A Baseline for the "Reasonable Patient Standard"

Investigators: John T. James, PhD, Patient Safety America, Houston, TX (retired NASA Chief Toxicologist) and Darwin J. Eakins, MS, (retired statistical expert, University of Kansas), Survey Consultant, Lawrence, KS

Background: Recent changes in the law on informed consent in the U.K. to favor a "reasonable patient standard" over a "reasonable clinicians' standard" prompted experts on informed consent to survey the situation in the U.S. Laws defining informed consent vary from state to state. Laws in half the states favor the reasonable-patient-standard (RPS) and others favor the reasonable-clinicians-standard.[i] A debate ensued about the problems with the RPS because it is going to vary from patient to patient. As part of the debate, an opponent of the RPS stated that perhaps a baseline RPS could be formulated.[ii] It is our intent to begin to define a general baseline for the RPS. This is essential if patient-centered-care and shared-decision making are to become a reality. Texas is a RPS state.[iii] Please note that for our purposes a "reasonable person" and a "reasonable patient" are identical.

Methods: We will use the Survey Monkey Platform to capture the demographics of each survey participant, and then they will answer 10 questions related to what they would like to know when facing the possibility of an invasive procedure while hospitalized. There are two identical versions of the survey, one intended to be taken simultaneously by an audience, and the other to be taken by individuals to whom the survey-link is sent via email. The survey platform prevents individuals from taking the survey more than once from their electronic device or computer. A link to the beta-version of the survey is given here: https://www.surveymonkey.com/r/8Y5Q3MF. Those taking the survey have 5 choices to express the degree to which they would like to know an answer to the question posed in the survey. Those responses range in 5 levels from "Definitely no" to "Definitely yes."

Recruitment: Our plan is to survey up to 1,000 adults in a variety of categories. These have not been fully fixed at this point, but our target groups are as follows: students of nursing, mature and retired nurses, health professions educators, retired individuals, people with knowledge of patient safety issues, and a nationally representative group of adults. Subjects will be recruited vis email or at presentations to groups, such as nursing students (see below). Our **primary hypothesis** is that across the survey groups and for most of the questions the participants will answer either "probably yes" or "definitely yes" to the questions. Our secondary goal is to discover groups that differ significantly from the overall average. We will use t-tests to determine statistical ($P<0.05$) differences between groups for selected questions that seem worth exploring.

Results: At this point the survey has been administered to nursing students attending a lecture on informed consent at Galveston College (April 19, 2018). There were 77 respondents to the survey, which was taken early in the lecture. Later in the lecture, the results of the survey were presented to the group of students. The data were readily available in graphical and numerical form to the audience. This was done to prove-out our ability to capture data in near-real time.

Funding: The research is being funding by Patient Safety America, Houston, TX. This will be less than $1,000 for the survey platform and additional costs if we choose to survey a nationally representative group to which we purchase access.

[i] https://jamanetwork.com/journals/jama/fullarticle/2516469
[ii] https://jamanetwork.com/journals/jama/article-abstract/2547748?redirect=true
[iii] CIVIL PRACTICE AND REMEDIES CODE
TITLE 4. LIABILITY IN TORT
CHAPTER 74. MEDICAL LIABILITY
SUBCHAPTER C. INFORMED CONSENT
Sec. 74.101. THEORY OF RECOVERY. In a suit against a physician or health care provider involving a health care liability claim that is based on the failure of the physician or health care provider to disclose or adequately disclose the risks and hazards involved in the medical care or surgical procedure rendered by the physician or health care provider, the only theory on which recovery may be obtained is that of negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent.