Appendix A: Questionnaire

PROPPR

Pragmatic, Randomized Optimal Platelet and Plasma Ratios

Random Digit Dialing Telephone Community Consultation
TORONTO SITE

Telephone Script

Hello, my name is _____, and I'm a research assistant at Sunnybrook Trauma Research Program. This call does not involve sales of any kind. We are currently conducting a survey on behalf of Tory Regional Trauma Centre/ Sunnybrook Health Sciences Centre to obtain community opinions and views on a medical research study involving severely injured patients. The Sunnybrook Hospital will be using your opinions to help determine whether the study is acceptable to the community. Your answers will be confidential.

The survey will take approximately 10 minutes of your time, during which I will describe the study to you and ask for your opinions about it. I will also ask you a few questions about yourself. You do not have to answer any questions you do not want to, and you may stop the survey at any time.

Would you be willing to offer your opinions and answer some questions about yourself after I give you details about the study?
[If YES then continue, if NO, say thank you for your time]

Are you eighteen years old or older?
[If YES, continue--- if NO, ask to speak to someone 18 years old or older; reintroduce yourself with paragraph 1] Thank you!

---[READ THE FOLLOWING PRIOR TO ASKING SURVEY QUESTIONS]---

A study comparing ways to give blood transfusions is being proposed in patients with severe injuries, like those that can occur in bad car accidents, who have a significant chance of dying from their injuries and blood loss. Usually, patients are told about a study, its risks, and its potential benefits, and then they provide a written consent. However, in the case of severe injury, it is not always possible for patients to give written consent because they may be unconscious, and their families may not always be available to speak for them.

Canadian Research Ethics Boards and Health Canada allow for certain studies to be performed with delayed consent in emergency settings, but only if patients have a high risk of dying without treatment; cannot communicate because of their condition, and don't have family available to speak for them; and an independent physician (who is not the investigator for the study in question). Policies governing research in emergency situations

advise researchers to **discuss the research to be undertaken** in the community in advance. We would like your opinion on our proposed study which involves severely injured patients. **First, I will give you information about the study and then I will ask you for your opinion.**

Trauma refers to a "body wound or shock" produced by sudden physical injury, as from violence or accidents. Trauma injuries are the leading cause of death in people under the age of 45 years old, and nearly 50% of these deaths occur before the patient reaches the hospital. For those that reach the hospital, about 40% experience severe bleeding and require a massive transfusion of at least 10 units of blood. Bleeding complications are the leading causes of **early** death in trauma patients. People who have suffered trauma may require specialized care, including blood transfusions and surgery.

The purpose of this study is to help determine which blood transfusion combination will provide the best outcomes for the trauma patients receiving them. In addition to Sunnybrook Hospital in Toronto, we are proposing to conduct this multi-center study at other Trauma Centers across the U.S.

The knowledge we gain will likely impact the way in which patients who are severely bleeding are transfused, and lower the amount of otherwise preventable deaths resulting from hemorrhagic shock. The trauma surgeon on call in the emergency department will use information obtained when a patient arrives to the emergency department to predict if the patient will require a significant amount of blood products. The information includes their blood pressure, pulse, type of injury, and an ultrasound test to see if they are bleeding in the abdomen.

For patients that are eligible for this study, the blood bank will be notified to randomize (a process like flipping a coin) the patient to receive one of two blood combination groups -- one that gives more plasma and platelets and one that gives less.

All other treatments will be the same.

All blood products we use will be just like the normal products from Canadian Blood Services (CBS) patients get for transfusions, and all blood products are approved by Health Canada. All blood is typed, and will be tested for infectious diseases. This is the standard practice if you receive a blood transfusion. As with any blood transfusion, there are risks involved, which include chance of transmission of an infectious disease, low blood pressure, allergic reaction, shortness of breath, fever, and blood clotting problems.

-Patients and/or family members/legal representatives can decide at any time to withdraw from the study.
-Patients will receive the same care whether or not they are in the study. The patient will only receive blood products if the physician determines they need the blood. The patient will not receive extra blood products because of the study.
-There is no extra cost for being in the study.
-Every effort will be made to ensure patient privacy.
-All information reviewed for the purposes of this study will be made anonymous.

If anyone in the community does not wish to take part in this type of study, they can call a special number to request an "opt out" bracelet or identification card (ID card) that would notify Emergency Medical personnel that they do not wish to be enrolled. The "opt out" bracelet is a colored, plastic bracelet with the word "PROPPR Ø" on it will be available for those who **DO NOT** want to be considered for this study. The ID card will be about the size of a driver's license or credit card with the word "PROPPR Ø" on it. If a patient arrives to the ED with this bracelet on, they will not be screened or enrolled in this study

As I mentioned before, we called to speak to you today because patients who are eligible for the study will be unable to consent and will be entered into the study with delayed informed consent. We will make every attempt to get consent from their legal representative and/or family member; and will inform patients about the study and try to obtain consent from them (if they recover) as soon as we are able.

We would like to ask you some questions about your opinion on this.

1. Based on the information I just read to you, do you understand what this study is about?
a. Yes
b. No
c. Don't know
d. Refused

2. At any moment, we are all at risk of serious injury, especially in an automobile. If you were severely injured and it was determined that you would need blood products, would you find it acceptable to be enrolled in this study with an independent physician authorization and delayed informed consent?
a. Yes
b. No
c. Don't know
d. Refused

3. Do you believe that this exception to written consent before enrolling a patient into this study is justified?
a. Yes
b. No*
c. Don't know
d. Refused
* If NO: What is your reason for concern? _____
_____

4. Why do you feel this exception to consent before enrolling a patient is justified?
a. It is in the best interest of the patient
b. It is in the best interest of the community
c. It is in the best interests of both the patient and the community
d. Don't know
e. Refused
f. Other: _____

5. Do you believe the research is in the best interest of the patients and community?
a. Yes
b. No*
c. Don't know
d. Refused
* If NO: What is your reason for concern? _____
_____

6. Injury is the leading cause of death in teenagers, ages 15-18 years, and because they have the same risk and benefits with the transfusion ratios as adults, do you think it is appropriate to include 15-18 year old children in this study?
a. Yes
b. No*
c. Don't know
d. Refused
* If NO: Please tell me why? _____
_____

7. Do you have any additional comments about giving this experimental transfusion ratio without written consent by the patient? [*Record verbatim*]
_____
_____
_____
_____
_____
_____
_____

If you would like more information regarding the study, I can give you a name and number for the local study coordinator or you can visit the study's website address, would you like any of that information?

Sandy Trpcic

Local Site number_____

Website: http://www.uth.tmc.edu/cetir/PROPPR/index.html

We thank you for your time so far. The following questions are only to make sure that we have a representative sampling of our community's opinions. Your answers will be kept confidential.

8. What is your age? _____

9. Are you the parent or legal guardian of a child or children ages 15-18 years old?

_____

10a. What is your race? [*Record one response*]
a. Caucasian/White
b. Black
c. Asian
d. Latin American
e. Mixed Race
f. Aboriginal
g. Other [SPECIFY]_____
h. Don't know
i. Refused

10b. What is your ethnicity? _____

11. What is the highest level of education you have completed?
a. Less than 9th grade
b. 9th to 12th grade- no diploma
c. High School graduate/ Equivalency (GED)
c. Associate, Technical or Vocational degree
d. Bachelor's degree
e. Post-graduate degree
f. Refused

12. What is your occupation?

_____

13. What is the zip code where you live? _____

14. What is your approximate annual household income?

_____

-This concludes our survey. We thank you very much for your time!-

Citizen's gender:

1. Male 2. Female

_____

_____

Interviewer Name **Date**