



In blood debate, new consent effort aims to open research doors

*BY ROBIN ERB
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It's unclear what health secrets may be locked in millions of dime-sized, rust-colored blood spots of nearly every Michigander born since July 1984.

Now, scientists may have the chance to find out. The Michigan Department of Community Health is opening to researchers its archive of blood spots taken from every baby born in Michigan in the last 26 years -- information stored on more than 4 million index cards at Wayne State University's TechTown. In addition to research on the old samples, the department is hoping to make available the blood of new babies, too.

Michigan will join a handful of states, including California and Texas, allowing broader research on the state-mandated blood samples. The researchers will look for genetic clues to help them answer questions such as: Which counties have what diseases? Can you predict childhood leukemia or prevent autism? Research is now limited to screening for genetic disorders such as sickle-cell anemia.

Michigan will actively be seeking parental consent for research on the blood of new babies. Those whose blood is on existing cards will be able to opt out.

Andrea Marlow, 29, said she wouldn't hesitate to give consent. "More research is good," the Sterling Heights resident said Wednesday, a day after giving birth.

Others say they're concerned about privacy.

'You have to hope'

Laura Wright isn't concerned that Michigan has stored a bit of her toddler's blood for possible use by researchers.

"You have to hope, and you have to trust, that the researchers have the best intentions," she said.

Two of Wright's uncles died of ALS, a progressive neurodegenerative disease. And perhaps, her 2-year-old daughter's blood spots might help scientists cure that kind of suffering, said Wright, 34, of Warren. "If I can help make that possible, stop another family from having to go through that, well, I'm OK with it."

Michigan Department of Community Health officials say they are hoping to find plenty of parents like Wright as they launch a new parental consent procedure for research on blood spots taken from babies within hours of their birth.

Drawn from the baby's heel, the blood is tested now for genetic disorders, but many don't know that the state keeps the blood spots indefinitely.

But now the department is hoping to use the blood for broader research and is seeking consent. Those whose blood or children's blood already is in the system may opt out of the testing.

Last year, the Texas Department of State Health Services agreed to destroy more than 5 million stored newborn blood spots to settle a lawsuit by the Texas Civil Rights project -- a group angry that the state stored the blood spots for research without the consent of parents.

Michigan's public health leaders say they hope that raising awareness of the public health potential of their research and assuring parents that their baby's blood spots are stripped of identifiers will override parents' initial concerns.

Parent Toya Aaro, 39, of Madison Heights says she's won over by the possibility of medical breakthroughs with newborn blood. Her 19-month-old son, Jordan, has autism and she said research could help determine why the disease occurs.

By the end of the month, 12 hospitals around the state, including Rochester Hills-based Crittenton Hospital Medical Center, will begin asking for consent forms from new moms to use the blood for research. It is hoped the program will go statewide shortly afterward.

The forms are the culmination of more than a year's worth of discussions with the public, bioethicists, doctors, nurses and community leaders. The move makes the state a "sort of a beta test site for the rest of the country," said Brad Therrell of the U.S. Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children.

"They're being up front. 'Here's what might happen with these blood spots. We want you to be comfortable with it, and if you're not, you don't have to do it.' "

How it works

The blood spots are taken when a baby is just 24-36 hours old. With a pinprick to the heel, blood is drawn and dropped into small circles on filter paper that looks much like a common index card.

The testing -- begun in 1965 for a rare metabolic disease called Phenylketonuria (PKU) -- today screens for another 48 diseases and conditions. If a test detects one of those conditions, parents will be contacted.

In limited circumstances, such as religious reasons, parents can opt out of the screening program that's mandatory in Michigan and in every other state.

But then comes the second, less well-known part of the process: The residual, or leftover, blood spots are sent to the Michigan Department of Community Health. There, they are stripped of identifiers such as names, addresses or dates of birth, and filed with an individual barcode, mainly for quality assurance in the screening process.

If a parent has questions later, he or she can ask for the sample. But in recent years, with better understanding of human DNA, researchers have begun to recognize the enormous potential for research dried on these millions of cards.

The state now is in the process of moving those cards from a document warehouse in Lansing to Michigan's Neonatal Biobank, a climate-controlled, state-of-the-art facility in Detroit. Staff there will catalog and store the samples, then send them to researchers whose proposals have been vetted by a research review board.

Not everyone has the same faith in the process as Wright.

Ajay Hoque, 32, of Warren was irritated to learn last week that the blood of his preschooler, Tasmin, was on file with the state. Now, he wants it removed.

What they'll do with the materials or their research, "well, you don't really know," he said.

And Brett Guay, a 28-year-old college student, was blunt when he learned the state had stored his blood spots for 21 1/2 years, as required by law at the time: "It's creepy any time they have too much information."

What experts say

State officials are quick to note that both the existing samples and any future samples will be used only for medical research. And under the law, they cannot to be released to law enforcement, insurance companies or other third parties.

"The potential and the protections -- both are great," said Nigel Paneth, a child health epidemiologist at Michigan State University.

Paneth has found that blood spots contain messenger RNA that he said acts like a biological snapshot of the newborn at the time of birth. He said he hopes to find clues to stressors that might help scientists learn what causes cerebral palsy.

Understanding the causes, he said, may lead to a cure.

Already, the state has allowed some limited research on some of the 4 million or so samples it has stored.

All the samples -- both old and new -- will be double-blinded. Beyond being initially stripped of identifying information that is replaced with barcodes, they will be stripped of those barcodes before they leave the biobank in Detroit and reassigned new ones before going to researchers.

But there's no shortage of complex ethical questions, said Tom Tomlinson, director of MSU's Center for Ethics and Humanities in the Life Sciences.

He asked whether a parent would, for example, offer consent if the research might lead to clearer information about fetal health that, in turn, could lead to more abortions? Would it be a concern if a researcher tries to correlate racial or ethnic identities and educational achievement data?

Perhaps the stickiest issue may be what to allow with the 4 million blood spots now on file. That's why the community education campaign this summer is expected to be important.

A more informed process might mean more parents refuse to allow their child's blood to be used for research, said James McCurtis, spokesman for the Michigan Department of Community Health.

"But it's important that we're transparent," he said.