Considerations and Recommendations for National Guidance Regarding the Retention and Use of Residual Dried Blood Spot Specimens after Newborn Screening

Secretary's Advisory Committee on Heritable Disorders in Newborns and Children

September 16, 2010

Presented by Alissa Johnson, Johnson Policy Consulting

Public Comments/Responses/Edits to Draft Report

- Approximately 550 individuals submitted e-mail comments/responses/reactions

- 13 Organizations submitted comments/edits/revisions

Public Comments/Responses – Specific Concerns & Interpretations

1. Recommends the Committee "simply" develop national guidance for consent or dissent for the secondary use of specimens.
2. Asserts a public claim on the DNA of newborn citizens.
3. Claims that "newborn blood" is necessary for "population surveillance."
4. Claims that newborn screening test development is not research.
5. Claims that state screening programs are charged with "stewardship" of newborn DNA samples—'ensuring appropriate use'—rather than charged with "simply" testing each newborn.

Public Comments/Responses – Specific Concerns & Interpretations

6. Fails to recommend informed written consent requirements for the storage and use of “newborn DNA” for research and other purposes.

7. Does not support the 22 state genetic privacy laws and the 5 state genetic ownership laws that may or do require consent.

8. Does not include public opinion data from the Univ. of Michigan study regarding “unconsented” storage and research

9. Recommends parent education instead of informed parent consent requirements that would enforce such education.

Public Comments/ Responses - Summary

Summary of Individual Comments:

- Interpretation that the recommendations for the storage and use of "newborn DNA" do not acknowledge the consent, privacy, parent, and DNA property rights of individual
- Belief that the Committee is advocating for the expansion of government power over the individual's "most intimate property"
- Opinion that the recommendations advocate for the reduction of constitutional rights of individual citizens, and as proposed do not comply with the legal individual rights and informed written consent requirements as secured by the Fourth Amendment privacy and property protections
- Perception that the Committee seeks to establish and support government banking and ownership of "citizen DNA" at birth through the creation of 50 state government DNA warehouses for nationwide genetic research on the American public without the informed written consent of citizens

Organizational Comments/ Responses received from:

American Health Insurance Plan

Center for Biomedical Ethics and Society, Vanderbilt University School of Medicine

Citizen's Council of Health Care

Genetic Alliance

March of Dimes

Michigan Department of Community Health

National Institute of Health

Secretary's Advisory Committee on Genetics, Health, and Society

Society for Inherited Metabolic Disabilities

Texas Department of State Health Services

University of Minnesota: Epidemiology Steering Committee of the Children's Oncology Group

University of Washington School of Medicine

Wadsworth Center - State of New York Department of Health

Edits to the Residual Dried Blood Specimen Paper

- Introduction - The SACHDNC encourages an approach to guidance that ***maintains the standard uses of the residual blood specimens*** by newborn screening programs and upholds the core principles of benefiting infants, families and society, protecting privacy and confidentiality, and ensuring the public‘s trust while recognizing the research value of residual newborn screening specimens and their potential for advancing science and clinical care. (p.6)

Edits to the Residual Dried Blood Specimen Paper

- Introduction - The recommendations related to the retention and use of residual dried blood spot specimens are intended to work in concert with – and not to weaken – longstanding and highly effective state newborn screening programs. (p.6)

Edits to the Residual Dried Blood Specimen Paper

- Sections renamed and reordered to now include International Policy, Federal Policy and State Policy under Ethical, Legal and Social Issues
- Sections renamed Engaging the Providers and the Public and Ensuring the Public Trust through Empowerment to highlight areas where the paper responds to public concerns/public comments

Edits to the Residual Dried Blood Specimen Paper

- Standard Newborn Screening Program Uses of Residual Dried Blood Specimens (pp. 6 and 7) – Program Evaluation and Quality Assurance, Treatment Efficacy, Test Refinement and Result Verification
- Other Uses (p.7) – New Test Development, Population Surveillance, Parental Request for Other Testing, Family Requested Identification of Remains and Research

Edits to the Residual Dried Blood Specimen Paper

- Two principal purposes -- The first purpose is to review the issues facing state newborn screening programs related to the retention and use of residual dried blood spot specimens *(reference to research deleted)*. The second purpose is to lay the foundation for developing national guidance to states in this area. (p.6)
- Because newborn screening specimens are usually the first blood specimen drawn in a baby‘s life, they represent a unique timeframe where **MOST** influences on the contents of the blood are *in utero* exposures. (p.7)

Edits to the Residual Dried Blood Specimen Paper

- Section on GINA - Greater public understanding of the protections mandated by GINA could mitigate parents‘ concerns about possible risk of genetic discrimination if their children‘s bloodspots are retained. (p.9)

Edits to the Residual Dried Blood Specimen Paper

- Section on voluntary national repository - One method for establishing a voluntary repository under discussion that could be accomplished without the collection of de novo specimens involves the use of newborn screening biobanks to develop a national newborn research biobank. There are challenges to the establishment of any non-newborn screening repository comprising residual newborn screening specimens, and significant issues would need to be addressed, including variations in state law, regulation and policies. (p.11)

Edits to the Residual Dried Blood Specimen Paper

- Section on voluntary national repository – Sentence removed: The National Children's Study established by the National Institutes of Health (NIH) provides the impetus for a U.S. national biobank based on similar hypotheses (p.11)
- Section on national IRB - A locally structured IRB lacking public health expertise may not suffice to serve a national biorepository being used for public health research. (p.11)

Edits to the Residual Dried Blood Specimen Paper

- Section on state laws and regulations – reference to examples of state forms deleted from text and appendix, reference to new table on state statutes and regulations on the storage and use of residual dried blood specimens added (Appendix C) (p.13)
- Section on ownership – Nonetheless, potential uncertainty about ***who has the authority to make decisions*** with regard to specimens and the information gathered, produced or potentially revealed as part of newborn screening or related processes remains. (p.13)

Edits to the Residual Dried Blood Specimen Paper

- Section on Michigan Biotrust for Health – Changes made based on updated information from the program (pp. 14-15 and Appendix A)
- Discussion of the Denmark biobank moved to a text box (Denmark: An International Perspective) in the section on state policies on the storage of residual dried blood specimens (p.15)

Edits to the Residual Dried Blood Specimen Paper

- Section on consent/dissent – New paragraph added (p.18)
  - Newborn screening programs may utilize several methods to provide parents or guardians with alternatives regarding specimen storage and use.
  - The alternatives involve an opt-in or opt-out process whereby individuals are informed of the potential storage and use of specimens, and either one of the following occurs:

Edits to the Residual Dried Blood Specimen Paper

- Section on consent/dissent – New paragraph added (p.18)
  - 1) A newborn‘s specimen is not stored or available for allowable, approved uses after screening is complete unless the parent/guardian opts into the biobank. Parental consent is sought and possibly formalized through a signed document; or

Edits to the Residual Dried Blood Specimen Paper

- Section on consent/dissent – New paragraph added (p.18)
  - 2) A newborn‘s specimen is stored and available for allowable, approved uses unless the parent/guardian objects or indicates dissent. (ref. added Singelton, P, Wadsworth, M) The decision to opt out also may be formalized through a signed document. Longitudinal studies of children who eventually transition to adulthood should retain some degree of flexibility to account for the decision-making authority of children as compared to adults.

Edits to the Residual Dried Blood Specimen Paper

- Conclusion – sentences reworded: (p.23)
  - Nevertheless, aspects of the current public policy environment, including differing or lacking state policies on the need for explicit consent (an opt in approach to secondary use of residual dried blood specimens) or dissent (an opt out approach to secondary use of residual dried blood specimens that presumes consent unless explicitly refused),[120] potential uncertainty about authority over decision-making with regard to residual newborn screening specimens in states without a well-defined policy, and minimal public awareness of newborn screening, send an unclear message to the public about the purpose of storage and use of residual blood specimens.

Edits to the Residual Dried Blood Specimen Paper

- Conclusion – sentences reworded:
  - This has engendered some public concern about the storage of residual newborn screening specimens even for standard newborn screening program uses. (p.23)
  - The storage and use of residual blood specimens for non-standard uses such as research may not be adequately addressed in current state laws or policies. (p.24)

Edits to the Residual Dried Blood Specimen Paper

- Conclusion – sentences added (p.24):
  - Policies developed for the storage and use of residual dried blood specimens for research should not harm longstanding and highly effective state newborn screening programs, including their ability to store and use specimens for program activities.
  - Rather, these policies should strengthen these well-established public health programs through increased public education and engagement.

Edits to the Residual Dried Blood Specimen Paper

- Recommendations (p.24)
  - More detailed explanation of recommendations removed from the Executive Summary
  - Explanation of recommendation shortened and sentence about access to policies added to recommendation 1.
  - Standard Uses provided in and sentence regarding access to policies added to recommendation 2.

Edits to the Residual Dried Blood Specimen Paper

- Recommendations (p.25)
  - "Potential use for research" changed to "potential uses" in recommendation 3.
  - Educational programs should focus on pre-natal care providers as the ***primary target***. ***Education of post-natal care providers should instruct them to follow-up on pre-natal educational efforts*** and be cognizant of new parents who did not have access to prenatal care, and, therefore, did not receive prior information about the newborn screening system.

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  - Reference to prenatal care providers being primarily responsible for parental education added to recommendation 5

Edits to the Residual Dried Blood Specimen Paper

- Recommendations (p.26)
  - Recommendations 6 and 7 separated and reworded to explain goal of recommendation as primary focus (improved education and facilitating a national dialogue) rather than request for funding to support these activities
  - Recommendation 8 is new.
    - The Secretary of Health and Human Services should explore the utility and feasibility of establishing a voluntary national repository.

Edits to the Residual Dried Blood Specimen Paper

- Recommendation 8 continued.
  - To implement this recommendation, SACHDNC recommends that the Secretary instruct and provide additional funding for the National Institutes of Health and the Centers for Disease Control and Prevention, in consultation with the Office of Human Research Protections and other relevant federal agencies and nongovernmental organizations, to draft policies and guidelines addressing the support and maintenance of the repository. Issues to be addressed include, stewardship of the collection, establishment of oversight systems, a national human subjects review structure, access and retention policies, and how legal and ethical issues would be addressed, including variations in state laws.

State Statutes and Regulations on Storage and Use of Residual Dried Blood Specimens

- As of August 2010, statutes and/or regulations in 19* states discuss storage *and* use issues to some degree
- CA, ID, IN, IA, ME, MA, MI, MN, MS, MO, NE, NH, ND, OK, SC, TX, UT, WA, WI

* State policies that refer to storage and use of information or test results only or without specifically discussing specimens and genetic privacy laws not included

State Statutes and Regulations on Storage and Use of Residual Dried Blood Specimens

Examples of Recent State Statutes and Regulations

- Idaho – IDAPA 16.02.12 (July 2010): (1) use is limited to routine calibration of newborn screening laboratory equipment and quality assurance; (2) for other uses the express written consent of parent/guardian is required; (3) storage period is up to 18 months; and (4) re-testing a specimen in the event of a symptomatic diagnosis or death is permitted

State Statutes and Regulations on Storage and Use of Residual Dried Blood Specimens

Examples of Recent State Statutes and Regulations

- 2010 Oklahoma SB 1250 “A laboratory, medical facility, hospital or birthing place is prohibited from the unauthorized storage, transferring, use or databasing of DNA of any newborn child without express parental consent.”

Examples of State Websites on Storage and Use Policies

- Minnesota
  - http://www.health.state.mn.us/newborns creening/research.html
  - Newborn screening studies (quality assurance/quality improvement for existing tests and evaluation/feasibility of new screening tests)
  - Non-newborn screening studies

Examples of State Websites on Storage and Use Policies

- Texas
  - http://www.dshs.state.tx.us/lab/nbsBloodspotsUse.shtm
  - Quality assurance and quality control
  - Research Uses
  - Information on studies from 2001-2010

Contact Information

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