

PATIENT FOCUS GROUP GUIDE

Study Background:

Welcome and thank you for agreeing to participate in this focus group. We know that you have very busy schedules and we appreciate your willingness to participate in today's discussion. The purpose of this focus group is to understand your perspectives on a type of research that we'll refer to as "research on medical practices". We will show you videos to help you understand what this means, but very briefly, hospitals and clinics conduct this type of research to improve day-to-day care, or to learn more about how well medical treatments being used now work in real life. As more and more hospitals and clinics start to do this type of research, we want to figure out how to get it right. Hospitals would like guidance on how to best do this kind of research, and how to let patients know it is happening. This focus group is part of a larger project that we hope will inform future practices. Your input is really important to us and will help shape the best approach. We are interested in any thoughts or ideas you have on these questions—there is no right or wrong answer. Our goal is to learn about what value you see in this research and what concerns you might have about it. We will use this information to create a survey that we will send out to patients nationwide.

I. Introductions

Each person here has important insights to offer and we hope that you will all actively participate in the discussion. We would like to take a few moments for introductions. Could you please introduce yourself by giving us your first name and what interested you in this topic? Again, your names will be deleted from the final transcripts – this is just to facilitate our discussion together.

Thank you. To begin, we want to get a sense of your views about how doctors make decisions.

(1) What do you think leads a doctor to prescribe a particular drug for a patient? Let's say in this case, to help manage high blood pressure? (10 minutes)

Probe: What else do you think might influence a doctor's decisions? How do you think doctors eventually decide what is the better drug or treatment to use with a patient?

Thank you. To help inform our discussion we want to show you three short video clips. These were designed to help explain what we mean by research on medical practices, using the example of managing high blood pressure. The videos will help introduce a few key concepts including research on medical practices, randomization, and consent. We will present the video in segments by topic, and we'll stop after each segment for discussion.

II. Variation in Practice Show Video #1 (10 min including 4 minutes to watch video)

(2) Did the video change your impression of how doctors make treatment decisions in everyday practice?

(3) Does the general issue of how doctors decide what is best, raise any concerns for you?

III. Research on Medical Practice & Randomization Show Video #2: (40 min)

The video discussed research on medical practice as it compares to regular decisions doctors make every day. The simplest approach to this research is called **Observation**. That is, where physicians or hospitals observe and keep track of outcomes of different treatments, procedures or medications and try to learn over time what works best. Other physicians or hospitals use what's called **Randomization**. We'd like to take some time to talk about each of these approaches, but first we'd like to know your overall impressions of this general idea of doing research on medical practice.

(1) Thinking about research on medical practice and drawing upon your personal experience, what do you see as the potential advantages and disadvantages, or risks and benefits of research on medical practice?

Probe: Do you have any particular ethical concerns about doing this kind of research?

Probe: If you have concerns, do you have the same concerns about Observation as you do about Randomization?

(2) Now let's look more closely at Randomization: What would you think and feel about your doctor deciding which blood pressure medication to use based on Randomization?

Probe: Do you think randomization may have any benefits for how doctors make decisions to treat you?

Probe: Do you think there may be benefits to other patients?

Probe: Do you have any concerns?

(3) Research using randomization may affect an individual doctor's ability to make specific treatment decisions for individual patients, since patients are assigned randomly to treatment options. Do you have any concerns about this?

Probe: [Encourage them to elaborate on specific concerns.]

(4) Research on Medical Practice—using observation or randomization—can go even faster when doctors at different HCOs share with other HCOs health information about how their patients respond to different treatments. Do you have any concerns about having your health information [your child's health information] shared across doctors or hospitals?

Probe: [Encourage them to elaborate on specific concerns.]

Probe: Do you think the trade off of having increased risks of having your health information shared more widely is reasonable when balanced by the benefit of knowing more quickly what medications or treatments work best?

(1) What information would you like to be told about any of these activities related to research on medical practice?

Probe: What type of information would it be important to include? How general or specific should the information be?

Probe: Do your views about the types of information change depending on whether the approach is observation or randomization?

(2) Would you want your health care provider to provide specific information about research on medical practices *to you*, as opposed to just receiving general information that the hospital is engaged in research on medical practice? [Refer back to video images if needed: sign in lobby, handout in doctor's office, conversation with doctor.]

Probe: Do you feel the same way whether the research method being used is either observation or randomization?

(3) In addition to information about the research, would you want your health care provider to ask for your consent—that is, *agreement to participate [have your child participate]* in research on medical practices?

Probe: Do you feel the same way about observation and randomization—should agreement be required for one but not the other, neither, or both?

Probe: What tradeoffs come to mind in asking patients to agree up front for research on medical practice? Can you think of any downsides to requiring consent of each patient? And what are the benefits of getting consent vs. offering general information about the research?

(4) Do you think you would agree if you were asked to participate [have your child participate] in research on medical practice? What factors would play into your decision?

Probe: Would your position change depending on whether the approach taken is observation or randomization?

Probe: Would your views change if the health issue were more serious? That is, we have been talking about the example of high blood pressure. Let's say the study was looking instead at comparing 3 different cancer drugs—all being used by different doctors as standard treatments, but we would like to compare them and learn which is best.

(5) In research we refer to guidance and protection of patients and participants as "oversight". What type of oversight for this research would you expect and who should be responsible for oversight?

Probe: Do you think patients or community members should play a role in oversight? If so, what input could they provide?

VI. Wrap Up and Final Comments (10 mins)

(1) Now that you've had time to consider ethical issues surrounding research in medical practice, do you have additional thoughts you would like to add?

(2) As we mentioned, we're planning to use these videos in a survey. We would like to get your input on what you liked and didn't like about the videos, and most importantly, if you have any suggestions for changes, so we can edit them before including them in the survey.

Thank you so much for participating in this focus group. Again, your comments will be anonymized in the transcription process. If you have any follow up questions about what we have discussed, please contact us. You can reach us by contacting Adrienne Meyer at: gevjon@uw.edu.