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*

**2009**
- Consent process & booklet
- Parent Video
- NBS, BioTrust Websites

**2010**
- Hospital coordinator trainings
- NBS Kit Re-design
- Early implementation hospitals
- Director’s letter to hospitals
- Training: 89 hospitals & childbirth educators
- Materials to hospitals & midwives
- Media coverage & Editorial board meetings
- E-Letter to WIC & MIHP professionals
- Public Education: Health Fairs, WIC clinics

**Oct. 1, 2010: Statewide Consent Process Implemented**
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
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
BioTrust Consent Process...Early Implementation

- 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 midwives and doulas (those that submitted NBS since 2008) provided information and opportunity for training

*As of January 2010, 86 Birthing Hospitals*
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
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
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