers which datasets to cite, how to format data citations in the standard reference list to ensure they are both human and machine readable, and how to create useful Data Availability Statements.
Encourage or require authors to deposit open data in suitable publicly available repositories.
Increase awareness of the benefits of open data sharing among authors.
Examine portfolios from the perspective of increasing LMIC researcher access to APC waivers, which may include raising awareness of fee waivers, streamlining application processes, increasing waiver-eligible titles, and increasing the number of countries that have access to waivers.
Bolster Research4Life by partnering with the program, contributing greater levels of OA content, and reducing costs.
Offer low- or no-cost read-and-publish agreements to institutions in LMICs, ensuring OA for readers and authors from those institutions.
Increase transparency around the costs of publication.
Consider more nuanced tiered fee discounts and waivers not just for countries, but for different types of institutions, or for various levels of funding available to researchers in different local areas or career stages.
Increase representation on editorial boards, publication teams, and peer reviewers of institutions and individuals in LMICs, people of color, women, and other underrepresented groups.
Craft policies that reflect a commitment that any article submitted that reports results from research or experiences in specific LMICs should include authors from these countries.
Work with authors to address language barriers.

Table 2. Recommendations for Institutions

<b>Recommendations for All Institutions</b>
Provide education and information about Open Medicine to researchers and students. Teach related data management and data sharing practices explicitly in the curricula, via departmental trainings, and/or through institutional library programs.
Establish institutional repositories for publications, data, source, and code.
Establish OA publication funds.
Purchase institutional subscriptions that provide discounts on OA publication fees.
Convert institution-based journals to OA.
Enact institutional policies that mandate and provide guidelines for open dissemination of publications, data, source, and code.
Reduce reliance on impact factors when evaluating researchers for promotion or tenure; instead reward OA publishing and the open sharing of data, source, code, etc.
Fund open science specialists, data science centers, and academic data managers.

<b>Recommendations for All Institutions</b>
Acknowledge inequities in cross-cultural research norms, advocate for change, and campaign funders to facilitate equitable funding between HIC and LMIC institutions.
Adopt flexible research agendas, explore shared priorities with collaborative partners, and embrace OA publishing and open data, source, and code practices in all collaborations.
Develop mentoring arrangements between HIC and LMIC researchers in the areas of project design, funding applications, English language proof-reading, publishing, and navigating the Open Medicine ecosystem.
Support LMIC-based journals and academic societies and work to locate international society meetings in LMICs and/or virtually.
<b>Recommendations for Institutions in LMICs</b>
Seek out and provide stable funding for research and development activities, including Open Medicine infrastructure and training.
Establish incentives for scientific research and publications and promote and support training of young researchers.
Create tenure-track academic positions with significant research dedication and create PhD programs at the institutional and/or regional level.
Offer and advertise continuing education opportunities in biostatistics, biosafety, scientific writing, and navigation of Open Medicine methodologies and infrastructure.
Advocate for stronger collaborations among institutions across LMICs.
Leverage influence in the areas of government and policy to encourage investment in science, creation of a national health research bureau and policy, drafting of national standards for research ethics with human and animal subjects, drafting of national standards for biosafety and biosecurity, and promotion of collaboration with governments and institutions from HICs.
Proactively negotiate authorship, author position, and equitable data sharing practices with HIC researchers and institutions and reject non-equitable proposals.
Seek international grants and budget transparently within the institution to reduce financial dependence on HIC institutions.
Encourage authors to negotiate increased visibility through presenting collaborative and independent research at international conferences and take advantage of OA publishing fee waivers to publish in international journals when feasible.
<b>Recommendations for Institutions in HICs</b>
Factor LMIC institutional overheads and capacity building activities into research at the planning stages and avoid 'token' LMIC co-authorship by collaborating genuinely in both intellectual and financial ways.
Provide training to LMIC universities and institutions when visiting to collect data or for other research activities and share unused field equipment with LMIC partners when not in active use for project data collection.
When discussing research activities, avoid possessive references to study communities (e.g., "our field site"), which propagate harmful connotations about ownership of access to a LMIC community.
Provide rewards for the time and effort required by researchers to forge equitable collaborations with LMIC researchers.
Strengthen teaching around the dangers of extractive research from LMICs to HICs.

**Table 3. Recommendations for Funders**

<b>Funders</b>
Craft specific policies under which OA and data-sharing costs are eligible for reimbursement from research grants and which encourage or require researchers to budget for them in funding applications.
Create grants specifically designed to fund OA and data-sharing costs for researchers who have fixed-term project grants that lack funds for OA cost reimbursement.
Support OA publishing infrastructures and/or develop OA publishing platforms that are directly commissioned by the funding organization.

<b>Funders</b>
Implement open data policies that ask grantees to 1) ensure that any consent forms used for research projects involving human subjects allow for de-identified open data-sharing, 2) acquire digital object identifiers for datasets to facilitate citations, 3) cite datasets within any publications, 4) clarify within publications where datasets can be accessed, and 5) share metadata to facilitate machine readability. Also ask researchers for data management plans along with funding applications, for underlying publication data to be shared openly, for all data to be shared openly (when reasonable), and for grantees to share data in a public repository, and within a specific time frame.
Offer free workshops or trainings on data management and provide example data management plans or templates.
Create funding programs specifically targeted to researchers in LMICs.
Create funding programs specifically targeted to researchers in HICs that collaborate equitably with researchers in LMICs.

**Table 4. Recommendations for Researchers**

<b>Researchers</b>
Work toward practicing “open science by design” by leveraging open science technologies and principles at every stage of a research project.
Search OA, open data, and open source/code archives. Use database and text mining tools, including AI-based tools, to identify new concepts, pinpoint gaps in the body of scientific knowledge, find unanswered research questions, and identify where novel contributions can be made.
Create a data management plan when applying for funding, and, as appropriate, preregister research plans and protocols in an open repository.
Seek guidance on which open data repositories are favored by the research discipline or required by the funder/institution to guide data storage and structuring throughout the project.
Use web-based electronic notebooks to store data and code, rather than paper notebooks or locally stored data files.
Use open data techniques to analyze, interpret, and validate findings. which may then be submit articles for OA publication.
Present data at conferences and on preprint servers for open peer review and refinement.
Submit publications to OA journals.
Revise and improve work based on formal and informal peer review.
Select a public copyright license upon acceptance of publications.
Ensure metadata describing the data and code maximize machine and human readability and usability.
Deposit final peer-reviewed articles into an open archive and research data, code, and sources into FAIR data archives. Provide clear and persistent links from the article.
Take advantage of training programs offered by libraries or training projects to learn the necessary skills.

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