

Preparing Birthing Hospitals to Implement Parental Consent for the Michigan BioTrust for Health Challenges and Successes One Year Later



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2011 Newborn Screening and Genetic Testing Symposium
Association of Public Health Laboratories

The BioTrust: 18 Months Later



- ❑ May 2010 NBS & Genetic Testing Symposium
 - MI public health code allows storage/use
 - Community engagement results supported storage/use
 - Parent consent process required for prospectively collected DBS..pilot phase planned

- ❑ November 2011 NBS & Genetic Testing Symposium
 - On-going community education
 - *Parental consent process implemented in all birth hospitals*

BioTrust Consent Process...*Timeline*



BioTrust Parental Consent Process..

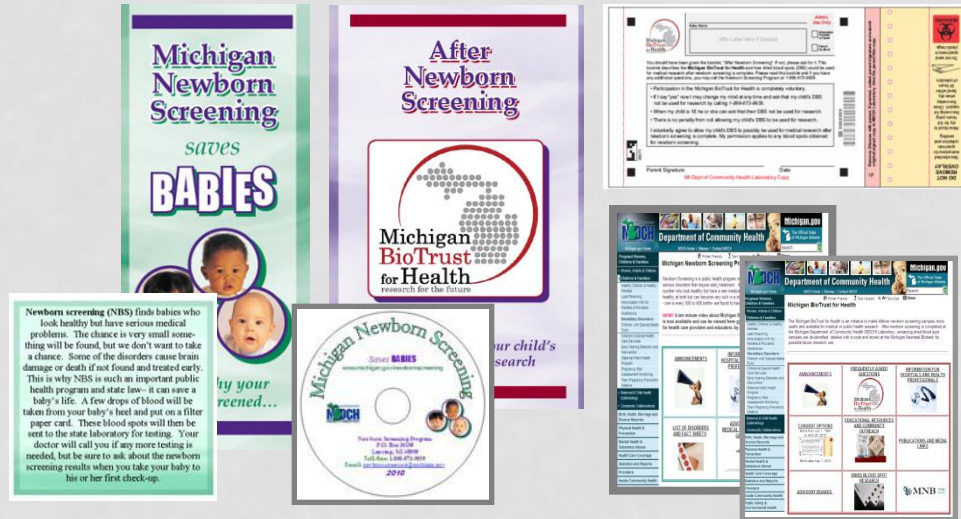
The Educational Tools

□ For Parents

- Revised NBS Brochure
- Video introducing NBS and BioTrust (DVD and online)
- BioTrust Consent Booklet & Form
- NBS and BioTrust websites

□ For Professionals

- Pocket script cards
- Quarterly NBS newsletter
- Nursing CEs

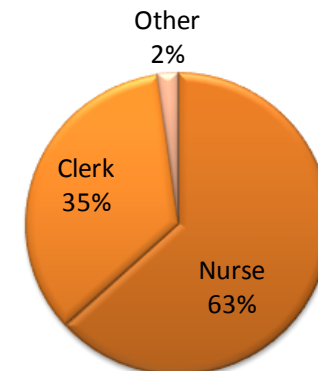


BioTrust Consent Process..*Early Implementation*

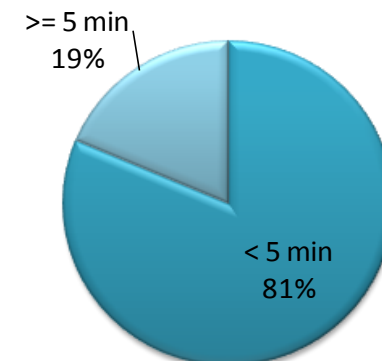
- 11 hospitals with diverse demographics, size and geographic location
 - Implemented May through July 2010
- Best practices identified prior to statewide implementation
- Feedback collected on patient encounters

N=658 Patient Encounters, Reported by 8 hospitals

Staff Explaining BioTrust



Time Spent with Parent



BioTrust Consent Process..Early Implementation

Michigan BioTrust for Health

Baby Name _____
Aller Label Here if Desired _____

Information Requested
 Parent Declined

You should have been given the booklet, "After Newborn Screening". If not, please ask for it. This booklet describes the Michigan BioTrust for Health and how dried blood spots (DBS) could be used for medical research after newborn screening is complete. Please read this booklet and if you have any additional questions, you may call the Newborn Screening Program at 1-866-673-9809.

- Participation in the Michigan BioTrust for Health is completely voluntary.
- If I say "yes" now I may change my mind at any time and ask that my child's DBS not be used for research by calling 1-866-673-9809.
- When my child is 18 he or she can ask that their DBS not be used for research.
- There is no penalty from not allowing my child's DBS to be used for research.

I voluntarily agree to allow my child's DBS to possibly be used for medical research after newborn screening is complete. My permission applies to any blood spots obtained for newborn screening.

Parent Signature _____ Date _____
MI Dept of Community Health Laboratory Copy

DO NOT REMOVE OVERLAY
See instructions for handling and collection of specimen.
Allow blood to dry for 24 hours using the correct Clean the overlay for the overlay.
Send within 24 hours when dry.
Do not use plastic bags.

1F Remove. Dispose with care. If granted, collect parent's signature and a blank original signed copy to MDCH Laboratory. Use the parent's copy.

- Logistical feasibility demonstrated
- Need for documentation of parental “decline”
 - MDCH tracking
 - Parent comfort
- Administrative Uses Box with “Parent Declined” checkbox added

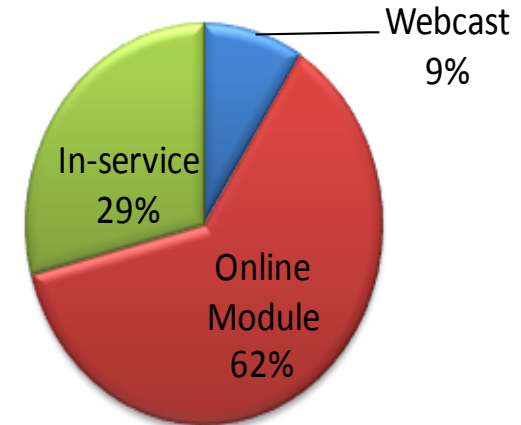
~70% granted consent during the pilot phase with 21% refusing and 9% of forms returned blank.



BioTrust Consent Process.. *State-wide Implementation*

- All birthing hospitals (89) trained by MDCH staff
 - Issued >650 nursing CEs (to date)
 - Childbirth educators invited to participate
- All mid-wives and doulas (those that submitted NBS since 2008) provided information and opportunity for training

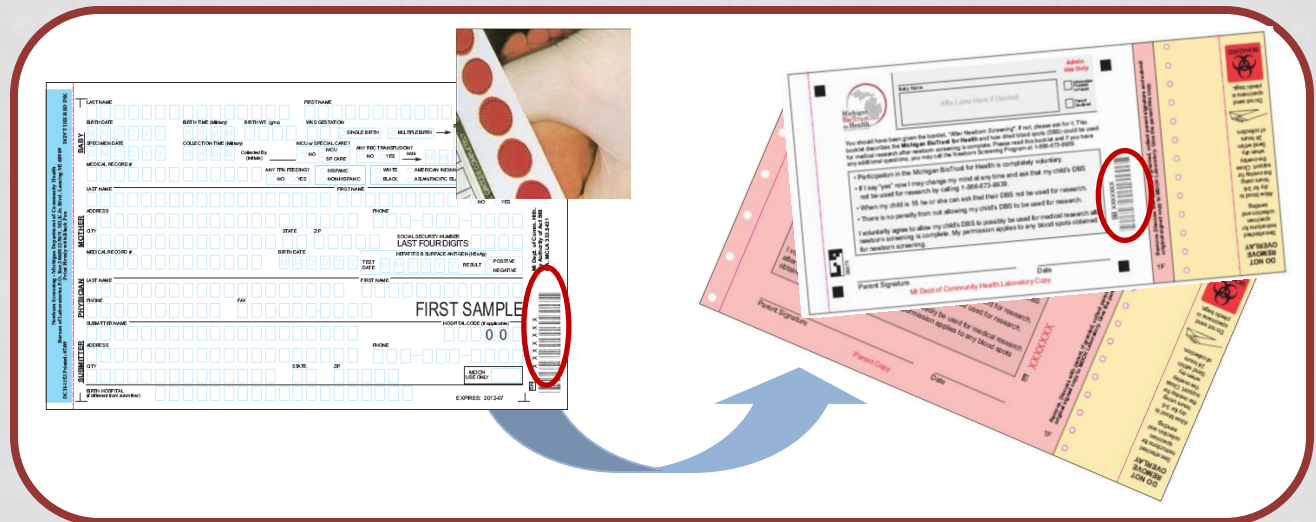
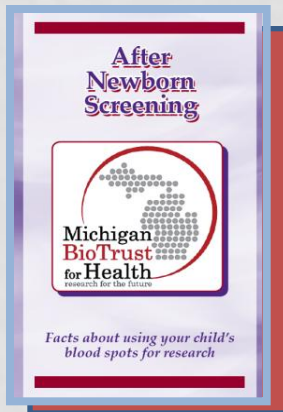
Training Method



*As of January 2010, 86 Birthing Hospitals

BioTrust Consent Process

Parental consent implemented state-wide October 1, 2010*



After reading the BioTrust consent booklet, after delivery parent(s) have the option to grant consent to allow use of DBS in health research by signing the BioTrust consent form on the back of the NBS card. Only specimens with consent will be made available for research. Consents linked to DBS by unique NBS ID#.

* Pilot consent process in 11 Michigan hospitals began May 1, 2010. Therefore specimens collected after April 30, 2010 not used for research unless written parental consent is on file at MDCH

BioTrust Consent Process... *State-wide Implementation*

- 103,492 infants were screened from October 1, 2010 – August 31, 2011
 - **92%** consent forms returned:
 - **63.8%** signed
 - **15.8%** refused
 - **20.4%** blank
 - **81%** of hospitals have **>50%** of parents granting consent

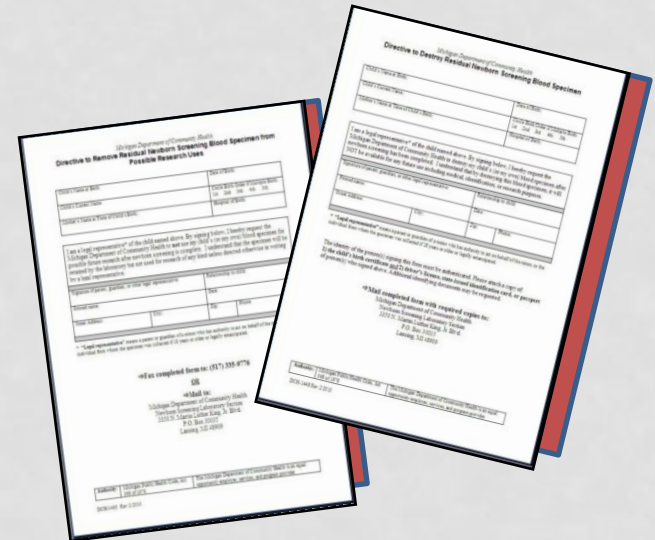


*Additional analysis for co-founding variables must be undertaken.

Opt-Out Options for Specimens Collected Between July, 1984 and April 30, 2010



- Individual may request that samples be retained but NOT used for research
- Individual may request that sample be destroyed
- To date in 2011
 - 38 Directives to Store Only (37 in 2010)
 - 15 Directives to Destroy (34 in 2010)



BioTrust Consent Process: *Impact on Newborn Screening*

- No significant increase in % declining NBS
 - <0.5% births
- Increased Education in 2011
 - 22 MDCH presentations to health care providers
 - 12/22 for prenatal care providers
 - 16 community education events
 - 8 college campus presentations



www.michigan.gov/biotrust

The Michigan BioTrust for Health: *Future Direction*

- Ongoing work to ensure hospital staff compliance
 - Continue work to decrease the rate of “blank” forms
 - Staff turn-over dictates need for continued education/oversight
- Increase education for expectant parents
- Analysis of population declining v. consenting
- Evaluation of entire consent process
- Increase use of DBS
 - 2011 (*to date*), 4 studies have been reviewed and approved
 - 2010, 6 studies were reviewed and approved

Acknowledgements

- MDCH Bureau of Laboratories
- MDCH Bureau of Epidemiology
 - NBS FU Program
- BioTrust Community Values Advisory Board