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Citations and Open Access: Questionable Benefits

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Some of my recent editorials have dealt with the impact that open access (OA) has on the scientific and economic aspects of the *American Journal of Neuroradiology* (*AJNR*). As is well known, in addition to being a public service, OA allows greater dissemination of articles. In general, medical journals offer these types of access:

- Subscription access—articles only available to those who pay subscription fees.
- Selective (or partial) OA—selected articles, such as reviews or those funded by government monies, can be viewed immediately for free.
- Delayed OA—part of or all articles can be viewed for free after a period of time, generally 1–2 years. This type of access can be combined with selective OA; *AJNR* offers this type of combined access.
- Pay per view—anyone can view an article by paying a 1-time fee.
- OA—all articles are free immediately after publication. (A complete OA model was tried by the *British Medical Journal* [*BMJ*], but some years later it was modified to protect its subscription revenue.)

An indirect and welcome effect of OA is that of increased citations that lead to a higher impact factor, thus increasing a journal's prestige. This is what is called "citation advantage," and it has been confirmed for sciences outside of medicine.[1] The citation advantage is thought by some to be related to self-selection: that is, authors who are highly citable publish in OA journals, OA articles are promoted more, editors choose prestigious articles for OA, and OA articles are found in free self-archives. All published studies concluding that OA increases impact factor have been retrospective in design.[2]

In July 2008, the *BMJ* published an article in which investigators performed a randomized prospective trial of OA.[3] From 11 journals published by the American Physiologic Society, they randomly assigned 247 articles to immediate OA and used another 1372 subscription-only articles as controls (these were OA 1 year after publication). Articles from both groups were culled from a 3-month period (January to April), and data for analyses were retrieved the next January. These are some of the observations made in that important article:

- OA articles had 89% more full text downloads, 42% more PDF downloads, and 23% more unique visitors.
- Review articles showed increased downloads.
- Articles featured in press releases or appearing on the cover of a journal had increased downloads.
- Longer articles with more references, those that appear in journals with a high impact factor, and those found in self-archives had increased downloads.

Despite all of these seemingly positive effects, the most important conclusion was that OA did not result in more citation counts! Fifty-nine percent of OA articles were cited 9–12 months after publication compared with 63% of subscription-only articles. These conclusions go against our expectations and deserve some thought but are similar to those for other fields such as astrophysics.[4] The first caveat that comes to mind is that the period of time after publication was too short and some citation activity was therefore missed. However, other studies have noted differences in citations just 10 months after OA publication.[5] To account for the high number of downloads, articles must have been viewed (and hopefully read) by many individuals who did not cite them (the general public? communities of individuals who are not investigators?). It is also possible that investigators who are actively citing articles are those who already subscribe to journals and do not require free access to them. Although articles featured on the covers of journals receive more attention, the same cannot be said of their position in the table of contents and of the position of the table of contents in the journal; both have no effect on citations. Most readers never view a table of contents. This is because most articles are electronically accessed, and readers are taken directly to them by search engines.[4]

Do the results of the *BMJ* study negate the advantages of OA? One's initial reaction is to answer yes. This means that we should not expect OA to increase a journal's impact factor. I think that the problem is not with the OA models but rather with the impact factor. It is clear that the impact factor no longer reflects article usage and dissemination of knowledge as it did in the past. Researchers choosing to send their work to a specific journal based on its impact factor and committees awarding promotions and tenures based on impact factors are making their decisions, in my opinion, on an outdated model. Academic institutions will need to create new criteria (number of hits? number of PDF and full-text downloads and other on-line profiles?) to assess the importance of research. For example, *AJNR's* impact factor is 2.338, but this score does not reflect the fact that more than 3.4 million articles were downloaded from our Website last year (Fig 1). Though our impact factor increased from 2006 to 2007, this increase does not echo the 1 million additional downloads occurring during the same time period when compared with the previous year. If the on-line usage trend continues, this year we will see more than 4 million *AJNR* article downloads! It is obvious that the selective type of OA that *AJNR* uses has had a significant impact on article availability. I am not sure which OA model will work

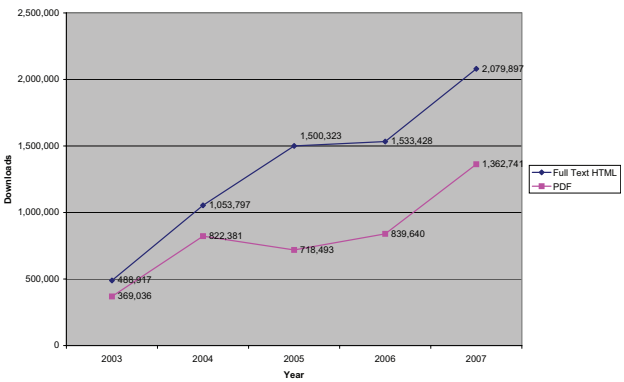

Fig 1. *AJNR* data downloads by year.

better for *AJNR*, or which will prevail in medical publications, but OA is here to stay and we need to embrace it.

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EDITORIAL

Humanitarians, Compassion, and the Food and Drug Administration: Guidance for the Practitioner

Without approval for marketing by the US Food and Drug Administration (FDA), even the most brilliant new medical device has essentially no economic value. Any strategy for bringing a novel device to the market must focus on the "regulatory pathway." The federal government has developed several such pathways, the choice of which has substantial effect not only on the expense required to gain approval but also on how the device can later be marketed and used. We suspect that many interventional neuroradiologists pay little attention to the nuances of "regulatory pathways." However, the advisability of regulatory naïveté has diminished with the advent of the now often-used "Humanitarian Device Exemption (HDE)" regulatory pathway.[1] It is the purpose of this paper to briefly review the HDE regulatory pathway and, more importantly, to focus the physician on the constraints, regulations, and practitioner responsibilities associated with these Humanitarian Use Devices (HUDs).

Regulatory Pathways

In general, there are 4 primary methods for marketing a medical device, including premarket approval (PMA)/product development protocol (PDP), premarket notification (510(k)) clearance, exempt devices, and HDE. The FDA defines several "classes" of devices, ranging from class I devices (for which potential harm is minimal) to class III (which support or sustain human life; are of substantial importance in preventing impairment of human health; or which present a potential, unreasonable risk for illness or injury). The regulatory path to market is primarily dictated by these device classifications. PMA/PDP devices are class III and typically carry the burden of large clinical trials to establish safety and efficacy. The 510(k) devices are class II, and the application process requires the submitter to establish that the device is "substantially equivalent" to a previously marketed class II device. Exempt devices, on the market before 1976 with a long history of use, are typically class I and do not require an application to be submitted to the FDA. An HDE represents an exemption to permit marketing of HUDs. This type of exemption stems from a waiver of burden of proof for efficacy. For an HDE, there is limited burden other than to demonstrate that the device is safe and that there is "probable benefit" in a population affected with a disease or condition that is manifested in fewer than 4000 patients per year.

The amount of clinical data required, and thus the expense incurred, to gain approval plummets when moving from PMA to HDE.[2] However, as in most of life, there is no free lunch at the FDA because the less onerous pathways are associated with greater restrictions than the more onerous pathways. For example, the 510(k) clearance process requires that the new device be "substantially equivalent" to an existing device. As such, the company must rely on effective marketing to convince us that we should use, and potentially pay a premium for, a device that is "substantially equivalent" to existing devices. Fortunately for industry, physicians have a strong track record in succumbing to such marketing. In comparison with both the PMA-approved and 510(k)-cleared devices, though, the restrictions on use of HUD are severe and, whether or not they know it, may affect physicians' responsibilities and liabilities.

HDE-Associated Constraints

No one likes to be labeled. Medical devices, unfortunately, have no choice in the matter. Each device is approved or cleared for a specific indication or indications, which are reflected in the "label." PMA-approved and 510(k)-cleared devices may be freely used "off-label," which means that these devices may be applied for an indication not listed on the label. Indeed, a physician could put one of these devices in someone's eyeball without any oversight, if such physician deems it appropriate. As is well reported even in the lay press, the company cannot specifically promote this "off-label use." Companies may choose to gain PMA approval or 510(k) clearance for a relatively uncommon "usage" while anticipating that physicians will take it upon themselves to use the device (frequently, off-label) for a more common condition than that on the label.

HUDs do not enjoy such liberties as those enjoyed by PMA-approved and 510(k)-cleared devices. HUDs must be reviewed by an Institutional Review Board (IRB) before use, though specialized, individual patient consent is not required by the regulations for their on-label use. In some cases, however, the IRB may require individual patient consent. Furthermore, the Principal Investigator for an HUD study needs to ensure that everyone who will use the device is listed on the protocol and that any serious and unanticipated adverse events that occur with use of the device are reported to the IRB and to the company. Failure to follow the rules could place those using the device, as well as their institution, not only at risk for loss of human research privileges but also subject to other liabilities. Not only are companies limited in how many devices they can sell annually (typically on the order of 4000), but also the off-label use of HUDs is severely limited. Physicians cannot simply use the device in an off-label fashion and move on. Instead, federal law outlines specific recommenda-