Potential implications of wider data transparency in medical communications

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Abstract

The current medical communication environment is characterised by growing calls for increased data transparency. There are ongoing concerns about the selective publication of trial results and the potential impact on use of medicines by prescribers and patients in both Europe and the US. This article outlines some of the background to current developments and considers the potential impact on those working in the field of medical communications.

Keywords: Publication guidelines, Publishing standards, Information dissemination, Publication bias

The medical communication environment will be strongly influenced by ongoing campaigns to ensure that individuals and organisations are transparent and maintain ethical practices surrounding the publication of data.[1] Also, the recent proposals for revised EU legal frameworks for clinical trials[2] and medical devices/*in vitro* diagnostics[3] are supportive of wider data transparency.

The availability and use of data

The results of clinical trials are acknowledged as having an important influence on medical practice, but the growing impact of such information in additional areas needs to be considered. For example, health technology assessment agencies have considerable interest in detailed trial information and so there are implications for reimbursement of medicines and therefore patient access to therapies.

Incomplete information or the selective reporting of data can lead to inappropriate conclusions being made about results, which has implications for any decisions based on those conclusions. The current discussions concerning data transparency have been prompted by a number of published examples where there appeared to be weaknesses with respect to data transparency or possible selective reporting bias.[4–7] At the same time, there are concerns that the publication of large amounts of data may lead to a 'data overload', potentially increasing the risk of certain data being erroneously analysed outside of its scientific context.

Cases have been identified where it might have been possible to reach different conclusions regarding a particular drug, depending on whether only published information was used as the source or a full range of data including unpublished sources was accessible. In the UK such information could have potentially altered opinions about antidepressants by the Committee on Safety of Medicines and the National Institute for Health and Care Excellence.[4] In Germany, a perceived lack of data transparency affected an evaluation of an antidepressant by the Institute for Quality and Economic Efficiency in Health Care.[5] In the US, a study of 164 efficacy trials for 33 approved new drug applications for new molecular entities from 2001 to 2002 noted discrepancies between trial information reviewed by the FDA and information in published trials.[6] The authors of this study stated that selective reporting undermined the integrity of the evidence concerning drugs and that it deprived clinicians of accurate data upon which they could make appropriate prescribing decisions. They also expressed concern that publication bias was masking the distinction between effective and ineffective therapies.

Consequently, there has been growing interest from independent researchers in improving access to unpublished clinical data. The EMA has been the recipient of a number of requests from researchers seeking access to company product data not present in the public domain but available to regulators. In April 2012, EMA reviewers published their updated views on data transparency, suggesting that trial sponsors and regulators did not have a 'monopoly on analysing trial results' and that

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clinical trial data should not *per se* be considered as commercial confidential information.[7] However, the EMA reviewers remained concerned about the uncontrolled mass release of raw data, since this could lead to reports based on misleading results, which might result in unfounded health scares and even lead to patients discontinuing their treatments.[7] They recommended dialogue with other stakeholders to ensure that trial data were made available in formats that would be in the best interest to the general public and all those involved in the conduct of clinical trials.[7] In November 2012, an EMA workshop identified five key areas (protecting patient confidentiality, clinical trial data formats, rules of engagement, good analysis practice, and legal aspects) in which regulators would work with stakeholders to move towards proactive data disclosure.[8]

Possible implications of increased data transparency

Future requirements are anticipated to result in a greater amount of trial data being made available through publications. In this more open environment, journals will have to consider what additional information is of interest to readers. For example, as sponsors assess data generated across trials, they may have legitimate reasons to conduct and seek to publish the results of *post hoc* subgroup analyses on certain patient populations. Journals will need to reassess their policies on accepting such manuscripts, which may include fulfilling the basic criteria for expert involvement and steering committees. At present, journal preference tends to be for primary trial information, involving collection of original data with assessment criteria prospectively defined. As *post hoc* studies might examine subgroups not prespecified at the time of the original trials, journals may view positive results less favourably and suspect them of being influenced by a post-trial hypothesis. It is worth noting that the extent to which such analyses will be possible will depend on the outcome of the ongoing revision of the EU legal framework for data protection.[9] The European Commission's current proposals set out to update and modernise the principles enshrined in the 1995 Data Protection Directive to guarantee privacy rights in the future.[10] The proposals are now with the European Parliament and EU Member States for further discussion.[10] They are set to take effect two years after they have been adopted and may have relevance due to reconsideration of informed consent requirements.

New guidelines and recommendations that emerge from initiatives focusing on clinical trial data and transparency will have a noticeable impact on medical writers, as the scope of their work will change. They are likely to be involved in preparing more extensive trial information for publication than is available at present from accessible sources. The expanded scope of work will need to be accounted for in terms of budgets, resourcing, timelines, and qualifications. In addition, medical writers' training regarding guidelines and standards will need to be kept up to date. Completion of training will need to be formally documented and records maintained so that they can be independently verified.

Conclusion

Within the healthcare field, there are different interpretations of what meaningful data transparency entails and the processes for making detailed information available to interested parties remain to be defined. Furthermore, wider accessibility to data will need to be managed with the intended audience in mind so that the information can be disseminated in a format that can be understood and used by the intended audience. Although not all details are in place yet, it is important to start considering the implications of wider data transparency as it will profoundly influence the future medical communications environment.

Disclaimer

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The flat world of medicine

Writing this issue's Tool Box, I began with the phrase 'The world is flat, even in medical writing.' Then I paused and asked myself – would the EMWA readership be privy to this metaphor borrowed from Thomas Friedman's bestseller published 7 years ago? The book has become an icon, and 'flat world' a favourite buzzword in commerce and technology. But how widespread is the use of this phrase in other fields? In medicine? I did a quick search in good old PubMed and here is what I found:

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Well, it seems that the global playing field in medicine has also been flattened. But what about in medical writing?

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