From Newborn Screening to Population Health Research: Implementation of the Michigan BioTrust for Health

CARRIE LANGBO, MS, CGC^a

JANICE BACH, MS, CGC^a

MARY KLEYN, MS^a

FRANCES POUCH DOWNES, DrPH^b

ABSTRACT

In June 2009, the Michigan Department of Community Health launched the Michigan BioTrust for Health to improve preservation and utility of residual dried blood spots from newborn screening (NBS) for biomedical research while maintaining public support and integrity of NBS. In this article, we chronicle implementation of the BioTrust and document its impact on NBS. Overall, the percentage of new parents who consent to possible future research use of their children's dried blood spots through the BioTrust has remained consistent with previous public opinion surveys. No significant increase in refusal of NBS has been observed despite increased publicity. There was, however, a slight increase in requests to destroy samples following completion of NBS, indicating readily accessible opt-out information. Given adequate training and cooperation of birthing hospital staff, as well as outreach education for parents and health-care providers, we conclude it is possible to implement a biobanking initiative without adversely impacting NBS.

^aMichigan Department of Community Health, Bureau of Disease Control, Prevention and Epidemiology, Lansing, MI

^bMichigan State University, Program in Public Health and BioMedical Laboratory Diagnostics Program, East Lansing, MI

Address correspondence to: Carrie Langbo, MS, CGC, Michigan Department of Community Health, Bureau of Disease Control, Prevention and Epidemiology, 201 Townsend St., PO Box 30195, Lansing, MI 48909; tel. 517-335-6497; fax 517-335-9790; e-mail <langboc@michigan.gov>.

©2013 Association of Schools and Programs of Public Health

Newborn screening (NBS) for phenylketonuria marked the advent of a vital public health program leading to the identification and treatment of more than 4,691 Michigan newborns with serious disorders since 1965. Recently, state NBS programs have grappled with residual dried blood spot storage and research, but Michigan first began the stepwise process of examining these issues more than two decades ago (Figure 1). In 1987, the Michigan Department of Community Health (MDCH) implemented a policy of storing residual dried blood spots for 21.5 years, after receiving legal advice on appropriate retention periods. In 1999, the Governor's Commission on Genetic Privacy and Progress recommended that residual dried blood spots be retained indefinitely because of their potential utility in health research.¹ As a result, the Michigan Legislature amended the public health code in 2000 to allow the use of residual dried blood spots during the retention period, as long as human subjects and privacy were protected.² Language directing MDCH to set the retention schedule was included in the law, and the current laboratory policy of indefinite storage was established in 2008.³

While Michigan's public health code established the foundation for storage and research use of residual dried blood spots, numerous challenges had to be

addressed to ensure adequate community education and public support. Historically, parents were advised of retention practices and potential research use of residual dried blood spots through a paragraph in the Michigan NBS brochure distributed at the time of delivery. Concerns developed about whether parents read the brochure or were truly informed of options. Policy questions also arose on how best to balance individual autonomy and public benefit from dried blood spot research, particularly if demand for use increased. Therefore, MDCH undertook a process to formalize dried blood spot storage and use policies through creation of the Michigan BioTrust for Health (hereafter, BioTrust), drawing heavily from stakeholder input. The original aims of the BioTrust were to improve the preservation and utility of dried blood spots through more optimal storage conditions and to promote their use for biomedical and public health research while maintaining the public support and integrity of Michigan NBS.

BIOTRUST DEVELOPMENT

Planning

Before developing the BioTrust, MDCH used multiple methods to gauge interest in dried blood spot research

Figure 1. Michigan BioTrust for Health timeline

Year	Action
1987	After receiving legal advice, MDCH implements a 21.5-year retention schedule for dried blood spots.
1999	Governor's Commission on Genetic Privacy and Progress issues recommendation to retain blood spots indefinitely.
2000	Michigan Legislature amends Michigan Public Health Code to allow dried blood spot research.
2006	MDCH convenes the Michigan Blood Spot Symposium.
2007	MDCH develops white paper. MDCH convenes stakeholders meeting. MDCH and partners establish steering committee and workgroups.
2008	MDCH revises blood spot retention policy. MDCH and partners initiate community engagement activities (i.e., focus groups, BRFS, and online survey). MDCH and partners develop business plan. MDCH convenes legal roundtable. MDCH IRB reviews and approves parental consent policy. Michigan Neonatal Biobank incorporates as a 501(c)(3) nonprofit organization.
2009	MDCH launches the Michigan BioTrust for Health. MDCH convenes the BioTrust Community Values Advisory Board. The Michigan Neonatal Biobank establishes a board of directors.
2010	MDCH establishes the BioTrust Scientific Advisory Board. MDCH launches a community, health professional, and hospital education initiative. MDCH implements the BioTrust parental consent process.
2011	MDCH ensures that ongoing community, health professional, and hospital education remains a priority.

MDCH = Michigan Department of Community Health

BRFS = Behavioral Risk Factor Survey

IRB = Institutional Review Board

within the scientific community and to assess public acceptance, including literature reviews, stakeholder meetings, focus groups, surveys, and discussions with experts and advocacy groups. Researchers representing Michigan's three major research universities were brought together for a Blood Spot Symposium in 2006 and affirmed sufficient interest in dried blood spot research to warrant further investigations. In 2007, MDCH convened stakeholders to assist with the formation of a steering committee and three working groups charged with developing a business plan, identifying research priorities, and recommending community engagement methods.

Throughout the planning process, the steering committee and workgroups emphasized privacy, community perceptions, and the need for appropriate research guidelines. MDCH added an accessible opt-out process to the Michigan NBS website and, in 2008, implemented a plan to solicit opinions from focus group participants derived from diverse communities, especially those representing the "general public," who might have concerns as stakeholders in the BioTrust. Neutral facilitators led 10 focus group discussions addressing key questions surrounding the use of dried blood spots, with participants completing opinion surveys before and after discussion.⁴ MDCH staff provided numerous informational presentations, with surveys collected from audience members. In addition, MDCH disseminated a Web-based survey and added four questions to the 2008 Michigan Behavioral Risk Factor Survey (BRFS), an annual random-digit-dialed telephone survey, to gauge public support for the use of dried blood spots in specific types of health research.⁵ Ethical, legal, public health, and research representatives assembled in a roundtable meeting to discuss ownership issues, appropriate guidelines for dried blood spot use within legal parameters, and ethical concerns to be considered when defining the state's "qualified ownership" of dried blood spots.⁶

Infrastructure development

On June 1, 2009, MDCH announced plans to proceed with development of the BioTrust through a news release and press conference for media.⁷ Primary partners were the Van Andel Institute, Michigan State University, University of Michigan, and Wayne State University, which arranged to house the Michigan Neonatal Biobank (MNB) as part of the university's Biobanking Center of Excellence. The MNB, a 501(c)(3) nonprofit organization, was designated as the repository for storage of residual dried blood spots for potential future research use. Under supervision of the NBS laboratory manager, student assistants

began to separate each dried blood spot filter paper card from the NBS kit and label it with a bar code before transferring it to the MNB for storage. Three formal advisory boards were appointed to guide policy development, including a Community Values Advisory Board (CVAB), Scientific Advisory Board (SAB), and MNB Board of Directors. Existing NBS staff members were designated to coordinate BioTrust outreach and education and to develop a protocol for the approval of research applications and use of MDCH data. To enhance communication and planning, an MDCH intradepartmental workgroup met monthly, with members consisting of senior leadership from the NBS Program (laboratory and follow-up), Epidemiology, Institutional Review Board (IRB), Legal Affairs, and Public Health Administration, as well as the department's Chief Medical Executive.

Parental consent process

A proposal to store dried blood spots in the MNB for possible future research was presented to the MDCH IRB in 2009. After consulting with the U.S. Department of Health and Human Services' Office of Human Research Protections, the IRB directed Michigan NBS to develop a parental consent process for research use of prospectively collected specimens. A National Institutes of Health Certificate of Confidentiality was also requested and received in 2010. Staff worked during a 10-month period to develop the consent process, with considerable input from the CVAB and hospital nursery personnel. Existing Michigan NBS brochures were updated, an educational DVD was produced, and BioTrust educational materials were developed. Michigan NBS brochures and BioTrust consent booklets were focus group tested for readability and translated into Arabic and Spanish. The NBS kit was revised to include a BioTrust consent form, and a database was created to record consent form results.

Regional trainings for hospital NBS coordinators were held across the state in 2009, allowing introduction of the BioTrust consent process. Eleven hospitals, selected for geographic diversity and number of births, were willing to participate in an early implementation phase that began in May 2010. These hospitals received a small supply of NBS kits at no charge in exchange for their feedback. After best practices were identified, the MDCH director notified remaining birthing hospitals by letter that effective October 1, 2010, Michigan NBS would require a parent's consent for research use of residual dried blood spots.

Staff then launched an extensive training initiative to ensure birthing hospitals were prepared to inform parents about NBS and implement the BioTrust

consent process. Two part-time temporary educators were hired to assist the BioTrust Community Outreach Coordinator and NBS Nurse Consultant with the education campaign. Neonatal nurses, childbirth educators, midwives, and a number of prenatal/pediatric clinicians were invited to participate in in-service presentations, a webcast, and/or online training modules (voice-recorded PowerPoint presentations) provided by Michigan NBS staff.

OUTCOMES

MDCH community engagement endeavors revealed that a majority of adult Michigan residents supported the use of dried blood spots in research generally, with even higher support for specific categories of research such as childhood disorders. For instance, 61.7% of focus group participants strongly supported research use, while 24.7% somewhat supported it. Among BRFS respondents, 72% said they favored such use.^{4,5} Considering the responsibilities of public health departments, as established in Michigan law, the legal roundtable determined that MDCH had “qualified ownership” of residual dried blood spots.⁶ This ownership allows MDCH to exercise control over the use of dried blood spots for the benefit of the child and the public, while taking into account ethical considerations. MDCH is ultimately legally and ethically obligated to follow regulatory research requirements while serving as a trustee or steward of dried blood spots.⁶

CVAB member organizations were originally chosen after the Community Engagement Workgroup identified the following sectors as important for assuring the representation of diverse communities that embody “the public”: (1) general public, including business and legal representatives; (2) cultural, religious, and historical group representatives; (3) health professionals; and (4) disease/health advocacy groups (Figure 2). The CVAB has played an important role in guiding MDCH on the development of policies and written materials. Members also made recommendations to further diversify the committee’s composition, hosted BioTrust presentations for some of their own organizations, and helped MDCH staff prioritize venues for community education.

While deliberating the need for parental consent for future research use of prospectively collected dried blood spots, the IRB granted a waiver of consent for the use of archived specimens due to the low risk to human subjects and impracticability of recontacting millions of individuals. Provisional to this waiver was that Michigan NBS make efforts to widely publicize the BioTrust, including methods for individuals to opt out.

Accordingly, MDCH initiated an awareness campaign informing communities about the importance of NBS and promoting informed decision-making regarding BioTrust participation. During a two-year period, interviews were granted with reporters, and meetings were held with the state’s two largest newspaper editorial boards, leading to considerable print and television exposure, including a front-page article in Detroit’s major newspaper. Local public health employees from Women, Infants and Children, Children’s Special Health Care Services, and the Maternal Infant Health Program were informed of the BioTrust via mass e-mail. Additional outreach activities are ongoing and include health fair and early childhood conference exhibits, information tables at health clinics, grand rounds presentations, and lectures to college students. By the end of 2011, more than 3,500 individuals had been reached at 75 events.

As of May 2012, more than one-third (>1.5 million/4.5 million) of dried blood spot samples in Michigan’s archive had been transferred to the MNB. The MNB cannot access any MDCH data or registries; thus, samples are de-identified while stored. Preservation of specimens has been optimized by MNB humidity and temperature controls, and samples collected since January 2009 are now frozen at -20°C .

Protocols were developed for a two-step review and de-identification process prior to the release of dried

Figure 2. Organizations represented on the Michigan BioTrust for Health Community Values Advisory Board^a

ACCESS

American Cancer Society Great Lakes Division, Inc.
American Civil Liberties Union of Michigan
The Asian Center
Cristo Rey Community Center (Hispanic community organization)
March of Dimes—Michigan Chapter
MichBio
Michigan Association of Black Social Workers
Michigan Association of Genetic Counselors, Inc.
Michigan Council for Maternal and Child Health
Michigan Developmental Disabilities Council
Michigan Environmental Council
Michigan Health and Hospital Association
Michigan Minority Health Coalition
National Alliance on Mental Illness—Michigan
The Network for Public Health Law—Mid-States Region

^aReflects membership as of May 2012. Representatives from a faith-based organization and a Native American tribal organization also held seats and are in the process of being reappointed. The Board is currently seeking two members-at-large.

ACCESS = Arab Community Center for Economic and Social Services

blood spots. First, the MDCH IRB and BioTrust SAB review panel must approve the study proposal. Following approval, Michigan NBS tells MNB which samples to release by barcode number. MNB then replaces the code used for storage with a research-specific code that MDCH does not receive. A “user-fee” structure for research studies was established that takes into account requested specimen size, number of samples, and complexity of associated data request. The SAB, comprising members with diverse scientific expertise, ensures that requests for dried blood spots have scientific merit and adhere to BioTrust Research Guidelines. These guidelines were based on themes originally identified by the Research Workgroup and include (1) conducting research to benefit the public’s health, (2) protecting human subjects, (3) balancing private gain and public good, and (4) respecting the role of public input. After endorsement by the CVAB, the guidelines provided a framework for the formal MDCH Policy.⁸

Feedback from eight of 11 hospitals during the early implementation phase of the BioTrust consent process identified best practices prior to statewide implementation. In the majority (81.5%) of total patient encounters ($n=658$), staff required less than five minutes to clarify questions after parents read the BioTrust consent material. Hospital employees facilitating the consent process were predominantly nurses (62.3%) or clerks (34.1%). They spent similar amounts of time with patients, but parents were more likely to sign consent forms administered by a nurse (76%) than by a clerk (70%). Minor revisions to the BioTrust consent form were recommended by hospital staff and parents to ensure dissent was clearly delineated. A checkbox added to the form allowed hospital staff to mark “parent declined.”

Following the pilot phase, all 78 remaining birthing hospitals were enrolled in training sessions provided by MDCH. Sixty-two percent of hospitals participated in online training modules, 29% in in-service presentations, and 9% in a webcast hosted by Michigan NBS. On the post-training evaluation form, 98% of the 501 participants with completed post-evaluation forms indicated their intention to alter patient education processes not only about the BioTrust but also about NBS, with 78.2% stating that more information would be provided, 60% stating that more time would be spent with parents, and 51% indicating that different information would be provided. As of December 2011, continuing education credit had been issued to 635 nurses, and BioTrust/NBS presentations had been provided at 14 pediatric/obstetric and gynecology grand rounds and five hospital pediatric business meetings.

Approximately 99.6% of Michigan births undergo

NBS, resulting in 166,992 NBS cards submitted to the state public health laboratory, the designated testing facility, during an 18-month period from October 1, 2010, through March 31, 2012. To track adherence to the process, birthing hospitals are instructed to return a BioTrust consent form for every screened birth. During this time period, 59.2% ($n=98,932$) of consent forms were signed, granting consent; 15.5% ($n=25,946$) were marked “parent declined,” documenting dissent; 17.2% ($n=28,685$) were returned blank; and 8.0% ($n=13,429$) were not returned. The majority (82%) of birthing hospitals had more than 50% of parents grant consent for use of their child’s residual dried blood spots in research through the BioTrust.

Following the Michigan NBS education campaign, there was a slight increase in parental requests to specify disposition of their child’s dried blood spots after completion of NBS, but overall, the number of such requests remains low. Nine requests were received in 2009 to have dried blood spot samples destroyed. The number of requests for dried blood spot sample destruction increased to 34 in 2010, while 37 requests were made to label dried blood spot samples unavailable for research. In 2011, the numbers remained similar, with 45 requests for destruction and 22 for removal from the research pool. The number of parents declining NBS following a hospital birth increased following implementation of the BioTrust parental consent process—18 parents (0.02%) declined in 2009 compared with 41 parents (0.04%) in 2010 and 40 parents (0.04%) in 2011. However, it is difficult to disentangle effects of the BioTrust consent process from increased awareness of NBS due to educational efforts.⁹

LESSONS LEARNED

MDCH recognizes research as one of the 10 Essential Public Health Services that can lead to new insights and innovative solutions to health problems, ultimately improving the public’s health; but numerous ethical layers and challenges arise in using residual dried blood spots not initially collected for such a purpose.^{6,10}

In addition, MDCH acknowledges the need to monitor ongoing challenges and emerging national guidelines pursuant to recommendations from the U.S. Secretary of Health and Human Services’ Advisory Committee on Heritable Disorders in Newborns and Children (SACHDNC).¹¹ Figure 3 illustrates Michigan responses to key SACHDNC recommendations. While MDCH has placed emphasis on complying with these recommendations, we recognize that ultimate resolution for each state depends on existing infrastructure, policies, and laws.¹² Michigan’s public health code

Figure 3. MDCH responses to recommendations for state NBS programs from the U.S. SACHDNC^a

<i>SACHDNC recommendations</i>	<i>MDCH responses</i>
All state NBS programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority that specifies who may access and use dried blood specimens once they arrive at the state-designated NBS laboratory, including further access after NBS tests are completed.	1999 Governor's Commission on Genetic Privacy and Progress final recommendations to store dried blood spots indefinitely because of their potential use in health research prompts an amendment of MDCH public health code in 2000 to allow the use of residual dried blood spots in research.
All state NBS programs should have a policy in place that has been reviewed by the state attorney general or other appropriate legal authority addressing the disposition of dried blood specimens remaining after NBS. Policy makers should consider the value of the specimens as a promising resource for research, the importance of protecting the privacy and confidentiality of families, and the necessity of ensuring the public's trust.	Michigan Attorney General Office is apprised of BioTrust policies and procedures. MDCH Chief Medical Executive, IRB Chair, Public Health Deputy, Public Health Legal Advisor, Laboratory Director, and State Epidemiologist become involved in BioTrust policy development.
All state NBS programs should develop a well-defined strategy to educate health-care professionals who provide patients with prenatal and postnatal care about NBS and the potential uses of residual NBS specimens.	An education initiative for health-care professionals targets prenatal and pediatric care providers, as well as childbirth educators and hospital nursery staff, through in-service presentations, online training modules, grand rounds, webcasts, and dissemination of written material.
All state NBS programs should work proactively to ensure that all families of newborns are educated about NBS as a part of prenatal and postnatal care.	MDCH revises NBS brochures and website, makes an educational video available for parents, and staffs NBS displays at local health and baby fairs.
All state NBS programs should create policies that are in compliance with federal research regulations, assure that parents are aware of these activities, and consider whether documentation of parents' wishes and willingness to participate are required.	MDCH consults with federal Office for Human Research Protections, leading to an IRB decision to waive informed consent for the use of archived residual dried blood spots, with the caveat that MDCH make an effort to inform the public about their options. MDCH IRB determines that informed consent should be required for research use of any prospectively collected dried blood spots beginning May 1, 2010.

^aTherrell BL Jr, Hannon WH, Bailey DB Jr, Goldman EB, Monaco J, Norgaard-Pedersen B, et al. Committee report: considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening. *Genet Med* 2011;13:621-4.

MDCH = Michigan Department of Community Health

NBS = newborn screening

SACHDNC = Secretary of Health and Human Services' Advisory Committee on Heritable Disorders in Newborns and Children

IRB = Institutional Review Board

allowed implementation of the BioTrust, but other states may be limited in their ability to launch such initiatives without similar regulations. Government-sponsored population-based biobanks depend on public participation, acceptance of research visions, and trust in safeguards for participants.¹³

Retention and use of residual dried blood spots for research have been the subject of national discourse for several years, with multiple studies conducted to assess both general public and parental attitudes, as well as preferences for opt-in vs. opt-out consent processes.^{4,5,14} However, Michigan was the first state to proactively implement a universal parental consent process as part of routine NBS procedures. A combination of factors allowed us to build a foundation for the use of dried

blood spots acceptable to the public, including our law, commitment to community engagement, and consent process. Our findings, based on the actual proportion of Michigan parents granting consent for use of their child's specimen in the BioTrust, are consistent with previously measured baselines of public support for dried blood spot research in Michigan and nationally using survey data.^{4,5,15}

Two critical measures of a universal consent process are the potential impact on NBS and the population of blood spots remaining available for research. We have not observed a substantial increase in parental refusal for NBS, despite potential concerns that increased publicity might negatively impact the program.¹⁶ Historically, nearly all blood spots collected were available

for health research. Of the more recent specimens collected since 2010, currently 59.2% are available for use based on parental consent. While this is a significant reduction, it may be a necessary tradeoff to ensure public support and continued availability of any specimens for health research. Work is underway to determine whether the consented population has similar demographics to the newborn population and if additional or different outreach measures are needed.

Michigan's existing NBS infrastructure was critical in developing the BioTrust, which could not have occurred without collaboration among NBS laboratory and follow-up personnel, advisory committees, hospitals, and health-care providers. In particular, previously designated NBS coordinators in all birthing hospitals were a significant asset for adoption of the BioTrust consent process. Through this collaboration and the MDCH policy to collect blank forms, hospitals with low consent form return rates can be quickly identified, and interventions can be implemented to help them meet performance targets. The need to monitor consent process metrics is demonstrated by three large birthing hospitals continually submitting significant numbers (>75%) of incomplete consent forms. This statistic emphasizes one of the most challenging aspects of this initiative, namely, implementing the BioTrust consent process in the absence of a state mandate. Fortunately, most birthing hospitals were receptive, and even though consent is not obtained for NBS itself, there are anecdotal reports that the process has led to increased parent education on NBS and policies regarding the storage and use of residual dried blood spots.

Presumably, a lack of funding is a significant barrier for other states to embark on a similar endeavor. Although the goal for the BioTrust is to one day be self-sustaining based on research user fees, significant staff time, technology, and materials have been donated or funded through small grant awards thus far. Revising an existing employee's work plan to include implementation and coordination of the BioTrust has also been necessary.

Additional challenges included establishing policies and procedures for specimen storage and use while Michigan NBS continued to accrue new samples. Various phases of the BioTrust had to be implemented while certain policies were being refined. This process created the need to ensure that all staff and partners remained abreast of rapidly occurring changes so that accurate information was disseminated.

CONCLUSION

Michigan has expanded the potential public health "good" of NBS by making residual dried blood spots available for population-based health research in a manner that is acceptable to the public using a parental consent process administered by birthing hospitals. We remain cognizant of the need for continued transparency, community outreach, and education to assure that new parents, as well as individuals whose specimens were archived in the BioTrust, are aware of their options. With CVAB guidance, future efforts will focus on outreach to increase parental awareness during prenatal education, evaluation of the consent process from parent and hospital perspectives, increased use of social media to inform people aged 18–25 years that their dried blood spots are stored, and placement of questions on state population surveys to monitor changes in public awareness or attitudes.

Since formal implementation of the BioTrust, 14 research proposals (2009–2011) have been approved for use of residual dried blood spots. These research proposals demonstrate a heightened awareness of the availability of residual dried blood spots, as only 10 studies had been approved during the previous 10-year period from 2000 to 2009. In the future, SAB members plan to focus on promoting dried blood spot use in the scientific community to increase utilization of BioTrust resources, and the state of Michigan also plans to partner with the Newborn Screening Translational Research Network's Virtual Repository of Dried Blood Spots to help achieve benefits of population health research using residual dried blood spots.

The authors thank the many workgroup and board members who contributed their time and insight to development of the BioTrust; Jean Chabut, Corinne Miller, Kevin Cavanagh, Harry Hawkins, Bill Young, and other NBS personnel; and birthing hospital staff.

Initial work to ascertain the feasibility of using Michigan dried blood spots for research was supported in part by Cooperative Agreement #U58/CCU522826 from the Centers for Disease Control and Prevention (CDC), Office of Public Health Genomics, which also provided subsequent funding for production of the Michigan Newborn Screening/BioTrust educational video. The findings and conclusions in this article are those of the authors and do not necessarily represent the official position of CDC.

The work described in this article was conducted in accordance with the policies and procedures of the Michigan Department of Community Health (MDCH), including requirements for approval by the MDCH Institutional Review Board.

REFERENCES

1. Michigan Commission on Genetic Privacy and Progress. Final report and recommendations. Lansing (MI): Michigan Department of

- Community Health; 1999. Also available from: URL: http://www.michigan.gov/documents/GeneticsReport_11649_7.pdf [cited 2012 Jun 1].
2. Public Health Code. Michigan Compiled Laws, §333.5431(7)(b) (1978).
3. State of Michigan, Department of Community Health. Newborn screening specimen retention policy. 2008 [cited 2012 Jun 1]. Available from: URL: http://www.michigan.gov/documents/mdch/11.1_NBSspecimenretentionpolicy_316310_7.pdf
4. Duquette D, Langbo C, Bach J, Kleyn M. Michigan BioTrust for Health: public support for using residual dried blood spot samples for health research. *Public Health Genomics* 2012;15:146-55.
5. Duquette D, Rafferty A, Fussman C, Gehring J, Meyer S, Bach J. Public support for the use of newborn screening dried blood spots in health research. *Public Health Genomics* 2011;14:143-52.
6. Chrysler D, McGee H, Bach J, Goldman E, Jacobson PD. The Michigan BioTrust for Health: using dried bloodspots for research to benefit the community while respecting the individual. *J Law Med Ethics* 2011;39 Suppl 1:98-101.
7. State of Michigan, Department of Community Health. Michigan Department of Community Health collaborates with state universities, Van Andel Institute to create Michigan BioTrust for Health [press release]; 2009 Jun 1 [cited 2012 Jun 1]. Available from: URL: <http://www.michigan.gov/mdch/0,1607,7-132-8347-215747--,00.html>
8. State of Michigan, Department of Community Health. Policy and procedure manual. Guidelines for research use of dried blood spots. Policy #11.4. 2010 [cited 2012 Jun 1]. Available from: URL: http://www.michigan.gov/documents/mdch/DCH_Policy_11.4_366131_7.pdf
9. State of Michigan, Department of Community Health. Michigan Newborn Screening Program annual report 2010 [cited 2012 Jun 1]. Available from: URL: http://www.michigan.gov/documents/mdch/NBS_Annual_Report_2010_361032_7.pdf
10. Centers for Disease Control and Prevention (US). 10 essential public health services [cited 2012 Jun 1]. Available from: URL: <http://www.cdc.gov/nphsp/essentialservices.html>
11. Therrell BL Jr, Hannon WH, Bailey DB Jr, Goldman EB, Monaco J, Norgaard-Pedersen B, et al. Committee report: considerations and recommendations for national guidance regarding the retention and use of residual dried blood spot specimens after newborn screening. *Genet Med* 2011;13:621-4.
12. Lewis MH, Goldenberg A, Anderson R, Rothwell E, Botkin J. State laws regarding the retention and use of residual newborn screening blood samples. *Pediatrics* 2011;127:703-12.
13. Swede H, Stone CL, Norwood AR. National population-based biobanks for genetic research. *Genet Med* 2007;9:141-9.
14. Botkin JR, Rothwell E, Anderson R, Stark L, Goldenberg A, Lewis M, et al. Public attitudes regarding the use of residual newborn screening specimens for research. *Pediatrics* 2012;129:231-8.
15. Tarini BA, Goldenberg A, Singer D, Clark SJ, Butchart A, Davis MM. Not without my permission: parents' willingness to permit use of newborn screening samples for research. *Public Health Genomics* 2010;13:125-30.
16. Rothwell EW, Anderson RA, Burbank MJ, Goldenberg AJ, Lewis MH, Stark LA, et al. Concerns of newborn blood screening advisory committee members regarding storage and use of residual newborn screening blood spots. *Am J Public Health* 2011;101:2111-6.