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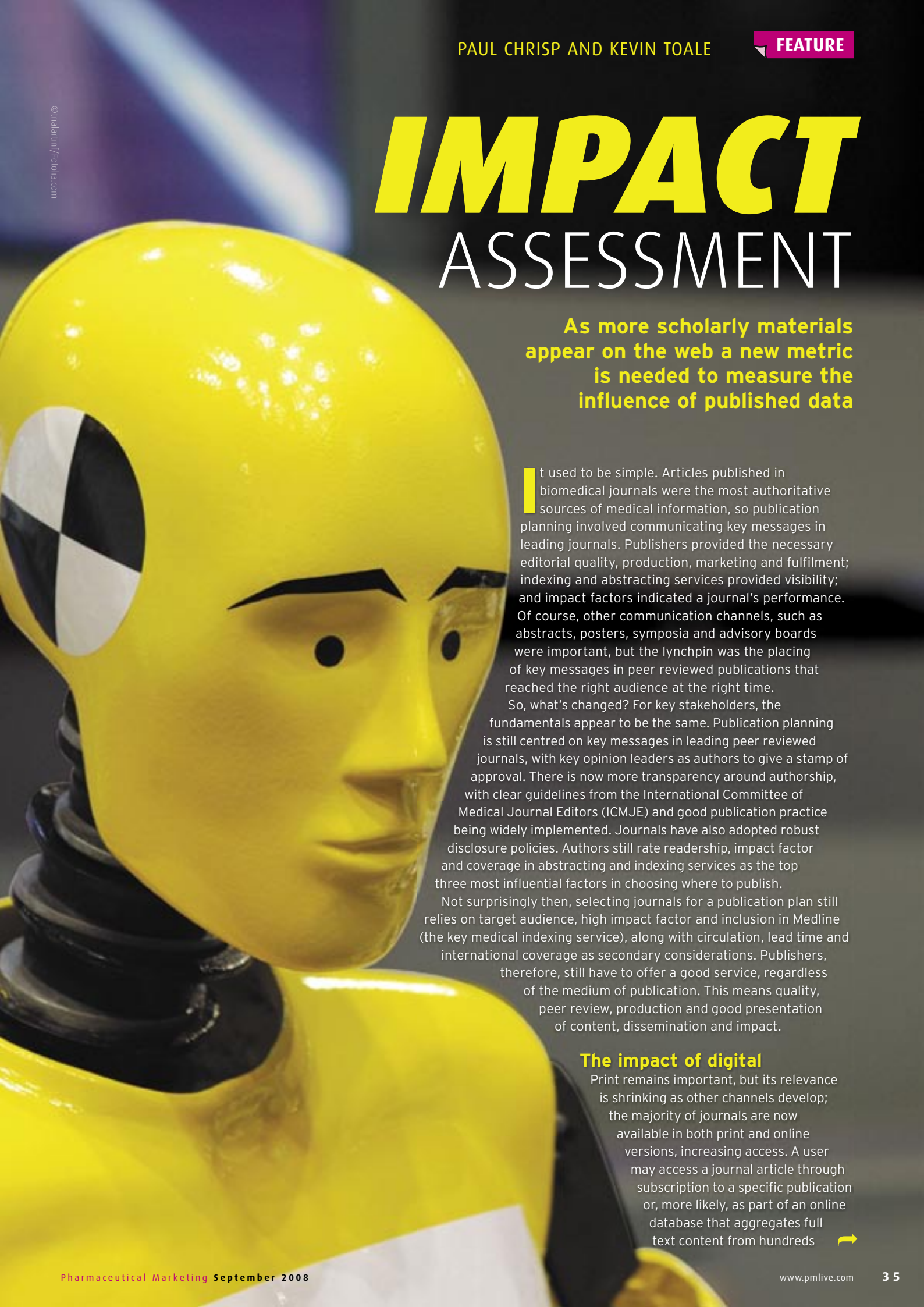
FEATURE



IMPACT ASSESSMENT

As more scholarly materials appear on the web a new metric is needed to measure the influence of published data

It used to be simple. Articles published in biomedical journals were the most authoritative sources of medical information, so publication planning involved communicating key messages in leading journals. Publishers provided the necessary editorial quality, production, marketing and fulfilment; indexing and abstracting services provided visibility; and impact factors indicated a journal's performance. Of course, other communication channels, such as abstracts, posters, symposia and advisory boards were important, but the lynchpin was the placing of key messages in peer reviewed publications that reached the right audience at the right time.

So, what's changed? For key stakeholders, the fundamentals appear to be the same. Publication planning is still centred on key messages in leading peer reviewed journals, with key opinion leaders as authors to give a stamp of approval. There is now more transparency around authorship, with clear guidelines from the International Committee of Medical Journal Editors (ICMJE) and good publication practice being widely implemented. Journals have also adopted robust disclosure policies. Authors still rate readership, impact factor and coverage in abstracting and indexing services as the top three most influential factors in choosing where to publish.

Not surprisingly then, selecting journals for a publication plan still relies on target audience, high impact factor and inclusion in Medline (the key medical indexing service), along with circulation, lead time and international coverage as secondary considerations. Publishers, therefore, still have to offer a good service, regardless of the medium of publication. This means quality, peer review, production and good presentation of content, dissemination and impact.

The impact of digital

Print remains important, but its relevance is shrinking as other channels develop; the majority of journals are now available in both print and online versions, increasing access. A user may access a journal article through subscription to a specific publication or, more likely, as part of an online database that aggregates full text content from hundreds

of journals for a particular institution. Whether the article is read in a paper-based journal or accessed via the web, the end result is still the article – technology merely enables access and provides an alternative economic channel.

Open access has emerged in the last few years as a serious alternative to traditional commercial publishing models, taking the benefits afforded by technology one step further. In this model, authors are charged for publishing services, and readers can access, download, print and distribute papers free at the point of use. The trigger for open access was the increasing number (and cost) of journal subscriptions and the decrease in library budgets. Although its ultimate goal is the free availability of information online, open access is not the same as free access – publishing services still cost money. Open access is seen as an evolution, with author behaviour and funding hindering its more rapid adoption.

> "The boundary between a journal and a database is thus becoming blurred"

Other characteristics of open access journals are that authors retain copyright and they must self-archive content in an independent repository. Such repositories are becoming more common and may be publicly accessible (eg PubMed Central) or specific to an institution.

With this move towards online access and repositories, the unit of publication changes from being the journal issue to the single article. The boundary between a journal and a database is thus becoming blurred. Abstracts and journal articles are searched and retrieved from online databases; conversely, researchers are depositing results in databases rather than publishing them in journal articles. These databases are, however, not peer reviewed and do not have a uniform citation system at present.

Registration of trials

A particularly pertinent development, which lies at the interface of journal articles and databases, is the advent of clinical trial registration and results disclosure. The influential ICMJE, representing the editors of leading medical journals including *New England Journal of Medicine, BMJ,* and *The Lancet*, now requires that trials considered for publication be registered in a publicly available electronic registry at, or before, the time patients are enrolled. The leading registry is ClinicalTrials.gov, but most companies also maintain registries on their own websites.

The driver behind this initiative was the perception of publication bias, ie the feeling that only trials with positive results were getting published and negative or equivocal data were being suppressed. Although registries like ClinicalTrials.gov prospectively post trial protocols and, therefore, potentially minimise the chances of non-publication, they do not post results. In September 2007, the FDA mandated that the registry must link to results of trials that form the primary basis of an efficacy claim within 12 months of trial completion or within 30 days of drug approval. Currently, the most comprehensive database of trial results is ClinicalStudyResults.org, sponsored by Pharmaceutical Research and Manufacturers of America (PhRMA). Reporting on this site remains voluntary. Standards of reporting on trial results registries are not yet fixed, but could have a big impact on subsequent publication in a peer reviewed journal. The ICMJE has said that posting study results as a brief (<500 word) abstract or table would not jeopardise full publication. One standard format, ICH-E3, which has been adopted by the State of Maine is, however, more extensive than a simple 500 word abstract and could affect publication. But the ICMJE seems to be comfortable with this, suggesting that even if results are not published in a peer reviewed journal, trial results could be posted on a public registry 24 months after closure of data collection. The irony here, of course, is that expanding access to trial protocols and results via online databases bypasses peer review and could result in the widespread dissemination of results from poorly designed studies. One suggestion is that the data be added to a trial results registry, while journals continue to publish peer reviewed articles with clinical interpretation.

Abstracting and indexing

Everyone involved in publication planning knows the database Medline. Medline is often wrongly used interchangeably with PubMed, but Medline is, in fact, the bibliographic database of article references indexed using the National Library of Medicine's controlled vocabulary and is the main component of PubMed - the freely accessible online citation and abstracting database that also includes other records (eg in-process citations, full text submitted to PubMedCentral). Medline is perceived as the key bibliographic citation database in biomedical literature; if a journal is not included in Medline, it is much harder to thrive or be part of a publication plan. Inclusion in Medline is not automatic - journals are judged by a committee on the basis of their scope, content, editorial quality, production quality and relevance for health professionals. Despite these criteria, the system is not perfect. It discriminates against new journals trying to get established, and some relevant journals are not included. The other leading biomedical and

pharmacological citation database, EMBASE, has 1691 unique journals not found on Medline, the overlap in journals between the two databases is 3012 and Medline has 2152 unique publications.

Another consideration when choosing a publication is whether it is included in an abstracting and indexing database specific to a target audience, for example, inclusion in CINAHL is important for nursing and allied health publications.

Whichever indexing system is used, so-called good journals may publish poor studies and, conversely, so-called poor journals may publish good articles. Furthermore, traditional abstracting and indexing systems designed to help researchers find information in peer reviewed journals, overlook other sources such as biomedical databases, registries, websites, and so on. Newer searching tools are being implemented that allow access to this wider range of information. These include Elsevier's Scopus (www.info.scopus.com/about) and Google Scholar (http://scholar.google.co.uk). Scopus claims to cover peer reviewed articles, open access journals, conference proceedings, abstracts and 'quality' scientific web pages. Google Scholar, meanwhile, aims to do for to scholarly literature what Google did for web searching. Usage statistics are recorded as users click through from a citation to an article on a publisher's or online host's website.

This interesting model addresses two other concerns regarding current indexing systems: selection and citation impact. Google Scholar is an open system available to any publisher who submits a publication. It has been suggested by some medical journal editors that Google-like searches will render indexing systems obsolete.

> "Google Scholar aims to do for scholarly literature what Google did for web searching"

Measuring impact

The impact, or rank, of an article located using Google Scholar is decided, to a large extent, by how often it is cited by others. In this respect it has something in common with the final subject of this article, impact factors.

Impact factors are frequently used, but often misunderstood. They are used in publication planning as a quick way to gauge a journal's performance – the higher the impact factor, the better the journal. Impact factors were originally devised by the Institute for Scientific Information (ISI) as a bibliometric indicator, not a measure of scientific quality. They are used to help librarians select which journals to subscribe to; researchers decide where to publish their work and academic departments decide who to employ – a practice that has received much criticism. The impact factor for a journal in a given year is defined as the total number of citations in that year to articles published in the journal in the previous two years, divided by the total number of citable articles in the previous two years.

Impact factors determine whether or not a journal is included in the Science Citation Index (SCI). Possibly because they are widely available and quantitative, these factors and rankings have a huge and disproportionate influence on assessments of journal performance. However, the impact factor has some sources of potential bias, which limit its use and mean that, on its own, it is not enough for informed decision making. Sources of bias to the impact factor (IF) include:

Coverage

- only 25 per cent of peer reviewed journals included in SCI database

Differences in subject areas

- articles in areas with rapid developments cite more recent references, leading to higher IFs
- basic research may also be cited in clinical medicine, increasing IFs

Differences in journals independent of quality

- Inclusion of items judged non-citable increases the IF
- Review articles are cited more and increase IF
- Open access increases IF
- Sudden increase in number of articles decreases IF

Journal versus article

- Citations are to individual articles, they are not spread evenly throughout a journal

Active manipulation

- Self citation

There are also other reasons to be cautious about placing too much emphasis on the validity of IFs. Journals with high impact factors were not found to publish better quality clinical trials, and an analysis of articles included in the gold-standard *Guide to Clinical Preventive Services* by the US Preventive Services Task Force (USPSTF) revealed that content from low impact journals was frequently cited. In other words, IF did not appear to measure quality, importance or usefulness, at least in practical clinical literature. It may not even be a useful measure of interest, since a manuscript may be read more times than it is cited, and research shows that online hits per article do not correlate with IF.

A number of alternatives to the IF have been proposed to overcome potential bias, but they are not widely known and still rely on the assumption that subjective quality and objective citations are linked. Moreover, they do not truly assess usefulness and impact.

Today's prescribing decisions are not solely the responsibility of the physician looking at a clinical trial from a high impact factor journal. In an era of evidence-based medicine, adoption of new drugs is increasingly influenced by other stakeholders such as formulary managers, prescribing advisers, policy makers, healthcare commissioners and pharmacy benefit managers, who use technology appraisals and clinical guidelines based on an evaluation of all the available data. In this new world, attempting to influence market adoption

by placing a clinical trial in a high impact, possibly research-based, journal appears to be out of step with reality.

So what should replace IF as a guide? Impact, particularly digital impact, may be thought of as a product of volume or diffusion of information, and its influence or ability to effect change. A key consideration is, therefore, what will have the greatest influence? Many clinical publications, for example, in public health and formulary management, have low or even no impact factors, yet they are influential and useful. By measuring the number of citations, regardless of the citing journal, impact factors do not measure this prestige. Prestige takes into account the standing of the citing journal or author. The y-factor has been introduced as a combination of IF and prestige based on Google's PageRank, which weights web pages based on the number of links to the page and the status of the pages that the links originate from.

An important development along these lines is the SCImago Journal Rank (SJR). This new journal indicator is based on the Scopus abstracting and indexing system and includes a much larger body of evidence than SCI. Moreover, it is open access rather than a subscription service. Its most compelling feature, however, is that it weights citations depending on the prestige of the citing journal, with prestige calculated according to the amount of incoming and outgoing connections (not citations) of the sources. The SJR also includes the h-index of a journal, which quantifies both the actual scientific productivity and the apparent scientific impact of a journal, and is based on the set of the journal's most quoted papers and the number of citations received in other publications.

Frank Davidoff, editor emeritus of the *Annals of Internal Medicine*, believes "There's a nobel prize waiting for the person who can develop a reliable and meaningful clinical impact factor." He suggests collecting input from doctors about which articles resulted in a change in practice, or to measure clinical outcomes for patients whose care was influenced by the articles. Interestingly, a similar process is recommended by the Accreditation Council for Continuing Medical Education (ACCME) to assess the impact of CME programmes.

Some efforts have been made in this direction. In 2001, five members of the international advisory board of the ANZJP selected nine articles that they believed would have the greatest impact based on one or more of the following criteria:

- Adds consequentially to the field through original, innovative research findings
- Expands or challenges current knowledge
- Opens additional areas for new research activity
- Opens a pathway to advance knowledge
- Integrates discoveries obtained by different approaches and/or disciplines through creative synthesis, thus bringing new insights to bear on original research
- Reflects critically on research findings to guide the direction of further research.

The opinion leaders engaged in this post-publication peer review were selected on their scholarship, professional integrity and knowledge of the subject area.

The Faculty of 1000 (www.f1000medicine.com) is an extension of this initiative. It asks opinion leaders in clinical practice and research to select the most influential articles in 18 medical specialties. Articles are evaluated and ranked as 'recommended', 'must read' or 'exceptional', assigned a score known as the F1000 factor, and judged on whether they could result in a change in practice or not. This goes some way towards a 'clinical impact factor', but addresses only the influence component of digital impact, and not the diffusion or volume part.

SOME KEY TECHNOLOGICAL TRENDS AFFECTING TRADITIONAL PUBLICATION PLANNING		
Print	→	Online
Citation	→	Download
Journal	→	Single article
Peer reviewed publications	→	Databases
Subscription	→	Open access
Closed abstracting and indexing systems	→	Open abstracting and indexing systems
Popularity	→	Prestige
Interest	→	Relevance
Reference	→	Usefulness

What does this mean?

Clearly, the issues discussed above have profound implications for publication planning. The table above shows the trends that need to be taken into account.

In today's dynamic environment relying on traditional print-based journals, chosen on their Medline inclusion and impact factor, is not enough. The key considerations are:

- Choose a journal that is available online
- Use multiple channels to content and choose journals that are widely diffused in multiple databases and repositories and are deeply linked to other content
- Think about the potential advantages of an open access journal, eg available to a wide audience – including prescribers and consumers, author (or company) retains copyright and can therefore distribute reprints without purchasing them from the publisher, ease of publication and the fact that most open access journals rely on outside grants or institutional sponsorship
- When making a decision based on indexing look at journals included in specialist indexing services used by your target (do not just focus on Medline), check for inclusion in Google Scholar and remember other factors such as target audience, circulation, lead times, geographic distribution and editorial quality are often more important
- Impact factor ie do not decide where to publish simply based on SCI impact factor and journal ranking, think about what the publication plan is aiming to do and use other metrics to gauge importance and relevance
- Trial registries ie ensure trials are registered on ClinicalTrials.gov and keep up with developments in results registries, particularly standards. The pressure is on to publish equivocal results.

Conclusion

As more and more scholarly materials appear on the web, the supremacy of tools like Medline and SCI impact factors is being challenged by new, less narrowly defined methods of judging merit. Diffusion or visibility of information (eg open access, Google Scholar) and its influence or quality (eg F1000 factor, SJR) are the key issues for publication planning. It is possible that these elements could be combined to define a 'digital footprint' or 'digital impact index' (DI^2) that determines the true ability of a publication to influence adoption of a new drug.

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