

Legal Issues Surrounding Residual Dried Blood Specimens in NBS (and Related Information)

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Background

- Old: DBS (Does state have authority?)
 - Lack of knowledge about use and public benefit of use
- New: Info and DBS (Does state have authority?)
 - More complicated issues
 - Interplay with other state laws (i.e. genetic privacy)
 - Growing interest in the use of samples and information

Email to Me

- In the process of looking into the possibility of adding tests for benzene, arsenic, cotinine and, perhaps, other pollutants into the XX Newborn Screen, I read with interest your 2011 Pediatrics article "State Laws Regarding the Retention and Use of Residual Newborn Screening Blood Samples" V127, 703.
- In it, it would appear that XX falls into that group of 30 states that do not have any regulations related to NBS retention/use - but is one of the 14 states with statutes/regulations related to release and protection of confidential information obtained from the spots. Is that (still) correct?
- -
- We would like to use totally de-identified papers - i.e. just the residual spots - to work out the statistical pattern of variation of pollutant levels and develop high-throughput techniques for recognizing the pollutants.

Email to Me (cont.)

- To do that, we would need the residual 'presumptive negative' individual spots that are about to be destroyed . . . , not be destroyed, but rather totally de-identified except for date of collection - and then sent to . . . PerkinElmer. . .
- From my understanding of Federal IRB regulations, this kind of preliminary analysis of to-be-discarded, de-identified blood does not constitute 'Human Subject' research that requires consent - but rather is a laboratory investigation, and is completely legal.
- But before we ask PE - we would need to be sure.
- **I would greatly appreciate your opinions on this - your opinions both as a physician and lawyer.**

Ways States Can Address Issues

- Statutes-enacted by state legislature
- Regulations-have the force of law
- Policy-departmental policy
- Silent on issue

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- **Specific Aim 2: To develop a legal toolkit for state policy-makers to consider in the development of state laws, regulations, and policies related to the retention and use of residual newborn screening dried blood samples.**
- **Analysis of state nbs laws**

SA 2: Methods

- State statutes and regulations were accessed online between 1/13 and 7/13.
- Included statutes and regulations because both are binding upon state departments of health.
- To conduct the analysis, we developed a coding system based upon an initial set of categories identified by the research team. Categories included topics such as state control over DBS, information provided to parents, and whether parents were permitted to opt-out of research

Methods

- Caveats
 - Interpretations may differ
 - Not comprehensive, only reviewed NBS laws (with a few exceptions)
- With this iteration, included more information about potential use of information.
- 2 reasons:
 - Minnesota definition of genetic information
 - Advance in genomic technologies-whole genome sequencing in newborn—then have information

Preliminary Results

- Retention &/or use of DBS authorized n=24
- Retention &/or use of information authorized n=27
- Purposes for which DBS may be used specified n=15
- Purposes for which info may be used specified n= 20
- Parents informed of retention &/or use of DBS n=7
- Parents informed of retention &/or use of info n=5
- Parental consent req'd for retention &/or some uses of DBS n=8
- Opt-out permitted n=6
- Parental consent req'd for retention &/or some uses of info n=16
- Opt out permitted of retention or use of info related to DBS n=3

Wide Variability

- States have wide variability in their policies re the retention and secondary use of DBS and related information.
- Vary with respect to:
- Which party, the parent or the state, has authority to determine the disposition of DBS and related information;
- Under what circumstances DBS and/or information may be used and for what purposes
- How much information parents are provided about the retention and use of DBS and related information

Lack of Uniformity

- Lack of uniformity across states may prevent consistent interpretation of state laws
- What is considered research?
- Pilot studies?
- Quality assurance activities may not be considered research by public health officials

Confidentiality

- State efforts to maintain privacy and confidentiality of infants and their families vary widely.
- A consistent approach should be developed.
- States should communicate to parents about the privacy protections in place in order to bolster public confidence in state nbs programs and build support for the retention and use of DBS.

Distinction btw Info and DBS

- The distinction between the DBS and its related information is an area that needs clarity.
- Laws that address the use of information were intended to prevent breaches of confidentiality but may not be sufficient to address issues that arise with new technology.
- Distinction will become less clear in future as genetic sequencing technology evolves.
- Current laws intended to address use of demographic information may not be sufficient to address the use of genetic information obtained from DBS or even test results.

Commercialization

- Commercial possibilities and access to DBS by 3d parties such as law enforcement or the military should be addressed.
- Access to 3d parties may be objectionable to parents who might not otherwise object to the use of their child's DBS for medical research.

Vulnerabilities of State NBS Programs

- Lack of effective education for parents about the retention and use of DBS and related information could foster public mistrust and create barriers to the research use of these samples.
- Parental education, particularly about privacy safeguards, is critical given the growing focus on the uses of big data and concerns about governmental surveillance of private information.
- Could also jeopardize the public health mission of nbs programs.
- Michigan provides information about the retention and use of DBS and has not seen increase in number of refusals for newborn screening.

Conclusions re State Laws

- Few states have addressed comprehensive policies related to these issues.
- Many states have not addressed key issues.
- Some states that retain DBS without parental permission may be acting outside the scope of their legal authority.
- The lack of transparency on the part of states retaining DBS without parental knowledge may undermine public trust in the nbs program and the research enterprise.
- If your state retains DBS and related information FOR ANY PURPOSE, suggest legal authorization for retention and desired use (including QA)

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- **Specific Aim 2: To develop a legal toolkit for state policy-makers to consider in the development of state laws, regulations, and policies related to the retention and use of residual newborn screening dried blood samples.**
- **Multiple functionalities**
- **Why do this?**

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Policy Toolkit for Newborn Screening DBS



Newborn screening is a vital public health program that detects serious medical conditions that can cause devastating effects if treatment is not given prior to the onset of symptoms. Testing is mandatory in 49 states and the District of Columbia. The testing process involves the collection of a few drops of blood from a newborn's heel. Not all of the blood samples collected from newborns is used during routine screening, however, and after testing has been completed, many states retain the residual dried blood samples (DBS). These DBS have a broad range of potential uses, including program evaluation, development of new tests, public health and biomedical research unrelated to newborn screening, and surveillance for environmental contaminants.

This toolkit is intended to assist state policy-makers to develop or improve policies for the use of DBS and related information. It includes the following three tools:

- [Survey of Laws By State](#)
- [Survey of Laws By Topic Covered](#)
- [Menu of Suggested Provisions for State Laws for Secondary Uses of Residual Newborn](#)



Newborn Screening Laws Regarding Use of Residual Dried Blood Samples and Related Information

Scope of Laws in Iowa

The following chart provides information about the extent to which Iowa state statutes and/or regulations address core topics related to the retention and use of residual newborn screening dried blood samples and related information. State statutes and regulations were accessed online between 7/12 and 7/13.

Core provisions related to the retention and/or use of DBS or related information	X in box if state statute or regulations address this issue
Retention of DBS authorized	X
Retention of information related to DBS (including nbs test results) authorized	X
Purposes for which DBS may be used specified	X
Purposes for which information related to DBS may be used specified	X
Parents informed of retention and/or use of DBS	X
Parents informed of retention and/or use of information related to DBS	X
Parental consent required for some uses of DBS and/or retention of DBS	X
Opt-out permitted of DBS retention and/or use	X
Parental consent required for some uses of information related to DBS and/or retention of the information	X
Opt-out permitted of retention or use of information related to DBS	
Statute: Iowa Code §136A.1 through 136A.9	
Regulation: Iowa Admin. Code §641-4.1 through 641-4.3	
Iowa NBS Program Website	

Topics & Resources

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Survey of State Laws by Topic

The following topics have been covered by one or more states by statute and/or regulation. To see relevant excerpts of law for the states that have covered a topic within a category, click on the topic. State statutes and regulations were accessed online between July 2013 and July 2013.

Coverage	States
Retention & Disposal	
♦ Retention of DBS	CA, CT, DE, HI, IN, IA, ME, MI, MN, MS, MO, NE, NH, NM, ND, OH, OK, SD, TX, WA
♦ Parents may request destruction of DBS	MN, MO, SC, TX, WA
♦ Child may request destruction of DBS when turns 18	SC
♦ Disposition of information related to DBS	AK, MN, MO, NE, ND, WI
Ownership & Control	
♦ DBS become property of the state	UT, WA
♦ Information becomes property of the state unless parents object	CA, ME
♦ DOH has authority over use of information	MA, PA, TX, UT, WI
Use & Disclosure	
♦ Permissible uses of DBS	CA, DE, ID, IN, IA, ME, MI, MN, MO, NE, ND, SC, UT, WA, WI
♦ Uses of DBS for which parental permission is not required	CA, ME, MN, MO, SC, UT, WA
♦ Prohibited uses of DBS	ID, MS, NH, NM
♦ Permissible uses of information	AK, AZ, CA, FL, HI, IN, IA, ME, MD, MN, MS, MO, NE, NJ, OK, OR, TN, TX, VA, WI
♦ Use of DBS and information for NBS program operations	MN
♦ Use of DBS with consent for testing of conditions not on NBS panel	MA
♦ Sharing information within department, with other systems, departments or states	NJ, OH, TX, VA
♦ Obligation to publish results of research	ME
♦ DOH may notify parents of research results if information may benefit health of child	SC



Privacy & Security

◆ Confidentiality of information	AK, AZ, AR, CA, CO, DE, DC, FL, HI, ID, IL, IN, IA, LA, MD, MA, MI, MN, MS, MO, NV, NH, NJ, ND, OK, PA, SC, TN, TX. VA. WA, WV, WI
◆ DOH must code DBS before release	SC
◆ DOH shall have written agreement with recipient of data	CA
◆ Results published without identifying information	ME
◆ Only de-identified information may be published	VA
◆ Security of storage of DBS	CA, IA, ME, NE, WA
◆ Security of health information	AK, CA, MS, NE, NH, ND, VA, WA
◆ Restricted access to DBS and information	WA

Review and Approval

◆ Research projects using DBS must be approved by the DOH	CA, IA, MO, NE, ND, UT, WA
◆ Department has authority to approve researchers who may have access to DBS	CA, ME, NE, WA
◆ IRB approval required to use DBS for research	CA, IA, MN, ND, SC, UT, WA
◆ IRB approval required for research using information	CA, DE, MA, MN, NE, ND, TX
◆ Circumstances in which IRB approval is required to contact information source	WI
◆ Requirements for research approval specified	CA, NE
◆ Content of application for release of DBS for research specified	NE, UT
◆ Content of application to release information for research specified	WI
◆ Department may use other IRBs to approve research activities	CA
◆ Notice posted on website regarding approval to disclose	TX
◆ Researcher must provide DOH with documents produced from research project for review of compliance with terms of use	ND

Notification & Consent

◆ Parents must be provided information re the retention of DBS	IA, MI, MN, NE, SC, TX, UT, WA
◆ Parents must be informed of the benefits of storage of DBS	SC
◆ Information provided to parents about retention/release of info	IA, MD, TX, WI
◆ Parents must be informed of scope of the information to be released	AK, CA, DC, MD, MN, MO
◆ Statistical data not considered confidential and may be released without consent	AK, AR, CA, CO, DE, DC, MS, MO, NE, NV, NJ, ND, TN, TX, UT, VA



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♦ Information provided to parents about retention/release of info	IA, MD, TX, WI
♦ Parents must be informed of scope of the information to be released	AK, CA, DC, MD, MN, MO
♦ Statistical data not considered confidential and may be released without consent	AK, AR, CA, CO, DE, DC, MS, MO, NE, NV, NJ, ND, TN, TX, UT, VA
♦ Parental consent required under certain circumstances to release DBS	ID, IA, ME, MN, NE, NH, UT, WA
♦ Opt-out permitted for use of DBS for research	CA, IA, ME, MO, SC, WA
♦ Expiration of consent to release identifiable information	AK

Fees

♦ State may charge a fee for use of DBS	CA, MO, NE, ND
♦ Fee may not exceed cost of administering the program	CA
♦ State may charge a reasonable fee for use of DBS	MO, NE

SUPPORTERS



State May Charge a Reasonable Fee for Use of DBS

The following states have laws covering this topic.

State statutes and regulations were accessed online between 7/12 and 7/13.

Missouri

Statutes:

Mo. Rev. Stat. § 191.331, § 191.317

Section 191.331: Infants to be tested for metabolic and genetic diseases -- reports -- exceptions -- refusal to test -- fee for screening test, department may impose by rule, use of fees -- formula provided by department, when -- assistance available, when.

9. The department shall have authority over the use, retention, and disposal of biological specimens and all related information collected in connection with newborn screening tests conducted under subsection 1 of this section. The use of such specimens and related information shall only be made for public health purposes and shall comply with all applicable provisions of federal law. The department may charge a reasonable fee for the use of such specimens for public health research and preparing and supplying specimens for research proposals approved by the department.

Nebraska

Statutes:

Neb. § 71-519

§ 71-519. Screening test; duties; disease management; duties; fees authorized; immunity from liability.

(4) . . .

(c) The department shall adopt and promulgate rules and regulations relating to the use of such specimens and related information. Such use shall only be made for public health purposes and shall comply with all applicable provisions of federal law. The department may charge a reasonable fee for evaluating proposals relating to the use of



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Menu of Options

- The toolkit will include a checklist of categories of issues that states should address regarding DBS use including, for example, access, consent, acceptable uses, parent education, research protocol review, destruction of DBS, etc.

Menu of Options

- Each category of issues will be linked to a menu of options and the content analysis of state laws described above.
- This menu will provide practitioners, attorneys, legislators and other policy-makers with examples of state laws by category for building a legal framework for residual DBS research use.

Checklist for Comprehensive Policy

DBS: (would have similar list re information derived from DBS)

Degree of parental control over use of DBS

- Parents informed?
- Parents permission for use of identifiable samples:
 - -Opt out
 - -Opt in

Retention of DBS

- Parents informed?
- Can parents request destruction of DBS?
- Can child request DBS when turns 18?

Storage of samples

- How long kept?
- How stored?
- Must they be stored coded, with identifiers or de-identified?

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- Specific Aim 1 Project 1: To evaluate the effects of the Michigan policy to require informed consent from parents to release DBS for secondary research on refusal rates for newborn screening.
- Study population: Infants born in Michigan from 2009-2011

Evaluation of Michigan Process

- Pre-implementation was the 5 quarters before the program began (1/1/09-3/31/10)
- Post-implementation was the 5 quarters after statewide implementation of the consent process (10/1/10-12/31/11)
- 2 quarters during pilot excluded
- Data from Michigan Department of Community Health

Michigan Consent Process

Table 4. Summary NBS Refusal Rate by Birth Location, Pre- and Post-Implementation of the BioTrust for Health Consent Process, Michigan

		Pre-implementation	Post-implementation	Poisson P-value	Chi-Square P-value
		Jan 2009-March 2010	Oct 2010-Dec 2011		
Hospital	Number of refusals	29	50	0.0175	0.0129
	Number of births*	143019	139106		
	Refusal rate (per 1,000)	0.2	0.4		
Non-hospital	Number of refusals	427	408	0.5108	0.0106
	Number of births*	1443	1603		
	Refusal rate (per 1,000)	295.9	254.5		
Overall	Number of refusals	456	458	0.9473	0.6421
	Number of births*	144462	140709		
	Refusal rate (per 1,000)	3.2	3.3		

Possible Uses of DBS & Information

Departmental Activities	QA	PH Surveillance	"Pilot studies"	Research
DBS	X			
Information	X			

External Research	
DBS	?
Information	?

Conclusion

- Get to know the attorneys responsible for nbs program in your state
- Determine the desired retention and/or use of DBS and/or information policies
- Seek legal advice re whether state has legal authority to conduct the desired activities
- Preserve trust in nbs programs
- Develop research resource
- **TRANSPARENCY** is key!

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