Public Attitudes Regarding the Use of Residual Newborn Screening Specimens for Research

WHAT’S KNOWN ON THIS SUBJECT: The retention and use of residual bloodspots is a practice of many state newborn screening programs. This practice has become controversial, and little is known about public attitudes on the retention and research use of newborn residual bloodspots.

WHAT THIS STUDY ADDS: This study offers a detailed analysis of public attitudes regarding bloodspot retention and use for biomedical research. The results also offer insights on how education regarding this practice influences support for newborn screening and residual bloodspot use.

BACKGROUND AND OBJECTIVES: Many state newborn screening (NBS) programs retain residual NBS bloodspots after the completion of screening. Potential uses for residual specimens include laboratory quality assurance, biomedical research, and, rarely, forensic applications. Our objective was to evaluate public opinion about the policies and practices relevant to the retention and use of residual bloodspots for biomedical research.

METHODS: A total of 3855 respondents were recruited using 3 methods: focus groups (n = 157), paper or telephone surveys (n = 1418), and a Knowledge Networks panel (n = 2280). Some participants (n = 1769) viewed a 22-minute movie about the retention and use of residual specimens while other participants were provided only written information about this practice. All participants were surveyed using a 38-item questionnaire.

RESULTS: A diverse set of participants was recruited. Respondents were very supportive of NBS in general and accepting of the use of residual bloodspots for important research activities. Respondents were evenly divided on the acceptability of NBS without parental permission, but the majority of respondents supported the use of an “opt-in” process for parental permission for residual bloodspot retention and use. Viewing the educational movie was associated with greater support for bloodspot retention and use.

CONCLUSIONS: Our results show that the general public surveyed here was supportive of NBS and residual sample retention and research use. However, there was a clear preference for an informed permission process for parents regarding these activities. Education about NBS was associated with a higher level of support and may be important to maintain public trust in these important programs. Pediatrics 2012;129:231–238

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KEY WORDS: newborn screening, biobank, informed consent, survey

ABBREVIATIONS: DBS—dried bloodspots
KN—Knowledge Networks
NBS—newborn screening
OR—odds ratio
PRAMS—Pregnancy Risk Assessment Monitoring System
QA—quality assurance

All authors meet each of the following criteria: (1) substantial contributions to conception and design, acquisition of data, and analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; and (3) final approval of the version submitted.

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Funded by the National Institutes of Health (NIH).
Newborn screening (NBS) is performed by state public health departments on almost all of the 4 million infants born in the United States each year to enable the early identification of certain genetic, metabolic, infectious, and endocrine disorders. Testing is conducted with dried bloodspots (DBS) on filter paper with specimens obtained within the first few days of life. The bloodspots and identifying information are mailed to state NBS laboratories or a commercial partner where testing is performed. Sufficient blood is obtained to enable screening tests to be conducted and to allow for validation of the initial assessment and second-tier testing when indicated.

This approach to screening results in residual bloodspots remaining in the possession of state health departments, at least temporarily, for almost every newborn in the country. These specimens can be used for several purposes, including quality assurance (QA), forensics, and biomedical research.1 More than 40% of state programs store residual specimens for >1 year, and several states retain them indefinitely.2 A number of states have made these residual bloodspots available for biomedical and environmental research for a broad range of projects.3–6

The storage and use of residual specimens for research have become controversial, primarily because of public concerns over the lack of parental awareness and consent.7 Research demonstrates that parents are poorly informed about NBS programs in general, even when conducted with permission, and are largely unfamiliar with the practice of many health departments to retain and use residual bloodspots.8,9 Within the last 5 years, 2 states, Texas and Minnesota, have been sued by parents because of the retention of residual bloodspots without parental permission. Texas, in a negotiated settlement with plaintiffs, agreed to destroy ~5 million retained specimens in 2010.10 DBS retention has been the subject of a recent Institute of Medicine Roundtable11 and a report by the Secretary’s Advisory Committee on Heritable Diseases in Newborns and Children.12

In light of the controversial nature of this retention practice, our study was designed to ascertain public opinion on the storage and research use of residual DBS. Given the complexity of this issue and the lack of general public awareness about this practice, we were interested in assessing opinions after the provision of different amounts of information about the topic. Our study used several methods by which public health departments typically garner public opinion, such as focus groups and telephone/paper surveys.

METHODS

Survey Instrument

Our 38-item instrument provided brief written educational information on NBS and sample retention and use to all participants. Twenty-four of the questions assessed participant knowledge and attitudes regarding NBS and the retention and use of residual specimens. Validation for comprehension, clarity, and balance was conducted through a Knowledge Networks (KN) panel of 70 general population participants. Public attitudes were ascertained through 3 methods by using different sets of participants: focus groups, paper/telephone surveys, and the KN panel. The project received institutional review board approval at the University of Utah and the Utah Department of Health.

Focus Groups

Focus groups with members of the general population were held in the states of Texas, Colorado, Utah, New Mexico, Arizona, and Oregon. Commercial survey organizations were used to recruit 15 groups; however, data from 1 group were not recorded due to technical problems and are not included in this analysis. Three online focus groups from a random US sample were conducted through KN. Altogether, data were collected from 17 focus groups consisting of members of the general public (7 groups, n = 68), African American subjects (3 groups, n = 20), Hispanic subjects (3 groups, n = 51), and mothers of young children (4 groups, n = 38). All focus groups were shown an educational movie regarding NBS and the retention and use of residual specimens. One of the authors (Dr Rothwell) then led a discussion of the issues with expert support on NBS provided by a pediatrician (Dr Botkin). After the discussion, participants completed the survey.

Telephone/Paper Surveys

Participants were surveyed in Texas, Colorado, Utah, New Mexico, Arizona, Montana, and Nevada using telephone-based and paper instruments. A commercial survey company, Dan Jones and Associates, was employed to conduct the telephone surveys in English. This method is similar to methods used by health departments in their Behavioral Risk Factor Surveillance System surveys of the general population.13 African American, Hispanic, Native American, and Asian/Pacific Islander subjects were oversampled.

A subset of telephone/paper survey participants (n = 200) were recruited through the Pregnancy Risk Assessment Monitoring System (PRAMS) in Utah with the collaboration of the Utah Department of Health. This program, sponsored by the Centers for Disease Control and Prevention, conducts postnatal surveys of new mothers within 1 year of delivery on health issues relevant to pregnancy, childbirth, and infancy.14 Our project contracted with the Utah State Health Department to separately implement our instrument by using their standard PRAMS methods.
KN Panel

The third method of survey administration was through KN panels. KN is a company that conducts Internet-based surveys and online focus groups using a large, pre-established panel with a nationally representative probability sample.15 This approach is a high-technology alternative to traditional survey methods and focus groups. The KN participants were both from the Mountain States region and the national sample. The KN panel was oversampled for individuals who describe themselves as African American, Hispanic, Native American, and mothers of young children (<1 year old) to allow for a meaningful analysis of these groups. To assess the impact of the movie, some KN panel participants were randomly selected to view the movie before completion of the survey. The other KN participants were provided only brief written educational information within the survey instrument.

Educational Intervention

A 22-minute movie was developed for this project by the Genetic Science Learning Center at the University of Utah and is available online.16 The movie explains NBS and the possibility of the retention and use of residual movie. The majority of responses were collected using the KN method (59.1%). Nearly half of the participants viewed the NBS educational movie (45.8%). The participants were primarily non-Hispanic (77.3%), white (61.4%), a parent (77.6%), and female (63.6%). Minority group participation included African American (23.7%), Asian/Native Hawaiian/Other (11%), and Native American subjects (3.9%). Mothers of young children comprised 12% of the sample.15 This approach is a high-technology alternative to traditional survey methods and focus groups. The KN panel was oversampled for individuals who describe themselves as African American, Hispanic, Native American, and mothers of young children (<1 year old) to allow for a meaningful analysis of these groups. To assess the impact of the movie, some KN panel participants were randomly selected to view the movie before completion of the survey. The other KN participants were provided only brief written educational information within the survey instrument.

Statistical Analysis

General linear modeling was conducted with SPSS 19 (SPSS Inc, Chicago, IL) to assess the relationship between participant responses and the basic demographic data (gender, age, ethnicity, race, income, parenthood, education, status of being a mother with young children, and residing in the Mountain States region), as well as the type of survey method (telephone/paper, focus group, and KN) and level of information provided. Linear regression was chosen over ordinal regression for ease of interpretation of estimated coefficients. Ordinal regression (results not shown) provided equivalent findings. Logistic regression was used to assess the relationship of the aforementioned variables and the dichotomized outcome questions. For all analyses, an α level of 0.05 was considered statistically significant.

RESULTS

A total of 3855 surveys were collected from March through November 2010. Table 2 shows frequency counts and percentages for all variables of interest. The majority of responses were collected using the KN method (59.1%). Nearly half of the participants viewed the NBS educational movie (45.8%). The participants were primarily non-Hispanic (77.3%), white (61.4%), a parent (77.6%), and female (63.6%). Minority group participation included African American (23.7%), Asian/Native Hawaiian/Other (11%), and Native American subjects (3.9%). Mothers of young children comprised 12% of the participants. Recruitment rates varied according to method: 63% for the KN general population sample, 67% for the PRAMS sample, and 5% for the Dan Jones and Associates general population survey.

Survey Responses

The majority of participants (55%) were aware that NBS is done, although focus group discussions revealed that knowledge about NBS is limited. When asked about their level of support for NBS (Table 3), a large majority was either...
TABLE 3 General Linear Modeling Results and Effect Sizes

<table>
<thead>
<tr>
<th>Variable</th>
<th>How Supportive Are You of Health Departments Doing These Blood Tests on All New Infants?</th>
<th>Do You Think It Is Alright That These Tests Are Done Without Permission From the Parents?</th>
<th>How Concerned Would You Be If Health Departments Saved the Leftover Blood Samples From Infants After the Testing Is Done?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± SD response</td>
<td>1–4 Likert scale anchors (% responses)</td>
<td>Mean ± SD response</td>
</tr>
<tr>
<td></td>
<td>1.45 ± 0.71</td>
<td>2.58 ± 1.18</td>
<td>2.60 ± 1.15</td>
</tr>
<tr>
<td>NBS education</td>
<td>11.05*** −0.13</td>
<td>5.30* −0.15</td>
<td>61.52*** −0.51</td>
</tr>
<tr>
<td>Survey method (baseline = KN)</td>
<td>2.03</td>
<td>1.88</td>
<td>4.48*</td>
</tr>
<tr>
<td>Focus groups</td>
<td>−</td>
<td>−</td>
<td>1.89</td>
</tr>
<tr>
<td>Telephone/paper</td>
<td>0.26</td>
<td>0.00</td>
<td>1.17</td>
</tr>
<tr>
<td>Age</td>
<td>0.24</td>
<td>−0.02</td>
<td>1.17</td>
</tr>
<tr>
<td>Female</td>
<td>44.16*** −0.18</td>
<td>4.82* −0.10</td>
<td>0.42</td>
</tr>
<tr>
<td>Hispanic</td>
<td>0.04</td>
<td>0.14</td>
<td>4.30*</td>
</tr>
<tr>
<td>Race (baseline = white)</td>
<td>1.89</td>
<td>−</td>
<td>11.41***</td>
</tr>
<tr>
<td>Black/African American</td>
<td>−</td>
<td>−</td>
<td>29.78***</td>
</tr>
<tr>
<td>Native American</td>
<td>−</td>
<td>−</td>
<td>4.14*</td>
</tr>
<tr>
<td>Asian/other</td>
<td>−</td>
<td>−</td>
<td>1.07</td>
</tr>
<tr>
<td>Mountain Region</td>
<td>1.31</td>
<td>−0.04</td>
<td>0.20</td>
</tr>
<tr>
<td>Mother with young child</td>
<td>1.12</td>
<td>0.04</td>
<td>0.03</td>
</tr>
<tr>
<td>Parent</td>
<td>14.26*** −0.12</td>
<td>0.27</td>
<td>0.11</td>
</tr>
<tr>
<td>Income</td>
<td>0.00</td>
<td>0.04</td>
<td>1.09</td>
</tr>
<tr>
<td>Education</td>
<td>12.17*** −0.03</td>
<td>4.41* −0.03</td>
<td>8.61** −0.04</td>
</tr>
</tbody>
</table>

F, F test statistic; β, unstandardized regression coefficient; −, not significant.
* P < .05;
** P < .01;
*** P < .001.

“very supportive” (64.5%) or “somewhat supportive” (29%). Only 3% of participants stated that they were “not supportive” of NBS. As Table 3 shows, variables that had a statistically significant effect in the direction of more support for NBS include: viewing the movie (P < .001), being female (P < .001), being a parent (P < .001), and having a higher education level (P < .001). We then asked if it is “alright” to do NBS without the parents’ permission. Our participants were evenly split with 25.5% responding “definitely alright,” 4% “probably alright,” 18% “probably not alright,” and 32% “definitely not alright.” In the regression model, variables that had a significant effect on responses in the direction of higher approval include movie education (P < .05), older age (P < .05), female gender (P < .05), and higher education level (P < .05).

Our participants were evenly distributed across a spectrum of concern with respect to the practice of bloodspot retention. Although 25% indicated that they were “not at all concerned” about this practice, 30% were “very concerned.” In the regression model, several variables had a significant effect in the direction of lower concern, including: movie education (P < .001), white race compared with African American (P < .001), white race compared with Native American (P < .001), non-Hispanic ethnicity (P < .05), mother of young children (P < .01), paper/telephone survey method (P < .01), and higher education level (P < .01). As detailed in Tables 4 and 5, we posed 3 questions that addressed potential uses of residual bloodspots, including maintaining the quality of existing tests, research to address diseases affecting mothers and infants, and research addressing diseases that affect the general public. For each of these questions, ~80% of the participants indicated that these uses were either “definitely” or “probably alright.” Therefore, participants did not make a clear distinction between residual sample use for QA and health research and/or between pediatric research and general research applications.

The survey included a brief vignette for the next question. Participants were asked to imagine that a health department has been saving DBS for 10 years without the permission of parents. Then they were asked to imagine that the health department wanted to use the samples for important health research. We asked: “It may be very difficult and costly to find many parents after several years. If parents cannot be contacted, what would be the best thing to do with their baby’s leftover samples?” The majority of our participants (71%) would allow the samples
to be used for important health research with privacy safeguards in place (Table 6). Our survey also addressed the potential tradeoff between removing identifiers from samples and the return of results. A short paragraph informed participants that removing identifiers would increase privacy protections but, if identifying information is kept with the samples, important results about the infant’s health could be returned to the parents. When asked which approach is more appropriate, 64% responded that allowing notification of parents of results was more important than providing greater privacy protection. A number of variables in our model had a significant effect on this response, as indicated in Table 6.

The survey instrument included information explaining that some people believe that state health departments should keep residual samples only if the parents sign a form giving permission (an opt-in consent model), whereas others believe it is acceptable to retain the samples unless parents contact the health department to have their child’s sample removed (an opt-out model). When asked to choose between these approaches, 62% responded that the samples should be kept only if parents sign a form. Variables associated with selection of the opt-out approach included movie education (odds ratio [OR]: 2.02; P < .001), older age (OR: 1.01; P < .001), and a higher level of education (OR: 1.09; P < .01).

The final question in the survey returned to the general question of acceptability of sample retention and research use. Our rationale was that completion of the survey instrument itself could be educational by highlighting aspects of policy and practice. We asked: “After thinking about these questions for the last few minutes, we want your final opinion: Do you think it is alright to use these leftover blood samples for doing important research?” Responses indicated that 81.5% were either “definitely” or “probably alright” with this practice (Table 5). Only 9.5% stated that use of residual samples for research was “definitely not alright.”

### DISCUSSION

Residual bloodspots are essential for QA purposes for NBS programs but also can be used for a broad range of biomedical research. However, given the limited information readily available to parents about NBS and bloodspot retention and use, it is not surprising that this practice has become controversial. Lay advocates in both Minnesota and Texas characterize the practice in alarmist terms, including the sale of infant t-shirts exclaiming “Help!!! The Govt Has My DNA.” Both states have been involved in litigation over this issue, and many states are concerned about public backlash against NBS programs in general.

A number of professional organizations have commented on the retention of DBS. The American Academy of Pediatrics Task Force issued a detailed set of recommendations in 2001. The task force recommended that research with unlinked specimens (not individually identifiable) was appropriate when consistent with the goals of NBS programs and that parents should be informed that residual specimens might be used for QA or epidemiologic research. Furthermore, they recommended that research with identifiable specimens should be conducted with parental permission and only when the DBS are the optimal resource for the proposed research. The Institute of Medicine organized a roundtable discussion in 2010 that highlighted many of the benefits and complexities of QA and research with retained DBS, and speakers emphasized the need for better communication and collaboration.

### TABLE 4 General Linear Modeling Results and Effect Sizes

<table>
<thead>
<tr>
<th></th>
<th>In Your Opinion, Should Health Departments Use These Leftover Blood Samples to Maintain the Quality of Existing Tests for Newborns?</th>
<th>Do You Think It Would Be Alright for These Leftover Blood Samples To Be Used for Important Research on Diseases That Affect Mothers and Infants?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± response</td>
<td>Mean ± response</td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>β</td>
</tr>
<tr>
<td>NBS education</td>
<td>58.23***</td>
<td>−0.40</td>
</tr>
<tr>
<td>Survey method (baseline = KN)</td>
<td>9.07***</td>
<td>−</td>
</tr>
<tr>
<td>Focus groups</td>
<td>3.68</td>
<td>−0.19</td>
</tr>
<tr>
<td>Traditional telephone/paper</td>
<td>15.69***</td>
<td>−0.27</td>
</tr>
<tr>
<td>Age</td>
<td>1.93</td>
<td>0.00</td>
</tr>
<tr>
<td>Hispanic</td>
<td>11.35***</td>
<td>−0.12</td>
</tr>
<tr>
<td>Race (baseline = white)</td>
<td>0.94</td>
<td>−0.05</td>
</tr>
<tr>
<td>Black/African American</td>
<td>1.49</td>
<td>−</td>
</tr>
<tr>
<td>Native American</td>
<td>−</td>
<td>−</td>
</tr>
<tr>
<td>Asian/other</td>
<td>−</td>
<td>−</td>
</tr>
<tr>
<td>Mountain Region</td>
<td>0.70</td>
<td>0.04</td>
</tr>
<tr>
<td>Mother with young child</td>
<td>5.45*</td>
<td>−0.15</td>
</tr>
<tr>
<td>Parent</td>
<td>0.25</td>
<td>−0.02</td>
</tr>
<tr>
<td>Income</td>
<td>1.18</td>
<td>0.01</td>
</tr>
<tr>
<td>Education</td>
<td>10.44**</td>
<td>−0.04</td>
</tr>
</tbody>
</table>

F: F test statistic; β: unstandardized regression coefficient; −: not significant.
* P < .05;
** P < .01;
*** P < .001.
with parents to maintain trust in these public health programs.\textsuperscript{8}

The Secretary’s Advisory Committee on Heritable Diseases in Newborns and Children issued a briefing paper in 2010 addressing policy issues in the retention and use of DBS.\textsuperscript{9} They recommended the development of well-defined strategies and policies, including the promotion of education for parents and health professionals. Both the American College of Medical Genetics and the Association of Public Health Laboratories have issued statements on this topic that emphasize the value of the specimens and the need for new policies to protect the privacy and confidentiality of families.\textsuperscript{18,19}

Research using DBS is generally conducted with de-identified specimens, and we have not identified any reports of harm or breaches of privacy from projects using DBS. Beyond the NBS context, use of residual clinical biospecimens is a common practice in biomedical research.\textsuperscript{20} Although the ethical and regulatory issues in biobanking

<table>
<thead>
<tr>
<th>TABLE 5 General Linear Modeling Results and Effect Sizes</th>
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<tbody>
<tr>
<td><strong>Do You Think It Would Be Alright for These Leftover Blood Samples To Be Used for Important Research on Diseases That Affect the General Public?</strong></td>
</tr>
<tr>
<td>Mean ± response</td>
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<tr>
<td>1–4 Likert scale anchors (% responses)</td>
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<tr>
<td>NBS education</td>
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<tr>
<td>Survey method (baseline = KN)</td>
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<tr>
<td>Focus groups</td>
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<tr>
<td>Telephone/paper</td>
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<tr>
<td>Age</td>
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<tr>
<td>Female</td>
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<tr>
<td>Hispanic</td>
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<tr>
<td>Race (baseline = white)</td>
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<td>Black/African American</td>
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<tr>
<td>Native American</td>
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<tr>
<td>Asian/other</td>
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<tr>
<td>Mountain region</td>
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<tr>
<td>Mother with young child</td>
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<tr>
<td>Parent</td>
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<tr>
<td>Income</td>
</tr>
<tr>
<td>Education</td>
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F, F test statistic; β, unstandardized regression coefficient; −, not significant.

* P < .05;
** P < .01;
*** P < .001.

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<thead>
<tr>
<th>TABLE 6 Logistic Regression Results</th>
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<tr>
<td><strong>More Important To Allow Notification of Parents If Something Important Is Learned Versus Provide Greater Privacy Protection</strong></td>
</tr>
<tr>
<td>Frequency and percentages</td>
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<td>Wald</td>
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<tr>
<td>NBS education</td>
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<tr>
<td>Survey method (baseline = KN)</td>
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<td>Focus groups</td>
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<td>Parent</td>
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<tr>
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<tr>
<td>Education</td>
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</tbody>
</table>

Wald, Wald test statistic; −, not significant.

* P < .05;
** P < .01;
*** P < .001.
have been a topic of active discussion, there has been little public controversy over these practices. Public sensitivities may be heightened in the NBS context due to the lack of parental consent or adequate education for the clinical service, the acquisition of specimens from a vulnerable population, a direct role of state government, and the perception that genetic research poses special risks.

A significant concern in the pediatric and public health communities is that greater public awareness of the retention and use of residual specimens will impair the efficacy of NBS. The worry is that parents will refuse NBS because of concerns over DBS retention and use. Our results demonstrate a high level of support for NBS in general and are consistent with other recent results in the field. Furthermore, we found that support for NBS was enhanced through more in-depth education on the issues. Therefore, our results do not suggest that there is a major conflict between education about NBS and support for NBS generally or sample retention and use specifically.

However, our results also demonstrate that there is a substantial minority of individuals who are highly concerned about this practice. The recent legal cases illustrate that vocal citizens with strongly held opinions can have significant impacts on program policy and function. The litigants in these cases are primarily demanding a parental permission process. We found that despite an evenly divided set of opinions about parental permission for NBS clinical services, a majority of our participants (62%) support an opt-in approach to DBS retention and use. The focus group discussions clearly demonstrated that participants support NBS and DBS retention and use but that they want more information about both and a choice over the latter. Our results are consistent with those of Tarini et al in this regard. It is notable that the American Academy of Pediatrics, the Institute of Medicine, and the Secretary’s Advisory Committee on Heritable Diseases in Newborns and Children statements advocate more education and public transparency relevant to this practice and so appear consistent with our measure of public expectations.

We found that the single most consistent independent variable associated with support for DBS use was viewing the educational movie. Despite the strong statistical significance of the association between viewing the movie and support for DBS use, the magnitude of this effect (β) was modest in practical terms. Other variables associated with more support on these particular questions include female gender, survey method, higher education, older age, and being the mother of a young child. These variables also had modest effects. Variables such as race, ethnicity, income, parenthood, and geographic location had no meaningful effect on responses to most questions.

A weakness of the study is that we received approval from only 1 state, Utah, to conduct the PRAMS-like survey, raising uncertainty about the generalizability of data from this important group. Another weakness is a dependence on the movie and the written information in the survey for educating the general public about a complex, unfamiliar topic.

CONCLUSIONS

The general public included in this study had only limited awareness of NBS and essentially no awareness of the retention and use of residual bloodspots. When made aware of the issues, the public was strongly supportive of NBS and was accepting of the retention and research use of these specimens. Acceptability by the public of sample retention and use was enhanced by providing substantive information about the pros and cons of this practice through an educational movie. Although accepting of the use of these valuable resources, the public preferred an opt-in approach to decision-making by new or expectant parents in determining whether residual bloodspots are retained and used. The need for more attention to prenatal education and informed choice is clear: Greater transparency and increased education by public health programs about these policies and practices are likely to be important in maintaining public trust and acceptance for these valuable programs and research activities.

ACKNOWLEDGMENTS

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REFERENCES


2. Olney RS, Moore CA, Ojodu JA, Lindegren ML, Hannon WH. Storage and use of residual dried blood spots from state newborn
Supplemental Information

Dialogue on the Use of NBS Samples for Research Use

PI Jeffrey Botkin, MD, MPH
University of Utah

Hello. I'm ________ calling from Dan Jones & Associates, a professional public opinion research company. We are conducting an opinion survey of households for a research project regarding some health care issues. May I speak to someone in your household who is 18 years of age or older? [Once secured] May I ask your opinions on some questions? Your participation in this research is voluntary.

To start, let me explain a little about our questions today...

When a baby is born, all state health departments require that a small blood sample be taken to test for several diseases. For these diseases, it is very important to test and treat the baby before the baby gets sick. Early treatment of these diseases can prevent death or mental retardation in children. Because these tests are so important for babies, parents are not asked their permission before doing the tests. However, most hospitals give new parents information about newborn screening, often in a brochure. Sometimes the doctor or nurse in the hospital will talk about newborn screening with the parents. Most states allow parents to refuse newborn screening for religious or philosophical reasons.

The public's input is very important, and we want your opinion on these issues.

1: Did you know that these tests are done?
☐ 1 - Yes
☐ 2 - No

2: How supportive are you of Health Departments doing these blood tests on all new babies?
☐ 1 - Very supportive
☐ 2 - Somewhat supportive
☐ 3 - Somewhat not supportive
☐ 4 - Not supportive
☐ 5 - Don't know

3: Do you think it is alright that these tests are done without permission from the parents?
☐ 1 - Definitely alright
☐ 2 - Probably alright
☐ 3 - Probably not alright
☐ 4 - Definitely not alright
☐ 5 - Don't know

After testing, there is usually a small amount of blood left over from each baby. There have been some discussions about what should be done with these leftover blood samples.

4: How concerned would you be if Health Departments saved the leftover blood samples from babies after the testing is done?
☐ 1 - Very concerned
☐ 2 - Somewhat concerned
☐ 3 - Only a little concerned
☐ 4 - Not at all concerned
☐ 5 - Don't know

Leftover blood samples from babies can be used for different purposes. One use is to maintain the quality of the screening tests for babies. The samples also can be very valuable for research on diseases that affect mothers and babies, or for general health research. National regulations require that all research be approved by a committee that oversees the protection of the rights, welfare, and privacy of people involved in research.
There are 2 key issues about how these samples are used. First, should this be done with or without the parents’ permission? And second, should the baby’s name and identifying information be kept on the sample?

Please answer the following questions on a scale of 1 to 4 where 1 means “Definitely alright,” and 4 means “definitely NOT alright.”

8: Would it be alright to use these leftover samples for research WITH parents permission and WITH the baby’s name attached?

9: Would it be alright to use these leftover samples for research WITH parents permission and WITHOUT the baby’s name attached?

10: Would it be alright to use these leftover samples for research WITHOUT parents permission and WITH the baby’s name attached?

11: Would it be alright to use these leftover samples for research WITHOUT parents permission and WITHOUT the baby’s name attached?

For these next 2 questions, please answer on a 1 to 4 scale, where 1 means “there is no risk at all” and 4 means there is “high risk”. If the leftover blood samples are used for research, how much risk would this be for babies…(READ EACH OPTION)
12: If the leftover blood samples are used for research, how much risk would this be for babies if the baby’s name is attached?

<table>
<thead>
<tr>
<th></th>
<th>1 - No risk at all</th>
<th>2 - A little risk</th>
<th>3 - Some risk</th>
<th>4 - High risk</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

13: If the leftover blood samples are used for research, how much risk would this be for babies if the baby’s name is NOT attached?

<table>
<thead>
<tr>
<th></th>
<th>1 - No risk at all</th>
<th>2 - A little risk</th>
<th>3 - Some risk</th>
<th>4 - High risk</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

How much do you trust each of the following groups to use the leftover blood samples for research in an ethical manner? Please rate on a 1 to 4 scale, with 1 meaning you have “A lot of trust” and 4 meaning you have “No trust at all” in the group.

14: How much do you trust HEALTH DEPARTMENTS to use the leftover blood samples for research in an ethical manner?

<table>
<thead>
<tr>
<th></th>
<th>1 - A lot of trust</th>
<th>2 - Some trust</th>
<th>3 - A little trust</th>
<th>4 - No trust at all</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

15: How much do you trust UNIVERSITY RESEARCHERS to use the leftover blood samples for research in an ethical manner?

<table>
<thead>
<tr>
<th></th>
<th>1 - A lot of trust</th>
<th>2 - Some trust</th>
<th>3 - A little trust</th>
<th>4 - No trust at all</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

16: How much do you trust PRIVATE RESEARCH COMPANIES to use the leftover blood samples for research in an ethical manner?

<table>
<thead>
<tr>
<th></th>
<th>1 - A lot of trust</th>
<th>2 - Some trust</th>
<th>3 - A little trust</th>
<th>4 - No trust at all</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

17: How much do you trust FEDERAL HEALTH AGENCIES to use the leftover blood samples for research in an ethical manner?

<table>
<thead>
<tr>
<th></th>
<th>1 - A lot of trust</th>
<th>2 - Some trust</th>
<th>3 - A little trust</th>
<th>4 - No trust at all</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

18: If for practical reasons parents cannot be asked for permission would it be alright for a group representing your local community to approve research using leftover blood samples?

<table>
<thead>
<tr>
<th></th>
<th>1 - Definitely alright</th>
<th>2 - Probably alright</th>
<th>3 - Probably not alright</th>
<th>4 - Definitely not alright</th>
<th>5 - Don’t know</th>
</tr>
</thead>
</table>

Imagine that a Health Department has been saving leftover samples during the last 10 years without permission from the parents. Now imagine that researchers want to use the samples for important health research.
19: It may be very difficult and costly to find many parents after several years: If parents cannot be contacted, what would be the best thing to do with their baby's leftover samples?

☐ 1 - With privacy safeguards in place, allow the samples to be used for important health research
☐ 2 - Do not allow the samples to be used for important health research

If a baby's name is kept with the leftover blood sample, researchers will be able to notify parents if something important is learned about the baby's health. But, if a baby's name is not kept with the sample, it gives greater privacy protection:

20: Do you think it is more important to

☐ 1 - Provide greater privacy protection
☐ 2 - Allow notification of parents if something important is learned

Some Health Departments keep samples only if the parents agree to this by signing a form. In other states, all samples are kept unless the parents contact the Health Department and say they want their child's sample destroyed:

21: What do you think is the best thing to do?

☐ 1 - Keep samples only if parents sign a form
☐ 2 - Keep samples unless parents contact the Health Department to have them destroyed

Imagine that the Health Department in the state where you were born had been saving these leftover blood samples for many years and now wanted to use them for research.

Please answer the next 2 questions using a scale of 1 to 4, with 1 meaning it would be “Definitely alright” and 4 meaning it is “Definitely NOT alright.”

22: Would it be alright to use your sample for research if information connecting you to the sample was REMOVED?

☐ 1 - Definitely alright
☐ 2 - Probably alright
☐ 3 - Probably not alright
☐ 4 - Definitely not alright
☐ 5 - Don't know

23: Would it be alright for them to use your leftover blood sample if information connecting you to the sample is STILL ATTACHED?

☐ 1 - Definitely alright
☐ 2 - Probably alright
☐ 3 - Probably not alright
☐ 4 - Definitely not alright
☐ 5 - Don't know

After thinking about these questions for the last few minutes, we want your final opinion.

24: Do you think it is alright to use these leftover blood samples for doing important research?

☐ 1 - Definitely alright
☐ 2 - Probably alright
☐ 3 - Probably not alright
☐ 4 - Definitely not alright
☐ 5 - Don't know

For question 25, Variable name is “comment” not Q25.

25: Finally, do you have any comments you want to share with us about the retention and use of leftover blood samples?

____________________________________________________

Now a few questions to help us analyze the information…
26: Have you heard about the use of leftover newborn blood samples in the news?  
- 1 - Yes  
- 2 - No  

27: What is your Gender?  
- Male  
- Female  

28: How old are you (in years)?  

29: What is your Zip code?  

30: What is your highest level of education you have completed?  
- Some high school or less  
- High school diploma or GED  
- Some college  
- Associates degree  
- Bachelors degree  
- Graduate degree  

31: How many children have you ever had, not including stillbirths?  
- One  
- Two  
- Three  
- Four  
- More than four  
- None  

32: Do any of your children have a history of serious health problems?  
- Yes  
- No  

33: Is there any history of serious health problems in your immediate family?  
- Yes  
- No  

34: Are you of Hispanic or Latino descent?  
- Yes  
- No  

35: Which of the following best describes your race?  
- White  
- Black or African American  
- American Indian or Alaska Native  
- Asian  
- Native Hawaiian & Other Pacific Islander  
- Other  

36: In politics today, do you usually think of yourself as?  
- Republican  
- Democrat  
- Independent  
- Something else  
- Don't know
37: In politics today, would you say you are?

- Very conservative
- Somewhat conservative
- Moderate
- Somewhat liberal
- Very liberal

38: What, if anything, is your religion?

- Catholic
- Baptist
- No religion
- Christian
- Methodist
- Lutheran
- Presbyterian
- Protestant
- Pentecostal
- Episcopal/Anglican
- Jewish
- The Church of Jesus Christ of Latter-Day Saints
- Churches of Christ
- Non-denominational
- Congregational/UC
- Jehovah's Witnesses
- Assemblies of God
- Muslim/Islamic
- Buddhist
- Evangelical/Born Again
- Church of God
- Seventh Day Adventist
- Something else

39: Aside from weddings and funerals, how often do you attend religious services?

- More than once a week
- Once a week
- Once or twice a month
- A few times a year
- Seldom or never

40: Last year, what was your total family income from all sources, before taxes?

- Less than $20,000
- 20 to under $30,000
- 30 to under $40,000
- 40 to under $50,000
- 50 to under $75,000
- 75 to under $100,000
- 100 to under $150,000
- $150,000 or more

Thank you for your participation! If you have any question or concerns about this research you can contact Dr Jeff Botkin at the University of Utah. His phone number is 801 581 7170.
Public Attitudes Regarding the Use of Residual Newborn Screening Specimens for Research

Jeffrey R. Botkin, Erin Rothwell, Rebecca Anderson, Louisa Stark, Aaron Goldenberg, Michelle Lewis, Matthew Burbank and Bob Wong

*Pediatrics*; originally published online January 16, 2012;
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