CDC Genetic Forum - Laboratory Workgroup
Summary of Meeting
February 23, 2000
Arlington, Virginia

1. Introductions and Charge to Group

   The meeting was opened with introductions by attendees (see attached list), followed by Drs. Baker and Khoury reviewing the proposed agenda and purpose of the meeting.

2. Brief review of informal discussions that took place during January 25-26 snowstorm.

   Drs. Baker, Popovich, Charache, and Howell who were present at the Baltimore 'snow-gathering'- meeting reviewed some of the informal discussion that took place. Among the issues informally discussed were orphan diseases, informed consent, stages of testing, data collection, definitions of genetic testing, and a public/private partnership.

3. Review of Clinical Laboratory Improvement Advisory Committee (CLIAC) Recommendations in Proposed CLIA *Notice of Intent.*

   The proposed CLIA *Notice of Intent* was distributed, but not reviewed.

4. Discussion of how a Public/Private Consortium might work to address genetic testing issues.

   Dr. Baker moderated a discussion of several issues related to the structure and function of the group. It was decided to call the group a Forum to avoid confusion with existing and proposed consortia, including the public/private consortia on data collection for cystic fibrosis and hemochromatosis . The group determined that addressing issues in some sort of hierarchy would be appropriate and that formalizing the current informal process of dialogue about issues that takes place among groups would be useful. The initial issue to be addressed was a review of the purpose and value of such a group. The members, after discussion, concluded that the purpose of the group was to assure that laboratory issues related to the quality of genetic testing are appropriately addressed. It was determined that indeed such a group would serve an important purpose as a Forum to help address:

   1. Understanding the type and level of contributions of professional organizations and others as adjunctive to existing laboratory regulatory processes. There was agreement that this effort would require staff support and that clarification of mission would be important.

2. Identification/clarification of specific issues (e.g., how would the Forum contribute to assessment of the quality of genetic testing and the stages through which an assay moves - research, clinical trials, broader use, educational/information sharing, etc.

3. Definition of relationships with other committees/advisory groups

The Forum could provide support when requested by either the SACGT or CLIAC. The group could be proactive with CLIA to help identify and/or address genetic issues around laboratory testing. The Forum, as well as other interested groups, could also bring issues of importance to the attention of SACGT and CLIAC. Other groups with which this Forum would interact include the Genetics Advisory Panel in FDA.

It was understood that the activities of the forum required resources and that members of the forum would be required to address conflict of interest issues. This forum would also provide practical suggestions about laboratory implementation of tests.

The group agreed that the focus should be on laboratory testing issues even though there may be a laboratory component associated with some broader. The forum would begin its tasks by 1) assessing the current regulatory paradigm; 2) identifying laboratory testing gaps; 3) addressing possible solutions for those gaps; and 4) assisting with practical implementation as indicated.

Dr. Gutman commented that this forum would be valuable from FDA's standpoint because although industry input on laboratory testing was readily supplied, it was often difficult to obtain input from professional laboratory organizations simply because it was often difficult to identify the appropriate individuals with whom to interact in a timely fashion.

5. Scope and Support Issues

Membership - Membership of a core group of approximately 20 individuals would be comprised of representatives of organizations whose members were themselves providers or significant users of genetic laboratory testing services and the federal agencies dealing with genetics (e.g., CDC, FDA, HCFA, NIH, HRSA, NIST). If issues came up that required broader input, other professional organizations or experts and representatives of the public would be called upon to participate.

Staffing - In order for the Forum to be effective, the attendees agreed that someone would need to manage day-to-day affairs for the group.

Staffing to meet this need was accepted as a CDC responsibility.

6. Discussion of a Genetics Regulatory Paradigm

The regulatory agencies have been discussing possible paradigms that may be models for examination by this forum. For example a tiered approach for addressing new genetic tests was discussed at the CLIAC meeting last September and a more recent "phasing in" approach was discussed recently among the agencies.

Dr. Gutman reviewed a new concept that was based upon consideration of whether the test was a predictive presymptomatic test or symptomatic. In the former case, if the test was the major or sole determinant and the disease was high risk (e.g., breast cancer and BRAC1) then this test would fall into a "high scrutiny" category. This category would be most appropriate for most stringent oversight using FDA authority. Work could be done by FDA, could be contracted out, or could be granted deemed status and performed by other government agencies or the group/consortium now being considered.

If the disease were low risk, but the predictive test was still the sole determinant, then it would fall into a category of "low scrutiny." Such tests might be appropriate for analytical characterization under existing CLIA oversight, or could be addressed in the way described above.

If the test was performed on a patient with symptoms of a particular genetic disorder and the test was the major determinant of the presence of disease which was high risk, then it would fall into a third category of "moderate scrutiny."

7. Summary

At the conclusion of the meeting it was determined that:

1. A Forum could make important contributions to the process of quality laboratory testing and the implementation of new tests.

2. The Forum would be staffed by CDC .

3. The next meeting of the Forum would address various paradigms that have been presented. Appropriate modifications will be discussed.

The next Forum meeting was tentatively scheduled for April/May 2000.

Added Note: The next meeting of the Forum has now been scheduled. It will occur at the Holiday Inn, 3377 Peachtree Road NE, Atlanta, GA (404-264-1111) on Friday, June 2, from 8:30 am - 5 pm.

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