Policies for Handling Residual Newborn Blood Samples for Human Health Research

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Newborn screening prevents thousands of premature illnesses and deaths every year and is one of the most successful public health programs in the US. Lately, there has been considerable controversy regarding the retention and use of residual newborn blood samples after their initial use in screening without obtaining parental informed consent. The concerns have focused on the confidentiality, privacy, and autonomy rights of parents to decide whether to permit the secondary use of these samples for research. This ongoing controversy regarding the preservation and use of dried blood samples in research has led to the destruction of several million archived samples and potentially more in the near future if no further actions are taken. Left out of the discussion, however, have been the benefits of making the residual blood samples available for biomedical research. A recent article published in Science Translational Medicine highlighted the impact that destruction of these samples would have on biomedical research and public health (1). The authors of this article also discussed possible strategies to preserve these samples for their use in research while ensuring protection of the privacy and rights of individuals without compromising the main functions of the newborn screening program.

Residual newborn blood samples have various uses, such as in providing for general quality assurance and test validation of the screening program, the fulfillment of additional tests requested by parents, the development of new screening tests, and the conduct of additional biomedical and human health research. Although the benefits of research with these samples have yet to be substantiated, the preservation of these samples is seen to provide unprecedented opportunities for the research and scientific community to study underlying diseases at this early stage. The destruction of residual blood samples may threaten the quality control and quality-assurance system of the newborn screening process and impede ongoing and future research activities.

Privacy concerns are particularly important and need to be resolved to make possible the retention and secondary use of these samples for research. Whereas the research community has focused on the identity of the samples, the public’s concerns have centered on the use of these samples without parental knowledge, which it views as a violation of the public trust by the research community. Although privacy issues can make biomedical research difficult, addressing such concerns is essential.

Current state laws and regulations regarding the retention and secondary use of newborn blood samples vary substantially. Some states require informed consent. Others allow only the release of deidentified information to researchers, even with parental consent, whereas the remaining states have yet to formally address the issue. Future privacy considerations should include not only secure storage mechanisms but also criteria regarding who can have access to these samples and under what circumstances and for what purposes.

The major challenge in resolving this controversy is to balance respecting parental involvement in decisions about the retention and secondary use of residual blood samples while recognizing the great value these samples bring to the research community and the future improvement of public health. This controversy and the resulting regulations may carry implications for other areas of biomedical research, such as the use of other types of archived samples. To move this issue forward requires encouraging more public discussion so that all viewpoints are vocalized and common ground can be identified, with the goal of fostering partnership and collaboration between the research community and the public.

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