

## Comments on Ottawa Statement Part 2

### *Preamble*

The realities of operationalising are more complex and challenging than establishing principles, however with several major registries in place, we now have more experience of the practicalities than at the time of finalising Part 1. We also have the ICMJE timelines in place establishing prior registration as a prerequisite for publication. Finally, the WHO platform has continued to evolve, setting minimal standards.

Continuing discovery of fraud and data suppression, places some urgency and credibility on the proposals outlined here, and the moral case for mandatory universal registration has become considerably strengthened as has its acceptability.

Furthermore it is becoming increasingly clear that registration forms only one piece of an evolving concept of the return to essential scientific norms and the requirement for a fundamental culture change replacing competitiveness, secrecy and commercial interests with collaboration, disclosure, transparency and accountability. Other parallel initiatives include protocol publication and registration of results.

While WHO is evolving practice closer to existing systems, the Ottawa statement has the opportunity to articulate what should happen.

### *2. Unique ID*

The advantages of a unique reference number are clear. It is envisaged that eventually there will be a number of internationally accepted registries. Registration in one registry will be required, and there should be no duplication across registries. The registry holding the research data will be the registry of record, but will be cross referenced through a linkage system connecting all registries. Assignment of a unique ID by the registry of record would have some advantages in terms of efficiency and immediacy.

Operationally this would involve searching the system for duplicate records (both within and across registries) and if not found, assigning a unique number from a central global database, where the use of that ID would be recorded. Registration would be refused if a duplicate record was found, but might require revising or updating the extant documentation.

Ideally potential registrants should be asked to complete a search themselves and to declare having done so, and how.

Also, ideally, the unique ID would have an identifier for the registry of record embedded in it or appended, for ease of location.

Common standards between registries should simplify the choice of registry. These are being developed by the WHO ICTRP. It is anticipated that ICTRP will supervise the allocation of IDs as conceptualised in the UTRN.

### 3. *Minimum Protocol Items*

#### 3.1

Registered protocol items should be sufficient to enable efficient searching, determination of eligibility for search strategies and incorporation into systematic reviews.

#### 3.3

Items to be considered should also include those in the Australian Clinical Trials Registry.

#### 3.4

This need to be updated, this is the April 2000 dataset. Also there is no longer a magic five items selected for potential for escrow. WHO's position on this is clearly outlined in their call for submissions on disclosure timing for the February 6<sup>th</sup> IAB.

The October 21<sup>st</sup> 2005 dataset is here:

[http://www.who.int/ictrp/Registration\\_Data\\_Set2.2.htm](http://www.who.int/ictrp/Registration_Data_Set2.2.htm)

#### 3.5.1

Since this is a cultural change, transition phases are acceptable provided that there are clear plans for evolution.

#### 3.5.2

Delaying release of these (five) items would make the dataset meaningless

#### 3.6

What is proposed here is expanding the 20 item set to 37 items.

#### 3.6.14

I suspect we are going to need all REBs included to make sense to participants. Just as important is the inclusion of any REBs that did not approve the protocol. Furthermore inclusion of *all* participating REBs facilitates communication between REBs.

This will need to be adaptive. For instance as protocol and results registration come on line, these will need to be linked to existing registry data, as will subsequent publications, and articles citing the study.

#### 4. Registries

There should not be too much detail here. Membership is contingent on being compliant with the technical requirements, which may be subject to change.

##### 4.1

To fulfil the goals of public accessibility, the data should be available in the official languages of the countries in which recruitment is taking place. It is conceivable though, that there might be two versions of the database, such as a health professional, and general public version.

##### 4.3.2c

Unclear. Is it the relationship between databases in English and another language *within* a registry that is referred to here, or between one registry and another?

##### 4.3.2d

Could also be disease specific

##### 4.3.2e

This will be difficult to determine, but the policies of medical journals with respect to geography and access fees could be a starting point.

##### 4.3.2i

The relationship with REBs needs clarifying. Data can be entered without the trial being fully registered, as a work in progress. If all data is complete except the REB field, a provisional registration could be issued to provide to an REB. Final registration would require a statement that REB review has taken place and that any scientific or ethical concerns have been met.

*5. Search Portal*

This is rather duplicative of 4, so perhaps general principles such as transparency could be in an introduction or appendix.

*6. Next Steps*

This is very much a work in evolution, that will need to encompass developments in related areas.

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