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Mothers' Decisions About Donating Newborns' Blood Spots for Research

A Qualitative Study

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ABSTRACT

Residual dried blood spots from millions of newborns are being stored and used for research. The state of Michigan proactively developed a broad consent process for research use of newborns' blood spots. However, the extent to which mothers make informed choices about this research is unclear. A descriptive, qualitative study was conducted examining this issue. Twenty-nine observations of the consent process and 20 semistructured interviews were conducted with mothers on the postpartum unit of a large, academic hospital in Michigan. Content analysis of the transcripts was conducted. While most mothers agreed to donate the blood spots ($n = 14/20$; 70%), findings indicated that most decisions were uninformed ($n = 16/20$; 80%), as mothers lacked knowledge of biobanking research. Misunderstandings about anonymity, the consenter's credentials, and entity conducting the research seemed to influence decision making. Suggestions for improving the consent process include (1) changing the venue of blood spot education and consent from the postpartum period to the perinatal period, (2) strengthening the depth of information and delivery of information provided about the topic, including ethical and values clarification, and (3) increasing consenter education and training. Implementation may help increase the proportion of informed decisions.

Key Words: biological specimen banks, ethics, informed consent, newborn blood spot screening, nurses

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Residual dried blood spots (rDBS) are biospecimens that remain after legally required newborn screening (NBS) is completed on the nearly 4 million infants born annually in the United States.[1,2] The rDBS are frequently stored and used for research, often without parental consent.[2] The collection of human biological specimens for future, unspecified research (ie, biobanking) has become a widespread practice.[2,3] By retaining, storing, and distributing rDBS, NBS programs, managed by state departments of health, are a major source of pediatric biospecimens for research.[4] While this research has led to important medical advancements,[5] it has also introduced new ethical issues including risks to genetic privacy and other personal values.[4,6-8]

Taking note of ethical concerns, in 2010, the Michigan Department of Health and Human Services (MDHHS) was the first to adopt a broad consent process for rDBS research as part of the NBS that occurs about 24 hours after birth.[9] However, because broad consent provides few details about future research, it

may not provide adequate information for informed decision-making[10] and thereby could contribute to decisional regret and moral distress.[11] Thus, it is also essential to determine whether donors (or surrogate decision makers such as parents) possess adequate knowledge and understanding of biobanking to make an informed choice.[12] As NBS and rDBS research occurs globally, this concern has international implications.[13]

BACKGROUND

Genetic privacy

It is important for individuals to understand the risk for a potential breach of genetic privacy before donating biospecimens to a biobank.[14] Deoxyribonucleic acid (DNA) in biospecimens reveals individuals' unique attributes and genetic predispositions to a host of diseases, including many that potentially carry social stigma (eg, schizophrenia, alcoholism).[15] Unwanted exposure of private genetic information may cause personal embarrassment, distress, or discrimination (eg, employment, insurance, or social) despite partial protective legislation.[15,16] Because DNA is unique to each human, replacing names, birth dates, and other identifiers with a code may not fully protect genetic privacy.[15] In addition, without specific (or in some cases any) consent, rDBS have been used to study issues such as maternal cocaine and tobacco use,[17,18] which may also be perceived as an invasion of privacy.

Moral risk

Because intended research uses of rDBS are often unspecified at the time of donation, alignment of the research with personal values may be unclear or unknown. This lack of clarity may precipitate moral risk, defined as the possibility that biospecimens may be used in research activities misaligned with the parents' (or donors') personal, religious, or cultural values.[7,8,15] A recent literature review noted several religious concerns related to biobanking including blood storage, cloning, and genetic analysis.[19] Lack of transparency, at the time of consent, about potential uses for biospecimens may pose conflicts with personal values and lead to moral distress.[11]

Theoretical framework

The multidimensional measure of informed choice[12] (hereafter MMIC) was the theoretical framework guiding this study (see Figure 1, derived from Marteau et al.[12]). The main concepts are knowledge, attitudes, and the participation decisions. Knowledge is defined as participants' understanding of key information about

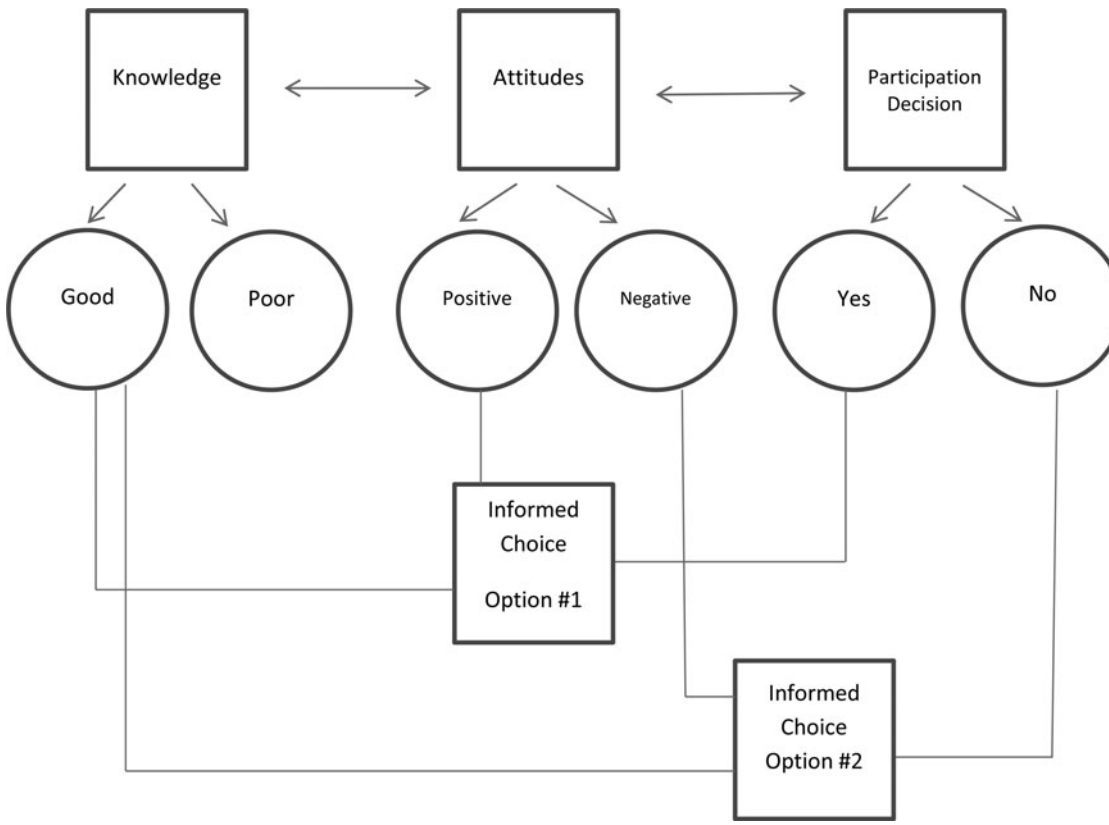

Figure 1. Informed choices per the multidimensional measure of informed choice.

the topic, deemed essential by professional consensus for making an informed choice. Attitudes are individuals' value-based judgments about facts and information.[12] In this model, an informed choice is based on adequate knowledge and consistent with decision makers' personal values, as reflected by their attitudes.[12] While the MMIC has often been used in studies about prenatal testing,[12,20,21] to our knowledge, this is the first study to use it to guide the examination of mothers' decisions about donating newborns' rDBS for research.

METHODS

Design

This article presents the qualitative component of a larger triangulated study[22] conducted to investigate factors influencing mothers' decisions to donate their newborn's rDBS to the Michigan BioTrust for Health (ie, "the BioTrust"). This program of the MDHHS is charged with oversight of the research use of rDBS, including the consent process.[9] The specific aim of the qualitative portion of the study was to describe the context and content of the consent process, mothers' knowledge of the BioTrust and biobanking, and the influence of personal and religious values on their decisions to donate their newborn's rDBS for research purposes. Furthermore, this study sought to determine the proportion of decisions deemed informed choices, as measured by the MMIC.[12] A descriptive, qualitative design[23] was used to characterize factors that influenced these decisions, including the context of the postpartum unit, mothers' knowledge of biobanking, their personal values, experience with the consent process, and demographic characteristics.

Setting and sample

The BioTrust consent process occurred in private rooms on the mother/baby unit of a large, academic medical center; the unit has 50 private maternity rooms and delivers nearly 4000 newborns each year. A convenience sample was recruited by the principal investigator (PI) as mothers were approached by hospital personnel about NBS and consent for rDBS research. The PI shadowed the staff member responsible for obtaining BioTrust consent (ie, "the consenter"). When the consenter approached each mother to explain NBS and the BioTrust, she also explained the PI's presence. Verbal permission was obtained from each mother for observation of the BioTrust consent process. After the mother rendered a decision about the BioTrust, the mother was asked to participate in a brief semistructured interview regarding her decision. To be eligible to participate in the semistructured interview, mothers had to be (1) 18 years or older, (2) able to speak English, (3) seen within a 24-hour window of rendering the decision of interest, and (4) willing to be audiotaped. Once eligibility was determined, the study was explained in detail and written informed consent was obtained. Interviews were conducted in the mother's hospital room at that time or later the same day. Family members (eg, newborn's father) who were present were allowed to stay with the participant's permission and were made aware the interview would be audiotaped.

Ethical considerations

Approval to conduct the study was obtained from the appropriate university institutional review board. Mothers were free to stop the interview at any point or decline to answer particular interview questions. No names were included on audiotapes or transcripts to ensure confidentiality of the participants. No incentives were offered for participating in the interviews.

Data collection

Observations

Passive participant observation was used to collect data on (1) the physical setting in which the consent discussion occurred, (2) informational materials provided, (3) individuals present in the room during the consent and interviews, (4) activities and interactions, and (5) nonverbal behaviors to emphasize the importance of contextual factors of the postpartum period during the BioTrust consent process.

Semistructured interviews

An interview guide was developed (see Table 1) using information in the BioTrust brochure,[24] essential biobanking informed consent topics,[14] and concepts in the MMIC.[12] Content validity was established by team members with expertise in informed consent (A.R.T.) and maternity care (ie, certified nurse midwife [L.K.L.]). The interview guide was pilot tested with 5 mothers. Additional questions were asked at the completion of the 5 interviews to elicit feedback about the interview process and to assess whether anything asked was unclear. As no suggestions for change were provided, these 5 interviews were included in the final sample.

Following the consent process, mothers were interviewed to examine their knowledge of the rDBS and biobanking research, experience with the consent process, and personal values. Knowledge was assessed by asking each participant to describe her understanding of the blood spots, NBS, the BioTrust, and biobanking. Next, each mother was asked to describe the informed consent process that had just occurred and to reflect

Table 1. **Interview questions, probes, and categories**

Interview questions	Probes	Category
First, please describe to me what you know about the blood spots from the newborn screening test?	What do you understand about the blood spots from the newborn screening test?	Newborn screening knowledge
Please tell me what you know about the Michigan BioTrust.		BioTrust knowledge
Next, please describe how you were asked for permission to donate the leftover blood spots to the BioTrust as you experienced it.	Who asked for your permission? What did he or she tell you? What happened?	Informed consent
What was your decision about the donating your baby's blood spots to the biobank?	Did you agree or not agree to donate your baby's blood spot to the biobank?	Donation decision[a]
What kinds of thoughts, questions, or concerns were in your mind as you made your decision?		Values/attitudes perceived risks
Do you think your questions were answered? How was this done?	By whom or by what information?	Informed consent
Do you think you were you able to get the information that you needed to make the decision?		Informed consent
Is there any additional information that would have been helpful to you in making this decision?		Informed consent
If you had more time, would you be willing to find more information?		Informed consent
What did you find helpful or unhelpful to you to make the decision to donate your baby's blood spot to the Michigan BioTrust?		Informed consent
Please tell me about how you chose (yes/no)?	What was important to you in making the decision?	Values/attitudes
What personal experiences, values, opinions, or religious beliefs of yours do you think may have influenced your decision?	How did _____ affect your decision? Can you give me an example?	Values/attitudes
What have you heard about biobanking?	Can you please describe biobanking in your own words?	Biobanking knowledge
What is the purpose of the Michigan BioTrust?		Knowledge informed consent
Next, please describe your expectations about medical research involving your child's genetic information/blood spots.		Attitudes/values
Do you have any concerns about medical research involving your child's genetic information/blood spots? If yes, please explain.		Perceived risks
Are there things you would want or would not want the blood spots used for?	Like what? Can you please give me an example?	Attitudes/values
On a scale of 1-5 (rating described), how would you rate your confidence in your decision?		Confidence
If you were to change your mind about donating, what would you have to do?		Informed consent
Please complete the following sentence: For me, personally, donating (or not donating) my newborn's blood spots for research is_(fill in the blank)____.[b]		Attitudes
Anything you would like to add about your experience and decision regarding the BioTrust?		Summation

[a]19 of 20 decisions were observed as they were made.
[b]Question adapted from Marteau et al.[12]

on questions or concerns she may have had during the decision-making process. Then, each mother was asked to repeat her decision and describe why she agreed or declined to donate her newborn's blood spots for research. Finally, each mother was asked to describe any personal experiences or personal or religious values she thought may have influenced her decision.

At the end of each interview, each mother was given an opportunity to provide any additional descriptions of her experience. Demographic data including age, education, race, religion, insurance status, and parity were also collected. After confirmation with the mother that she had no additional information to share, the interview was considered complete. The observations and interviews were conducted over 4 days during October to November 2016.

Data analysis

Data were analyzed using qualitative content analysis; steps included (1) preparation, (2) organizing and coding the data, and (3) reporting the results.[25] Preparation included verbatim transcription of the audiotaped interviews (E.R.E.). This involved scrutinizing the data, accomplished by listening to each interview multiple times as part of the transcription process, and then by reading, rereading, and abstracting the interview transcripts (E.R.E. and C.M.A-E.). Next, data were organized using codes developed on the basis of categories in the MMIC framework and interview questions (eg, knowledge, attitudes, and decisions), key words, and phrases. Narrative data were extracted from the transcripts, organized in tables, reviewed, and iteratively compared. Data matrices were then created to compare and contrast responses and demographics of mothers who decided to donate or not donate their newborn's rDBS. The unit of analysis was the collective experiences of the 20 mothers who participated in the qualitative interviews.

To classify decisions as informed or uninformed, responses to knowledge questions were classified as either good (+) or poor (−) by 2 coders (E.R.E. and C.M.A-E.). Responses consistent with factual materials (eg, per the BioTrust brochure[24]) were classified as good knowledge, whereas inconsistent responses or statements such as "I do not know" were classified as poor knowledge. Similarly, attitudes were classified into positive and negative categories. Favorable, optimistic thoughts or feelings toward blood spot research were characterized as positive attitudes, whereas negative attitudes were marked by suspicious thoughts or feelings toward such research. Using the MMIC definition of an informed choice, there were only 2 possible combinations of knowledge, attitude, and donation decisions that would constitute an informed decision.[12] Option 1 was when a mother had (*a*) good knowledge about the BioTrust and biobanking, (*b*) a positive attitude toward rDBS research, and (*c*) agreed to donate her newborn's rDBS. The other option was when a mother had (*a*) good knowledge about the BioTrust and biobanking, (*b*) a negative attitude toward rDBS research, and (*c*) declined to donate her newborn's rDBS (see the Figure). Choices based on poor knowledge and/or attitudes incongruent with decision making were classified as uninformed choices per the MMIC framework.[12]

Trustworthiness of the data was reinforced by the use of audiotape and subsequent verbatim transcription of the interviews. Participants' views were confirmed through informal member checking and probes used during the interviews to clarify statements.[26] The sample size was deemed adequate after the 14th interview as determined by data saturation, the point when new information stops occurring and established responses continue to repeat.[26,27] Interrater reliability was established using the approach of Miles and Huberman[28] (the number of agreements divided by the total number of agreements and disagreements). Categorization of participants' responses (ie, good or poor knowledge, positive or negative attitudes, level of perceived risk) was iteratively discussed, classified, and revised as needed between 2 coders (E.R.E. and C.M.A-E.). Two evaluations of biobanking knowledge were changed from good to poor. Discordance was reconciled by further discussion and 100% consensus was reached.

RESULTS

Observations

The BioTrust consent process was observed 29 times and was estimated to be, on average, 5 minutes in length. Mothers who had given birth the previous day were identified from a daily census and approached regarding NBS education and potential rDBS donation. The same consenter, an unlicensed member of the ancillary staff, was observed for all consent interactions. The consenter arranged her visits with mothers according to time of delivery and approached mothers before the heel stick procedure for NBS occurred. While the consenter strived to give each mother as much time to rest after birth as possible time constraints existed, as NBS must be conducted after the newborn is 24 hours old but before leaving the hospital.

The consenter respectfully introduced herself to the mother by name and job title and explained she was there to talk about NBS. Next, the consenter asked each mother whether she was familiar with the newborn heel stick and described the process. At this institution, mothers were given a folder of information at

admission, including brochures on NBS[29] and the BioTrust,[24] and these folders were observed to be present in the mother's room during the consent process. The consenter verbally referenced the brochures stating, "There's a pamphlet in your folder . . . ." However, a detailed review of those materials was not observed, nor were informational materials used that explained potential controversial types of research (ie, moral risks). The consenter explained that 6 blood spots would be collected to screen for more than 50 metabolic diseases, often briefly describing examples (eg, phenylketonuria and cystic fibrosis). Next, the consenter described the difference between screening and research by stating: "The state also wants me to ask if they can use the leftover blood for anonymous medical research. The screening is required, but you can say yes or no to the research." The manner used to present the information and the language used were the same at each encounter. Before checking a yes or no box to indicate a participation choice, each mother looked at the BioTrust consent form on the back of the NBS blood spot card that summarizes key information.[30] However, the extent to which mothers actually read or understood the information is unknown. Mothers (and fathers) tended not to ask questions during the BioTrust consent process. Eye contact and puzzled facial expressions were observed between mothers and fathers before responding to the consent question. If silence was prolonged, the consenter prompted the mother by stating, "The blood spots either go to the biobank for research or sit with the state. It's up to you." Mothers (or fathers) verbally expressed a choice and then one signed the blood spot card accordingly. During one observation, parents contradicted each other's decision to donate: the mother stated she wanted to agree, and the father stated he wanted to decline donation. Subsequently, the mother declined. Family members were frequently observed in the room with the mother (eg, fathers were present in 15/20 [75%] interviews). Mothers identified others present at the time of the BioTrust consent and/or the interviews as an aunt, a sister-in-law, and grandparents.

Interviews

Twenty mothers (20/29; 69%) participated in the semistructured interviews, and 9 mothers declined (9/29; 31%). Interviews lasted 6 to 20 minutes (median = 8 minutes). The median age of participants was 32 years (range, 23-42 years); most were multiparous (n = 15), with this birth most often being their second child (n = 10). Three-fourths (n = 15) had at least some college or a college degree. Sixty-three percent of the mothers identified a religious affiliation and indicated the practice of their faith was important (n = 12/19; 63%). Of those mothers who identified a religion, the importance of the practice of their faith was rated highly (average 8.75 on a 10-point scale).[31] Characteristics of the participants are presented in Table 2.

Knowledge

Fourteen mothers (70%) were able to correctly describe knowledge of the NBS by stating: " . . . screening for these different diseases and they will tell us if our child has them and what we need to do to treat them to prevent certain symptoms" and " . . . check[ing] for different diseases or illnesses that babies could have." Conversely, when asked to describe the Michigan BioTrust, most mothers (16/20; 80%) stated, "I don't know anything about it" or "nothing" about it. Similar responses were noted when asked to describe biobanking. Most mothers (n = 16/20; 80%) indicated they did not have any knowledge of it, stating, "Biobanking? I don't know" and "Sorry, I don't know."

Five of the mothers who declined to donate the rDBS for research described a "lack of information around the process" and clearly stated, "I just really didn't know anything . . . about the research part of it so that's why my answer was no." Mothers described "the inability to get clear information" and their unwillingness to "put my child out there" because "I just don't know a lot of information." One mother perceived that donation options were not "presented equally" and described the BioTrust brochure as "definitely geared toward you saying yes."

In addition, 4 types of misunderstandings emerged from the narrative data, involving 11 of the mothers. One mother who declined donation misunderstood the procedure and said, "I just don't want him to be more uncomfortable," believing donation would require the newborn to have a second heel stick. Two other mothers agreed to donate because they perceived that "it's [the university hospital] asking me" and felt "[the university hospital] does a lot of good research . . . I am happy to participate." Four other mothers who agreed to donate stated since " . . . it's totally anonymous," and one said, "If it wasn't anonymous, I probably wouldn't do it . . . ." Five mothers indicated a "nurse" entered the room to ask for consent.

Attitudes

All of the mothers who agreed to donate rDBS (n = 14) had attitudes about the research classified as positive. The 6 mothers who declined to donate rDBS had attitudes classified as negative. No choice was inconsistent with the stated attitudes about the research.

Mothers who agreed to donate their newborn's blood spots (n = 14; 70%) overwhelmingly described wanting to do "good" and to "help" others. One mother said

Table 2. **Characteristics of interviewed mothers**[a]

		Donation decision	
		Yes ($n = 14$), %	**No ($n = 6$), %**
Age, y			
Median	32	34	24
Range	23-42	25-42	23-29
	***n* (%)**	***n* (%)**	***n* (%)**
Race			
Asian	1 (5)	0 (0)	1 (17)
Black or African American	2 (10)	0 (0)	2 (33)
White or Caucasian	12 (60)	11 (79)	1 (17)
Other (Arabic, mixed-race, other)	4 (20)	3 (21)	1 (17)
Missing[b]	1 (5)	0 (0)	1 (17)
Religion			
Christian	6 (30)	3 (21)	3 (50)
Muslim	5 (25)	3 (21)	2 (33)
None	7 (35)	7 (50)	0 (0)
Unitarian	1 (5)	1 (7)	0 (0)
Missing[b]	1 (5)	0 (0)	1 (17)
Highest level of education completed			
High school	4 (20)	1 (7)	3 (50)
Some college	6 (30)	5 (36)	1 (17)
Bachelor's degree	4 (20)	4 (29)	0 (0)
Master's degree	4 (20)	3 (21)	1 (17)
Professional degree (PhD, MD)	1 (5)	1 (7)	0 (0)
Missing[b]	1 (5)	0 (0)	1 (17)
Insurance coverage			
Public (Medicaid)	8 (40)	5 (36)	3 (50)
Private (employer/ self-insured)	10 (50)	9 (64)	1 (17)
Both	1 (5)	0 (0)	1 (17)
Missing[b]	1 (5)	0 (0)	1 (17)
No. of live births (including this baby)			
1	4 (20)	3 (21)	1 (17)
2	10 (50)	7 (50)	3 (50)
≥3	5 (25)	4 (29)	1 (17)
Missing[b]	1 (5)	0 (0)	1 (17)
Confidence in decision—average (1, uncertain; 5, very confident)			
Overall	4.4	4.5	4.2

[a] % Columns may not total 100% due to rounding.
[b] Missing data = 1 mother declined to answer demographic questions.

donating blood spots was about "helping, helping others, finding cure, helping finding cure, hopefully." Mothers described blood spot donation as a way "... to be socially responsible..." and "... advance medical care...." Mothers frequently ($n = 12$; 60%) expressed the perception of research as a benevolent act. One mother said, "... research is good. Let's do that!" and 2 other mothers stated they were "always pro-research."

Perceived risk

Three mothers who agreed to donate rDBS perceived no risks with the research. One participant stated, "They're not ... to harm my child, so, why not [participate]!" Nine others who agreed to donate perceived "little" or "small" risks, and one of these mothers expressed that the research was "low enough risk that I'm not too worried about it." The perception of low risk was often linked to the fact the blood spots were "leftover" and there would not be "an extra prick" for the newborn.

However, mothers who declined to donate perceived more risk and stated, "... it's private information. I don't want it to go out in public," and expressed concerns the blood spots would be used for "commercial reasons

. . . for profit." Additional concerns included "any negative research" and "uncertainty about how it's going to be used."

Six mothers (30%) mentioned religious, spiritual, or moral issues as they described their donation decisions. Two mothers who agreed to donate associated "trying to help each other" with their religious beliefs. They stated, "[My congregation] really believe in the inner connectedness of all livings beings" and "I hope to God they find cures for illnesses." Two other mothers agreed to donate despite expressing moral concerns. They said: "Just don't clone them" or use the blood spots for "anything like immoral, like . . . abortion." One mother who declined to donate stated, ". . . I believe in certain things like being Christian for one, and in Christ and all that," and she feared the blood spots may be used for "witchcraft." Another mother denied that "visions" (ie, religious or spiritual entities) led her to say no but stated she declined on the basis of her lack of knowledge.

Mothers' descriptions of consent process

The majority of mothers ($n = 12/20$; 60%) were able to describe the difference between NBS and the request to use rDBS for research. One mother stated:

> She came . . . in and . . . described . . . the state requires six blood spots and they do some testing for children . . . and then . . . she asked . . . if we would be willing to . . . use the leftover blood spots for research.

However, 8 mothers were unable to describe the difference clearly. One mother stated, "She just really just asked me if I . . . want to it get a researched [*sic*] and I said yes, but I don't want those remaining blood kept."

Four mothers characterized the consent process as "straightforward" or "no big deal" and as an "easy decision." Two of these mothers reported "details" were not provided, nor were they always perceived as necessary. One mother stated, ". . . I think she didn't specify more details just because I didn't ask for them . . . ."

Two mothers stated the speed at which the decision was made was ". . . like a one second decision!" and ". . . I made it on the fly!" A third mother stated, "I didn't think twice of it."

Two mothers specifically reported the brief explanation provided by the consenter to be "helpful" in making the decision and that the consenter "kind of went over it a little bit with us." Two other mothers stated they appreciated "having a choice" about donation (one said yes and one said no to donation), and 3 mothers explicitly denied feeling any pressure imposed by the consenter to influence their decisions. One said it was "very low pressure . . . like it was okay either way." Another one stated she felt "no pressure at all," and the third mother said "it felt normal." However, another mother described that she did not find the process helpful stating: ". . . how can we give informed consent . . . [a] couple of hours after a birth, when they've [*sic*] had all kind of narcotics and drugs, and trauma? And there is somebody in the room every half hour . . . ."

When asked, "If you were to change your mind about donating what would you have to do?" Four mothers were able to described the process to withdraw from the BioTrust stating they would "[use] the Internet," "read the pamphlet," or "contact the state." Eight other mothers described it as "telling the lady" or "telling you guys," whereas others stated they did not know ($n = 5$) or did not understand the question ($n = 3$).

Demographics and decisions

A total of 14 mothers agreed to donate their newborn's blood spots to the BioTrust, and 6 declined. Mothers who self-identified their race as white tended to agree to donate, whereas mothers who self-identified their race as nonwhite were split in their decisions (see Table 2). In addition, mothers who declined to donate tended to be younger in age (in their 20s) than mothers who agreed to donate rDBS, who were mostly in their 30s or older than 40 years. Twelve mothers ($n = 12/19$; 63% of those who answered demographic questions) reported a religious affiliation (ie, Christian, Muslim, or Unitarian); 5 of those 12 (42%) mothers declined to donate rDBS, whereas all 7 mothers who indicated no religious affiliation agreed to donate their newborn's rDBS. Education, insurance status, and number of births did not seem to be exclusively associated with any particular donation decisions (see Table 2).

On the basis of the MMIC[12] classifications, 4 mothers (20%) made an informed choice: a choice congruent with both (*a*) possessing good knowledge and (*b*) consistent with personal attitudes toward blood spot research. Sixteen mothers (80%) lacked adequate knowledge to make an informed choice. Informed choices included 3 mothers who agreed to donate and 1 mother who declined. Only 3 of the 4 mothers who made an informed choice were willing to answer demographic questions. All 3 of these mothers were in their 30s, had at least some college education, and identified a religious affiliation. Two had private insurance and one had public insurance (ie, Medicaid). Two mothers were multiparous and one a first-time mother; fathers were present in 2 out of 4 instances of informed choice. All mothers indicated they were fairly confident with their decisions (see Table 2).

DISCUSSION

Observation of the BioTrust consent process indicated that information provided to mothers lacked depth, which may have contributed to lack of adequate knowledge and frequent misunderstandings. This finding is consistent with a recent focus group study that included 69 participants from 3 states and reported that individuals frequently found information on the MDHHS blood spot card consent form confusing.[32] Observations also confirmed previous reports[33,34] that the postpartum environment is not conducive to education about NBS and rDBS research, as mothers described being sleep-deprived, fatigued, under the effect of medication or in pain, and were observed to be preoccupied with their new baby. While the consenter's approach was professional and friendly, it was also routine, brief, and observed to elicit only a yes or no response. Routinization of consent for other postpartum decisions (eg, newborn care, pain medication, breastfeeding, and male circumcision) has been noted to overlook patients' values and the emotional consequences of the decisions and thereby impede meaningful informed consent.[35,36] Shared decision-making[37] in which patients' values and preferences are openly discussed and clarified might be a better approach to aid informed choices. Extended discussion with a person knowledgeable about details of the research is still the most efficacious intervention to aid understanding of consent information.[38,39]

Semistructured interviews revealed that the majority of the mothers ($n = 16$; 80%) made the decision without adequate knowledge of the BioTrust or biobanking and thus these decisions failed to reach the threshold of an informed choice.[12] Findings were consistent with the current literature, which indicates that many participants lack understanding of key elements of informed consent for biobanking[40] and that low knowledge scores contribute to other uninformed decisions including those involving prenatal testing[12,20,21] and declining to vaccinate children.[41]

The 6 mothers who declined to donate perceived higher risks to personal values (eg, privacy and research uses). However, even 2 mothers who agreed to donate expressed moral caveats on research involving abortion and cloning, indicating perceptions of moral risk. Indeed, rDBS have been used to study birth defects and develop new techniques for prenatal genetic diagnosis.[42,43] Research from Canada and the United Kingdom demonstrated that advances in prenatal genetic testing have contributed to an increase in abortions due to the presence of fetal anomalies.[44,45] Moreover, one of these mothers held the misperception that the request for rDBS was emanating from the hospital, a trusted institution in the community, although the request was actually from the MDHHS. Misperceptions about anonymity, the consenter's credentials, and the entity conducting the research were common. Thus, it is crucial to clarify specific points including that blood spots are coded, but not anonymous, the consenter's credentials (eg, registered nurses vs unlicensed personnel), which have been shown to influence biobanking decision making,[40,46] and that the request for rDBS is coming from the state department of health, not a trusted hospital or consenter. Parents need accurate information on which to base their donation decisions, and understanding should be verified. Observations also indicated that fathers wanted to be more involved in rDBS education and decision making.

Limitations

The study sample was a small, convenience sample of mothers derived from a single data collection site, where only one consenter was observed, which may limit the generalizability of results. The MMIC[12] attributes an informed choice to only 3 categories: knowledge, attitudes, and participation. An informed choice may be more complex and involve deliberation,[21] which is not captured in the MMIC. Finally, despite efforts by the PI to be as unobtrusive during the consent process, the potential for a Hawthorne effect cannot be ruled out. The consenter knew she was being observed, which may have influenced her behavior.[26] Nevertheless, this study provided valuable data on the BioTrust consent process and mothers' decision-making process.

Clinical Implications

Based on findings from this study, 3 recommendations are put forth: (1) education about NBS and rDBS research should begin at prenatal visits, outside of the postpartum environment; (2) information provided to parents about research on rDBS must be accurate, comprehensive, and include ethical implications of biobanking; and (3) consenters should be required to complete training on communication skills, ethical issues involved in rDBS research, and shared decision-making techniques, in addition to formal human subjects' training.[47]

CONCLUSION

This study examined the consent process and decisions of mothers asked to donate their newborn's rDBS for research purposes to the Michigan BioTrust. While most mothers agreed to donate the blood spots, many decisions were based on inadequate knowledge and misunderstandings. Therefore, policy and procedure changes are needed to restructure the consent process to promote informed choices. While individuals' level of

biobanking knowledge may be difficult to improve, the context, content, and delivery of the BioTrust consent process may be more amenable to change.

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