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A multistakeholder discussion on open access and medical publishing

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Stakeholders

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^aStakeholder perspectives were provided for the April 2019 release of this white paper and are subject to change.

Introduction

Over the past two decades, technological developments have led to dramatic changes in how information is distributed and accessed. The internet has altered how readers expect to receive information, moving from print to online reading. 1.2 In the context of this growing digital infrastructure, there are calls for increased transparency in scientific research. As free access to information on the internet has become the norm, the expectation that research results (papers) should also be open has followed. This expectation has been reinforced by the following ethical arguments.

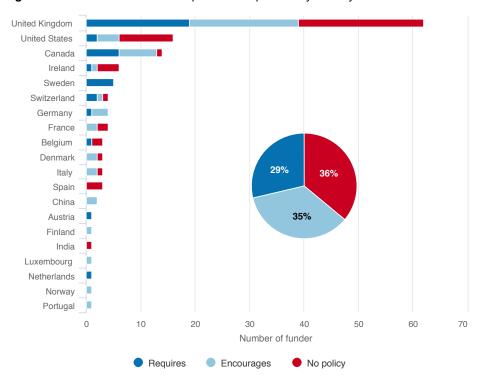
- · Publicly funded research results should be publicly accessible.
- Research is in the public interest and should be as open as possible to facilitate further research, avoid duplicated effort, and foster collaboration.
- Patients participating in research have a right to access the results.

In response to the increasing feasibility of digital publishing and the growing traction of ethical arguments in support of open access, many research bodies and funders are opting to implement open access publishing policies (**Figure 1**),^{3,4} and publishers have expanded the number of open access options available to authors.⁵ The UK Medical Research Council, the Wellcome Trust, the Bill & Melinda Gates Foundation, the European Commission, the US National Institutes of Health, and the National Science Foundation are notable examples of major private and governmental funders who have, or are developing, such policies.

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As free access

Figure 1. Number of funders with open access policies by country⁴



Source: Sherpa Juliet. Date accessed: April 19 2018.

Approximately half of all published clinical trials are funded by pharmaceutical, biotechnology, and medical device companies (in this paper collectively described as 'industry'), and this proportion appears to be increasing.^{6,7} At the time of writing, there are two industry funders with an active policy requiring all research it funds to be published open access. Shire, now a part of Takeda, introduced its policy in January 2018, and Ipsen announced its policy in January 2019.^{8,9}

In September 2018, a group of 11 European research funding bodies, with the support of the European Commission and the European Research Council, announced the launch of cOAlition S, an initiative to make full and immediate open access a requirement. All research supported by the sponsors involved must be published open access in line with cOAlition S's principles, known as 'Plan S', as of January 2020. 10 The announcement of Plan S stands to accelerate the open access movement, but it is not without its critics.

The aim of the present white paper is to provide an awareness of the options and implications of open access publishing for industry and other stakeholders in medical publishing against the backdrop of a rapidly changing landscape.

Plan S

Plan S is guided by 10 key principles developed by the original signatories (**Figure 2**). These principles have now been endorsed by other national research funders, such as that of Finland, and not-for-profit funders, such as the Wellcome Trust. The plan is set to cause major changes in the way that research funded by these bodies is published. Publishers provide online access to the research papers they publish, typically available under one or more of three funding options: journal subscription (either personal or institutional), pay per view (paid for by the reader), or journal/article open access (generally paid for by the authors, the lead author's institution, or the research funder). Under the terms of Plan S, the payment of **article-processing charges (APCs) to 'hybrid' open access journals** will not be compliant. The hybrid open access model offers authors a choice either to publish behind a paywall free of charge or to publish open access for a fee.

Plan S has received a mixed reaction. Concerns have been raised that conflicting open access requirements from various research funders may lead to contradictory requirements and an increased administrative burden both for individual researchers and for research collaborations between institutions following different policies. Plan S has explicitly outlined in its principles the responsibility of subscribing funders to align their policies to reduce the burden on researchers, but there have already been differences emerging between policies of member funders. For instance, the Wellcome Trust and Bill & Melinda Gates Foundation require that all articles be published with a specific Creative Commons Attribution (**CC BY**) license, whereas the other Plan S funders only recommend it.

Researchers may face consequences such as loss of future funding if they fail to comply with open access policies of the funding agency. Recently a group of academic researchers issued an appeal in protest of Plan S, arguing that forbidding researchers to publish in existing subscription journals has many unwanted side effects. If Plan S moves forward as originally conceived, it will undermine the existence of hybrid journals, which is of particular concern to

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academics and learned societies. Forced gold open access publishing could lead to higher production costs for many subscription journals with a high volume of submissions and an increase in papers of limited novelty or lower quality in open access journals. This could also result in a breeding ground for predatory journals. Plan S could negatively impact research collaborations between the coAlition S countries and the rest of the world. Additionally, insofar as it mandates a limited set of publication venues (e.g. journals and repository platforms), many hold the view that Plan S violates researchers' academic freedom.¹¹

Figure 2. Plan S 10 principles¹⁰



Article-processing charges are covered by research funders and institutions, not authors

Article processing charges must be standardized and capped

Authors retain copyright of their work, preferably under a CC BY license

Institutional repositories will likely be a valuable tool for meeting these targets



Hybrid journals are not compliant



Funders must work together to make consistent criteria that publishers must meet

Funders will work with universities to ensure that policies and strategies are aligned

In areas of unmet need, funders will incentivize and support new platforms and publishing avenues

Funders will monitor compliance and sanction noncompliance



For books and monographs, the timeline may be extended beyond 2020

Evolution of open access publishing

The terminology used to describe open access is often unclear and is used inconsistently by different sources. Two of the first and most frequently cited definitions of open access were devised in the early 2000s and stem from the Budapest Open Access Initiative and the Bethesda–Berlin declarations on open access. ^{12,13} These definitions assert that both free access to any given article and various reuse rights are central to defining open access.

Budapest definition

"By 'open access' to this literature, we mean its free availability on the public internet, permitting any users to read, download, copy, distribute, print, search, or link to the full texts of these articles, crawl them for indexing, pass them as data to software, or use them for any other lawful purpose, without financial, legal, or technical barriers other than those inseparable from gaining access to the internet itself. The only constraint on reproduction and distribution, and the only role for copyright in this domain, should be to give authors control over the integrity of their work and the right to be properly acknowledged and cited." ¹³

Bethesda-Berlin definition

For a work to be open access, the copyright holder must consent in advance to let users "copy, use, distribute, transmit, and display the work publicly and to make and distribute derivative works, in any digital medium for any responsible purpose, subject to proper attribution of authorship."¹²

Whichever definition is used, practically speaking, there are a number of options offered by publishers categorized as gold, green, bronze, or platinum (**Figure 3**).

Broadly speaking, **gold open access** options allow free access to the published version of record (**VoR**) of a manuscript on the journal's website from the time of publication under a **Creative Commons license**. Gold open access options for articles published in medical journals are typically available upon payment of an APC by the research author, institution, or funder.

Figure 3. Common open access options

Gold open access				
Where?	Available on the publisher's website (only full open access or hybrid journals)			
Which version?	Published version of record			
When?	Available immediately upon publication			
Cost?	Typically subject to \$3000–\$5000 article-processing charge			
Copyright?	Author retains copyright under a Creative Commons license			

Green open access				
Where?	Available on an online repository separate from the publisher's website and self archived by the author			
Which version?	The accepted pre-typeset version or the version of record depending on publisher policy			
When?	Exclusive rights typically reserved by publisher for embargo period of 6 to 12 months			
Cost?	Free of charge			
Copyright?	Author typically transfers copyright to publisher, limiting reuse rights			

Where? Available on the publisher's website Which version? Published version of record Available either immediately upon publication or after an embargo period and at the publisher's discretion Cost? Free of charge Copyright? Author typically transfers copyright to publisher, limiting reuse rights

Pla	tinun	n open access
W	nere?	Available on the publisher's website
	hich sion?	Published version of record
w	hen?	Available immediately upon publication
С	ost?	Free of charge
Copy	yright?	Author retains copyright under a Creative Commons license

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Green open access articles often are not associated with a Creative Commons license, are posted on an online repository separate to that of the journal's website (e.g. PubMed Central), are posted at no financial cost to the author, and are frequently subject to an embargo period of 6–12 months after publication, during which time only the paywalled version in the journal is available. Either the version accepted by the journal or the VoR may be made public as part of green open access publishing, depending on publisher policies.

Although green and gold are the most frequently used open access options, others do exist. **Bronze open access** articles^a are available to read on the journal website for free (with or without an embargo) but are not published under a Creative Commons license.⁵ Bronze open access is at the editor's or publisher's discretion. **Platinum open access** articles are published by a journal under a Creative Commons license but do not require payment of APCs by the submitter.¹⁴ Another frequently used distinction includes 'gratis' and 'libre' open access. Gratis access simply ensures the article is free to read (as with green and bronze options), whereas libre articles are free to read, and further reuse rights are also permitted (as with gold and platinum options).¹⁵

3.1 A closer look: Creative Commons licenses

In addition to these initial groupings, the type of Creative Commons license that constitutes 'gold' is important. The Creative Commons licenses were developed to make licensing easy for those authoring content that is posted online and enables users to easily add reuse rights to their work. The most commonly used licenses in the context of research publications are: the **CC BY license**, which permits readers to distribute, adapt, and build upon work as long as they credit the original author; the **CC BY-NC (noncommercial) license**, which permits readers to adapt and build upon work for noncommercial purposes only as long as the original author is credited; the **CC BY-ND (no derivatives) license**, which permits readers to reuse the original work, commercially or noncommercially, provided that the content is not altered, and the original author is credited; and the **CC BY-NC-ND license**, which permits readers to download and share work as long as they credit the original author but do not change it in any way or use it commercially (**Figure 4**). ¹⁶

For many large funders, including the Bill & Melinda Gates Foundation and the Wellcome Trust, CC BY is the only acceptable open access license. Under Plan S, the license should preferably be CC BY in order to comply with the Berlin Declaration per the Plan S open access principles. CC BY was chosen as the ideal license because it has the fewest restrictions on reuse beyond providing attribution. The limitations imposed by a CC BY-NC license mean that text, figures, and tables may not, for instance, be used on Wikipedia or on popular research websites,¹⁷ even if these are posted by their author. Data mining and artificial intelligence usage are also considered reuse by many publishers; therefore without CC BY, research using these techniques may be impeded. However, some publishers have amended their NC-ND licenses specifically to allow machine reading.

The less restrictive CC BY license is an option available from many publishers that allows the sharing and reuse of material for commercial purposes. Authors of industry-funded research are not typically permitted by journal publishers to opt for the CC BY license. ¹⁸ There is an argument, however, that not allowing this option for industry-funded research limits the scope of dissemination, and that once research has been validated by peer review, it should not face any barriers to distribution. ^{19,20}

Publishers and journal owners vary in the access options that they offer. For instance, some journals stipulate the timeframe in which the published article can be made freely available if the article has not been published under a gold license (i.e. whether there is an embargo period after publication); which version of the published article is available (e.g. the authors' accepted, pretypeset version or publisher's VoR); and the context in which articles can be

^aA term coined by Piwowar et al.⁵

shared (e.g. commercial or noncommercial settings). Gold open access options offered by journals are typically under CC BY-NC, ¹⁸ meaning that if companies wish to reuse elements from publications reporting the research they fund, they must pay fees to the publisher of the original work in order to permit reuse.

Figure 4. Summary of Creative Commons licensing options and a list of those commonly used in medical publishing





BY = attributionReuse permitted with attribution



ND = no dreivatives
Reuse permitted provided
the work is shared unchanged



NC = noncommercial Reuse permitted with attribution



SA = share alike Reuse permitted if new works have the same license as the parent work



0 = no rights reserved Reuse permitted in any context

CC O



Work is placed in the **public domain**. It may be freely reused by anyone for any purpose, with no attribution needed

CC BY



Free to distribute and adapt the original work, even commercially, as long as the original creation and authors are credited

CC BY-NC



Free to adapt the original work noncommercially and although derivative works must also acknowledge the authors and be noncommercial, they don't have to be licensed on the same terms

CC BY-ND



Free to **redistribute** the original work commercially or noncommercially, provided it is passed along **unchanged** and in whole, and the authors are **credited**

CC BY-NC-ND



Free to download the original work and share it as long as the authors are **credited**, but the work **cannot be adapted or used commercially**

Challenges introduced by the growth of scholarly publishing

The rate of growth in global research volume has increased dramatically. Total research outputs have roughly doubled every 9 years since the end of the Second World War, and the rate of growth is still increasing.²¹ This growth has been particularly pronounced in emerging economies such as China and India, with China overtaking the USA in early 2018 as the world's most prolific research nation in terms of scientific article output.²²

The increasing volume of research articles submitted and published has put pressure on the medical publishing infrastructure, the role of which has traditionally been to safeguard quality and publicize novel findings. This rapid growth has led to increased overheads for publishers, and a subsequent increase in expense for research institutions and libraries by way of journal subscription costs. Some funders and research institutions have become increasingly unwilling to meet these costs. As the proportion of research being published open access in hybrid journals grows, universities and libraries have pushed back on paying growing subscription fees for access to an ever shrinking number of paywalled research articles while having to pay increasing APCs for open access articles in those same journals. The standard medical publisher funding model will likely evolve in line with these new pressures from universities.

Another challenge for publishers is that of APCs as a primary funding stream. As APCs only cover the costs associated with the articles that are accepted, the expenses for articles that are not accepted for publication are not directly paid for. Therefore, journals with high rejection rates may have difficulty covering their costs with APCs alone, given that they process a high volume of submissions but only accept and publish a small number. In one calculation, *Nature* estimated that to maintain revenues based on APCs alone, approximately \$30,000–40,000 would need to be charged per paper published.²⁴

An increased use of the CC BY license may also have implications for reprint revenues. Reprint revenues from industry account for a significant proportion of income for some journals: for example, approximately 40% of profit at *The Lancet* is generated from industry reprints. Using CC BY licenses, industry would become able to reproduce their articles at cost price. While industry is still likely to purchase professionally printed and bound reprints or e-reprints or other electronic distribution rights, particularly from prestigious journals, this income stream may be impacted. More use of the CC BY license for manuscripts may also have implications for revenue from industry reuse of tables and figures from peer-reviewed publications.

While the sustainability of an open access future is a concern for some publishers, ²⁶ fully open access publishers do exist, although their commercial viability is uncertain. ^{27,28} Both PLOS and BioMed Central journals are open access and funded primarily using APCs. ^{29,30} Publishers may find new ways to secure an income stream from open access publishing such as charging a submission fee rather than a publication fee, meaning that publishers would be paid by the volume of articles they process rather than the number they actually publish. This model is currently used by *F1000Research*. ³¹

Although these new funding streams can work for some publishers, others (in particular independent society journals) still harbor concerns that the transition toward open access is happening too quickly.³² The increasing number of funder open access requirements places additional pressure on those publishers who are not yet optimized for open access but also has created opportunities for publishers to find and deliver new models for publishing research.

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Implications of open access for different stakeholders

5.1 Academic authors

Research into the citation rates of open access articles generally shows a modest, yet significant, citation boost for open access papers. In one of the broadest analyses of open access publications, published by Piwowar *et al.* in early 2018, it was found that, on average, open access articles received 18% more citations than paywalled articles.⁵ Another study found that open access research articles also achieve approximately 1.3–1.5 times higher Altmetric scores than those of closed access cohorts.³³

The 'impact' advantage of publishing with open access can be a double-edged sword, however. A mandatory open access policy, at the time of writing, precludes immediate open access publication in some of the most highly cited journals. Despite growing awareness of open access, many academic careers remain heavily reliant on producing publications that go on to be published in high-impact-factor journals.³⁴ Although new guidelines, such as the San Francisco Declaration on Research Assessment (DORA),³⁵ have been developed to reduce the significance of the impact factor as a criterion to assess researchers' work, until new evaluation metrics have been firmly established in academic hiring and the allocation of grant money, researchers working under open access mandates may worry more about promotions and grants than those whose funding does not mandate open access.

Open access publishing has the potential to increase the scope of data synthesis projects and systematic reviews greatly. In an article published by Copyright Literacy.org in February 2018, the importance of open access for synthesizing data and performing systematic reviews was presented.³⁶ Paywalls, as well as **digital rights management**, were barriers to the review conducted by the author of the article: of the hundreds of papers selected for inclusion in the review, only 25 were accessible. This made it difficult both to share research articles with global author and reviewer groups, and to meet the copyright restrictions applicable in their respective countries. This argument has also been made by researchers specializing in text and data mining, which are increasingly important components of meta-analyses. At present, only 37% of all research literature in the UK and 25% of global research literature are made freely available at the time of publication.⁵

5.2 Patients

A recent study found that 59% of adults in the USA had searched online for medical information in the previous year, and over a quarter of these had come to a paywall in the process.³⁷ Of those encountering paywalls, only 2% said that they had paid for access; the remaining groups either tried to find the same information elsewhere (83%) or gave up (13%). Although scientific publications serve to communicate to other experts and are not generally written to target patients, it is still important that members of the public are able to interpret those papers and gain useful information from them when plain language materials are not available. The ability to research the underlying evidence for each available option without having to spend a lot of money on journal subscriptions or pay-per-view articles is important for all patients and caregivers, and especially those whose lives are dominated by more extreme health circumstances such as a rare disease or a life-limiting or life-threatening condition.

Access to information is also important for patients who participate in clinical trials. A major reason that patients take part in research is to find out the results. In a large US study, most patients (91%) wanted to be informed about research findings or else would not participate in future clinical trials (68%). Clinical trial participation demands significant commitments from patients involved; close adherence to the treatment regimen, regular trips to the hospital, invasive tests and long follow-up periods, and the risk of adverse events to name but a few. Participation is an especially large commitment for patients with terminal diseases, for whom time is such a valuable commodity. As many as 95% of trial participants believe that they

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should be informed of the progress and outputs of studies in which they have taken part, but they are not guaranteed the opportunity to do so.³⁹ Patient access to research information may be achieved in part by lay summaries for patients, which have less complex language and are more understandable than scientific literature written for a specific healthcare provider audience.

5.3 Industry

Industry supports the ethical arguments for open access. However, the practicalities of moving toward increased or mandatory open access pose some challenges. Industry funders are subject to a higher number of restrictions than noncommercial research funders that do not always allow for the same open access publishing options as other types of funders.

Another concern is that certain open access policies might unduly impinge on authors' choice of journal and thus conflict with various good publication practices and guidelines such as those laid out by the International Committee of Medical Journal Editors⁴⁰ and in Good Publication Practice 3.⁴¹ In the case of researchers collaborating globally, European authors may be obliged to follow the guidelines of Plan S, whereas other authors may have more freedom in journal choice. As mandatory open access publishing is fast becoming a standard model for a few major not-for-profit funding organizations, the absence of the same provisions for industry-funded research could lessen the attractiveness of industry as a research funder to potential collaborators.

5.4 Not-for-profit funders

Affordable access to information is a leading consideration for not-for-profit funders mandating open access policies. Although publishers typically include confidentiality clauses relating to the nondisclosure of customer-specific costings for journal bundles in their contracts, data obtained through Freedom of Information Act 2000 requests suggest that these bundle prices can be extremely expensive⁴² and that the bundle system frequently provides access to journals that are not needed by institutions, thus inflating the cost and forcing the triage of other journal subscriptions.⁴³ Evidence gathered by the Electronic Information for Libraries organization has also highlighted the problems sometimes encountered in sharing research across national borders.⁴⁴ Some believe that a transition to open access as the primary funding model for journals would allow a more transparent and efficient system of access and would boost access for researchers in poorer institutions. However, as noted below, the organization Research4Life, a conglomerate of health organizations, universities, and publishers, was specifically established to reduce the knowledge gap between high-income countries and low- and middle-income countries by providing free or affordable access to scholarly, professional, and research information.⁴⁵

5.5 Learned societies

Learned societies support open access but also have specific concerns around the exclusion of hybrid and potentially **mirror journals** under Plan S. Without these options, there may likely be fewer journals, and many medical societies could be negatively impacted. One of the top reasons that members join a society is access to publications. Full open access journals erode the perceived value of publications as a member benefit and could result in fewer members. An unintended consequence might be a cost shift to other programs, higher member dues, or program cuts.

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The publishing ethos of leading medical societies values quality over quantity. Rigorous peer review, often accompanied by biostatistical reviews, is a hallmark of top-tier society journals to safeguard the public from studies with flawed methodologies and conclusions. And as the publicly accessible finances of PLOS and eLife show, publishing open access at quantity is financially challenging.^{27,46} Therefore, a diversified publishing model is essential for societies to launch and sustain money-losing or breakeven open access journals. There are also concerns around the potential misuse of content under the CC BY license, which could result in author reputational risk as well as a misinformation health risk to the public if the original work is adapted erroneously.

5.6 Publishers

In the open access conversation, research/information sharing is often conflated with research publishing. Technology has allowed information sharing (i.e. Wikipedia) to become more rapid and economical, but it is not necessarily the same with research publishing. The storage space and bandwidth, programming and design talent acquisition, new functionalities, security, and innovation costs associated with research publishing are significant and continue to rise. Publishers must keep pace with these demands against the backdrop of ensuring high-quality, high-reputation content.

Access challenges in low- and middle-income countries do exist, but they are often because of poor internet infrastructure rather than the journals being removed from those countries. To date, Research4Life has provided researchers at more than 8900 institutions in more than 120 low- and middle-income countries with free or low-cost online access to up to 90,000 leading journals and books in the fields of health, agriculture, environment, applied sciences, and legal information.⁴⁶ While publishing models vary, all publishers share a core commitment to facilitate the dissemination and discovery of their authors' scholarly articles.

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6

Stakeholder perspectives: what will the future of open access look like?

All academic authors want readers. Some consider their academic peers their main readers. Others would include nonacademics as a target audience. Whether one aims to address fellow academics or other members of society, one of the main appeals of open access for academic authors is the potential to enlarge our readership. Academic authors relish the potential to enhance our scholarly and societal impact – whether through increased citations or through increased use by nonacademics, which are sometimes promised as an effect of open access publication.

That said, different academic fields and different academic authors within fields may have different attitudes toward open access policies. When open access policies are presented as mandates, one can expect to encounter resistance from academics. People generally do not enjoy being told what to do; but academics have an especially well-developed sense of autonomy. Although it means different things in different contexts (for instance, in some countries it is written into law, in others not, and details vary), academics generally enjoy academic freedom. Since academic freedom often includes freedom of publication, any policy that may infringe that freedom will generate resistance. University

open access policies are instructive in several ways: 1) they were generally initiated and voted for by faculty; 2) they in no way restrict where faculty can publish; 3) they are designed to enhance the ability of faculty to make their manuscripts available to more readers; and 4) they typically include some way for faculty to opt out of making particular pieces of research available. Otto (2016)⁴⁷ offers an example of how to align open access policy outreach to faculty with faculty values.

Mandates that stem from funding agencies are different. Academic authors who are faculty at universities typically have a say in university policies in the form of shared governance. These same authors typically do not have a say in funder policies. Funder policies designed to align with the values shared by academic authors and to enhance their impact are likely to be welcomed; those designed for some other purpose – to disrupt scholarly publishing, for instance, as Plan S has stated its aim – are likely to encounter resistance from academic authors, even those who support open access.⁴⁸

The future of open access depends on smart policy making. Academic authors want to share their work; they do not want to be told how, where, and when to do so. Smart open access policy making would leverage the fact that academic authors already want to share their research as widely as possible, while taking account of the autonomy of academic authors. It is possible to design open access policies that would enhance author and reader autonomy at the same time. If I were a journal editor, I would focus more on the needs of my authors and readers than on the demands put forward by funders. I would urge funders to pay attention to their grantees, as well – not every problem is amenable to a systemic solution.

 Professor J. Britt Holbrook, Department of Humanities, New Jersey Institute of Technology; Member, European Commission Expert Group on Open Science Indicators

The Bill & Melinda Gates Foundation is committed to information sharing and transparency. We believe that published research resulting from our funding should be promptly and broadly disseminated. We have adopted an open access policy that enables the unrestricted access and reuse of all peer-reviewed published research funded, in whole or in part, by the foundation, including any underlying data sets. The foundation aims to ensure a future where 100% of the foundation's funded research outputs that are published in peer-reviewed journals are done so on open access terms. The vision is that this research can be openly and easily built upon to develop more efficient and effective

strategies to tackle the problems we are trying to solve.

The future of open access will include new and innovative systems that better leverage current technology. For example, in 2016 the foundation launched Gates Open Research, a completely transparent and open postpublication peer-review platform. This process supports more rapid publication of research results. Currently available only to foundation grantees (as they have already been vetted during the grant-making process), all submissions are accepted based on what the authors feel is important to share with the research community. No editorial time is spent on desk rejects. The scholarly communication landscape is and will continue to quickly shift and platforms such as Gates Open Research are built to adapt to such changes. As community research outputs is a critical part of the research process, discussion of these costs is increasing, and we can see a future where one model is funder-subsidized publishing platforms.

Ashley Farley, Associate Officer of Knowledge & Research Services,
 Bill & Melinda Gates Foundation

Academic authors want to share their work: they do not want to be told how. where, and when to do so. Smart open access policy making would leverage the fact that academic authors already want to share their research as widely as possible, while taking account of the autonomy of academic authors

We will not see a 'one-size fits all' open access publishing ecosystem as proposed by cOAlition S in Plan S. Open access will continue to see steady annual growth both in terms of percentage of total articles published and journals offering an open access option, hybrid or fully gold, with varying growth rates by discipline that is driven by the adoption of new and alternative measures of research impact for the awarding of grant funding and promotions. Funders will recognize that supporting open science and research communication is a more impactful use of resources than escalating funding of APCs.

Publishing model diversity based on an egalitarian, democratic publishing ethos in which anyone can publish in any journal regardless of geography, status, income, funding, or funding source will persevere and continue to fuel innovation in research communication. Leading journal brands in many disciplines will endure and publish both open access and paywalled content as authors and readers continue to recognize the importance of rigorous, traditional peer review, as slow and archaic as it may seem. Some hybrid journals will flip to fully gold open access upon reaching a tipping point based on percentage of open access articles published. And some disciplines will shift to completely new models of open research, leading to the wholesale change or demise of leading paywalled journals and the adoption of completely different 'publishing' models and platforms eschewing traditional peer review and publication policies and workflows.

For clinical research, I predict greater public access to the literature via school and public libraries through a multistakeholder initiative involving publishers, societies, library associations, and industry. Access to Research UK can serve as a model.

David Sampson, Vice President and Publisher, Publishing,
 American Society of Clinical Oncology

Open access is one component of the broader drive to open science that aims to deliver faster and more effective research discovery and impact. A world in which high-impact research is responsibly and expertly shared for communicating globally requires a sustainable transformation across all the processes of research communication – widely available access to the methodology and results, shared data, transparency in peer-review models and communication, increased collaboration, and accurate research attribution.

Compounding this need for improved research communication and outcomes is our current environment in which science is being more broadly debated and challenged within society. It is incumbent on all of us to make science more transparent and accessible for informed decision-making.

However, we are seeing that participating in open research and, in turn, open access poses varying challenges and opportunities across research disciplines and geographies. Increasing diversity in the forms of open access is already occurring as it becomes more widely embraced by research disciplines and their funders. It is unlikely, therefore, that the near future will offer one universal solution to open access publishing.

A successful transition to an era of open research validating and driving knowledge will emerge from partnerships among all stakeholders to build a sustainable approach. Beyond ensuring that research is as widely available and accessible as possible, the model needs to continue to ensure that the research is methodologically sound and continues to build on the body of knowledge in the therapy or subject area. In this way, new research continues to drive further investigation and discovery whilst simultaneously responsibly informing professional practice, public policy, and improved outcomes in our society.

During this transition phase, we will continue to see a mixed economy of open access models as outlined elsewhere in this paper. In certain disciplines a flip to a fully open access model will prove viable and/or necessary, others will maintain a hybrid model.

whilst others again may find a new model. At the center of it all is the researcher and author wanting to ethically source and comply with the requirements of research funding and communicate their research in an environment of academic freedom, inquiry, and diversity.

Ongoing investment in technology to support this process will be required, and so we will see a future that is not only more open, more collaborative, and more global, but also more technologically enabled.

- Martine Docking, VP, Global Corporate Sales, Wiley

"Optimism is a strategy for making a better future. Because unless you believe that the future can be better, you are unlikely to step up and take responsibility for making it so." – Noam Chomsky

I believe that the future of open access and, moreover, open science will be better and greater than the sum of its current parts. What we are witnessing today is a continued series of revolutions (rather than a single evolution) driven by varied groupings and, most recently, cOAlition S who are rightly challenging incumbent and ingrained research publishing practices as a strategy and a means for a better future.

But in looking to the future, it is worth going back to Sir Timothy Berners-Lee's original vision of the World Wide Web, founded 30 years ago this month. That vision and belief was for a platform that promoted openness, cooperation, and creativity. But the Web has evolved into something very different to Berners-Lee's original vision where most of the data we put online are now siloed on the servers of companies like Google, Facebook, and Twitter, and used to sell us as an audience for targeted advertising. The same is true for scientific data, and this is why I believe that the current open access drive will only be further amplified by the broader real challenges to a free and open web.

To address these challenges, the World Wide Web Foundation, established in 2009 by web inventor Sir Timothy Berners-Lee, is bringing together governments, companies, and citizens to negotiate and build a new Contract for the Web that outlines the rights and responsibilities we all have. I can foresee open science being a fundamental right and principle as part of that Contract, but the diverse open access groupings will have to coordinate better to contribute effectively.

Therefore, the future of open access will continue also to be more sophisticated in its interpretation. No longer will open access be conflated with just 'free access' to electronic facsimiles of printed journals, but it will inform data-intensive science and knowledge sharing and discovery.

For example, FORCE11 is a community of scholars, librarians, archivists, publishers, and research funders that has arisen organically to help facilitate this change toward improved knowledge creation and sharing. Their founding assumption is that semantically enhanced, media-rich digital publishing will be more powerful than traditional print media or electronic copies of printed works. They have a set of guiding principles to make data Findable, Accessible, Interoperable, and Reusable – FAIR.

Over the next 10 years, I foresee an even more rapid advancement of open access and data transparency. At the same time, I do not see this as being mutually exclusive from a continuation of the current range of diverse research journals whether subscription-based, open-access, luxury, or sound science. Why? Well I believe that new technologies, particularly artificial intelligence and machine-learning, will be sufficiently sophisticated to enable greater transparency, accountability, and efficiencies irrespective of a journal's business model.

- Martin Delahunty, Publishing Consultant

Ongoing investment in technology to support this process will be required, and so we will see a future that is not only more open, more collaborative, and more global, but also more technologically enabled.

The biopharmaceutical industry is interested in advancing scientific research and dissemination of its findings with the aim of offering health care providers, government agencies, patients, and other healthcare decision makers information that is transparent, timely, and accurate with the aim of bringing the best treatment options to bear for patients. This aim can be said to be no different from the aim of academic, government, or noncommercial scientific researchers or funders with whom the industry collaborates on a variety of research efforts. What may differentiate industry from some of the other funders of scientific research is its commercial context. As such, the industry strives to understand, contribute to, and follow standards in place for communication of its scientific research.

The internet provides many opportunities and challenges for all involved in scientific research. The key question for industry remains how to best follow current guidelines and policies and at the same time stay true to its aim of providing research findings in a transparent, timely, and accurate way. One can say the current channels allow for transparent and accurate provision of scientific information, but is it timely and do patients have access to study findings? The other question is whether open access provides patients with the right level of information in order to further their understanding of their condition and its treatment. Would patient lay summaries be more appropriate? Is there an opportunity for evolution of guidelines to require them as part of scientific publications? However we proceed, the industry remains committed to making sure the dialogue continues as we evolve and innovate in ways to reach said stakeholders and have access to transparent, timely, and accurate information about its research.

- Soheil Chavoshi, Head, Global Medical Capabilities, CVRM, AstraZeneca

However we proceed, the industry remains committed to making sure the dialogue continues as we evolve and innovate in ways to reach said stakeholders and have access to transparent, timely, and accurate information about its research.

In the last decade, the pharmaceutical industry has embraced a broader culture of transparency and data sharing by implementing guidelines around disclosures of payment to healthcare practitioners, providing public access to clinical studies information and results (including summarizing results in lay language), and enhancing patient-level data sharing with independent researchers. In 2018, Shire became the first pharmaceutical company to introduce a commitment to publishing its funded research in peer-reviewed journals with open access. Since then, a second company, Ipsen, has aimed to publish the results of all its affiliated research with open access.

The number of pharmaceutical companies committing to open access publishing is expected to go up very rapidly in the next few years. As this number grows, it is also expected that the publishing world will broaden access to certain Creative Commons licenses, such as CC BY, to pharmaceutical-funded research manuscripts and provide even easier access for not only healthcare practitioners but all patients, their families, and the general public.

Additionally, the introduction to Plan S principles by cOAlition S will accelerate the open access movement and will introduce further changes in the publishing industry and the way research is published and read.

 Valérie Philippon, Senior Director and Global Head, Scientific Publications, Global Medical Affairs, Shire, now a part of the Takeda group of companies Pharmaceutical companies are currently balancing the desire to freely share data with patients and healthcare professionals, the academic rights of authors, and the journal ecosystem's well-being.

Pharmaceutical companies are currently balancing the desire to freely share data with patients and healthcare professionals, the intellectual rights of authors, and the journal ecosystem's well-being. Given the need for rapid access to accurate clinical trial information in order to make informed treatment decisions, making trial results 'free to read' without a paywall is a clear option. Publishing in an open access journal or with an open access license can, in part, achieve this goal. However, to fulfill the information

gap for patients, I expect there will be a trend toward the inclusion of plain language summaries that employ graphics and or videos to enhance knowledge.

Although myriad stakeholders are waiting with anticipation to see how the publishing industry evolves in response to open access, others are evaluating options that address these concerns. Given that a mandate to publish all manuscripts open access could inhibit authors' ability to select journals due to the limited license options, some sponsors may be cautious about adopting the strictest of open access mandates. Instead, they might decide to strive to make all their trial data available, at a minimum, 'free to read' by whatever means are available (gold, green, hybrid etc.). In the future, as more journals expand license options for industry-funded research, this should become easier.

Overall, the rates of open access publishing are increasing organically over time.⁵ So continuing to support, but not mandate, open access, may be the common position for industry for the immediate future: it improves access to data that can impact lives and research, without limiting authors' journal choice, and give journals the time and motivation to generate innovative publishing models.

 LaVerne A. Mooney, Director & Team Leader: Publications, CI and Innovation, External Medical Communications, Pfizer

The paywalls are coming down. Either the publishers can remove them peacefully, or we patients will break them down.

We patients participate in trials to benefit humanity. Nobody ever says it that way, but that's why we do it. Sometimes of course we hope for personal benefit; better care perhaps, more attention, access to new treatments, or simply sheer hope or desperation. But on the whole, we take part in research because research benefits everyone. It helps people in the future, it helps other patients, it stops other people going through what we are going through, and it gives new knowledge and understanding to our doctors and nurses.

So, for all that to happen, you need to share the outcomes. And you need to share them widely. We have not participated in your research so that you can hide it behind a paywall and make money out of it. We did not do it so you can boost your academic career, or so your university can look good for funders, or so that your company can make a profit. We most certainly didn't do it so publishers can make money out of our sacrifice and our goodwill. Where were they on the ward or in the clinic, eh? We want your research – and our results – to benefit humanity. Publishers should not be putting a tax on knowledge, and they should not be making a profit out of one lot of sick people wanting to help another lot of sick people. The paywalls are coming down. Either the publishers can remove them peacefully, or we patients will break them down. Wake up and smell your breakfast beverage of choice. Patient power is in your arena.

 Richard Stephens, Patient/Patient Advocate; Editor-in-Chief, Research Involvement and Engagement

Where is the industry—publishing relationship heading?

In many ways, the industry journey toward open access has been dependent on the standard provisions offered by mainstream publishers. Industry funders of research are subject to a greater number of restrictions than noncommercial research funders. As skepticism surrounding research sponsored by industry is still prevalent, ⁴⁹ the publication of peer-reviewed papers in respected medical journals is essential for industry to be able to share the results of their scientific research.

At present, many journals do not permit industry researchers the option of publishing under a copyright license or embargo period that allows them to comply with the recommendations of major funder policies. ¹⁸ With the advent of Plan S and increasingly bold open access policies from noncommercial sources, it is possible that industry will be under increasing pressure to abide by standards they are not presently permitted to meet. It will be important, therefore, that a dialog is opened up between publishers and industry researchers to forge a new path toward enabling industry to access the same publishing options as noncommercial and publicly funded research.

8

Conclusion

Open access presents many potential benefits: greater transparency in disclosure of research, fewer barriers for groups conducting systematic reviews, higher citation counts and Altmetric scores, and greater access to up-to-date research for those without institutional access to subscriptions, such as local healthcare providers, researchers in developing nations, and patients.⁵⁰ Recent developments such as the announcement of Plan S stand to accelerate discussions and decision-making on the future of open access publishing.

Although open access can improve the dissemination of research in some ways, sustainability is an important consideration in any decision to pursue a defined open access policy. Concerns on the part of some publishers that an overly rapid transition to fully open access publishing could destabilize their industry and risk undermining the gatekeeping of scientific standards must be taken into consideration. Likewise, the concerns of researchers surrounding the possible impacts of open access policies on their careers should be considered.

Open access has been defined in many ways, and there are many stakeholder perspectives to consider. This, in conjunction with the restrictions that industry-sponsored research is subject to, makes the prospect of a move toward publishing in open access journals seem particularly challenging for industry. The first step toward forging a path for industry in the new open access landscape lies in education on the various implications of open access, and the initiation of discussions to try to identify common ground from which to progress.

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10 Glossary

VoR	Version of record
Mirror journals	Mirror journals are essentially new journals that piggyback off existing journals for the sole purpose of offering a fully open access option. Part A of a journal is the already-existing subscription or hybrid journal, and a new journal, part B, is a fully open access version of the same title. They are considered separate publications, with separate ISSNs. However, both parts A and B of the journal twins have the same editorial board, the same aims and scope, and the same editorial peer-review policies. Authors submit their manuscripts through one shared system for peer review. Upon acceptance, the author is given the choice of publishing the paper in the hybrid original title, or the fully open access title.
Hybrid journals	Hybrid journals are subscription-based journals in which some of the articles are open access. This status typically requires the payment of an article-processing charge to the publisher in order to publish an article open access, in addition to the continued payment of a subscription to access all other content.
Embargo	The period following official journal publication during which time freely accessible (green open access) versions of the accepted manuscript may not be posted on a repository apart from the publishing journal.
Digital rights management	Digital rights management (DRM) is a systematic approach to copyright protection for digital media. The purpose of DRM is to prevent unauthorized redistribution of digital media and restrict the ways consumers can copy content they have purchased.
Creative Commons license	A Creative Commons license is one of several public copyright licenses that enable the free distribution of an otherwise copyrighted 'work'. A Creative Commons license is used when an author wants to give other people the right to share, use, and build upon a work that he or she has created.
APC	Article-processing charge
Altmetrics	Alternative metrics have been developed to replace traditional, less paper-specific metrics such as impact factor. These can include citations in journals, and social media and news coverage. The company Altmetric tracks some of these outputs, although the word 'altmetric' is not specific to this company, and other providers and metrics exist.

Supporting resources

- Berlin Declaration on Open Access: https://openaccess.mpg.de/Berlin-Declaration
- Bethesda Statement on Open Access Publishing: http://legacy.earlham.edu/~peters/fos/bethesda.htm
- Budapest Open Access Initiative: 10 recommendations: http://www.budapestopenaccessinitiative.org/boai-10-recommendations
- cOAlition S website: www.scienceeurope.org/coalition-s
- Directory of Open Access Journals: https://doaj.org/
- Medical Publishing Insights & Practices open access reference site: https://www.mpip-initiative.org/transparencymatters/openaccess.html
- Open Access Scholarly Publishers Association: Best practices in licensing and attribution: https://oaspa.org/best-practices-licensing-attribution-need-to-know/
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- Science Open: http://www.mpip-initiative.org/transparencymatters/openaccess.html

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