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Considerations in the Construction of an Instrument to Assess Attitudes Regarding Critical Illness Gene Variation Research

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Abstract

Clinical studies conducted in intensive care units are associated with logistical and ethical challenges. Diseases investigated are precipitous and life-threatening, care is highly technological, and patients are often incapacitated and decision-making is provided by surrogates. These investigations increasingly involve collection of genetic data. The manner in which the exigencies of critical illness impact attitudes regarding genetic data collection is unstudied. Given interest in understanding stakeholder preferences as a foundation for the ethical conduct of research, filling this knowledge gap is timely. The conduct of opinion research in the critical care arena is novel.

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²In Figure 2a, our overarching goal is to gain insight into concerns regarding GVR conducted in the setting of critical illness. Our primary framework is to understand how concerns regarding GVR might differ from concerns regarding clinical research conducted in this context. We have represented this framework as two intersecting Venn diagrams. To the extent that genetic data are viewed as “exceptional” or distinct from nongenetic data, the area of intersection between clinical research and gene variation research would be expected to be small. In contrast, to the extent that genetic data are viewed as indistinct from nongenetic data, these two areas would be expected to overlap substantially. We postulate that two factors potentially influence these perceptions. Unique to our instrument is the role of the critical care experience in modulating these perceptions (indicated in Figure 2c and including such factors as severity of patient illness, comfort of respondent in SDM role, relationship between SDM and patient, etc.). In addition, and common to most studies quantifying perceptions of genetic data (presented in Table 1), are demographic variables (indicated in Figure 2b and including such factors as age, gender, ethnicity, religiosity, level of education, socioeconomic status, etc.). The construction of our instrument (summarized in Table 2) parallels this diagram.

This brief report describes the development of parallel patient/surrogate decision-maker quantitative survey instruments for use in this environment. Future research employing this instrument or a variant of it with diverse populations promises to inform research practices in critical illness gene variation research.

Keywords

genetic research; critical illness; intensive care unit; surveys; systematic review

Genomic technology is evolving quickly, transforming understanding of how genetic variation influences disease (Collins, 1999; Bell, 1998; Evans & Relling, 1999; Evans & McLeod, 2003). Use of genetic data to aid diagnosis, stratify risk, identify novel therapeutic targets, and guide treatment has potential to impact most facets of medicine (Collins, 1999; Bell, 1998; Freeman & McLeod, 2004; Freeman et al., 2001). Significant investment has produced both a more complete understanding of genomic structure and a refinement in techniques to facilitate acquisition, storage, and analysis of genetic data (Wadman, 2008). To enable translation of genetic technology “from bench to bedside,” genetic data are increasingly collected as part of both epidemiological studies and therapeutic trials (Espeland et al., 2006). As in other sectors, there is substantial interest in applying genomic techniques to the study of critically ill patients (Freeman & McLeod, 2004; Freeman et al., 2010). To date, numerous clinical studies involving collection of genetic data and enrolling (in aggregate) thousands of patients have been conducted in the field of sepsis alone (Freeman et al., 2010).

Clinical studies conducted in the setting of critical illness are associated with logistical and ethical challenges not encountered in less urgent environments (such as cancer or cardiovascular disease trials) (Ad Hoc Statement Committee of the American Thoracic Society, 2004; Freeman et al., 2001). Conditions prompting intensive care unit (ICU) admission are often precipitous and life-threatening and the care provided highly technological. Neither patients nor family members have typically had the opportunity for education regarding the nature of the disease process, expected outcome, treatment alternatives, or research opportunities. Further, patients in ICUs are frequently incapacitated and unable to provide informed consent permitting medical intervention or research participation (Davis et al., 2003; Luce, 2003b; Ad Hoc Statement Committee of the American Thoracic Society, 2004; Luce, 2003a; Silverman et al., 2005). Finally, many therapies (such as for sepsis, myocardial infarction, or stroke) must be administered quickly (within minutes to hours) following diagnosis. In order to enroll critically ill patients in clinical studies, permission must be obtained expediently from surrogate decision-makers (SDMs) (e.g., family members, guardians, or domestic partners), many of whom are being confronted with complex and serious medical issues for the first time (Ad Hoc Statement Committee of the American Thoracic Society, 2004). To the extent that genetic data entail risks and require protections beyond those associated with nongenomic research, ICU studies that include genetic data collection may prove particularly problematic.

A large number of studies have examined attitudes and perceptions related to gene variation research (GVR) (see Table 1 and Figure 1). These studies have employed a variety of techniques (structured surveys, individual interviews, and focus groups) in a diversity of settings (general population, patients with specific diseases or recruited from outpatient clinics, epidemiological study participants, researchers, and patients of family members). To date, no study has been designed to explore preferences of stakeholders in the critical care environment regarding GVR. Thus, in contrast to the nonacute or chronic illness setting, the manner in which the exigencies of acute illness impact perceptions of genetic data collection

is largely unknown (Lavery & Slutsky, 2006; Shelton et al., 2009). Conceivably, SDMs do not possess sufficient insight as to the nature of genetic data to permit informed decision-making. Alternatively, the emotional distress SDMs experience may overwhelm concerns that genetic data are exceptional or distinct from other types of commonly collected information. Finally, the views of patients and their surrogates pertaining to data collection may not be well-aligned, as has been reported from a variety of settings (Hare, Pratt, & Nelson, 1992; Coppolino & Ackerson, 2001). Given renewed interest in understanding stakeholder preferences as a foundation for the ethical conduct of genetic research, filling this knowledge gap is important to providing guidance to the investigative community and oversight bodies (Trinidad et al., 2011).

We have formed a research collaborative focused on investigating ethical issues related to critical care genetics. One facet of this study centers on efforts to assess attitudes held by SDMs and patients (following recovery from acute illness) related to collection of genetic data in the ICU context. Conducting opinion research in the critical care environment is relatively novel. Adapting survey instruments for use in this context requires consideration of factors uncommon to public opinion research conducted in the nonacute setting. This brief report describes the development of parallel patient/surrogate decision-maker survey instruments for use in this environment. It is our hope that this instrument, or variations of it based on our conceptual model, will prove useful in elucidating the range of concerns and attitudes that patients and surrogate decision-makers bring to genetic variant research conducted in the context of critical illness.

Methods

Conceptual Model

Our overarching goal is to gain greater insight into concerns regarding GVR conducted in the setting of critical illness. We have conceptualized this process by first considering the relationship between GVR and clinical (i.e., nongenetic) research (see Figure 2). Graphically, we have represented this relationship as intersecting Venn diagrams. To the extent that genetic data are viewed as “exceptional” or distinct from nongenetic data, the area of intersection between clinical research and GVR might be expected to be small. In contrast, to the extent that genetic data are viewed as similar to nongenetic data, the areas represented by the Venn diagram might be expected to substantially overlap. We postulate that two domains potentially influence research perceptions in the ICU setting. The first is the ICU experience (i.e., an individual’s level of comfort in the SDM role, emotional stress of dealing with a loved during critical illness, etc.). In addition, and analogous to studies conducted in the nonacute setting, is the influence of demographic variables on these perceptions.

Instrument Construction

Our conceptual model served as a guide for construction of our survey instruments. Two of the authors (DBJ, BC) were members of an investigative team that examined attitudes regarding use of discarded clinical specimens for GVR in an outpatient setting (Hull et al., 2008). Many of the themes explored in this prior study were pertinent to the proposed critical illness study. Further, because key elements of this survey had been validated in a large sample of respondents, and were representative of the content included in survey instruments in other settings (summarized in Table 1 and Figure 1), they were adapted for use and served as the foundation for our instrument. The rationale for use of the remaining items is described below (and is related to the conceptual model presented in Figure 2). The final SDM and patient survey instruments are summarized in Table 2 and may be found in a supplementary online document at dx.doi.org/10.1525/jer.2012.7.1.58.

RELATIONSHIP BETWEEN CLINICAL AND GENE VARIATION RESEARCH—

We determine SDMs' general views towards medical (specifically nongenetic) research. Similarly, we examine the receptivity of SDMs to personally participate in a clinical study. In parallel, we probe the receptivity of the SDM to permit patient participation and explore factors (purpose of the study, lack of direct personal benefit, funding source) which might influence receptivity (Godard, Marshall, & Laberge, 2006; Hallowell et al., 2009; Kaphingst et al., 2006; Nilstuln & Hermeren, 2006). We developed a similar set of items probing attitudes regarding GVR, and explore factors reflecting concerns regarding genetic specimen collection reported by others that might influence participation in the ICU setting (e.g., lack of confidentiality, potential for insurance and racial discrimination) (Bates et al., 2005; Godard et al., 2006; Hull et al., 2008; Kaphingst et al., 2006; Kaufman et al., 2009; McGuire et al., 2008; Murphy & Thompson, 2011; Schulz, Caldwell, & Foster, 2003)

CHALLENGES AND PERCEPTIONS OF THE SDM ROLE—We assess several factors potentially underlying SDM perceptions and challenges. We determine whether the decision-making process is perceived as an individual responsibility or one which is shared among the family or other tightly knit social group, as well as the overall complexity of this task. We characterize decision-making that the SDM has engaged in during the current episode of illness (such as permitting surgical intervention or other procedures). Comfort and perception of the decision-making role may be influenced by prior experience in this capacity, as well as whether discussion between the decision-maker and patient has previously occurred regarding healthcare preferences in the event that the patient is incapacitated (Hare et al., 1992; Coppolino & Ackerson, 2001). Similarly, the health status of the patient immediately preceding the current episode of illness may impact SDM opinions. For example, attitudes held by an SDM for a patient who is chronically ill might differ from those of an SDM for a patient who was previously healthy (such as those sustaining major trauma). We probe these areas as well as determine the degree of confidence with which the respondent feels they represent the patient's views.

CONFIDENCE IN THE INTEGRITY OF THE HEALTHCARE PROVIDERS AND THE HEALTHCARE SYSTEM—A basic impediment to research participation may be lack of trust or confidence in the integrity of the research enterprise (Achter, Parrott, & Silk, 2005; Dixon-Woods et al., 2007). This may be a particular issue in an ICU study given that events may have transpired compromising trust (poor communication, development of a complication of disease or therapy, unanticipated adverse event, etc.). We determine the degree of trust placed in the healthcare providers, as well the confidence SDMs have that they are receiving all necessary information so as to enable decision-making.

INFORMATION SOURCE—We determine the SDMs' primary source of patient information. In contrast to ambulatory practices and (non-ICU) hospital wards, there is substantial personnel turnover in an ICU due to duty shifts; further, care is provided by teams (physicians, nurses, respiratory therapists, etc). In the university setting where this instrument will be employed, the personnel pool is further expanded by the presence of trainees. As a consequence, communication between healthcare providers and family members may be fragmented. We postulate that understanding the primary information source will be important to the interpretation of results as well as to developing potential points of intervention for purposes of education and information dissemination.

DEMOGRAPHIC VARIABLES—We capture a number of demographic variables that potentially influence SDM outlook (age, gender, ethnicity, religiosity, health status, etc.) (Egalite, Ozdemir, & Godard, 2007; Halbert et al., 2006; McQuillan, Pan, & Porter, 2006). In addition, patient clinical and demographic variables that likewise may influence SDM

perspective are recorded (ICU length of stay, severity of illness as reflected in standard risk stratification scores, mortality or recovery, length of time in ICU at time of interview, etc.).

Results

Prior to fielding the final survey instruments, cognitive interviews were performed with six individuals recruited from the study sites in an effort to assess readability and clarity of the questions, uniformity in comprehension, and respondent comfort with the content. All respondents were female, mean ($\pm$ SD) age 41 ($\pm$ 20) years, three reported high school as the highest level of education completed, three reported completing some college. Four described their ethnicity as Caucasian, one described ethnicity as African American, and one described ethnicity as Native American. All reported Protestant religious affiliations. In spite of the seriousness of the situations confronting them, respondents were willing and able to participate in the interviews. As a result of the cognitive interviews, minor changes were made in several survey items so as to enhance clarity. The small number of individuals sampled for the cognitive interviews precludes a more detailed analysis of the findings.

Discussion

We designed instruments to capture attitudes of SDMs and patients regarding critical illness GVR. There are challenges to constructing an instrument for use in the critical care environment which would not be considerations for an instrument used to study chronic diseases and which would be administered in nonurgent settings. We are sensitive to the emotional stress that SDMs experience as a consequence of their ICU exposure. Similarly, we anticipate that patients recently recovered from critical illness may fatigue easily and have limited ability to concentrate for prolonged periods. These considerations impacted both the length and content of our instrument. Further, because perceptions and attitudes regarding genomics might be strongly influenced by the broader ICU experience, it was necessary for our instrument to explore both genomic and critical care domains. We intended our final product to be a concise, focused instrument designed to minimally tax participants, while at the same time producing meaningful and interpretable findings.

The foregoing considerations required trade-offs and compromises in construction and content. One such trade-off concerns future sample use. Studies conducted in the critical care environment that do not involve genetic specimen collection generally lack implication for a participant once the study is completed. For example, the mode of mechanical ventilation employed as part of a respiratory failure investigation in which the patient participated would be irrelevant once the patient had recovered. In contrast, critical illness studies that entail collection of genetic data do have implications for the patient extending beyond their ICU episode of care. Specifically, samples archived for future analysis prompt consideration of such issues as mechanisms of consent (i.e., need for recontact for consent, one-time blanket consent, tiered-consent, opt-out provisions, etc.) and communication of unanticipated findings. Such issues have been extensively researched and discussed for studies of chronic diseases (Basson, Futter, & Greenberg, 2007; Godard et al., 2006; Hoeyer et al., 2004; Hoop, Roberts, & Hammond, 2009; Kaphingst et al., 2006; Kaufman et al., 2009; McGuire et al., 2008; Moutel et al., 2005; Murphy et al., 2008; Nilstuln & Hermeren, 2006; Ormondroyd et al., 2007; Richards et al., 2003; Ruiz-Canela, Valle-Mansilla, & Sulmasy, 2009; Schwartz et al., 2001; Stegmayr & Aplund, 2002; Vermeulen et al., 2009). We do not specifically address respondent attitudes and preferences regarding future use or return of results. We felt that many of the concepts related to future use would be abstract to individuals grappling with the realities of acute, serious illness. Further, it is unlikely that studies on archived specimens which relate genotype to critical illness phenotype would have significant implications in terms of personal results. This would contrast with the

situation in an ambulatory setting where genotype might have implications for future health (such as disease predisposition or medication response). In addition, we examine issues related to the storage and future use of biospecimens (e.g., confidentiality, commercialization) in an indirect fashion.

An additional trade-off concerns the phrasing of the questions themselves. This survey was designed for use in urban, tertiary care medical centers. Many patients and SDMs in this setting possess low levels of formal education. Accordingly, we created questions that were as clear and unambiguous as possible. This level of clarity may come at the expense of lack of context for some of the areas we probe. For example, willingness to permit collection of a genetic specimen may depend on whether information is de-identified—a concept we don't specifically explore. However, we will examine the relationship between receptivity to participation in GVR and confidentiality concerns so as to understand the relationship between these domains and compensate for ambiguities in the questions we pose.

The practice of surrogates providing substituted judgment for critically ill patients is commonplace (e.g., invasive procedures, study enrollment, end of life goals, etc.). Nonetheless, the extent to which patient and SDM attitudes converge in this setting is poorly characterized (Coppolino & Ackerson, 2001). One goal of the current study is to examine patient-SDM concordance. One might question the relevance of concordance to critical illness genetic research. A more ethically rigorous approach might be to require a patient to recover before providing consent for study participation, bypassing the SDM's role. Such an approach would be difficult to operationalize and pose a significant burden to clinical research for several reasons: ICU phenotypes (such as for sepsis or respiratory failure) are complex and resource-intensive to generate; robust data sets require prospective, high-density information collection. In comparison, retrospective studies are lacking in detail, of poorer quality, and less informative. If regulatory bodies required patient (not surrogate) consent for study participation, data from patients who expire (a potentially informative subpopulation) would be lost. Similarly, data from patients who declined participation would be destroyed (after much effort and expense expended for collection).

Best Practices

The conduct of opinion research in the critical care environment is novel and poses unique challenges. Insights derived from such investigations are invaluable in guiding clinical investigation recruitment strategies, enhancing the transparency of the consent process, and ensuring that this research is conducted in a manner consistent with the wishes and preferences of those directly involved. Soliciting and acting on input of potential study participants is important to building and sustaining trust between the investigative enterprise and the public at large (Trinidad et al., 2011).

Research Agenda

The advancement of genomic research requires the involvement of participants who are willing to provide biologic samples linked to detailed medical profiles with the understanding that resulting studies may produce information pertaining to the risk for a potentially unlimited range of disorders (Green & Guyer, 2011). Further, these data will in many cases be broadly shared and continue to be used for many years in the future (Green & Guyer, 2011). The focus of this investigation is to further understanding of the manner in which the exigencies of acute illness impact the perceptions of risks and benefits of participating in such studies. The use of the instrument or concepts described herein with a variety of acute illnesses and with individuals from various demographic segments of the population will contribute much to our understanding of best practices for recruitment and consent.

Educational Implications

The approaches outlined have potential not only to characterize obstacles to informed participation in critical illness genomics investigation, but to provide insight as to how these obstacles might most effectively be surmounted (e.g., employment of alternative forms of consent or use of novel educational interventions).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Biographies

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*The bar for each setting represents the proportion of studies examining a given domain.

FIG. 1.
Overview of studies examining perceptions and attitudes pertaining to gene variation research (GVR)²

FIG. 2.
Conceptual model guiding the development of survey instrument.³

TABLE 1
Studies Examining Attitudes and Perceptions Regarding Gene Variation Research.

Author (Year)	Population/Setting	Study Design	Age ¹	Size	Synopsis of Content
Achter et al. (2005)	General population (Caucasian, African American)	Structured surveys	18 to 73	912	Perception of GVR, willingness to participate, trust in research enterprise
Basson et al. (2007)	Subset of patients participating in genetic association study of degenerative retinal disorder	Individual interviews	42 to 77	4	Motivation for participation, attitudes toward return of results
Bates et al. (2005)	General population	Focus groups, structured surveys	18 to 64	91	Concerns about GVR (racial and economic discrimination, privacy concerns, commercialization, scientific misuse)
Buchwald et al. (2006)	Patients, staff from Native American healthcare facility	Structured surveys	patient=39; staff=43 ²	420	Receptivity to genetic vs. nongenetic research (behavioral, pharmaceutical applications)
Diaz et al. (2008)	African American college students	Structured surveys	18 to ≥24	200	Willingness to participate in GVR vs. other types of clinical research
Dixon-Woods et al. (2007)	Participants recruited from GRAPHICS (a genetic epidemiology study examining candidate hypertension genes in healthy volunteers)	Individual interviews	23 to 61	29	Perception of research, motivation for participation, trust in research enterprise, perception of risk
Egalitie et al. (2007)	Genetics researchers representing a diversity of ethnic categories	Individual interviews	NA	13	Interest in studying ethnic differences, enthusiasm for the benefits, concerns for potential harms, awareness of the implications of research involving race, need for ethical oversight
Goddard et al. (2006)	Population-based study	Focus groups, structured surveys	NA	See table footnote 3	Confidentiality, return of results, data ownership
Haas et al. (2008)	Female outpatients attending gynecology clinic	Structured surveys	29.3 (±11.5) ⁴	279	Willingness to donate genetic sample, method (needle stick, saliva), use of discarded specimens, future use
Halbert et al. (2006)	African American smokers drawn from the general population	Structured surveys	44.8 (±10) ⁴	128	Examination of respondent-specific factors associated with likelihood of participation in genetic studies of tobacco-related illnesses
Henderson et al. (2008)	Prior participants of a colon cancer risk factor genetic epidemiology study	Structured surveys with qualitative analysis of subsample	64.3 (±9.9) ⁴	801	Overall perception of genetic research (i.e., positive or negative), willingness to participate in future studies
Hoeyer et al. (2004)	General population	Structured surveys	18 to 85	589	Attitudes regarding biobanked specimens, need for recontact, return of results
Hull et al. (2008)	Outpatients attending academic medical centers	Structured surveys	18 to ≥65	1,193	Relationship between anonymity and need for consent for discarded clinical specimens
Ishiyama et al. (2008)	General population	Structured surveys	20 to 69	4,000	General attitudes regarding genetic studies and the relationship of these attitudes to genetic literacy
Kaphingst et al. (2006)	Female breast cancer patients who had donated blood, tissue	Individual interviews	<40 to 50	26	Perceived benefits, general concerns, future use/need for consent, privacy, return of results

Author (Year)	Population/Setting	Study Design	Age ^J	Size	Synopsis of Content
Kaufman et al. (2008)	General population	Focus groups	NA	141	Concerns regarding the inclusion of children in longitudinal genetic epidemiology study (consent, risks vs. benefits, return of results)
MacQuillan et al. (2006)	Participants in National Health and Nutrition Examination Survey (NHANES)	Structured surveys	20 to >60	15,332	Receptivity to providing genetic sample in large epidemiology study
Marshall et al. (2006)	Native Nigerians, African Americans (US) enrolled in hypertension genetic epidemiology study	Structured surveys	NA	655	Voluntariness of consent, study comprehension
McGuire et al. (2008)	Patients who had participated in epilepsy re-sequencing study	Focus groups	18 to 75	15	Attitudes about data sharing ("broadcast of genetic data") and mechanisms of consent (blanket, opt-out, tiered, etc.)
Moutel et al. (2005)	Researchers, participants of pharmacogenetics study targeting HIV	Individual interviews (researchers), structured surveys (patients)	NA	125	Return of results
Murphy et al. (2008)	General population	Focus groups	NA	141	Return of results
Nilstun et al. (2006)	General population	Structured surveys	NA	926	Willingness to donate samples, need for informed consent, attitudes about future use and commercialization
Ormondroyd et al. (2007)	Family members of deceased prostate cancer patients who were found to be BRCA2 carriers	Individual interviews	NA	13	Return of results to a patient's family
Richards et al. (2003)	Breast cancer genetic epidemiology study participants	Individual interviews	NA	21	General perceptions of study participation, return of results
Roberts et al. (2005)	General population	Structured surveys, individual interviews	NA	63	General attitudes regarding genetic research, potential risks
Schulz et al. (2003)	General population (Latinos/AA)	Focus groups	20 to >61	52	General perceptions and attitudes concerning the Human Genome Project
Schwartz et al. (2001)	General population (Jewish)	Structured surveys	18 to 90	273	Attitudes regarding research on stored samples, future use, need for consent, etc.
Sheldon et al. (2007)	African Americans drawn from the general population	Individual interviews	NA	40	Perceptions of racial differences as they pertain to genetic science
Stegmayr et al. (2002)	Participants of longitudinal study, genetic epidemiology cardiovascular disease study	Structured surveys	25 to 64	1,342	Attitudes about future use, need for re-consent
Voracek et al. (2007)	Psychology, medical students (Australia, Malaysia, Romania, UK)	Structured surveys	18 to 56	556	Perceptions of genetic determinism, receptivity to psychiatric GVR
Vornet et al. (2008)	Alzheimer's disease genetic researchers, clinicians, patient representatives, ethicists	Focus groups	NA	12	Conduct of genetic Alzheimer's disease research (informed consent, social consequences)
Wang et al. (2001)	Participants of American Health Styles Survey	Structured surveys	NA	2,621	General attitudes regarding GVR
Williams et al. (2005)	Cardiology outpatients (Melbourne, Australia)	Structured surveys	NA	385	General attitudes regarding GVR (privacy concerns, potential for discrimination)

^J Age is presented as range, except as noted.

² Mean age (years).

³ Note: 23 focus groups, each consisting of 7 to 8 participants, 1,800 participants in quantitative survey. See text note [1].

⁴ Mean ($\pm$ SD) (years).

TABLE 2

Organization and Content of Surrogate Decision Maker (SDM) and Patient Survey Instruments.¹

Domain	Synopsis of Survey text
A. Relationship between clinical and gene variation research (GVR)	<p><i>Views and concerns regarding clinical research</i></p> <ul style="list-style-type: none"> • General familiarity with medical research • Utility of medical research • Willingness to participate in medical research • Willingness to allow patient to participate in medical research • Impact on purpose of research on willingness to participate • Impact of lack of direct benefit on willingness to participate • Impact of funding source on willingness to participate <p><i>Views and concerns regarding GVR</i></p> <ul style="list-style-type: none"> • General familiarity with genetic research • General perception of genetic research • Willingness to participate in genetic research • Willingness to allow patient to participate in genetic research • Confidentiality concerns • Potential for insurance discrimination • Potential for racial discrimination • Other concerns
B. ICU experience	<p><i>Challenges and perceptions of SDM role</i></p> <ul style="list-style-type: none"> • Respondent is functioning as SDM for patient • Others helping make decisions for patient • Number of others assisting respondent in decision making • Perceived difficulty of making decisions • Proportion of decision-making responsibility residing with SDM • Patient's health status preceding ICU admission • Has SDM made treatment decisions for patient? • Nature of treatment decisions SDM has made • Previous experience making medical decisions • Had discussion about making decisions • How confident decision making consistent with patient wishes <p><i>Confidence in integrity of healthcare providers</i></p> <ul style="list-style-type: none"> • Trust in doctors and nurses • Specific concerns regarding lack of trust • Confidence respondent is receiving all necessary information <p><i>Information source</i></p> <ul style="list-style-type: none"> • Source of information about patient's medical status
C. Demographic variables	Age, gender, ethnicity, religiosity, health status, etc.

¹ SDM, patient instruments are available as a supplementary online document at dx.doi.org/10.1525/jer.2012.7.1.58.