Lessons from the Residual Newborn Screening Dried Blood Sample Litigation

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Background
Most babies born each year in the U.S. undergo mandatory newborn screening to detect serious medical conditions that can cause devastating effects if treatment is not initiated prior to the onset of symptoms. Not all of the blood collected from newborns is used during routine newborn screening, and many states retain the residual dried blood samples (DBS). DBS have a broad range of potential uses, from program evaluation to public health and biomedical research unrelated to newborn screening. State laws vary regarding whether parental consent is required to use DBS for secondary research, but federal now requires parental consent for the use of DBS in federally funded research.

The use of DBS for secondary research without explicit parental permission has generated controversy, culminating in lawsuits against health departments in Texas, Minnesota, and Indiana. The issues raised by the lawsuits extend beyond the legal question of whether states had statutory authority to retain DBS for secondary use. Additional aspects of state practices related to the retention and use of DBS have been of concern to some parents.

The Texas Litigation
In 2009, five families sued the Texas Department of State Health Services (DSHS) alleging that the practice of retaining DBS without parental consent violated rights guaranteed by the U.S. Constitution. At the time of the lawsuit, Texas law was silent regarding the disposition of DBS after newborn screening had been completed, and parental consent was not obtained to retain or release DBS for de-identified research.

The plaintiffs in Beleno v. Texas Department of State Health Services claimed that by retaining their children’s DBS without consent, DSHS had deprived them of their Fourth Amendment right to be free from unlawful searches and seizures. The plaintiffs also claimed that they had been deprived of their Fourteenth Amendment liberty and privacy interests because DBS contain “deeply private medical and genetic information.”

During the dispute, the Texas newborn screening statute was amended to require DSHS to inform parents that DSHS may retain DBS for secondary use unless parents object. DSHS subsequently agreed to settle the lawsuit and destroy over five million DBS that had been retained without parental consent.

A few weeks later, an online journal reported that DSHS had given 800 DBS to the U.S. Armed Forces Pathology Laboratory for use in a forensic database. Attorneys in the Beleno case claimed that this information had been withheld during the settlement negotiations, and a second lawsuit, Higgins v. Texas Department of State Health Services, was filed. The second case was dismissed as moot since DSHS proved that the DBS of the plaintiffs were never released to any other entity and had been destroyed pursuant to the Beleno settlement agreement.

Neither the legal issues raised in the Beleno case nor the constitutionality of the opt-out provisions of the subsequent statutory amendment were ever adjudicated. Current Texas law permits DSHS to

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retain DBS for quality assurance (QA) purposes for up to two years but requires written parental permission to release DBS for external public health research.\textsuperscript{10}

The Minnesota Litigation

The Minnesota Department of Health (MDH) began retaining DBS in 1997. In 2006, the Minnesota legislature amended the Government Data Practices Act to include provisions that regulate the treatment of genetic information by a government entity (henceforth the Genetic Privacy Act). The amendment provides that unless otherwise expressly provided by law, genetic information about an individual may be collected, stored, or disseminated by a government entity only with the written informed consent of the individual.\textsuperscript{11}

In 2009, in \textit{Bearder v. State},\textsuperscript{12} nine families sued MDH in state court, claiming that DBS and newborn screening results constitute genetic information as defined by the Genetic Privacy Act, and therefore, the state practice of retaining DBS and newborn screening results unless parents object was a violation of the Genetic Privacy Act. The District Court and the Minnesota Court of Appeals found in favor of MDH.

The Minnesota Supreme Court reversed and held that the state newborn screening statute provided an express exception to the Genetic Privacy Act only to the extent that MDH “is authorized to administer newborn screening by testing the samples for heritable and congenital disorders, recording and reporting those test results, maintaining a registry of positive cases…, and storing those test results….”\textsuperscript{13} Written informed consent is required for any other collection, use, storage, or dissemination of DBS.

The Court’s decision turned upon its interpretation of the definition of “genetic information.” The Minnesota Genetic Privacy Act includes two definitions for the term “genetic information”:

\begin{itemize}
  \item a) “Genetic information” means information about an identifiable individual derived from the presence, absence, alteration, or mutation of a gene, or the presence or absence of a specific DNA or RNA marker, which has been obtained from an analysis of: (1) the individual’s biological information or specimen...
  \item b) “Genetic information” also means medical or biological information collected from an individual about a particular genetic condition that is or might be used to provide medical care to that individual....\textsuperscript{14}
\end{itemize}

The Minnesota Supreme Court held that “genetic information” under definition (a) does not include blood samples, but rather information obtained from an analysis of biological information. This definition applies to newborn screening results but not DBS.

The Court held that in definition (b), biological information includes blood samples, and therefore, an individual’s blood samples are biological information subject to protection under definition (b). According to the Court, it “is the DNA within the blood samples that is the information that brings the blood sample within the protection of the Genetic Privacy Act.”\textsuperscript{15}

The Minnesota Supreme Court decision would have precluded the use of DBS or newborn screening results for QA purposes. The Minnesota newborn screening statute subsequently was amended to permit the retention and use of DBS and test results for program operations, including quality assurance activities and the development of new newborn screening tests, and to require explicit parental consent for any other types of research.

The Indiana Litigation

Indiana law requires the State Department of Health (ISDH) to develop a system for using de-identified DBS for epidemiological survey and research purposes.\textsuperscript{16} In June 2013, ISDH began requiring parental consent to release DBS for secondary research.\textsuperscript{17}

In September 2014, one family sued ISDH claiming that by failing to inform parents of the intent to retain DBS for research, ISDH violated the Fourth Amendment right to be free from unreasonable searches and seizures, the Fifth Amendment prohibition against the taking of private property for public use, and the Fourteenth Amendment prohibition against a state actor depriving any person of life, liberty, or property without due process of law.\textsuperscript{18} The future impact of this litigation on the Indiana newborn screening program is unclear.

Discussion

The complaints filed against the Texas and Minnesota health departments demonstrate that although the right to privacy was the legal tool used to compel states to obtain parental permission to retain DBS for secondary use, parental concerns were broader than whether the state had legal authority to retain and use DBS without explicit parental permission. These concerns could have profound implications for the operation of state newborn screening programs.

The \textit{Higgins} case alleged that DSHS had “bartered or sold” DBS to for-profit companies. This perception that the state was attempting to commercialize DBS
and profit from their sale does not reflect the reality that the costs of curation, storage, and retrieval of DBS must be generated. However, the perceived commodification of DBS has resonated with the media and undermined the public trust in the work of state newborn screening programs. Alternative mechanisms to cover the costs associated with retention and use of DBS should be devised or clear policies should be developed that demonstrate that fees recouped for the retrieval of DBS are limited to administrative costs associated with sample curation, storage, and retrieval. Such mechanisms may assure the public that the state is not making a profit from the research use of DBS.

The litigation demonstrates that all secondary uses of DBS without parental consent, including QA activities, may be objectionable to some. Historically, there has been a distinction between the use of DBS for QA purposes and their use in secondary research, but the dividing line between the two types of activities is unclear. The Minnesota Supreme Court decision would have substantially reduced the number of DBS available for QA if the Minnesota newborn screening statute had not been amended to allow for the use of DBS in this manner. Further scholarship is needed to clarify the distinction between research, public health practice, and program operations. Defining these boundaries is critical so that health departments can continue their important work.

The distinction between DBS and information derived from them also is unclear. The Minnesota Supreme Court decision would have required the destruction of newborn screening results in addition to the destruction of DBS. This loss of data would have severely limited the ability of MDH to evaluate the efficacy of the newborn screening program and to conduct research that is vital to the advancement of its public health mission.

Transparency should be a key element in any policy related to the retention and secondary use of DBS. The Texas and Minnesota complaints alleged that DBS were being used for undisclosed purposes, and the Indiana complaint alleged that DBS were being stored at an undisclosed location. The perception that state health departments had been deceptive regarding their practices related to the retention and use of DBS was a major impetus for the litigation in all three states.

Conclusion

The DBS litigation had a profound impact on the operation of the Texas and Minnesota newborn screening programs. The litigation prompted multiple changes in laws, diverted resources, and resulted in the destruction of millions of DBS.

Although the impact of the requirement to obtain informed consent for the use of DBS in federally funded research is unclear, the lawsuits demonstrate the importance of express statutory authorization to retain DBS for secondary use. Interested stakeholders should advocate for laws that grant health departments express authority to retain DBS and use them for QA and secondary public health activities. States seeking to develop policies regarding these issues should pay close attention to the legal issues raised in the litigation and the parental concerns about state practices regarding how DBS and their related information are handled.

References


6. Beleno v. Texas Dept. of State Health Services, US District Court, Western District of Texas, SA09CA0188, filed March 12, 3009.
12. Bearder v. State, 806 N.W.2d 766 (Supreme Court of Minnesota, 2011).
13. Id.
14. Id.
15. Id.
18. Doe v. VanNess, Marion County Superior Court, 49D011409CT031, filed September 25, 2014.