

# **FINAL REPORT**

## **A new approach to the allocation of decisional authority**

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Inclusive Dates of Project 9/1/2001 to 8/31/2005

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We acknowledge support from the Agency for Healthcare Research and Quality:

Grant award number K08 HS11289

## **Structured abstract**

### *Purpose*

To better understand the allocation of decisional work between clinician and patient in medical decision making.

### *Scope*

Decision making within a variety of medical settings.

### *Methods*

1. An empirical study of the attitudes and experiences of practicing physicians toward shared decision making and informed consent.
2. An empirical study of the attitudes of pediatric oncologists toward the role of hope in their clinical practices.
3. Theoretical work exploring the work of decision making, with particular emphasis on shared decision making and informed consent.

### *Results*

The standard ethical view on decision making is that it is a process that should be shared between clinician and patient or, ideally, that the patient undertakes.

There is a standard ethical view on medical decision making, one that ranks decision making according to the active participant. In this view, clinicians should not make decisions for patients, shared decisions are acceptable, but ethically optimal decisions are made by patients whose clinicians have informed them but have empowered them to make the decisions themselves.

This view is defective because it fails to consider the heterogeneity of medical decisions. This study identified the specific underlying characteristics of decisions.

### *Key words*

Decision making; medical ethics; patient-physician relationship; patient autonomy.

## **Academic coursework**

PHS 1820, Applied Statistical Analysis I (analysis of research data using SAS)  
Taken at the University of Texas-Houston School of Public Health

As proposed in the original application, I took a course in statistical analysis at the University of Texas at Houston School of Public Health with Professor Lemuel Moye. This was a challenging but useful class that not only emphasized how to perform statistical analyses but also looked with great care and questions of statistical significance and their meaning; the class also included a very helpful approach to how data should be collected, stored, and retrieved.

Coursework planned on campus but modified for home study:

Psychology 527 (Thinking) and 512 (Decision Making)

As preparation for these courses, I read *Judgment under Uncertainty: Heuristics and Biases* (Kahneman, Slovic, and Tversky) and the relevant sections of *An Invitation to Cognitive Science* (ed. D.N. Osherson). I then had a conference with Professor Osherson, who teaches these courses at Rice. His opinion was that, by reading the book he edits, I had learned the heart of what the course provided, and he felt that my time would be better spent elsewhere.

Academic study added as a result of reviewer comments:

One of the grant reviewers commented, "It would be a great omission to forego a seminar in medical anthropology and medical sociology." Rice does not offer seminars in these topics at a time that works for me, but I am undertaking home study in both of these topics using the following readings:

Medical Anthropology:

Sargent and Johnson, *Medical Anthropology*  
Payer, *Medicine and Culture: Varieties of Treatment in the United States, England, West Germany, and France*  
Loustaunau and Sobo, *The Cultural Context of Health, Illness, and Medicine*  
Romanucci-Ross, Moerman, Moerman, and Tancredi, *Anthropology of Medicine*  
Delvecchio et al., *Pain as Human Experience: an Anthropological Perspective*  
Snow, *Walkin' Over Medicine*

Medical Sociology:

Rothman, *Strangers at the Bedside*  
Starr, *Social Transformation of American Medicine*  
Foucault, *The Birth of the Clinic: An Archeology of Medical Perception*  
Fadiman, *The Spirit Catches You and You Fall Down*  
Cockerham et al., *Readings in Medical Sociology*  
Schwartz, *Dominant Issues in Medical Sociology*

## **Mentoring**

From the beginning of the term of the grant, Dr. Volk and I have had a regularly scheduled meeting every Monday. We do not meet when there are holidays, when one of us is out of town, or when there is other urgent business; apart from that, we have met

faithfully. These discussions have been very important in my development as an academician and researcher.

### **Networking**

I have been very active in seeking out established leaders in bioethics for collaborative projects and in related fields, such as pediatric oncology, as appropriate. The best demonstration of this is the willingness of these people to collaborate as co-authors of a paper that I am working on now, which is near submission:

Howard Brody  
Margaret Holmes-Rovner  
Laurence McCullough  
Carl Schneider

### **Professional conferences**

During the term of the grant, I attended the following professional conferences during 2001, 2002, and 2003:

American Society for Bioethics and Humanities  
North American Primary Care Research Group  
Society for Medical Decision Making

### **PURPOSE**

There is a disconnect between the ethical theory of how medical decisions should be made and the everyday reality of clinical practice. In theory, clinicians should work to empower their patients to make their own choices. According to this approach, the clinician's primary responsibility is to educate the patient about his or her situation, providing the patient with the information necessary to make an informed choice. The empowered patient is then well positioned to make a choice that incorporates not only the medical evidence relevant to his or her situation but also his or her own values, goals, and preferences.

Practicing clinicians---and, for that matter, ordinary patients---know well that this theory does not often play out in practice the way it is supposed to. Some have argued that this is because clinicians are too domineering, patients are too passive, and there is little genuine concern for the importance of hoping patients make decisions that are right for them.

This project took a more open-minded approach to the disconnect described above. It was my belief that the everyday patterns of decision making that we observe in actual practice may reflect a more refined approach to medical choice, heretofore recognized.

The purpose of this project, therefore, was to explore both the empirical and the theoretical aspects of medical decision making, with special reference to the allocation of the work of decision making between patients and clinician.

## **SCOPE**

Some of the work in this project was of limited scope, particularly the interviews with pediatric oncologists. Even these interviews, however, shed light on widely applicable issues of the relationship between patient and clinician.

Most of the empirical work dealt with practicing physicians (as well as physicians in training) in a wide variety of specialties and practice settings.

We took special pains to ensure that all our theoretical work had as wide a scope as possible, hoping to stimulate informed thought about decision making that would be applicable in any setting.

## **METHODS**

*1. An empirical study of the attitudes and experiences of practicing physicians toward shared decision making and informed consent.*

This study was undertaken in collaboration with Dr. McCullough and Dr. McGuire. We interviewed physicians in training and practicing physicians in a variety of practice settings, specialties, and geographic areas. We were interested in their views both in regard to sharing decisions with patients and with regard to the advantages and disadvantages of the informed consent process.

*2. An empirical study of the attitudes of pediatric oncologists toward the role of hope in their clinical practices.*

This study was undertaken in collaboration with Drs. McCullough and McGuire and included Dr. Berg, a pediatric oncologist, and Dr. Fruge, a psychologist who works at the Texas Children's Cancer Center. In addition, we were joined by a community member, Karen Brisch, an attorney and mother who does not have formal medical or ethical training.

We were interested in pediatric oncology because it is a field reaching complex decisions of varying types, involving some very high-stakes situations. Hope is particularly relevant, because these very sick children have so little of it and need it so much. Their parents, the children, and the clinician-investigators work hard (and not always successfully) to negotiate an agreed-upon understanding of the child's clinical situation, the options available at that time, and what should be done next.

*3. Theoretical work exploring the work of decision making with particular emphasis on shared decision making and informed consent.*

## RESULTS

### *1. An empirical study of the attitudes and experiences of practicing physicians toward shared decision making and informed consent.*

With regard to shared decision making, we were impressed by the flexible approach exhibited by the clinicians we interviewed. They responded in a nuanced fashion to the specifics of the clinical situation, the patient's background and understanding, and the patient's interest in participating in the decision-making process, combining all these factors to fashion a decision-making process that they felt would work well for that particular patient. No doubt their professional judgments in this process will vary in success from patient to patient, but their understanding of the factors involved and willingness to attack general principles to specific circumstances were impressive.

With regard to informed consent, we had half-expected to confirm our a priori suspicion that clinicians view informed consent as a legalistic and bureaucratic imposition that contributes nothing to patient care. Instead, almost every clinician we interviewed (and we spoke with more than 50) has found a way to smoothly and confidently integrate informed consent into the overall decision-making process. Furthermore, these clinicians almost universally expressed great respect for the ethical importance of informed consent, mentioning such factors as its benefit in forcing clinician and patient to spend a little more time focusing on pros and cons of the proposed intervention, its role in preparing the patient for any possible consequences, and its role in building trust. Of course, informed consent also has a legally protective role for the point of view of the clinician; however, this aspect is not relevant to us, because we were interested in the informed consent role in promoting ethical and effective clinical care.

### *2. An empirical study of the attitudes of pediatric oncologists toward the role of hope in their clinical practices.*

We have not completed analysis of the data from these interviews. However, our insights gained as a result of these interviews and our discussion of the interviews were critical to preparing our third theoretical paper on decision making, discussed in the next section.

### *3. Theoretical work exploring the work of decision making with particular emphasis on shared decision making and informed consent.*

We have produced three major theoretical papers on the allocation of decisional authority between patient and clinician.

The first, published in *Medical Decision Making*, proposed a model of medical decisions based on two fundamental characteristics of each decision---its importance and its certainty or uncertainty. Combining these two characteristics identifies clinically relevant decision types. Decisions that are low in certainty and high in importance identified a

zone of patient priority, in which the clinician's expertise is limited and for which the patient should be encouraged to make the decision. Decisions of high certainty (for which there is clearly one optimal medical choice) and of low importance comprise the zone of physician priority; for these decisions, the clinician can confidently recommend one choice for the patient to consider.

There is also a general middle ground, which we identified as being a "shared priority," in which neither patient nor clinician can make an optimal decision acting alone. Finally, there is a zone of potential conflict, which consists of those decisions of high importance and high certainty. Because these decisions are of high certainty --in other words, there is clearly one best medical choice---the physician has priority for identifying and recommending that choice. However, because they are also of high importance, the patient's preference cannot be ignored or overridden. In most cases, these decisions are made without incident when the clinician recommends the best treatment and the patient accepts it. However, when the patient rejects the single best treatment, the likelihood of conflict is high.

The second paper, published in the *Annals of Internal Medicine*, distinguished shared decision making from informed consent and simple consent. In the past, people have often assumed that informed consent and shared decision making were essentially the same process, or at any rate that they should be. Our paper explained why this is not correct.

Informed consent is a process through which patients consent to (or reject) a high-risk intervention. Some of these interventions will also require shared decision making, because there is no single best choice and therefore the patient's preferences and values will come into play. For other high-risk interventions, however, there is a high degree of medical certainty that one intervention is optimal. In this case, we have informed consent without shared decision making, as the patient has no genuine choice (this is also true of the clinician). Finally, there can be shared decision making without informed consent, as is the case for any low or mid-risk clinical situation where there are two or more reasonable alternative treatments. In this case we have simple consent in place of informed consent.

The third theoretical paper, published in the *Journal of Clinical Oncology*, was an in-depth analysis of decision making within the context of pediatric cancer. Here again, the politically correct viewpoint is that the oncologist should present the facts and the options to the patient or the parents. Suitably armed with information, the patient/parents are then empowered to make the choice that best suits their individual circumstances.

This is in fact a process that takes place sometimes, but far from all the time. As before, the reason is not because oncologists are unwilling to offer choice to their patients. Instead, the explanation is that often that there is simply no choice to be had.

As in our first paper, we began by identifying to critical characteristics of any decision in pediatric oncology---namely, whether there is one clear best choice, whether there are two

or more possible choices for the particular situation, and the extent to which a cure for the child's disease is possible. Using this approach, we were able to identify distinct zones in which decisional priority should rest: with the patient, with the clinician, or shared.

#### **PUBLICATIONS IN REFEREED JOURNALS:**

**Whitney SN**, Brown BW, Brody H, Alcser KH, Bachman JG, Greely HT. Views of United States physicians and members of the American Medical Association House of Delegates on physician-assisted suicide. *J Gen Intern Med*. 2001;16:290-296.

**Whitney SN**. A new model of medical decisions: exploring the limits of shared decision making. *Med Decis Making*. 2003;23:275-280.

**Whitney SN**, McGuire AL, McCullough LB. A typology of shared decision making, informed consent, and simple consent. *Ann Intern Med*. 2004;140(1):54-9.

McGuire AL, McCullough LB, Weller SC, **Whitney SN**. Missed expectations? Physicians' views of patients' participation in medical decision making. *Med Care*. 2005; in press.

**Whitney, SN**, Ethier, AM, Frugé, E, Berg, S, McCullough LB, Hockenberry, M. Decision Making in Pediatric Oncology—Who Should Take the Lead? The Decisional Priority in Pediatric Oncology Model. *Journal of Clinical Oncology*, in press.

#### **BOOK CHAPTERS WRITTEN:**

**Whitney SN**. The preivable infant at the crossroads: ethical and legal considerations. In: Goldworth A, Frankel L, Silverman W, eds. *Ethics and Pediatrics: Clinical Issues and Perspectives*. Stanford, CA: Stanford University Press; in preparation.

**Whitney SN**. Near drowning, futility, and the limits of shared decision making. In: Goldworth A, Frankel L, Silverman W, eds. *Ethics and Pediatrics: Clinical Issues and Perspectives*. Stanford, CA: Stanford University Press; in preparation.

#### **INVITED LECTURES, PRESENTATIONS, AND RESEARCH SEMINARS:**

##### **a. REGIONAL:**

**Whitney SN**, McGuire A, McCullough L, Weller S. Physician Views of Shared Decision Making and Informed Consent. Poster presented at the Health Services



and Outcomes Research Conference, Rice University, Houston, TX, November 25, 2002.

Crouch MA, **Whitney S**, Volk R, McCullough L, Cheak N, Pavlik V. Effects of Informed Consent on Statin Therapy Decision Making: Preliminary Pilot Study Results. Poster copresented at the 4th Annual Kelsey Research Foundation Health Services and Outcomes Research Conference, Houston, TX, November 3, 2003.

**b. NATIONAL:**

Crouch MA, **Whitney SN**, Volk R, McCullough L, Pavlik VN. What Patients Believe about Statins and What We Can Teach Them. Poster presented at the 29th Annual Meeting of the North American Primary Care Research Group, Halifax, Nova Scotia, October 13-16, 2001.

Crouch MA, **Whitney SN**, McCullough L, Pavlik V, Volk RJ. Effects of a Statin Decision Aid on Explanatory Models and Shared Decision Making. Poster presented at 30th Annual Meeting of the North American Primary Care Research Group, New Orleans, LA, October 18, 2002.

Crouch MA, **Whitney SN**. Helping Patients Make Good Cholesterol Decisions by Using a Decision Aid: Qualitative Results and Plan for Controlled Trial. Poster presented at the Annual Conference of the North American Primary Care Research Group, New Orleans, LA, November 18, 2002.

**Whitney SN**, McGuire A, McCullough L, Weller S. Physician Views of Shared Decision Making and Informed Consent. Poster presented at the Annual Meeting of the North American Primary Care Research Group, New Orleans, LA, November 17, 2002.

**Whitney SN**. Invited participant, Lasker Forum on Ethical Challenges in Biomedical Research and Practice, Mary Woodard Lasker Charitable Trust, Washington, DC, May 14-16, 2003.

Crouch M, **Whitney SN**, McCullough L, Pavlik VN, Cheak N. Effect of Informed Consent on Compliance With Statin Therapy: A Pilot Study. Poster presented at the Annual Meeting of the North American Primary Care Research Group, Banff, Alberta, Canada, October 27, 2003.

**Whitney SN**, McGuire AL, McCullough LB, Davis JL, Volk RJ. Researchers Views of Human Subjects Protection. Poster presented at the Annual Meeting of the North American Primary Care Research Group, Banff, Alberta, Canada, October 27, 2003.

**Whitney SN.** Distinguishing Informed Consent and Shared Decision Making. Commentary presented as part of a panel discussion on informed consent held at the Annual Meeting of the American Society for Bioethics and Humanities, Montreal, Quebec, October 24, 2003.

**Whitney SN.** Organized a panel discussion on informed consent for the Annual Meeting of the American Society for Bioethics and Humanities held in Montreal, Quebec, October 24, 2003.

**Whitney SN, McGuire AL, McCullough LB, Davis JL, Volk RJ.** The Trouble with IRBs: Researcher's Views of Human Subjects Protection. Poster presented at the 18th Annual Meeting of the Applied Research Ethics National Association, Washington, DC, December 5-7, 2003.

**Whitney SN.** Informed Consent in Clinical Research Settings. Invited panel presentation given at the Strengthening the Process of Informed Consent to Address Racial and Ethnic Disparities in Healthcare and Research conference, Tuskegee University, Tuskegee, AL, June 29, 2004.

**Whitney SN, Berg SL, Fruge ED, McGuire AL, McCullough LB, Volk RJ.** Hope in Research: Views of Pediatric Cancer Researchers. Poster copresented at the 32nd Annual Meeting of the North American Primary Care Research Group, Orlando, FL, October 10-13, 2004.

**Whitney, SN, McCullough, LB, Volk, RJ, Ethier, A, Barrera, P, Gregurich, MA, Berg, S, Frugé, E, Hockenberry, M.** Decision Making in Pediatric Cancer—Who Should Take the Lead? Poster presented at the 7th annual meeting of the American Society for Bioethics and Humanities, Washington, DC, October 20, 2005.