Michigan BioTrust For Health

Opt-in Methodology for Residual Newborn Screening Blood Spot Storage and Research Use

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• Public Health Code 333.5431(7)(1)(a)(b) and (8)(d)
  – MDHHS may set the retention period
  – Residual stored blood spots may be used for research
  – NBS brochure must mention medical research use

• Formally launched June 1, 2009

• MDHHS initiative to oversee storage & use of residual newborn screening blood spots
  – Preserve and promote research use
  – Increase community awareness and engagement
  – Improve decision-making processes
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• Michigan blood spots
  – Coded to remove identifying information
  – Stored at Michigan Neonatal Biobank
    • Archived pool (July 1984-April 30, 2010), opt-out
    • Consented pool (May 1, 2010- present day), opt-in
  – Approximately 5 million samples
  – Spot stored at MDHHS for use by parent
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- Review process
- Coding process
- 2013-2014 studies
  - 22 approved
  - 4/22, federally funded
  - 19/22, academia
  - 2/22, private industry
  - 2/22, state NBS program
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• Consent brochure & form
  – Advisory board input, focus group testing, printing

• Early Implementation (Pilot)
  – May 1, 2010 to July 5, 2010
  – 11 hospitals
  – Identify best-practice guidelines
    • Staff wanted record of dissent
  – In-service training by MDHHS
  – Encounter information reported
    • ~80% encounters required <5 minutes to answer any remaining questions after reading consent brochure
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- Statewide Implementation
  - Deadline of October 1, 2010
  - Director’s letter to hospital CEOs
  - 100% enrollment in MDHHS training
    - 29% in-service
    - 62% on-line module
    - 9% webcast
    - >650 nursing CEs
  - Daily after hours hot-line
  - Homebirths
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- Prenatal introduction with consent process after delivery
- Separate consent brochure & declaration form in NBS card
First Quarter 2015

- 84% of BioTrust consent forms returned completed
  - 88% of hospitals returned >80% completed
  - 48% of hospitals returned >90% completed
- 66% of newborns screened have BioTrust consent on record
  - Blood spots stored indefinitely and made available for approved research through the BioTrust
- 18% of newborns screened have BioTrust refusal on record
  - Blood spots stored indefinitely and not used for approved research through the BioTrust
- 16% of newborns screened have no BioTrust decision on record
  - Blood spots stored indefinitely and not used for approved research through the BioTrust
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• Key elements to consider
  – Hospital engagement in research
  – Process delaying NBS
  – Distinguish NBS from BioTrust
  – Track & code specimen
    • NBS card number printed on form
  – Monitor hospital performance
    • Mechanism to ensure parents asked
    • Provide hospitals on-going feedback
    • Maintain hospital training