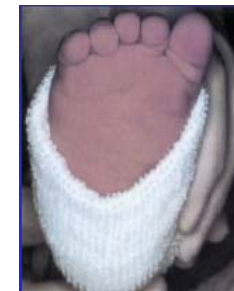


Questions and Answers

Newborn Screening Blood Spots and Michigan's BioTrust Initiative



Newborn Screening

Q. What is Newborn Screening?

Newborn Screening (NBS) is a public health program to find babies with rare but serious conditions that benefit from early treatment.

Q. When did NBS begin?

Newborn screening for a rare metabolic disease called PKU (phenylketonuria) began in 1965. PKU causes severe delays in development, but can be treated by limiting the amount of protein in the diet. Today, a child with PKU can have normal development when detected by NBS and treated early.

Q. How many disorders can be found today?

The number of disorders on the NBS panel has increased over the years as new technologies and treatments became available. The screening panel now includes 49 diseases. If these disorders are not found and treated soon after birth, permanent disability, illness or death may result.

Q. How many babies are found to have one of the disorders?

Each year, about 225 Michigan babies (1 in 530 births) are found to have one of the disorders. Over the years, more than 4,000 Michigan babies have been diagnosed and received treatment as a result of NBS.

Q. How is NBS done?

When a baby is 24-36 hours old, a few drops of blood are drawn from the baby's heel. The sample is put on a filter paper card (see Figure 1) and allowed to dry. It is then sent to the state public health laboratory at the Michigan Department of Community Health (MDCH) for testing. You can find more information about newborn screening at www.michigan.gov/newbornscreening.



Q. Who is in charge of the BioTrust?

MDCH continues to be responsible for the samples, holding the leftover spots "in trust" for future research. The laboratory contracts with the Michigan Neonatal Bio-bank (MNB), a non-profit organization, for storage and day-to-day management of the collection after samples are de-identified. MNB is part of the Biobanking Center of Excellence at Wayne State University. MDCH and MNB do not perform all the research, but make the samples available to qualified medical and public health researchers who follow the proper steps for using them.

Q. Who oversees the BioTrust?

A Board of Directors oversees MNB operations, and a Community Values Advisory Board provides guidance to MDCH, especially in regard to the ethical research uses of the DBS collection and keeping the public informed. Board members represent the major state universities, research institutions, disease organizations, community groups, professional societies and the general public. Before any DBS are provided to a researcher, a Scientific Review Board examines the request based on scientific and ethical guidelines. The MDCH Institutional Review Board assures protection of human subjects.

Q. How can I find out more about the BioTrust and the results of research that uses Michigan dried blood spots?

The Michigan Department of Community Health plans to create a webpage to keep the public informed. In the meantime, you can call 1-866-852-1247 or e-mail genetics@michigan.gov for more information. Michigan residents can also read about the BioTrust and give their input by filling out an online survey at www.michigan.gov/newbornscreening.

Michigan Department of Community Health

1-866-852-1247

genetics@michigan.gov

Q. Is there oversight of how dried blood spots are used for research?

Yes. Currently all research requests are reviewed by the Newborn Screening Laboratory Division Director, and then submitted to the Bureau of Laboratories Director for approval. To assure protection of human subjects, every proposed study is also reviewed by the MDCH Institutional Review Board (www.michigan.gov/irb), which includes two members from outside the department. With transition to the BioTrust, the Scientific Review Board will also provide oversight, as described below.

Q. What if I don't want my child's leftover dried blood spots used for research?

Parents should contact the Newborn Screening Program. They may request that their child's sample be stored but not used for any research, or that it be destroyed after screening is completed. Call 1-866-673-9939 for more information.

Michigan's BioTrust Initiative



Q. What is the BioTrust Initiative?

The Michigan BioTrust for Health is a project to make dried blood spots more useful for research. The dried blood spots are stored under conditions that better preserve the leftover samples. The BioTrust promotes use of leftover DBS for important medical and public health research studies.

Q. If newborn screening has been done since 1965, why is there interest in using the dried blood spots for research now?

The idea is not really new. In 1999, the Michigan Commission on Genetic Privacy and Progress recommended saving leftover spots because of their value for future research. In 2000, the Michigan Legislature passed a law allowing them to be used for research. Technology is now to the point where the samples are likely to be more useful than in the past.

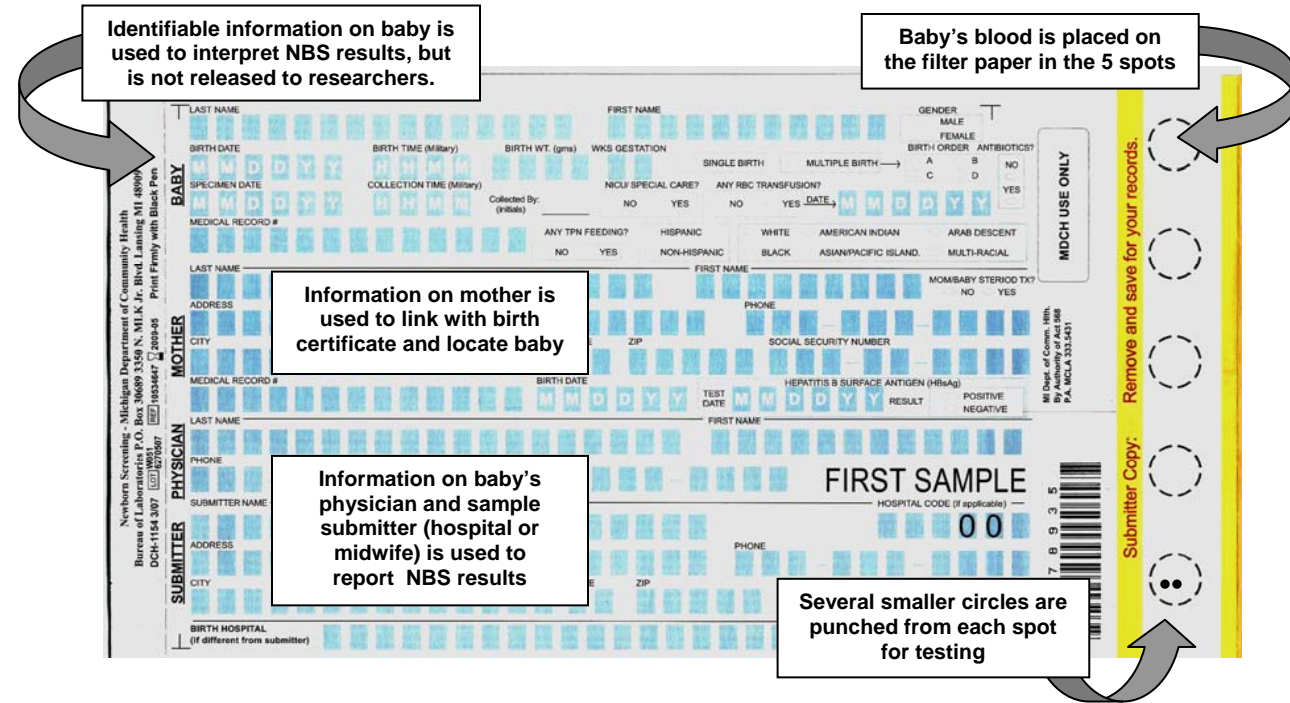


Figure 1
Michigan Department of Community Health
Newborn Screening filter paper card

Dried Blood Spots



Q. What is a dried blood spot?

The NBS blood samples on the filter paper card are often called "dried blood spots" (DBS).

Q. Are blood spots ever left over after testing?

Yes, one or two spots are often left over because most babies have normal results. Five spots of blood are usually collected to be sure there is enough for all the tests. In the event there is a positive (abnormal) test, the lab can double check the result with the extra spots. Having five spots available lowers the number of newborns who need to have their blood drawn again.

Q. What happens to the dried blood spots after screening is finished?

The filter paper cards are stored by the state public health laboratory.

Q. Is my child's or my own dried blood spot stored by the laboratory?

If you or your child was born in Michigan after 1984 and received a newborn screen, then it is likely that your DBS are stored.

Q. Why are dried blood spots stored?

Good laboratory practice requires that samples be kept for a period of time after testing is done. Also, federal regulations of laboratories require that documents related to testing be retained for two years. The State of Michigan Attorney General's office concluded that the DBS should be held in storage by the State until a child reaches 21.5 years. In 1999, a Governor's Commission on genetic privacy saw the potential for DBS to add to health research. They recommended the samples be retained indefinitely. In 2008, the MDCH laboratory changed its policy to keep samples for an indefinite period of time, as suggested by the commission.

Q. Are the blood spots used for anything else after NBS?

There are several possible uses:

- ◆ The state laboratory uses stored blood spots for developing new NBS tests, and to make sure screening equipment is working as it should be.
- ◆ To help ensure the health of all Michigan residents, the state laboratory may use blood spots to investigate the spread of infectious diseases or public health epidemics. For example, **anonymous** samples were used in the early 1990s to find out how many newborns were exposed to HIV.
- ◆ Parents may request that their own child's identifiable sample be used to assist in investigating crimes like a missing child. Also, if a child is enrolled in a research study, parents may request that their child's spot be sent to the researcher.
- ◆ State law allows leftover punches from samples to be used for medical research after newborn screening is complete. However, the sample is separated from all identifying information, so the researcher does not know whose dried blood spot is being used.



Q. What kinds of research could be done using dried blood spots?

A blood spot contains genetic and other biological information that may be useful for studying birth defects or chronic diseases like diabetes. DBS may also show if there was exposure to infections or toxic substances (such as pesticides, lead, etc) before birth.

Q. Why use leftover dried blood spots for research?

Studying DBS may lead to new screening tests. Research may also provide important clues about different factors that impact health or cause diseases not only in Michigan but worldwide. The samples are no longer needed after NBS is complete. Because many DBS samples can be provided at one time, it is easier for researchers to study very large numbers of people from all over the state. This is simpler than trying to collect a new sample from each person. This can help speed up the chance of new discoveries, improve quality, and possibly reduce the cost of research.

Q. What kind of research has been done, and would be allowed in the future?

The only studies that have been done and would be allowed in the future are for medical research. Some examples of studies that have been done include: (1) studying the incidence of different gene variants for an inherited condition (hereditary hemochromatosis); (2) developing additional laboratory screening methods (sickle cell diseases); and (3) searching for new disease markers (childhood leukemia).

Q. Has my child's (or my own) dried blood spot been used for medical research or public health investigations?

It is not possible to tell exactly which spots have been used, because all identifying information is removed. New procedures are being put in place to track samples with a barcode, but they will still not have any personal identifying information. It should also be noted that lab policy states at least one full spot is always saved for use by the child or his/her family in case it is ever needed.

