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Thematic Analysis of Cardiac Care Patients' Explanations for Declining Contribution to a Genomic Research-Based Biobank

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Abstract

Background—Health care delivery systems increasingly ask patients to contribute biological samples for future genomic-based health research during critical care admissions, as the result of genome-based research requirements of unprecedented large sample sizes. Few reports describe patients' perceptions and responses to actual biobanking approaches in clinical settings. A qualitative study was conducted to explore 568 cardiac care patients' explanations of why they declined to contribute their samples to a future genomic research biobank.

Objectives—To (1) identify themes emerging from explanations for declining contribution to the research biobanking initiative and (2) determine how the content informs the stewardship conceptual framework that addresses evidence-based clinical ethics practices in genomic and genetic research biobanking.

Methods—This qualitative study used an analytic method that combines inductive and deductive approaches to identify themes in patients' explanations for declining to contribute to a research biobank initiative. The hybrid design has relevance to health services research that seeks to develop taxonomy, themes, and theory.

Results—Inductive approaches showed that themes of intrusion and autonomy dominated explanations. Deductive approaches affirmed previously proposed elements of a stewardship conceptual framework that addresses ethics in biobanking.

Conclusion—Research in understanding patients' perceptions can guide nursing and biobank practices in developing best practices.

Health care delivery systems increasingly ask patients to contribute biological samples for future genomic-based health research during critical care admissions, because of the requirements of genome-based research for unprecedented large sample sizes. In this report, we refer to a clinical system of collecting samples from patients for future unspecified

genomic research as biobanking. Few reports exist to describe patients' perceptions and responses to actual biobanking approaches in the clinical setting. Those studying patients' responses did not engage patients in the clinical setting to understand their real-time perceptions.^{1,2}

Thus, we conducted a qualitative study to explore 568 cardiac care patients' explanations of why they declined to contribute their samples to a future genomic research biobank. Patients provided the explanations during their hospitalization. Research nurses recorded the explanations at the time the patients declined to participate. The aims of this study were to (1) identify themes emerging from explanations for declining contribution to the research bio-banking initiative and (2) determine how the content informs the stewardship conceptual framework that addresses evidence-based clinical ethics practices in genomic and genetic research biobanking.

This study was guided by the stewardship conceptual framework (hereafter "framework"), which addresses ethical and social implications of genomic research biobanking in US clinical care settings.^{3,4} The framework proposes that protecting the sample contributors' interests, maintaining public trust, and respecting human dignity in clinical site's biobanking practices are positive outcomes to value and achieve. Stewardship attributes in biobanking promote positive outcomes and mitigate risks of ethics violations that might arise in biobanking practices. The framework's relevance is implied by the unprecedented expectation of patients' trust in clinical system biobanking approaches.^{5,6}

Many current biobanking approaches do not engage in traditional informed consent processes with potential sample contributors.⁷ Instead, clinical systems often use "opt in" or "opt out" processes to engage and inform patients' participation,⁸ including a form in admissions record-keeping systems that requires a patient to opt out of participating in a biobank to supply future research. Under the opt-out rubric, the hospital system assumes the patient agrees to their medical waste (leftover collected tissue or blood) being automatically deidentified and bio-banked with linkage to the patients' health records, unless they overtly mark on the form that they are opting out.⁹ Opt-in consent, as proposed in this study's protocol, means that biobanking will not occur unless the patient overtly provides written informed consent.

Although efforts are made to align clinical setting biobanking consent and collection processes with the Belmont Report standards of research ethics,⁹ few reports describe tailored procedures for vulnerable patients. Patients with acute symptoms, critical diagnoses, emergency admissions, diminished capacity, and treatment considerations challenge an individual's ability to comprehend standardized opt-in or opt-out biobank consent approaches.⁹⁻¹¹ The standardized approaches' lack of consideration for challenges to patients' comprehension during critical care admissions presents a potential compromise of respect for human vulnerability and dignity. This study aims to understand the perspectives of patients admitted for critical care as they consider an opt-in approach to biobanking sample collection.

Methods

Design

This qualitative study was designed by using an analytic method that combines inductive and deductive approaches to identify the themes of hospitalized patients' reasons for refusing to contribute to and participate in a biobanking initiative. This hybrid design has relevance to health services research that seeks to develop taxonomy, themes, and theory.¹²

Biobank Enrollment Protocol

Trained research nurses approached cardiac critical care patients for their informed consent to participate in a biobank developed to store biological and clinical history data for future genetic research in cardiovascular disease. Patients were approached at various time points during their hospital stay. The research nurses used a standardized script to direct their informed consent process, approached patients at their bedside, within emergency departments, telemetry units, cardiac catheterization departments, coronary intensive care units, and coronary observation units at 2 academic health science hospitals.

The research nurse determined the best time to approach for consent on the basis of the patient's condition and ability to understand and provide informed consent. The nurse asked for patients to consider their willingness to contribute a blood sample, allow ongoing access to their medical records to link to the sample, answer a demographic and health history questionnaire, and complete an annual phone or mail questionnaire follow up. Sample contribution included an additional needle stick for a blood sample unless their hospital orders already included collection of a blood sample.

The study included English- and Spanish-speaking patients hospitalized in 2 large tertiary medical center hospitals in the southwestern United States. The informed consent forms were in English or Spanish and printed at an eighth-grade reading level. Approached patients were in the hospital for critical care related to cardiovascular disease, including acute coronary syndrome, angina, coronary artery bypass surgery, congestive heart failure, coronary valve replacement, or placement of a coronary stent. Nurses approached 4966 patients from January 1, 2006, through October 31, 2010, at their bedside to ask for their biobanking contribution and enrollment. Of those patients, 4397 elected to participate and enroll in the biobank; 569 declined to participate. The content of the 569 explanations of why the patient was not participating in the biobanking is the subject of this study.

After the research nurses asked patients choosing not to participate to explain their reason for declining participation, the nurses recorded the patients' reasons for declining participation by handwritten documentation, also recording the patient's sex, race or ethnicity, and age. The research nurses did not record identifiers for persons declining to participate.

Both hospital review boards and the University of Texas Health Science Center at Houston Committee for the Protection of Human Subjects approved the study. Informed consent was not required of nonparticipants because the data used were anonymous. The institutional

review board at the Medical University of South Carolina approved the secondary analysis study focused on reasons for declining to participate as presented in this report.

Data Analysis Methods

Research personnel transcribed the notes into an Excel spreadsheet and downloaded it into NVIVO 9.0 (QSR International, Pty, Doncaster, Victoria, Australia) software. This software supports qualitative analysis including codebooks, coding nodes/categories, sub-categories, and an audit trail.

Inductive Approach—The research question driving the first aim was, What are the themes in the patients' responses that may explain their reasons for declining participation in these biobank approaches? This question framed an inductive approach to identify themes emerging from the refusal explanations.¹² Each statement was coded initially to categorize the explicit reason for refusal, where readily identifiable. An iterative coding process was used to categorize statements containing no explicit reason for patients to decline as a group of statements that were analyzed for implicit, latent meanings in the statements. These latent meanings were coded into subcategories and grouped for common inferences. For example, within statements explicitly referring to collection of blood as motivating refusal, the subcategory reflected a variety of concerns. Some identified blood loss as a concern, whereas others focused on needle avoidance. Each blood-related issue became a subcategory within the coding scheme. This iterative categorical data-reduction process was used to develop common inferences and meaning and produced the themes reported here.^{13,14}

Deductive Approach—The original stewardship model proposed ethics applications for interaction and relationships between persons with a stake in the biobanking system: research participants, families, communities, and the investigator. After the original model's publication, expansions of biobank practices into clinical settings called for revisions to the model.¹⁵ The model was expanded to include the clinical setting and the biobank itself as parties with a stake in the biobanking system through its 2010 revisions.³ The revisions contrasted conceptualizations of the relationship between the sample's contributors and the biobanking system and proposed that the relationship may take the form of a gift exchange, research relationship or partnership, depending on the intent of the parties with a stake in the system. Updating the model to encompass divergent conceptualizations of the relationship between the parties with a stake was consistent with advances in theoretical discussions suggesting that stakeholder relationships between a biobank and the parties with a stake in the biobank could even be conceptualized as a social contract between the contributor and the scientific community.¹⁶

The revisions to the model also include expansion of the attributes of the stewardship relationship, regardless of whether it is a gift-giving, research, partnership, or social-contract type relationship. The attributes of the stewardship model include using the sample in conformity to the contributor's intent and the ethical principles relevant to the type of relationship, upholding trust, conserving the resource, protecting the contributor against risks, and using the samples to promote benefit and optimal nursing practices and research applications. The outcome anticipated from applying attributes of a stewardship relationship

is the promotion of research ethics, which involves minimizing potential risks and maximizing benefits and protection of the participants.^{3,4}

The research question driving the second aim and its deductive approach was, Do themes emerging from the refusals' content inform the theoretical constructs of the expanded stewardship model? The constructs from the stewardship model that framed the coding categories or "nodes" included expressed perceptions of the approach as a gift, research, or partnership, trust issues, risk issues, and human dignity concerns.

The a priori constructs extracted from the stewardship conceptual framework guided the initial coding matrix for a deductive approach to the statements.^{3,12} Coding the 568 statements involved identifying whether the content was represented within the dimensions of the stewardship conceptual framework as revised and published in 2010.³ After several iterative runs through the statements where content was reviewed against the a priori constructs of the conceptual framework, the matrix was reduced to the present form reported here. An audit trail was maintained and ongoing audit of themes, abstraction, and reduction was maintained among co-investigators.¹³

Results

Contextual Characteristics

Demographic characteristics are reported for patients' age, self-reported ethnicity, and sex. Patients' age ranged from 24 to 95 years. The self-reported ethnicities and respective percentage of the group of refusing patients were as follows: white 60%, black 27%, Hispanic 6%, Asian 3%, Indian 1%; the remaining 3% who represented less than 1% each were of Mediterranean or Italian ethnicity. The group was 39% women and 61% men.

Contextual themes surrounding the critical care setting emerged from the content. Family members were involved in many of the approaches and articulated some of the refusals, as some patients expressed a desire to have a family member consulted. Participation of patient family members as "gatekeepers" for research intrusion is consistent with best ethics practices in recruitment of hospitalized cardiac patients for clinical research.¹⁰ Another contextual theme was that of fatigue with research engagement requests during their hospitalization. The biobanking request that is the subject of this study report was not the first request or only research request during this hospitalization/illness. Patients' comments indicated repeated approaches for research during their hospitalization, which contributed to emergence of the intrusion theme discussed later.

Inductive Analysis Results

Two themes emerged from the content: perceptions of intrusion and autonomy. Each of these themes featured subthemes, and representative examples of them are reflected in Table 1.

Deductive Analysis Results

Table 2 is organized to describe the stewardship framework's a priori constructs and subconstructs found within the content, with representative examples.

Discussion

Perceptions of biobanking in the United States have been gathered with questionnaires, focus groups, and interviews with individuals outside clinical settings,^{6,11,17} but few studies have been done to analyze clinical patients' perceptions during the actual experience of being asked to contribute to a biobank for future genomic research. This report offers findings that address that gap, as we discuss results from thematic analysis of patient statements' content provided during actual biobank contribution requests. In addition, we propose future research directions for the development of biobank practices.

Results from Inductive Approach to Aim 1

A *theme of intrusion* emerged as a common thread. For example, a 49-year-old male patient explained, "That would be a little intrusive right now" in response to the approach. Others did not use the specific word "intrusion" but identified factors within their situational context that reflected that they thought their body, confidentiality, mental or health status would be intruded upon by engaging in the informed consent process.

Physical Intrusion—The frequency that refusal explanations referred to blood-related issues is consistent with other research findings.¹⁸ Table 1 depicts representative statements in this regard. Beyond blood issues, perceptions of physical intrusion also included statements such as, "I'm not feeling well and I haven't had any rest since I've been here" and "My headache is too bad to answer questions."

Confidentiality Intrusions—The concerns for confidentiality of genetic information and medical history are consistent with anticipated public concerns that fueled the Genetic Information Nondiscrimination Act and other state legislative actions.¹⁹ It is unclear whether this legislation will influence willingness to participate in genomic research initiatives, but the content of these refusals documents that the concerns are out there that influence refusals.

Intrusions on Vulnerability/Frailty Because of Illness/Hospitalization—Explanations such as "(I am) just trying to get well now" and "I just feel so dagum' bad right now" are examples in which patients mean that this process is too intrusive, considering their present illness or hospitalization. Many refusal explanations referred to other studies' recruitment approaches during this hospitalization. Statements such as: "I already signed up for a study or something" and "I'm supposed to be in the stem-cell research and I don't think I should do this too" are examples of references that suggest that these patients were approached or already enrolled in more than 1 research project. Referring to their other obligations as research subjects implied that patients felt they were already doing enough, and anything more would be intrusive.

Value Intrusion—Some content revealed that some patients thought the use of their blood intruded on their religious observances, especially those who self-identified as Jehovah's Witnesses. "[The patient is] not comfortable, [the patient] says it's a cultural belief" is an example of other content that was less specific but still clear about the intrusion on values.

A *theme of autonomy* emerged from explanations that reflected that individuals were exerting their entitlement to respect and freedom of choice. These explanations reflected that the patient or family member was comfortable exercising his or her own judgment whether the proposed biobanking was relevant to their own personal needs, wants, or best interests. Representative statements are given in Table 1.

Other explanations that demonstrated autonomy are those in which the patient not only refuses to enroll to contribute a sample, but also declines participation for a specific reason. Representative samples of such comments are depicted in Table 1.

Results from Deductive Approach to Aim 2

The patients' comments reflected divergent characterizations of the process the research nurse was proposing. Some patients' regarded the proposed process as research subject enrollment, whereas others indicated they regarded the proposed process as a gift or donation solicitation. Several statements referred to the approach as a proposal for "giving blood" as if they characterized the approach similarly to a blood drive. Some referred to their expectation that there be reciprocal benefits exchanges, as if the proposed process was a mutual benefit contract.¹⁶

Also, risk outcomes proposed in the stewardship framework's constructs were reflected in statements by patients. The content reflected that refusal content included consideration of 2 risks: the risk of confidentiality invasion and the lack of respect for human dignity, consistent with risks considered by the stewardship framework.

Confidentiality—Patient refusal content indicated concerns for insurance companies' access to and use of research information. Genetic privacy and concerns about how genetic data would influence future public response to genetic research and testing participation yielded the Genetic Information Nondiscrimination Act.¹⁹ The emergence of this concern in the refusals affirms the stewardship framework's proposition that potential threats to privacy influence decisions regarding participation in genetic/genomic research biobanks.

Respect for Human Dignity—References to intrusion, lack of understanding, stress, and insensitive timing emerged from refusal content. Patients explained that their vulnerability and incapacity needs acknowledgment during what they perceive as a "difficult" time. Other statements asserted autonomy in decision making. This content is consistent with descriptions of the dimensions of respect and dignity in health care practices.^{20,21} Respect is a construct that is closely interwoven with human dignity^{22,23} and for purposes of this analysis was considered a verb indicating the acknowledgment of dignity.

Limitations of Study

Because the sample in this study was not assembled by random selection or other design methods to promote the representativeness of critical care patients, the findings are limited to this set of statements from this set of patients and cannot support generalizable conclusions about the perceptions of all patients who decline to engage in genomic research biobank initiatives. However, the results do suggest new areas for further research and

scholarly inquiry into ethics- related phenomena where biobank and nursing practices intersect.

Conclusions

1. Intrusion and autonomy were the 2 primary themes emerging in the content of this set of explanations for refusing to contribute to the biobank and its related study.
2. The divergent characterizations of the proposed biobank contribution affirm the stewardship framework's proposition that patients may perceive biobanking approaches as relationships other than in the research context.
3. The content aligns with and affirms the stewardship framework's proposition that a positive outcome from the patients' perspective is respect for human dignity.²⁴

Implications for Future Biobank Practices and Research in Critical Care Settings — More Research Needed on Diverse Vulnerable Populations' Perceptions About Biobank Contribution Approaches While in Clinical Settings

Further research is needed to learn whether a standardized opt-in or opt-out approach conforms to best ethics in collecting samples from vulnerable patients. The intrusion on vulnerability revealed in the refusals illuminates the need to closely examine biobank opt-in/opt-out consent processes, especially the presumption that 1 process and protocol can fit all the patients in a given clinical system. In future research on new biobank collection processes, patient-oriented outcomes such as patient respect and protection of dignity should be measured. Future research of actual patients who experienced standardized opt-in/opt-out consent policies during critical care could be valuable key informants of whether they regard those processes as respectful of human dignity in the context.^{9,21,24,25}

Limit Needle Sticks

Investigators using biobanking approaches in hospitalized patients who potentially require an additional needle stick or collection of a blood sample should anticipate resistance motivated by concerns for blood loss and needle intolerance. Future development of biobanking best practices should explore how to approach patients to coordinate specimen collection with collection of blood samples for laboratory tests under care orders. Prioritizing this factor in collecting samples respects patients' dignity and integrity, consistent with the stewardship framework's constructs of promoting respect as a best-practice outcome. Clinical research could test opt-in biobank approaches such as the one described in this study and compare refusal rates between a group where an additional stick may be warranted and a group where all collection occurs during therapeutic blood sampling, testing the hypothesis that the group that is assured of no additional blood sticks will have a lower refusal rate.

Diminish Intrusiveness

Patients' perceptions of intrusion go beyond the blood and needle concerns. The intrusiveness theme also emerged from references to the poor timing of the approach, patients' stress, and avoidance of a perceived burden. This theme suggests a need for future

research that explores how biobanking approaches with patients admitted for acute, life-threatening circumstances can be consistent with respect for human dignity and minimize disrespectful intrusions. Screening for or assessing patients' stress, comfort, and preexisting research commitments before biobank research approaches may reduce perceptions of intrusiveness and promote trust of these research practices in clinical settings.

Future researchers could design and test bio-banking practices during discharge briefings, when presumably the patient is more stable. This unexplored time period for biobanking approaches would allow patients to consider their contribution decision while in the comfort of their own home, and consent processes and sample collection could occur during follow-up appointments. This timeline for biobank collection processes could serve as an alternative method to test for better outcomes, especially with patients who are having high indications of vulnerability during critical care hospitalization. Future research questions should address alternatives to biobank approaches, developing practices that are sensitive to fluctuations in decisional burden and capacity of patients during the course of hospitalization for critical care.

Support Patients' Autonomy in Biobanking Decisions

The emergence of the autonomy theme in the content suggests that patients expected to have the freedom to decide for themselves (or to delegate this decision to family members) whether to participate in biobanking initiatives. Future biobanking practices that promote informed choices and autonomy are consistent with maintaining public trust in bio banking practices. The autonomy reflected in the refusals' content suggests that patients want freedom to choose, even under stressful conditions. Future research can explore promoting autonomy by promoting decisional support before hospitalization or clinical care, when intrusion is minimal. Media campaigns²⁶ and online decisional support initiatives delivered outside clinical settings could promote public understanding and decisions to contribute to research biobanks.²⁷ Such interventions would address respect for the freedom to decide, the need for informed choices, and they would ultimately better prepare patients for biobanking decisions when exposed to them in clinical settings, when they are likely to be burdened with additional health challenges. Public health educational campaigns supporting informed biobank contribution decisions are areas to explore for support interventions before the decision.

Future consideration of these implications in biobank sample contribution will inform future policy and practice developments to maintain trust. Current biobank practices do not meet all the desires and expectations of patients and the public, as demonstrated by the refusals described here. Further investigation of our most vulnerable patients' expectations and priorities in biobank collection processes represents a new area to explore the research, gift, and social partnership ethics needed to guide best practices.

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Health care systems increasingly ask patients to contribute samples for future genomic-based health research.

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The content of explanations for not participating in the biobanking study was explored.

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A theme of fatigue with research engagement requests was identified.

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For this analysis the term *respect* was considered a verb indicating the acknowledgment of dignity.

Table 1

Results of inductive analysis

Subtheme by domain	Meaning abstraction	Demonstrative quotes
Perceptions of intrusion		
Physical intrusion (asking for blood)	Concern about blood loss/being stuck with needle as an unacceptable term of proposal	<p>“Too much blood has been drawn already.”</p> <p>“That’s too much blood.”</p> <p>“I don’t want to get stuck again for the blood.”</p> <p>“I hate needles. I don’t want any extra sticks.”</p>
Confidentiality intrusion	Explicit concern about health insurance and privacy	<p>“I’m one of those privacy buffs. I don’t like sharing information.”</p>
Intrusions on vulnerability/frailty in the context of being ill/hospitalized	Concerned that anticipated amount of effort in making consent decision or actual participation is unacceptable intrusion on their situation	<p>“I am overwhelmed by all that is happening to me”</p> <p>“I’ve got too many things on my mind right now.”</p> <p>“This is a bad time.”</p> <p>“I’m too sick. There’s too much going on.”</p>
Value intrusion	Proposal intrudes on my cultural and religious beliefs	<p>“I do not want to be in any DNA study.”</p> <p>“I am not comfortable.”</p> <p>“I’m a Jehovah’s Witness, and I don’t donate blood for anything.”</p>
Perceptions of autonomy		
I am free to decide the relevance of your request to my wants	Participation conditions did not fit what I want	<p>“I don’t want to sign anything.”</p> <p>“I’m just not interested in research”</p> <p>“I just don’t want to participate.”</p>
I am free to decide the relevance of your request to my situation	Research purpose is not relevant to my situation	<p>“My heart problem is because I had rheumatic fever as a child, so you don’t need my DNA.”</p> <p>“I’m adopted.”</p>

Table 2

Results of deductive analysis

Framework: a priori constructs	Subconstructs	Meaning	Demonstrative quotes
Patient's perception(s) of approach purpose	Research perception	Word choice—"study," "research," "subject" reflects perception that approach is related to research relationship	"I don't want to do any research." "We're just not interested in any study."
	Gift perception	Word choice—"gift," "donate," "giving" reflects perception that approach is related to gift process	"I'm not going to give my blood."
	Mutual benefit expectation	Indications that lack of reciprocal benefits is basis of decision	"If there are no benefits or results for me, I am too tired to answer questions." "I don't want to participate, since I can't benefit from it."
Risk outcomes in stewardship relationships	Confidentiality risks	Concern about confidentiality to protect against unjust economic, employment, insurance outcomes	"I am too concerned and worried about confidentiality and my insurance company." "I'm afraid of Medicare finding out."
		Generalized privacy concerns	"I don't like that information about me out and about."
Beneficial outcomes in stewardship relationship	Maintain human respect	Nurse respected patient's need for human respect in context of patient's capacity to assume a decisional burden during acute care expressed by patient	"I am just too stressed." "I'm just too worn out now." "I don't understand why I should do it. I'm not even understanding what the doctor is doing."
	Maintain respect for values, traditions, culture, integrity	Nurse respected patient's need for respect for values, traditions, culture and integrity expressed by patient	"I do not want to be in any DNA study." "I am not comfortable." "I'm a Jehovah's Witness and I don't donate blood for anything."