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Most states unclear about storage, use of babies' blood samples, new study finds

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State laws and policies governing the storage and use of surplus blood samples taken from newborns as part of the routine health screening process range from explicit to non-existent, leaving many parents ill-informed about how their babies' left over blood might be used, according to a team led by a member of the Johns Hopkins Berman Institute of Bioethics, in collaboration with researchers from the University of Utah. A report on their analysis of the subject is published March 28 in the journal *Pediatrics*.

The study is believed to be one of the first to provide in-depth analysis of the nation's fragmented newborn screening blood use policies. The authors say that their findings underscore the need for a comprehensive and transparent approach. At a minimum, all states should require that parents be fully informed about how babies' blood samples left over after the screening procedure will be stored and how they might be used, according to Michelle H. Lewis, M.D., J.D., a research scholar at the Berman Institute's Genetics and Public Policy Center.

The residual samples, typically dried blood spots, have been the center of public debate in recent years. In 2009, families in Minnesota and Texas sued their respective state health departments for storing surplus newborn blood samples without their knowledge or consent. News stories about the outrage expressed by parents—who claimed the practice violated their right to genetic privacy and full disclosure—spawned headlines such as CNN's: "The government has your baby's DNA."

"States have developed a wide range of policies regarding the retention and use of residual dried blood samples," says Lewis, "ranging from prohibiting their use for research under any circumstances, to allowing research with anonymous samples without parental consent, to requiring parental consent for any research using the samples."

Newborns in all 50 states, plus the District of Columbia, are routinely screened for a variety of genetic disorders, including phenylketonuria (pku) and sickle cell disease. State newborn screening programs began in the 1960s, and today, nearly all of the 4 million babies born each year in the United States undergo the procedure.

Once the screening has been completed, a small amount of dried blood often remains. This residual blood is often used for quality-assurance purposes to improve the operation of state newborn screening programs. Sometimes, the samples are also used for other types of biomedical research, including research unrelated to newborn screening.

Yet, state law in only 13 states specifies how residual samples of infant blood might be used. But these purposes often are often stated in broad language, according to Lewis and her co-authors. Among the detailed findings the researchers reported:

- Laws in 20 states address the retention and/or use of babies' blood samples.
- In 18 states, newborn screening laws fail to address the retention or use of the samples or their related information.
- Information related to newborn screening is deemed confidential in 26 states although limitations on that protection vary.

- Ten states specify the purposes for which information from the newborn blood samples may be used, such as public-health purposes, scientific research and research concerning medical, psychological or sociological issues.

- In four states, the samples become state property; in two of these states, parents can object in writing.

- Only eight states require that parents be provided information regarding the retention of newborn blood samples.

Overall, most states lack any requirement that parents be informed that their child's blood samples may be retained for future use, the researchers found. This was the problem in Texas, which settled out of court with the suing families last year. As part of the settlement agreement, the state Department of Health agreed to destroy more than 5 million samples that dated back to 2002, and a valuable research resource was lost.

"The destruction of those residual samples demonstrates the damage that can be done to the research enterprise if there is a public perception that states are using the samples for purposes other than that for which they were collected," Lewis says.

"I think some of the parents involved would have consented to the use of their baby's dried blood samples for research if they had been asked. These parents felt that their rights had been violated by not having been asked," Lewis added. "Even if the state did not intend to deceive the parents, there was a perception that the state was being deceptive, and this perception was damaging to the research enterprise."

The researchers agree that public discussion about the storage and use of newborn blood samples is vital, because people are becoming ever more

aware that such specimens contain precise, identifying information about their children. People also realize that research is increasingly able to yield valuable information from biological specimens.

"Part of the issue is that some parents are concerned that the state or private companies could profit from the use of their children's blood sample," Lewis says.

Although no state addresses all of these issues in a comprehensive manner, Lewis pointed to South Carolina as one that had more robust policies in place with respect to the information that must be provided to parents. There, state law requires that parents be told that they can ask that their babies' blood samples not be used for research purposes.

"As states move forward in consideration of these issues," Lewis concluded, "it is vital that state policies regarding the retention and use of residual samples not undermine the public's trust in state newborn screening programs—so that these programs can continue to protect the health of our nation's children."

Provided by Johns Hopkins Medical Institutions

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