The Future of Canadian Expanded Newborn Screening Programs

Erica Sutton
June 15, 2010
Presentation Overview

• Explain the newborn screening process
• Identify rationale behind storage of blood spots
• Question whether storage facilities are biobanks
• Introduce the controversy around consent
• Highlight screening approaches of other countries
• Underscore the risk of undermining the newborn screening program
The Heel Prick Process

- Heel pricked
- Card filled out
- Mailed to lab
- Analyzed for 28 conditions & carrier status
Why Are Samples Stored?

- Infant health
- Program quality control and evaluation
- Epidemiological and clinical research
- Forensic purposes
Biobanks for Bloodspots: Is this the Future?

Are newborn blood spot storage facilities biobanks?
Definitions of Biobanks

• Broad Definition:

“any collection of physical specimens from which DNA can be derived, the data that have been derived from DNA samples, or both” (Lorraine Sheremeta, 2003)
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  “any collection of physical specimens from which DNA can be derived, the data that have been derived from DNA samples, or both” (Lorraine Sheremeta, 2003)

- **Narrow Definition:**
  A registered, structured facility constructed explicitly for research purposes where informed consent is sought
Explicit Newborn Screening Biobanks

- Danish Newborn Screening Biobank
- Michigan Neonatal Biobank
Biobanks and Consent

• Do parents know that blood is stored for research?
• Danish Newborn Screening Biobank
  • Explicit informed consent process
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- Danish Newborn Screening Biobank
  - Explicit informed consent process
- Michigan Neonatal Biobank
  - Mandatory screening program
  - Parents can opt-out of the biobank
Lawsuits Around Storage

- Parents filing lawsuits against health authorities
- Not asked permission to store blood spots
Consent and Newborn Screening
What is the United States Doing?

Most programs are mandatory.

3 states implemented voluntary programs:

Wyoming, Maryland & Massachusetts
Verbal, Informed Consent
Other Countries’ Approaches

Explicit, Written, Voluntary Consent

United Kingdom

Denmark

Germany
What Model of Consent is Ontario Using?

- Implied consent model
- An “inherited” model
Why Is Newborn Screening Explicitly Voluntary in Ontario?

• Logistics of providing meaningful consent

• Cost of an explicit consent model

• Fear that parents would opt-out
What are the Assumptions Embedded within Non-Voluntary programs?

- Financial savings in the short term = financial savings in the long-term
What are the Assumptions Embedded within Non-Voluntary programs?

- Financial savings in the short term = financial savings in the long-term
- Parents will refuse screening if they knew
- That it cannot be done
Trust & Transparency: Important Public Health Values
Wrap-Up: Newborn Screening Programs Need...

- To be transparent
- To consider alternative approaches to consent
- To evaluate the ethical issues embedded within the program
Acknowledgments

• Study Participants
• Thesis Committee
  • Drs. Ross Upshur (supervisor), Fiona Miller, & Patricia McKeever
• Funding Organizations:
  • Canadian Institutes for Health Research
  • Health Care, Technology & Place
  • APOGEE-Net
  • University of Toronto
Thank You