

From: Lin, Jennifer S [mailto:Jennifer.S.Lin@kpchr.org]
Sent: Friday, June 18, 2010 3:19 PM
To: Genetic Testing Registry (NIH/OD/OSP)
Cc: Webber, Elizabeth M
Subject: Re: NIH Plan to Develop the Genetic Testing Registry

To Whom It May Concern:

We are researchers who conduct systematic reviews and are increasingly working on topics related to genomic testing and personalized medicine. We are very excited at the possibility of a central genetic test registry to help further the science and public policy surrounding this growing body of testing.

We have reviewed your request for comments and have a few thoughts/considerations which come primarily from our systematic review work in this field.

Regarding questions 1 and 2:

The genetic testing for inclusion in the registry depends entirely on the intended users. There is a large variety in types of testing (and categorization schemes of types of testing) which each have unique considerations for fields captured/reflected in the registry. Although it would be ideal to capture all testing that is available, it is, for researchers and policy makers, more important to capture newer tests (in development and consideration for clinical use, as opposed to older tests, e.g., compulsory testing used in newborn screening). Clinicians are increasingly taxed for time and (in my opinion as primary care clinician) are not likely to use a test registry for clinical decision making. In addition, there is a rapidly growing, and unregulated, field of direct-to-consumer marketed tests, largely outside the purview of clinical decision making that will be important to include if the audience includes the general public as consumers.

Regarding questions 5 and 6:

The proposed data elements in the genetic registry are quite comprehensive, and could be prohibitive or problematic for participation in a voluntary registry. The issue of blank fields could be helped by reducing the number of requested data elements and requiring crucial data elements to be required (with an opportunity to opt out with "not reported" versus "not available/unknown" versus "not applicable"). Items "a" through "l" and "p=cost/coverage" would be a great start and quite an undertaking in and of itself. Item "c" should also include if the genetic application/test has previous versions, as some tests have different names in their prior iterations during test development. If possible, it would also be helpful to include if there are different "makers"/manufacturers of the same test when applicable. Item "g" is a very broad/vague data element, we presume it refers to limitations in applicability rather than test performance, but it might be helpful for the registry to be more specific. Items "m" through "o" which applies to test performance, clinical validity and utility are clearly important pieces of information. However, completion of these fields to provide unbiased data/information literally requires review type work and is not feasible for manufacturers or most persons to complete for each entry (and would require unreasonable resources to check the data). Because most of the unpublished data relates to test performance, we suggest the registry capture who has performed the analytic validity testing and

proficiency testing for each test, so that it is at least transparent what unpublished and proprietary data exist.

Regarding question 9:

It would be extremely helpful for the registry to capture if tests have recommendations or regulatory approval from federal bodies (including FDA), independent bodies (e.g., USPSTF, EGAPP), as well as expert/professional societies.

We look forward to the inception of the registry in the near future.

Sincerely,

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