Engaging the Public/Parents and Enlisting Providers

National Conversation on Newborn Screening Research and Informed Consent

Educating the Public About Newborn Screening:
Current and Proposed Communication Strategies

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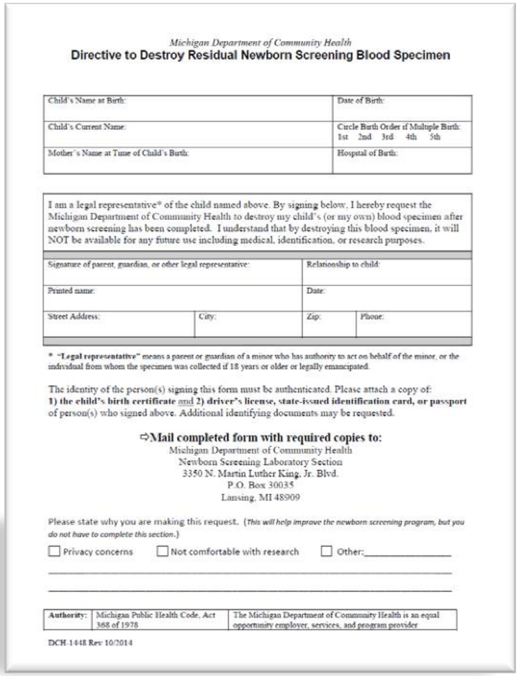
BioTrust Coordinator
June 1, 2015

MDHHS
Michigan Department of Health & Human Services
RICK SNYDER, GOVERNOR | NICK LYON, DIRECTOR

Current BioTrust Opt-Out Process

Samples Collected Between July 1984 and April 30, 2010

- Evolution of retention policy
- ~4 million samples
- Opt-out through directive to destroy or store only
- On-going awareness campaign and annual MDHHS IRB review



Michigan Department of Community Health

Directive to Destroy Residual Newborn Screening Blood Specimen

Child's Name at Birth:	Date of Birth:
Child's Current Name:	Circle Birth Order if Multiple Birth: 1st 2nd 3rd 4th 5th
Mother's Name at Time of Child's Birth:	Hospital of Birth:

I am a legal representative* of the child named above. By signing below, I hereby request the Michigan Department of Community Health to destroy my child's (or my own) blood specimen after newborn screening has been completed. I understand that by destroying this blood specimen, it will NOT be available for any future use including medical, identification, or research purposes.

Signature of parent, guardian, or other legal representative:		Relationship to child:	
Printed name:		Date:	
Street Address:	City:	Zip:	Phone:

* **"Legal representative"** means a parent or guardian of a minor who has authority to act on behalf of the minor, or the individual from whom the specimen was collected if 18 years or older or legally emancipated.

The identity of the person(s) signing this form must be authenticated. Please attach a copy of: **1) the child's birth certificate** and **2) driver's license, state-issued identification card, or passport** of person(s) who signed above. Additional identifying documents may be requested.

⇨Mail completed form with required copies to:

Michigan Department of Community Health
Newborn Screening Laboratory Section
3350 N. Martin Luther King, Jr. Blvd.
P.O. Box 30035
Lansing, MI 48909

Please state why you are making this request. (*This will help improve the newborn screening program, but you do not have to complete this section.*)

☐ Privacy concerns ☐ Not comfortable with research ☐ Other:____________

Authority:	Michigan Public Health Code, Act 368 of 1978	The Michigan Department of Community Health is an equal opportunity employer, services, and program provider

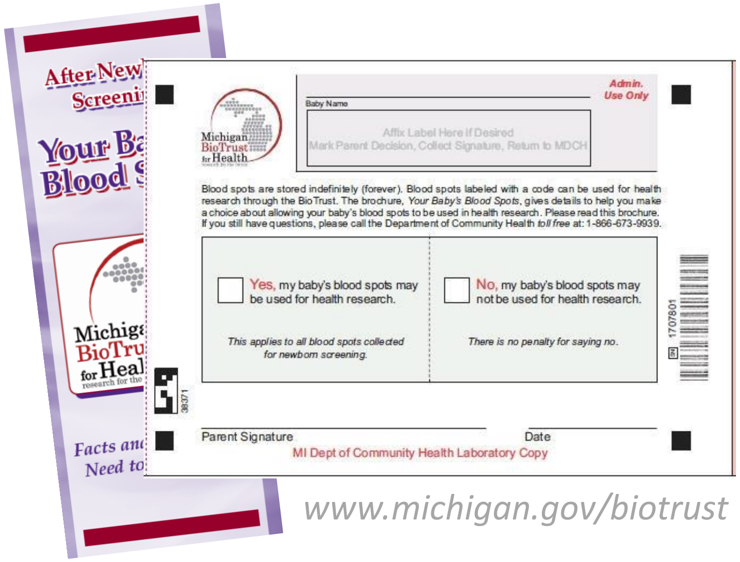
DCH-1448 Rev 10/2014

www.michigan.gov/biotrust

Current BioTrust Consent Process

Samples Collected May 1, 2010 Through Present Day

- Separate consent brochure & declaration form in NBS card
- Materials available for introduction in prenatal care settings with consent process after delivery
- Birthing hospital staff and home birth attendants acting on behalf of MDHHS to collect consent decision



Admin. Use Only

Baby Name

Affix Label Here If Desired
Mark Parent Decision, Collect Signature, Return to MDCH

Blood spots are stored indefinitely (forever). Blood spots labeled with a code can be used for health research through the BioTrust. The brochure, *Your Baby's Blood Spots*, gives details to help you make a choice about allowing your baby's blood spots to be used in health research. Please read this brochure. If you still have questions, please call the Department of Community Health *toll free* at: 1-866-673-9939.

☐ Yes, my baby's blood spots may be used for health research.

This applies to all blood spots collected for newborn screening.

☐ No, my baby's blood spots may not be used for health research.

There is no penalty for saying no.

1707801

38371

Parent Signature

Date

MI Dept of Community Health Laboratory Copy

www.michigan.gov/biotrust

Current BioTrust Options

Engaging and Informing the Public

- 9 Mass media segments
- ~120 Lectures/Exhibits
- ~30 Grand Rounds
- ~70 Social Media/Online
- 18 webinars, YouTube Videos, Newsletters
- 7 National Presentations
- 4 Peer-Reviewed Journal Articles

EXEC BOSSES:
E NEED
'COME
CLEAN'

A BEGINNER'S GUIDE

FROZEN FOUR

Before puck drops at Ford Field today, brush up

Detroit Free Press

'NO QUESTION THAT THEY'RE ON TRACK'

Things looking up fo

BABY BLOOD ARCHIVE OPEN

N TOMPOR
ware of new
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your

DICKERSON

www.michigan.gov/biotrust

Current BioTrust Options

Engaging and Informing the Community

- Community Values Advisory Board
- Transparent website

MDHHS Michigan Department of Health and Human Services

Putting people first, with the goal of helping all Michiganders lead healthier and more productive lives, no matter their stage in life.

Search

Birth, Death, Marriage and Divorce Records
Physical Health & Prevention
Pregnant Women, Children & Families
Women, Infants & Children
Children & Families
Healthy Children & Healthy Families
Lead Poisoning
Immunization Info for Families & Providers
Hereditary Disorders
Children's Special Health Care Services
Early Hearing Detection and Intervention
Pregnancy Risk Assessment Monitoring
Maternal & Child Health Epidemiology
Trauma & Toxic Stress
Behavioral Health & Developmental Disability
Health Care Coverage
Statistics and Reports
Providers
Inside Community Health
Public Safety & Environmental Health
Safe Delivery of Newborns
Infant Safe Sleep
Sign up for email from MDHHS!

MDCH > PREGNANT WOMEN, CHILDREN & FAMILIES > CHILDREN & FAMILIES > HEREDITARY DISORDERS

MICHIGAN BIOTRUST FOR HEALTH

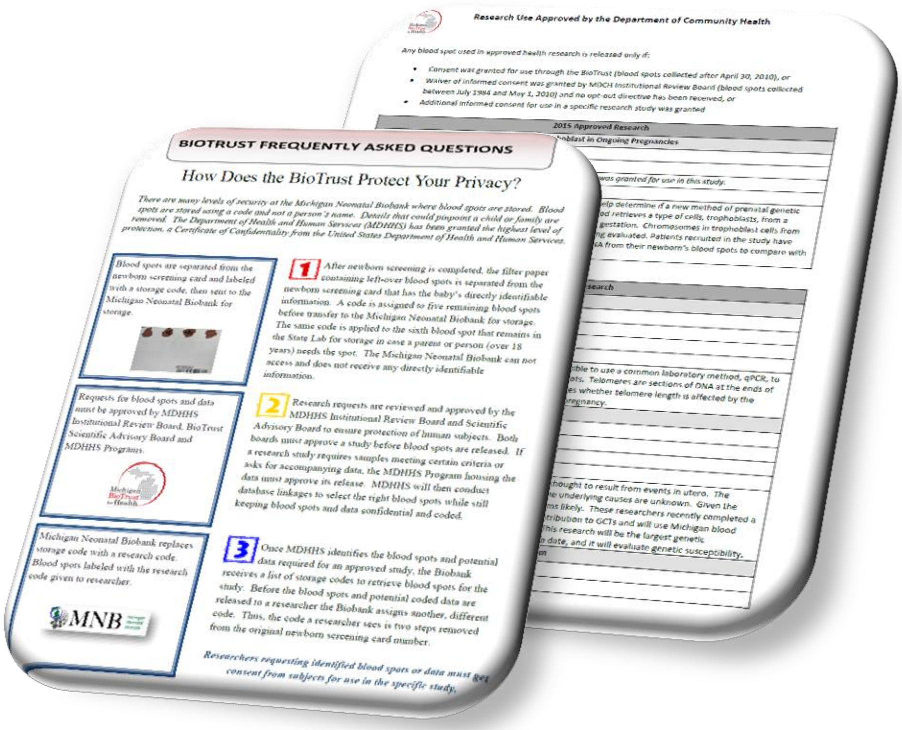
Welcome to the Michigan BioTrust for Health (BioTrust) website! The BioTrust is a program to oversee our state's stored blood spots and their use in health research. Five to six blood spots are collected from almost every newborn shortly after birth for newborn screening. After newborn screening is performed at the state laboratory, any unused blood spots (including parts of blood spots) are stored indefinitely (forever) unless a parent or grown child (18 years or older) opts-out. De-identified stored blood spots can be used for research. The choice to allow research use is yours to make. **Please explore this website to learn more!**

The Newborn Screening Saves Lives Reauthorization Act
The Newborn Screening Lives Reauthorization Act, signed into law by President Obama on December 18, 2014, helps sustain and improve newborn screening programs. The law also stipulates federally funded research using blood spots collected after March 15, 2015, must be considered human subjects research and waivers or alterations of informed consent cannot be applied. The Michigan BioTrust for Health, our state's newborn screening biobanking initiative, has always emphasized the importance of informed decision-making. A consent process for parents delivering at home or in hospitals has been in place since May 1, 2010, and an opt-out process is available for those whose spots were collected prior to this date. The BioTrust will continue to evolve to meet new legislative requirements and regulations with guidance from the Community Values Advisory Board. Please stay tuned and contact the BioTrust Coordinator (517-335-8497 or biotrust@michigan.gov) with any questions or concerns.

ANNOUNCEMENTS	CONSENT OPTIONS	INFORMATION FOR HOSPITALS AND HEALTH PROFESSIONALS
FREQUENTLY ASKED QUESTIONS	EDUCATIONAL RESOURCES AND COMMUNITY OUTREACH	PUBLICATIONS AND MEDIA LINKS
ADVISORY BOARDS	BLOOD SPOT RESEARCH	MNB

Go to Michigan Newborn Screening

Genomics and Genetic Disorders Section
Division of Genomics, Perinatal Health & Chronic Disease Epidemiology



Research Use Approved by the Department of Community Health

Any blood spot used in approved health research is released only if:

- *Consent was granted for use through the BioTrust (blood spots collected after April 30, 2010), or*
- *Waiver of informed consent was granted by MDCH Institutional Review Board (blood spots collected between July 1984 and May 1, 2010) and no opt-out directive has been received, or*
- *Additional informed consent for use in a specific research study was granted*

2015 Approved Research

BIOTRUST FREQUENTLY ASKED QUESTIONS

How Does the BioTrust Protect Your Privacy?

There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. Blood spots are stored using a code and not a person's name. Details that could pinpoint a child or family are removed. The Department of Health and Human Services (MDHHS) has been granted the highest level of protection, a Certificate of Confidentiality from the United States Department of Health and Human Services.

Blood spots are separated from the newborn screening card and labeled with a storage code, then sent to the Michigan Neonatal Biobank for storage.

1 After newborn screening is completed, the filter paper containing left-over blood spots is separated from the newborn screening card that has the baby's directly identifiable information. A code is assigned to five remaining blood spots before transfer to the Michigan Neonatal Biobank for storage. The same code is applied to the sixth blood spot that remains in the State Lab for storage in case a parent or person (over 18 years) needs the spot. The Michigan Neonatal Biobank can not access and does not receive any directly identifiable information.

Requests for blood spots and data must be approved by MDHHS Institutional Review Board, BioTrust Scientific Advisory Board and MDHHS Programs.

2 Research requests are reviewed and approved by the MDHHS Institutional Review Board and Scientific Advisory Board to ensure protection of human subjects. Both boards must approve a study before blood spots are released. If a research study requires samples meeting certain criteria or asks for accompanying data, the MDHHS Program housing the data must approve its release. MDHHS will then conduct database linkages to select the right blood spots while still keeping blood spots and data confidential and coded.

Michigan Neonatal Biobank replaces storage code with a research code. Blood spots labeled with the research code given to researcher.

3 Once MDHHS identifies the blood spots and potential data required for an approved study, the Biobank receives a list of storage codes to retrieve blood spots for the study. Before the blood spots and potential coded data are released to a researcher the Biobank assigns another, different code. Thus, the code a researcher sees is two steps removed from the original newborn screening card number.

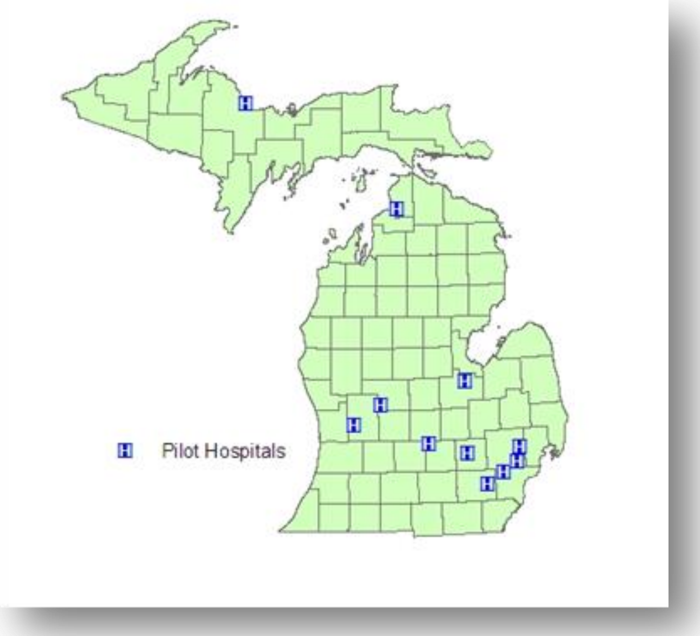
Researchers requesting identified blood spots or data must get consent from subjects for use in the specific study.

www.michigan.gov/biotrust

Achieving Hospital Buy-In

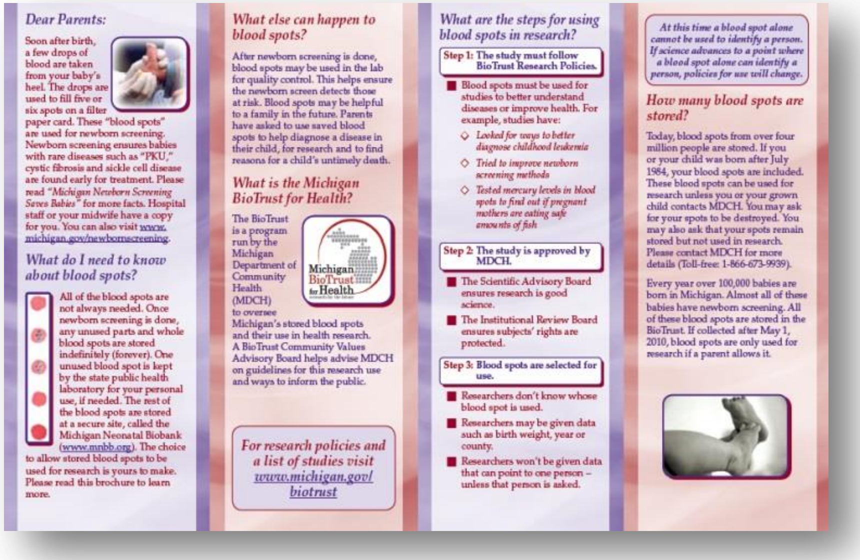
MDHHS is the investigator and ultimately responsible for the blood spots.

- *Alert* Hospitals
  - NBS Regional Trainings
  - BioTrust Hospital Preparation Letter
- *Enlist* Hospitals
  - Pilot/early implementation phase
- *Inform* Hospitals
  - Ongoing feedback and resources



Achieving Hospital Buy-In

- *Accommodate* Hospitals
  - Decrease potential burden on staff
    - Comprehensive detailed consent brochure



Dear Parents:

Soon after birth, a few drops of blood are taken from your baby's heel. The drops are used to fill five or six spots on a filter paper card. These "blood spots" are used for newborn screening. Newborn screening ensures babies with rare diseases such as "PKU," cystic fibrosis and sickle cell disease are found early for treatment. Please read *"Michigan Newborn Screening Saves Babies"* for more facts. Hospital staff or your midwife have a copy for you. You can also visit www.michigan.gov/newbornscreening.

What do I need to know about blood spots?

All of the blood spots are not always needed. Once newborn screening is done, any unused parts and whole blood spots are stored indefinitely (forever). One unused blood spot is kept by the state public health laboratory for your personal use, if needed. The rest of the blood spots are stored at a secure site, called the Michigan Neonatal Biobank (www.mnbb.org). The choice to allow stored blood spots to be used for research is yours to make. Please read this brochure to learn more.

What else can happen to blood spots?

After newborn screening is done, blood spots may be used in the lab for quality control. This helps ensure the newborn screen detects those at risk. Blood spots may be helpful to a family in the future. Parents have asked to use saved blood spots to help diagnose a disease in their child, for research and to find reasons for a child's untimely death.

What is the Michigan BioTrust for Health?

The BioTrust is a program run by the Michigan Department of Community Health (MDCH) to oversee Michigan's stored blood spots and their use in health research. A BioTrust Community Values Advisory Board helps advise MDCH on guidelines for this research use and ways to inform the public.

For research policies and a list of studies visit www.michigan.gov/biotrust

What are the steps for using blood spots in research?

Step 1: The study must follow BioTrust Research Policies.

- Blood spots must be used for studies to better understand diseases or improve health. For example, studies have:
  - *Looked for ways to better diagnose childhood leukemia*
  - *Tried to improve newborn screening methods*
  - *Tested mercury levels in blood spots to find out if pregnant mothers are eating safe amounts of fish*

Step 2: The study is approved by MDCH.

- The Scientific Advisory Board ensures research is good science.
- The Institutional Review Board ensures subjects' rights are protected.

Step 3: Blood spots are selected for use.

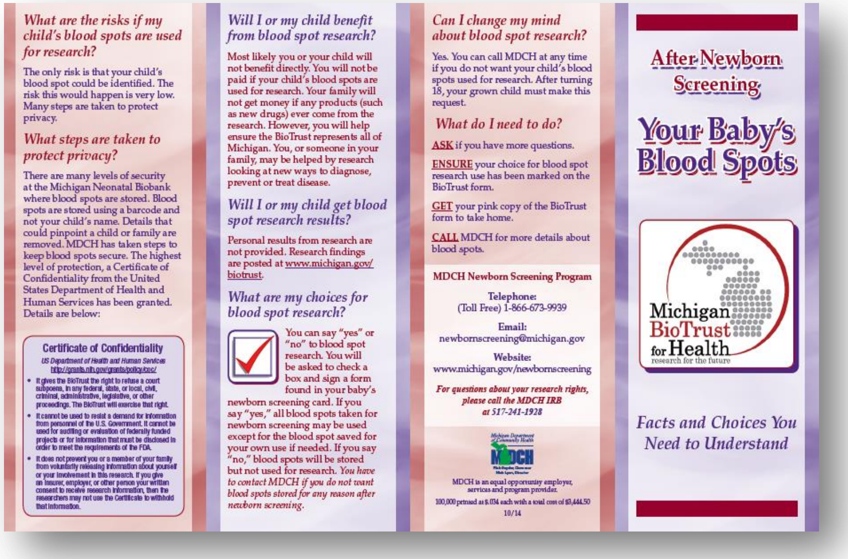
- Researchers don't know whose blood spot is used.
- Researchers may be given data such as birth weight, year or county.
- Researchers won't be given data that can point to one person – unless that person is asked.

At this time a blood spot alone cannot be used to identify a person. If science advances to a point where a blood spot alone can identify a person, policies for use will change.

How many blood spots are stored?

Today, blood spots from over four million people are stored. If you or your child was born after July 1984, your blood spots are included. These blood spots can be used for research unless you or your grown child contacts MDCH. You may ask for your spots to be destroyed. You may also ask that your spots remain stored but not used in research. Please contact MDCH for more details (Toll-free: 1-866-673-9939).

Every year over 100,000 babies are born in Michigan. Almost all of these babies have newborn screening. All of these blood spots are stored in the BioTrust. If collected after May 1, 2010, blood spots are only used for research if a parent allows it.



What are the risks if my child's blood spots are used for research?

The only risk is that your child's blood spot could be identified. The risk this would happen is very low. Many steps are taken to protect privacy.

What steps are taken to protect privacy?

There are many levels of security at the Michigan Neonatal Biobank where blood spots are stored. Blood spots are stored using a barcode and not your child's name. Details that could pinpoint a child or family are removed. MDCH has taken steps to keep blood spots secure. The highest level of protection, a Certificate of Confidentiality from the United States Department of Health and Human Services has been granted. Details are below:

Certificate of Confidentiality

US Department of Health and Human Services

http://grants.nih.gov/grants/policy/coc/

- It gives the BioTrust the right to refuse a court subpoena, in any federal, state, or local, civil, criminal, administrative, legislative, or other proceedings. The BioTrust will exercise that right.
- It cannot be used to resist a demand for information from personnel of the U.S. Government. It cannot be used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the FDA.
- It does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you give an insurer, employer, or other person your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

Will I or my child benefit from blood spot research?

Most likely you or your child will not benefit directly. You will not be paid if your child's blood spots are used for research. Your family will not get money if any products (such as new drugs) ever come from the research. However, you will help ensure the BioTrust represents all of Michigan. You, or someone in your family, may be helped by research looking at new ways to diagnose, prevent or treat disease.

Will I or my child get blood spot research results?

Personal results from research are not provided. Research findings are posted at www.michigan.gov/biotrust.

What are my choices for blood spot research?

☑ You can say "yes" or "no" to blood spot research. You will be asked to check a box and sign a form found in your baby's newborn screening card. If you say "yes," all blood spots taken for newborn screening may be used except for the blood spot saved for your own use if needed. If you say "no," blood spots will be stored but not used for research. *You have to contact MDCH if you do not want blood spots stored for any reason after newborn screening.*

Can I change my mind about blood spot research?

Yes. You can call MDCH at any time if you do not want your child's blood spots used for research. After turning 18, your grown child must make this request.

What do I need to do?

ASK if you have more questions.

ENSURE your choice for blood spot research use has been marked on the BioTrust form.

GET your pink copy of the BioTrust form to take home.

CALL MDCH for more details about blood spots.

MDCH Newborn Screening Program

Telephone:
(Toll Free) 1-866-673-9939

Email:
newbornscreening@michigan.gov

Website:
www.michigan.gov/newbornscreening

For questions about your research rights, please call the MDCH IRB at 517-241-1928

MDCH is an equal opportunity employer, services and program provider.

100,000 printed at $.034 each with a total cost of $3,444.50
10/14

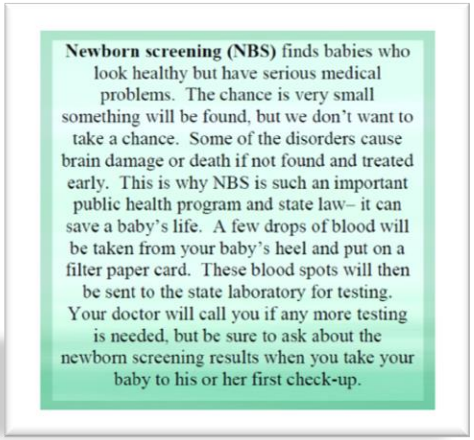
After Newborn Screening

Your Baby's Blood Spots

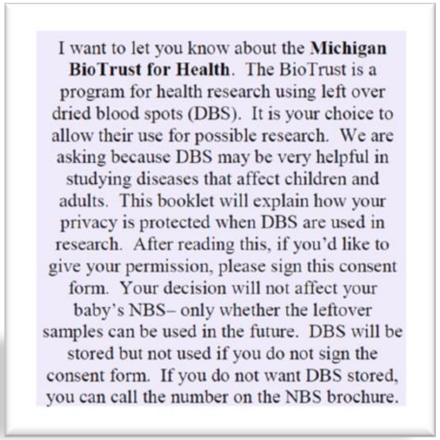
Facts and Choices You Need to Understand

Achieving Hospital Buy-In

- *Train* Hospitals
  - Facilitate conversations with parents (brochures alone won’t work)
  - Staff won’t discuss if uncertain of details
    - Pediatric grand rounds and business meetings
    - Nursing/birthing attendant trainings
    - Script badge cards and instruction fliers



Newborn screening (NBS) finds babies who look healthy but have serious medical problems. The chance is very small something will be found, but we don’t want to take a chance. Some of the disorders cause brain damage or death if not found and treated early. This is why NBS is such an important public health program and state law– it can save a baby’s life. A few drops of blood will be taken from your baby’s heel and put on a filter paper card. These blood spots will then be sent to the state laboratory for testing. Your doctor will call you if any more testing is needed, but be sure to ask about the newborn screening results when you take your baby to his or her first check-up.



I want to let you know about the **Michigan BioTrust for Health**. The BioTrust is a program for health research using left over dried blood spots (DBS). It is your choice to allow their use for possible research. We are asking because DBS may be very helpful in studying diseases that affect children and adults. This booklet will explain how your privacy is protected when DBS are used in research. After reading this, if you’d like to give your permission, please sign this consent form. Your decision will not affect your baby’s NBS– only whether the leftover samples can be used in the future. DBS will be stored but not used if you do not sign the consent form. If you do not want DBS stored, you can call the number on the NBS brochure.

Achieving Hospital Buy-In

- *Adapt to* Hospitals
  - Allow flexibility in administering consent process

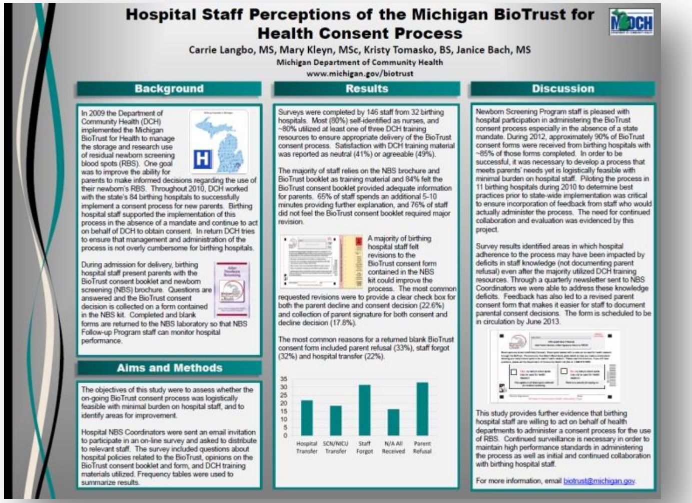
One-stop delivery suites ↔ Separate delivery and mother-baby unit

Collect decision with blood spot ↔ Collect decision prior to discharge

Nurse collection ↔ Lab or other staff collection

Achieving Hospital Buy-In

- *Incentivize* Hospitals
  - Continuing education credits
  - Lectures/workshops
- *Monitor* Hospitals
  - Quarterly quality assurance reports
  - Michigan Health and Hospital Association
- *Listen* to Hospitals
  - 2013 Survey
    - ~80% MDHHS trained (90% agreeable/neutral satisfaction)
    - 84% felt BioTrust brochure adequately informed parents
    - 65% spent additional 5-10 minutes answering questions
    - 23% wanted clearer “yes”/“no” box



Hospital Staff Perceptions of the Michigan BioTrust for Health Consent Process

Carrie Langbo, MS, Mary Kleyn, MSc, Kristy Tomasko, BS, Janice Bach, MS
Michigan Department of Community Health
www.michigan.gov/biotrust

Background

In 2009 the Department of Community Health (DCH) implemented the Michigan BioTrust for Health to manage the storage and research use of residual newborn screening blood spots (RBS). One goal was to improve the ability for parents to make informed decisions regarding the use of their newborn's RBS. Throughout 2010, DCH worked with the state's 84 birthing hospitals to successfully implement a consent process for new parents. Birthing hospital staff supported the implementation of this process in the absence of a mandate and continue to act on behalf of DCH to obtain consent. In return DCH tries to ensure that management and administration of the process is not overly cumbersome for birthing hospitals.

During admission for delivery, birthing hospital staff present parents with the BioTrust consent booklet and newborn screening (NBS) brochure. Questions are answered and the BioTrust consent decision is collected on a form contained in the NBS kit. Completed and blank forms are returned to the NBS laboratory so that NBS Follow-up Program staff can monitor hospital performance.

Aims and Methods

The objectives of this study were to assess whether the on-going BioTrust consent process was logistically feasible with minimal burden on hospital staff, and to identify areas for improvement.

Hospital NBS Coordinators were sent an email invitation to participate in an on-line survey and asked to distribute to relevant staff. The survey included questions about hospital policies related to the BioTrust, opinions on the BioTrust consent booklet and form, and DCH training materials utilized. Frequency tables were used to summarize results.

Results

Surveys were completed by 146 staff from 32 birthing hospitals. Most (80%) self-identified as nurses, and ~80% utilized at least one of three DCH training resources to ensure appropriate delivery of the BioTrust consent process. Satisfaction with DCH training material was reported as neutral (41%) or agreeable (49%).

The majority of staff relies on the NBS brochure and BioTrust booklet as training material and 84% felt the BioTrust consent booklet provided adequate information for parents. 65% of staff spends an additional 5-10 minutes providing further explanation, and 76% of staff did not feel the BioTrust consent booklet required major revision.

A majority of birthing hospital staff felt revisions to the BioTrust consent form contained in the NBS kit could improve the process. The most common requested revisions were to provide a clear check box for both the parent decline and consent decision (22.6%) and collection of parent signature for both consent and decline decision (17.8%).

The most common reasons for a returned blank BioTrust consent form included parent refusal (33%), staff forgot (32%) and hospital transfer (22%).

Discussion

Newborn Screening Program staff is pleased with hospital participation in administering the BioTrust consent process especially in the absence of a state mandate. During 2012, approximately 90% of BioTrust consent forms were received from birthing hospitals with ~85% of those forms completed. In order to be successful, it was necessary to develop a process that meets parents' needs yet is logistically feasible with minimal burden on hospital staff. Piloting the process in 11 birthing hospitals during 2010 to determine best practices prior to state-wide implementation was critical to ensure incorporation of feedback from staff who would actually administer the process. The need for continued collaboration and evaluation was evidenced by this project.

Survey results identified areas in which hospital adherence to the process may have been impacted by deficits in staff knowledge (not documenting parent refusal) even after the majority utilized DCH training resources. Through a quarterly newsletter sent to NBS Coordinators we were able to address these knowledge deficits. Feedback has also led to a revised parent consent form that makes it easier for staff to document parental consent decisions. The form is scheduled to be in circulation by June 2013.

This study provides further evidence that birthing hospital staff are willing to act on behalf of health departments to administer a consent process for the use of RBS. Continued surveillance is necessary in order to maintain high performance standards in administering the process as well as initial and continued collaboration with birthing hospital staff.

For more information, email biotrust@michigan.gov.

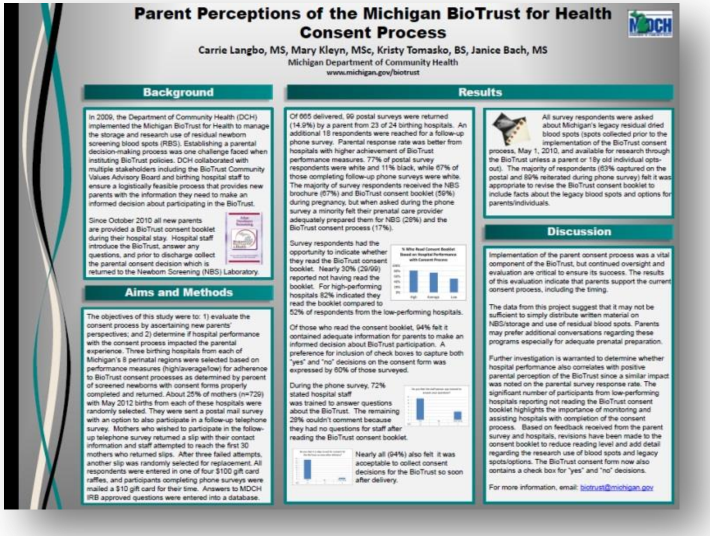
2013 NBSGTS Symposium Poster Presentation

Achieving Buy-In for Homebirths

- *Identify* homebirth attendants
  - Preparedness letter sent to all who submitted NBS since 2008
- *Invite* participation
  - Offer to attend functions
  - Partner with other programs to provide information
  - On-going efforts

Engaging Parents

- *Prepare and Listen to Parents*
  - Prenatal education
  - 2013 parent mail survey *(n=99)*
    - 52-82% read brochure (*higher percent from hospitals with better rates of completion)*
    - 67% received NBS brochure prenatally
    - 59% received BioTrust brochure prenatally
  - 2013 parent phone survey *(n=18)*
    - 72% felt staff prepared, 28% had no questions
    - 94% ok with decision collected at delivery



Parent Perceptions of the Michigan BioTrust for Health Consent Process

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Background

In 2009, the Department of Community Health (DCH) implemented the Michigan BioTrust for Health to manage the storage and research use of residual newborn screening blood spots (RBS). Establishing a parental decision-making process was one challenge faced when instituting BioTrust policies. DCH collaborated with multiple stakeholders including the BioTrust Community Values Advisory Board and birthing hospital staff to ensure a logistically feasible process that provides new parents with the information they need to make an informed decision about participating in the BioTrust.

Since October 2010 all new parents are provided a BioTrust consent booklet during their hospital stay. Hospital staff introduce the BioTrust, answer any questions, and prior to discharge collect the parental consent decision which is returned to the Newborn Screening (NBS) Laboratory.

Aims and Methods

The objectives of this study were to: 1) evaluate the consent process by ascertaining new parents' perspectives; and 2) determine if hospital performance with the consent process impacted the parental experience. Three birthing hospitals from each of Michigan's 8 perinatal regions were selected based on performance measures (high/average/low) for adherence to BioTrust consent processes as determined by percent of screened newborns with consent forms properly completed and returned. About 25% of mothers (n=729) with May 2012 births from each of these hospitals were randomly selected. They were sent a postal mail survey with an option to also participate in a follow-up telephone survey. Mothers who wished to participate in the follow-up telephone survey returned a slip with their contact information and staff attempted to reach the first 30 mothers who returned slips. After three failed attempts, another slip was randomly selected for replacement. All respondents were entered in one of four $100 gift card raffles, and participants completing phone surveys were mailed a $10 gift card for their time. Answers to MDCH IRB approved questions were entered into a database.

Results

Of 665 delivered, 99 postal surveys were returned (14.9%) by a parent from 23 of 24 birthing hospitals. An additional 18 respondents were reached for a follow-up phone survey. Parental response rate was better from hospitals with higher achievement of BioTrust performance measures. 77% of postal survey respondents were white and 11% black, while 67% of those completing follow-up phone surveys were white. The majority of survey respondents received the NBS brochure (67%) and BioTrust consent booklet (59%) during pregnancy, but when asked during the phone survey a minority felt their prenatal care provider adequately prepared them for NBS (28%) and the BioTrust consent process (17%).

Survey respondents had the opportunity to indicate whether they read the BioTrust consent booklet. Nearly 30% (29/99) reported not having read the booklet. For high-performing hospitals 82% indicated they read the booklet compared to 52% of respondents from the low-performing hospitals.

Of those who read the consent booklet, 94% felt it contained adequate information for parents to make an informed decision about BioTrust participation. A preference for inclusion of check boxes to capture both "yes" and "no" decisions on the consent form was expressed by 60% of those surveyed.

During the phone survey, 72% stated hospital staff was trained to answer questions about the BioTrust. The remaining 28% couldn't comment because they had no questions for staff after reading the BioTrust consent booklet.

Nearly all (94%) also felt it was acceptable to collect consent decisions for the BioTrust so soon after delivery.

All survey respondents were asked about Michigan's legacy residual dried blood spots (spots collected prior to the implementation of the BioTrust consent process, May 1, 2010, and available for research through the BioTrust unless a parent or 18y old individual opts-out). The majority of respondents (63% captured on the postal and 89% reiterated during phone survey) felt it was appropriate to revise the BioTrust consent booklet to include facts about the legacy blood spots and options for parents/individuals.

Discussion

Implementation of the parent consent process was a vital component of the BioTrust, but continued oversight and evaluation are critical to ensure its success. The results of this evaluation indicate that parents support the current consent process, including the timing.

The data from this project suggest that it may not be sufficient to simply distribute written material on NBS/storage and use of residual blood spots. Parents may prefer additional conversations regarding these programs especially for adequate prenatal preparation.

Further investigation is warranted to determine whether hospital performance also correlates with positive parental perception of the BioTrust since a similar impact was noted on the parental survey response rate. The significant number of participants from low-performing hospitals reporting not reading the BioTrust consent booklet highlights the importance of monitoring and assisting hospitals with completion of the consent process. Based on feedback received from the parent survey and hospitals, revisions have been made to the consent booklet to reduce reading level and add detail regarding the research use of blood spots and legacy spots/options. The BioTrust consent form now also contains a check box for "yes" and "no" decisions.

For more information, email: biotrust@michigan.gov

2013 NBSGTS Symposium Poster Presentation

Michigan BioTrust for Health
research for the future

Achieving Statewide Buy-In

- *Ultimate goal is to maintain integrity and success of newborn screening*

*In 2009, **99.5%** Michigan newborns benefitted from newborn screening.*

*In 2013, **99.5%** of Michigan newborns benefitted from newborn screening.*

Michigan BioTrust for Health

Thank you!

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