The Patient Perspective and Informed Consent

Jamie C. Brehaut, PhD
Jelissa Morgan
Clinical Research Training Course
Oct 20, 2014

I have no conflicts of interest related to this presentation

Objectives

1. To understand the basic principles underlying informed consent
2. To learn some tips for improving the informed consent process
3. To understand informed consent from the patient perspective
“FDA believes that obtaining a subject's oral or written informed consent is only part of the consent process.”

The informed consent process often continues after the consent form is signed …the subject may need additional opportunities to ask questions and receive answers throughout the clinical investigation.

U.S. FDA Informed Consent Guidance Sheet, July 2014

**Ethical Components of Informed Consent**

1. The decision to participate in clinical research must be made **voluntarily** and **free from coercion**;
2. The decision-maker must be **competent** to make the decision;
3. Full **disclosure** of relevant information must be given;
4. The information must be **understood** by the decision-maker.


**OHSN-REB Consent Form Template**

http://www.ohri.ca/ohsn-reb/consent_forms.htm
• Ran from 1938 to 1972
• 399 poor black sharecroppers with syphilis, studied untreated progression of disease
• Penicillin determined to be safe and effective for treatment of syphilis by 1947
• 1972 whistleblower and subsequent inquiries led to Belmont Report

---

**Tuskegee Syphilis Study**

**Marion County Health Department**

---

**Increased 36-Week Survival with High Oxygen Saturation Target in Extremely Preterm Infants**

Participation in this study may involve some added risks or discomforts. Because all of the treatments proposed in this study are standard of care, there is no predictable increase in risk for your baby. Infants randomized to the CPAP group may, at some point in their care, require intubation and assisted ventilation (methods to help them breathe). If the attending physician deems this necessary, participation in the study will not affect this decision. Some unknown risks may be learned during the study. If these occur, 2025, be informed by the study personnel. The only other risk of this study is the risk to confidentiality. Every effort will be made to keep your child’s medical record confidential. There will be no names or other patient identification in any study report that may be published after the study is completed. Measures taken to protect you and your baby’s identity are described in the confidentiality section of this document.

1. The paragraph does not include any information about the prior research and analyses that had been done looking at the relationship between oxygen and ROP, and what that work indicates about how changing the oxygen range might affect whether an infant develops ROP.

2. The paragraph does not include any information about the prior research and analyses that had been done looking at the relationship between oxygen and mortality and other forms of morbidity (apart from developing ROP).

3. The paragraph does not identify any specific risk relating to randomizing infants to a high or low range of oxygen.

**Problems with understanding...**

- Cross-section of oncology RCTs, 30% believed their treatment had been proven to be the best treatment for their cancer (Joffe et al, Lancet, 2001)

- RCT of B-blockers for MI, 44% of patients interviewed did not understand random assignment (Howard et al, Control Clin Trials, 1981)

- Oncology chemotherapy trial, half of patients could not name any drug they were about to receive, and most could not remember side effects described on the consent form (Oliver et al, Ann Onc, 1993)

Fkry & Emmanuel (2004) JAMA.

http://decisionaid.ohri.ca/
Simplify and Shorten

THROMBOPHILIA AND PREGNANCY

Women with thrombophilia, a tendency to develop blood clots in veins, are at increased risk during pregnancy of developing thrombosis, having a stroke, or dying from pulmonary embolism. The exact reason why thrombosis leads to these complications in pregnancy is unknown, but it is thought that small blood clots develop in the placenta and disrupt function.

Remember that most pregnant women with thrombophilia will not develop any complications and will have normal pregnancies.

See also: thrombophilia.

High blood pressure in pregnancy is also referred to as pre-eclampsia. This is a condition where blood pressure increases during the second and third trimesters. Pre-eclampsia is usually treated with medication, but often requires that the baby be delivered early. It can result in serious problems such as preeclampsia, eclampsia, diabetes, and liver failure, hemorrhagic fever, and even death.

Summarize Decision Options

You can decide

Not to join the study

- All routine care treatments will be available to you.
- You will be closely monitored for the development of high blood pressure, small birth weight babies and blood clots.

To join the study

- You will continue to receive routine care.
- You will be randomly assigned to either Group A or Group B and will be closely monitored.
- There may be additional risks and benefits to participating in these discussions on the next page.

Summarize repetitive procedures into tables

WHAT WILL I HAVE TO DO?

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Week 2</th>
<th>Week 3</th>
<th>Week 4</th>
<th>Week 5</th>
<th>Week 6</th>
<th>Week 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood test</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Ultrasound</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
</tr>
</tbody>
</table>

* As part of the study, women with thrombophilia are given blood thinners for 30 weeks after delivery. Very small quantities of dopamine are used in the treatment. Dalteparin is used intravenously in women, and subcutaneously in women who develop blood clots.
Describe risks with enough detail to help imagine the impact on one’s life

Not very helpful....
Drug X can have effects on the sensory and motor nerves.

Better...
Drug X can affect the sensory nerves that can cause numbness and tingling, and can interfere with activities that require coordination such as buttoning of clothes, writing, or trouble feeling where your feet are when you walk.

Not very helpful....
You may feel discomfort from the electrical stimulation

Better...
You may feel discomfort from the electrical stimulation, which may feel like mild muscle cramps, uncomfortable tingling (like hitting your funny bone).

Clairfying Values

WHICH OUTCOMES ARE MOST IMPORTANT TO YOU?

In order to decide whether or not to join the research study, we suggest you consider each part of the decision separately.

Please move the slider bar to indicate how important each is to you.