Ethical Challenges to Informed Consent for Genetic Research during Critical Illness

Prepared For:

Ellen Iverson, MPH
Aaron Celious, Ph.D.
Erica Shehane, MSW, MPH
Community Health Outcomes & Intervention Research
Children's Hospital Los Angeles

Bradley Freeman, MD
Carie Kennedy, RN
Department of Surgery
Washington University
School of Medicine, St. Louis, MO

Alexander Eastman, MD, MPH
Victoria Warren, RN
Department of Surgery
University of Texas
Southwestern Medical Center, Dallas, TX

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Presenter Disclosures

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NO RELATIONSHIPS TO DISCLOSE

Background

- Clinical research routinely collecting and storing patient genetic data; many obtaining consent to collect patient genetic material for future investigation or bio-banking.
- Growing evidence that lay genetic literacy is limited, far behind fast-moving pace of genetics and genomic science
- NHGRI/ELSI concerned that efforts to address ethical and social issues related to collection of genetic data keep pace with expanding application of genetics in clinical and research settings
- IRB's challenged to ensure that patients or those making decisions on their behalf are able to make fully informed decisions to participate in genetic research.

Genetic Research in Critical Care

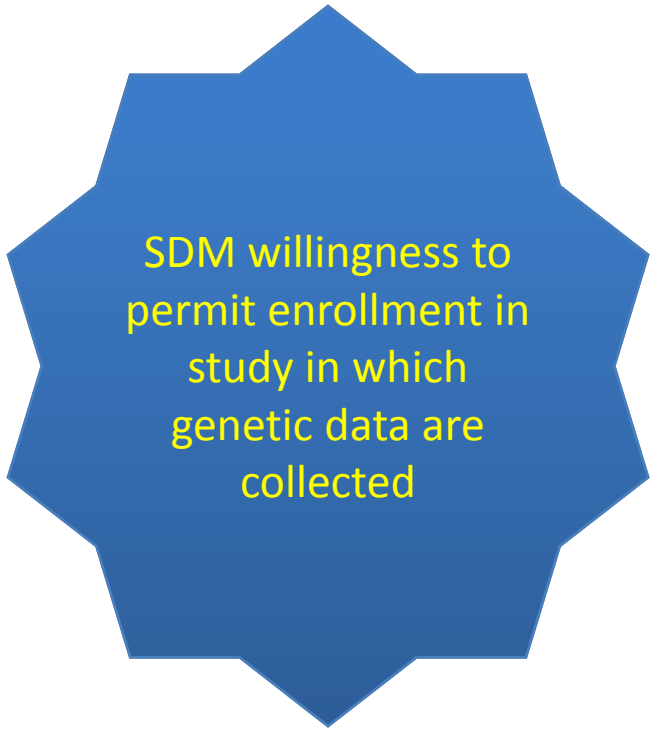
- Genetic research in critical care has potential to enhance understanding of predisposition and course of critical illness and guide treatment tailored to patients' genetic profile.
- Unique tension related to conducting genetic research in critical care[1]
  - Patient condition is often precarious, treatment is complex and decisions made quickly
  - Decision making about treatment or research participation often falls to surrogate decision makers (SDMs)
  - High levels of anxiety and limited time to make decisions
- No research has examined factors influencing SDMs decisions related to enrolling critically ill patients into clinical studies.

[1] Freeman, B. et al. (2009) Ethical considerations in the collection of genetic data from critically ill patients: What do published studies reveal about potential directions for empirical ethics research? *Pharmacogenomics J*;10:77-85;2010

Establishing the Ethical Framework for Critical Care Genetics

Phase 1 of NIH-funded multicenter study to characterize personal, social, cultural and psychological dimensions influencing SDMs attitudes pertaining to collection of genetic data for research in critical care

- SDM knowledge and perceptions of genetics & genetic research
- SDM understanding and interpretation of consent processes and language
- Information and communication necessary to ensure that SDMs understand genetic research participation



Methodology

Setting: Two urban, tertiary care hospitals Barnes-Jewish Hospital, St. Louis MO; Parkland Hospital, Dallas, TX

Design: Phase 1: Qualitative research with SDMs; 23 focus groups (69 participants) and 35 in-depth interviews

Sample: African-American, Caucasian and Hispanic SDMs for adult critical care patients

Themes: ***Part 1*** Knowledge of genetics; perceived benefits and concerns; ***Part 2*** Perceptions and understanding of medical and genetic research; receptivity to own and patient's research participation. Provided hypothetical scenarios and language abstracted from sample informed consent

Analysis: Atlas.ti software was used to conduct iterative, thematic content analysis.

Eligibility Criteria

- Self-Identify as an SDM for patient
- Patient mechanically ventilated or otherwise rendered incapable of making health care decision for themselves for at least 48 hours
- Patient $\geq$ 18 years old
- Caucasian, African American, Latino (Spanish and English-speaking)

Focus Group Participant Characteristics

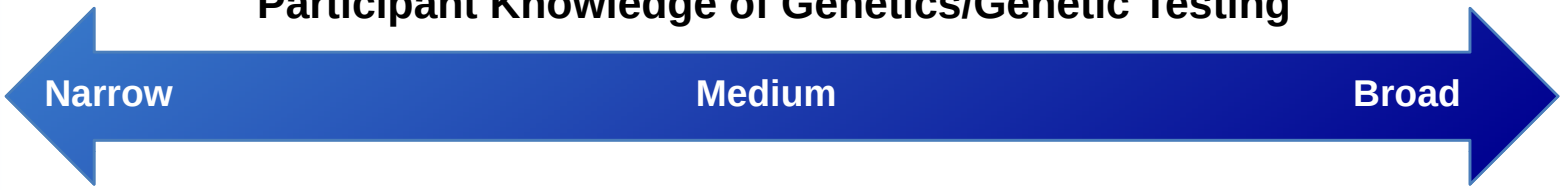
	Demographics	St. Louis	Dallas	Total
Age	Age (mean, +/- SD)*	51 (+/-) 13	44 (+/-) 16	48 (+/-) 15
Sex	Female	75%	69%	73%
Ethnicity	white	55%	24%	42%
	black	41%	24%	34%
	Latino	0%	52%	21%
	Other	4%	0%	3%
	Years of Education (mean, +/- SD) **	**14 (+/-) 2.5**	**11 (+/-) 4.5**	13 (+/-) 4
	Medical Research Experience	16%	12%	15%
	Experience with Genetics	32%	17%	27%

* p =.05
** p < .001

Knowledge about Genetics & Genetic Research

Participant knowledge of genetics was limited and based primarily on media exposure or personal experience. Even if participants appeared to have high levels of understanding, they still did not have a clear understanding of what genetic information could tell about future illness, how it could be used multiple times for a variety of studies.

Participant Knowledge of Genetics/Genetic Testing



Narrow

- No knowledge
- Links to crime, paternity, transplants
- Cloning
- Blood cells/blood type
- Identify allergies
- Insight into mind/thoughts
- Matched DNA can help cure
- Identify strength of your genes
- God's way of connecting people

Medium

- Family history/Ancestry
- Inherited diseases, conditions
- Inherited physical traits
- Newborn/prenatal screening
- Is a fast advancing field
- Diagnose health problems
- Genetic tests can make cures for diseases

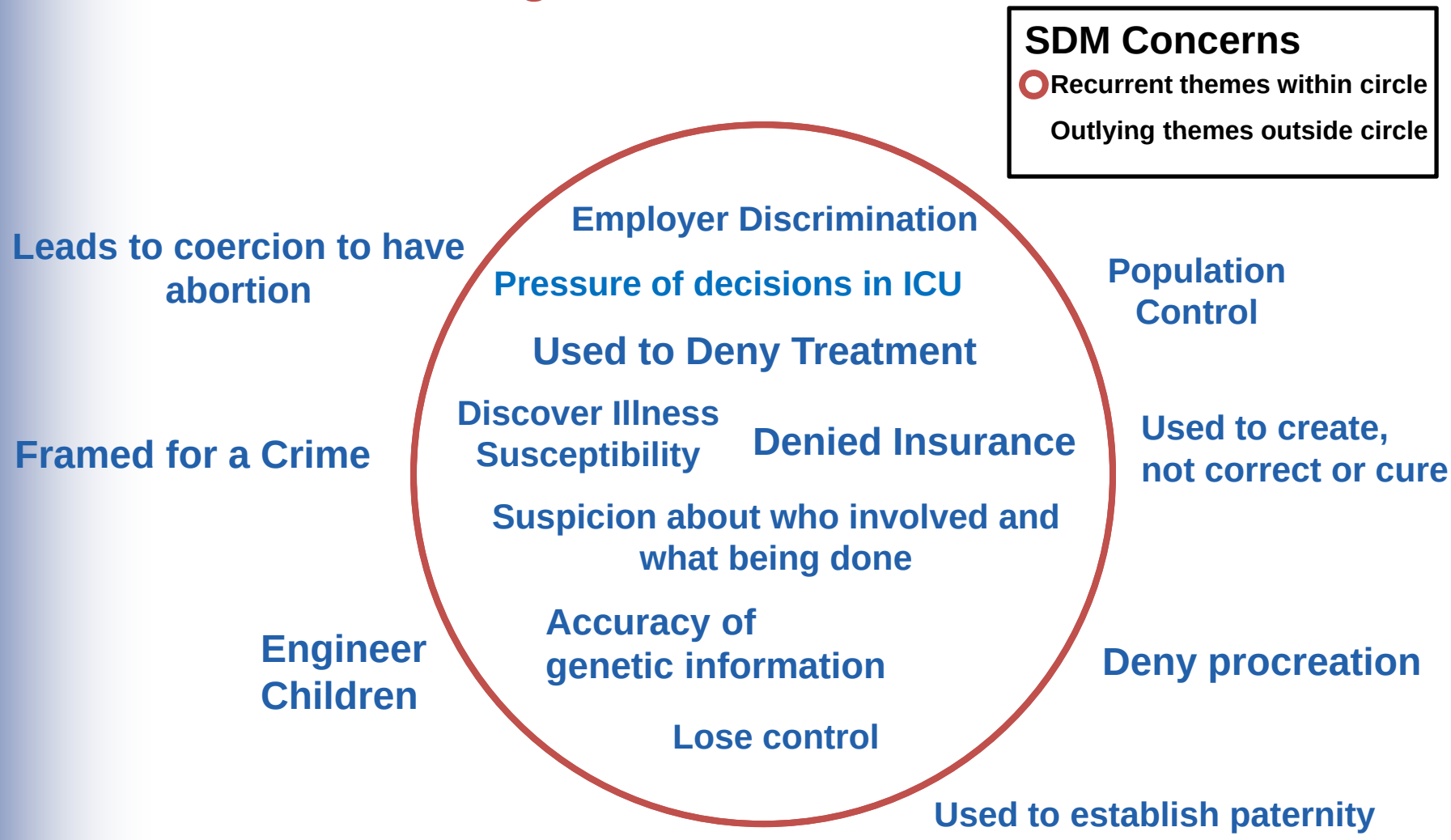
Broad

- Future treatments tailored to genetics
- Unique human signature
- Determine susceptibility
- Awareness of Human Genome Project, GINA, DTC marketing of gene tests
- Ethics need to parallel science

SDMs Perceptions of Medical Research

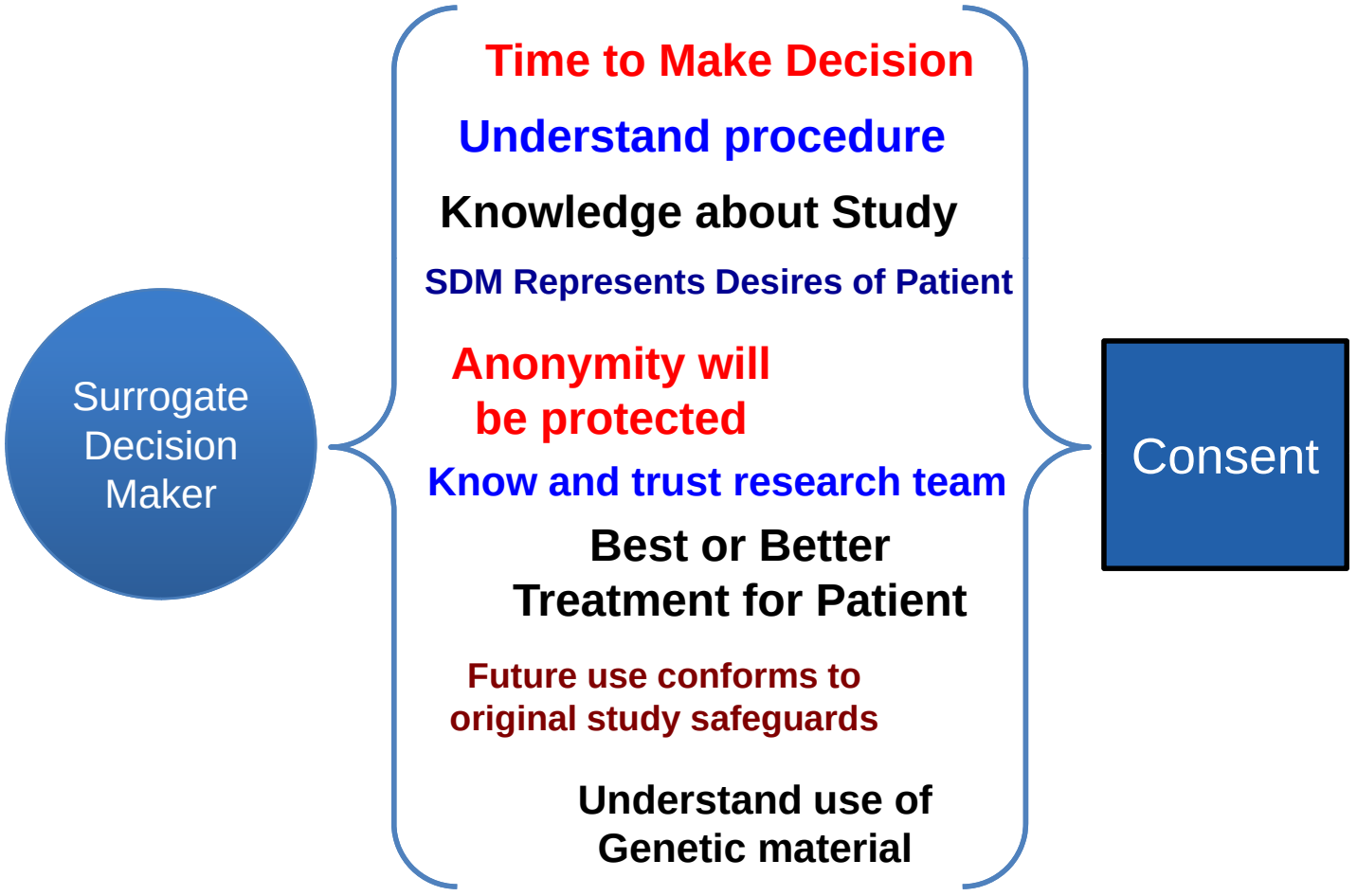
- Keen interest in medical research; it can help patient, family members, others in future with same condition
- Conditions for participation
  - Clear understanding of purpose
  - Trust in who is conducting research
  - Knowledge of procedures
    - Acceptable procedures: Painless blood or fluid specimen; gene tests; imaging
    - Unacceptable procedures: testing new drug, new treatment; invasive; didn't want to be guinea pig
- Blurring line between research and treatment; belief that participation can improve patient's condition

Concerns:
Genetics Testing & Research



SDM Consent to Genetic Research

While most respondents would permit family members' participation in genetic research, they required guidance to understand genetic data collection, including biobanking for future use, potential for commercialization, and protection of patients' data



Sample Question: Informed Consent

Sharing of Sample – Please check the appropriate box and initial

- ☐ I agree to have my family member's tissue/fluid sample shared with other researchers.
- ☐ I do not want my family member's tissue/fluid sample shared with other researchers.

Conclusions -- Consenting

- Conflict between need-to-know and anonymity. Once connection was made that satisfying need-to-know (e.g., future research, disclosure) would compromise anonymity, the desire for anonymity prevailed.
- Given the intensity of the ICU environment, the acuity of patients' condition, the barrage of consents, SDMs noted they would be more likely to consent.
- Anxiety about not knowing or understanding.
- Genetics not on the radar. Expressed strong desire to be educated, understand the terms of participation. With discussion, most were receptive to participation.
- As qualitative research, these findings cannot be generalized. Nonetheless, they offer insight they may be helpful to guide IRBs' and investigators ' approach to obtaining consent in the ICU.