

Comments on Disclosure Timing Submission to WHO International Clinical Trials Registry Platform January 2006

Introduction

We strongly endorse the guiding principles of the platform (ICTRP), including full disclosure of the minimal data set at the time of registration, as laid out in this round of invitations for submission of comments,¹ and supported by the Ottawa Statement.^{2,3}

At the same time we are cognizant of the concerns that have been expressed with respect to a potential negative impact of disclosure on competitive advantage, and the proposal that certain items be held in escrow for a defined period of time.⁴

Background

Fundamental principles in the philosophy of science were described by Richard Merton in the 1940s, and continue to be held as guiding norms. These are referred to as the Mertonian norms^{5,6}, namely that ‘*Science disinterestedly and with appropriate skepticism coupled with originality seeks universally valid knowledge as a public good*’.⁷ Of these, the principle of Communism states that the findings of science are public rather than private knowledge.

As Merton himself (1942) comments;

“The substantive findings of science are assigned to the community. Scientific claims to ‘intellectual property’ are limited to those of recognition and esteem. ... Secrecy is the antithesis of the norm; full and open communication its enactment.”

In their comments on the above, Stuart and Ding⁸ point out that;

“members of the scientific community confer peer recognition to those who are first to report important research findings... Because scientists who might prefer to temporarily shelter their research findings from the broader research community risk being scooped by competitors (and thus failing to obtain credit for their work), priority-based recognition promotes immediate dissemination of research findings.”

Subsequent erosion of these values by the commercialization of science does not weaken their primacy, but weakens the reliability of science, and public trust^{9,10,11}, a subject of considerable scholarly and public concern. It is precisely this erosion of values that the ICTRP seeks to reverse.

WHO position on intellectual property

WHO has had a longstanding interest in the question of intellectual property, its protection, and the need for balance with knowledge transfer.¹² In a recent call for submissions to the Bulletin of the World Health Organization, the question is posed “Are

*there viable alternatives to intellectual property rights that could be used to reward innovation?”*¹³

Earlier, a report by the Secretariat to the 56th World Health Assembly states that “*The current situation has gone too far in promulgating a culture of ownership, and if it is allowed to continue it will inevitably lead to further inequalities in health care*”,¹⁴ a situation that it further describes as “*complex and chaotic*”. To this end efforts have been made to provide health researchers in developing countries with expert training and legal counsel to enable them to tackle these problems (ibid).

Principles

Given that there are strong scientific, ethical and moral reasons for early and complete disclosure, the burden of proof that any perceived harms from such disclosure outweigh the acknowledged benefits, rests heavily on those that seek to withhold information.

The arguments against early disclosure based on competitive advantage are likely to be based more on perception than reality. This is not to deny the importance of the concepts of plagiarism and intellectual theft, but the existence of transgression of norms cannot be the basis for further deviation from fundamental values. The disclosure and registration of human subject and clinical trial research is a component of a necessary cultural change. We maintain that arguments against disclosure are based on a competitive rather than a collaborative culture.

Unfair use of disclosed information and concepts should be addressed, but does not in itself justify the deviations from norms that others have proposed.

Justification of delayed disclosure requires a series of tests. In the first instance there is a requirement to demonstrate real harm from early disclosure, as laid out in the invitation for submissions. In the second instance there must be a demonstration that no harm results from delayed disclosure. Finally there is the requirement to prove that any demonstrable harms are of sufficient magnitude to justify the proposed restrictions of the ethical, scientific and societal benefits of early disclosure.

Discussion

We have previously examined the arguments for and against early disclosure in some detail,¹⁵ and have made some suggestions for dealing with the concerns that have been raised.

Issues

With specific reference to the *timing* of disclosure, those who would argue for delay, would also need to justify the exact period of embargo. Excessive delay would be unreasonable and would seriously undermine the principles and purpose of the registry.

The specific *items* that would be delayed would each need to be individually justified. As noted by Krleza-Jeric and colleagues,¹⁶ removal of key elements from the data set would render the remaining available information useless.

A blanket policy would be unacceptable, since arguments for placing any data elements in escrow must be specifically justified to maintain the confidence and trust of the scientific community and the public.

Since any reasons advanced to justify delaying disclosure would necessarily be time dependent, any delay would need to be subject to regular prospective review.

Justice

Any consideration of potential harms from early disclosure requires a global perspective. By providing a level playing field both potential advantages and disadvantages apply to all players and negate much of the previously claimed harms related to competitive advantage.

Proof of Claim

Early disclosure and registration provides a proof of claim for concepts and intellectual property in the event of any subsequent dispute, and would be available to medical journal editors and reviewers (see below). Investigators who were concerned about disclosure have supported the concept when made aware of this aspect.¹⁷

Role of Institutions and Funders

Institutionally based investigators would be well advised to consult their patent, intellectual property or technology transfer policies and procedures, and to be familiar with document disclosure laws and regulations in their jurisdictions.

Role of Registries

Registries should expressly state a policy that such disclosure is for collaborative purposes only and that proven unauthorised use for commercial or competitive purposes would incur penalties such as refusal of further registration privileges.

Role of Journals and Reviewers

Authorship should include assurance and disclosure of a survey of previous and concurrent research,¹⁸ communication with other workers in the area, and the degree of originality of the work being proposed for publication. The International Committee of Medical Journal Editors (ICMJE) takes the ethics of research and authorship very seriously,^{19,20} in particular taking “*responsibility for the integrity of the work as a whole, from inception to published article*”.

Finally ICMJE has stated that delayed disclosure would fail to meet the standards of prior disclosure required by them for publication.^{21,22} In advocating for full and early disclosure, ICMJE are fully aware of the importance of intellectual property, for instance in commenting on peer review, they state, “*authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend*”.

Conclusions

While there are legitimate concerns that early disclosure might lead to intellectual theft, plagiarism or competitive disadvantage, the solution lies not in the erosion of transparency but in change in the culture of research from a competitive basis to one that is based on collaboration, transparency and accountability, and in seeking mechanisms for the acknowledgement and protection of intellectual property, once disclosed.

Respectfully submitted,

*Michael Goodyear BMedSc, MBBS, FRACP FRCPC FACP,
Department of Medicine, Queen Elizabeth II Health Sciences Centre,
Research Ethics Board, Capital District Health Authority
Dalhousie University, Halifax, Nova Scotia, Canada*

*Lisa Golec, RRT, BSc, MHSM
NICU, Perinatal and Gynecology Program, Sunnybrook and Women's College Health
Sciences Centre,
Research Ethics Board, Sunnybrook and Women's College Health Sciences Centre
University of Toronto, Toronto, Ontario, Canada*

Acknowledgements

Elisabeth Clark, Compliance Officer/Human Protections Administrator, McGill University Health Centre, Montreal, Quebec, and *Sabina Watts*, Department of Anaesthesia, McMaster University, Hamilton, Ontario, Canada reviewed earlier drafts and provided information and comments.

References

- 1 World Health Organization. International Clinical Trials Registry Platform. Open Comments: Disclosure Timing. <http://www.who.int/ictrp/comments4/en/index.html>
- 2 Krleza-Jeric K, Chan AW, Dickersin K, Sim I, Grimshaw J, Glud C. Principles for international registration of protocol information and results from human trials of health related interventions: Ottawa statement (part 1). *BMJ*. 2005 Apr 23;330(7497): 956-8.
- 3 Ottawa Statement on Trial Registration. <http://ottawagroup.ohri.ca>
- 4 Clinical Trials Registries & Results Databases. The Fordham University Summit NYC 10-11 January. White Paper
http://www.clinicaltrialethics.org/content/FordhamRegistriesDatabaseWhitePaper_Sept_2_2005.pdf
- 5 Merton RK A note on science and democracy. *J Legal Political Sociol* 1942 1: 115-126
- 6 Merton, R. K. *The sociology of science: Theoretical and empirical investigations*. 1973 Chicago: University of Chicago Press.
- 7 Bauer H. H. Science in the 21st century: knowledge monopolies and research cartels. *Journal of Scientific Exploration* 2004, 18, 643—60, at 645

-
- 8 Stuart, Toby E. and Waverly W. Ding. "The Social Structural Determinants of Academic Entrepreneurship: An Analysis of University Scientists' Participation in Commercial Ventures." in Academy of Management Conference. Seattle 2003. (in press, American Journal of Sociology)
- 9 Bauer *ibid* at 644
- 10 Broad, W., & Wade, N. *Betrayers of the Truth: Fraud and Deceit in the Halls of Science*. 1982 Simon & Schuster.
- 11 Korenman SG, Berk R, Wenger NS, Lew V. Evaluation of the research norms of scientists and administrators responsible for academic research integrity. *JAMA*. 1998 Jan 7; 279(1): 41-7.
- 12 Commission on Intellectual Property Rights, Innovation and Public Health.
<http://www.who.int/intellectualproperty/en/>
- 13 World Health Organization. *Bulletin of the World Health Organisation*. Bulletin theme issue on intellectual property rights and public health, 2005.
http://www.who.int/bulletin/volumes/83/intellectual_property_theme_call_for_papers/en/
- 14 WHO: Intellectual property rights, innovation and public health. Report by the Secretariat. Provisional Agenda Item 14.9, A56/17 12 May 2003 http://www.who.int/gb/ebwha/pdf_files/WHA56/ea5617.pdf
- 15 Goodyear M, Golec L, Watts, SC Commentary on WHO International Clinical Trials Registry Platform Nov. 11 2005 http://www.who.int/ictrp/MichaelGoodyear_11Nov2005.pdf
- 16 Krleza-Jeric K: Clinical Trial Registration: The Differing Views of Industry, the WHO, and the Ottawa Group. *PLoS Med*. 2005 Oct 18;2(11): e378
- 17 Dr Karmela Krleza-Jeric, personal communication. January 17th 2006
- 18 Young C, Horton R. Putting clinical trials into context. *Lancet*. 2005 Jul 9-15;366(9480): 107-8.
- 19 Davidoff F, DeAngelis CD, Drazen JM, Hoey J, Hojgaard L, Horton R, Kotzin S, Nylenna M, Overbeke AJ, Sox HC, Sox HC, Van Der Weyden MB, Wilkes MS. Sponsorship, authorship, and accountability. *Ann Intern Med*. 2001 Sep 18;135(6): 463-6
- 20 International Committee of Medical Journal Editors. Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication <http://www.icmje.org/>
- 21 De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, et al. (2005) Is this trial fully registered? A statement from the international committee of medical journal editors. *N Eng J Med* 2005: 2436-2438.
- 22 Dr Christine Laine, personal communication. January 19th 2006