Patient understanding of the content of informed consent: Reinforcing the degree of participant comprehension

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To test how much information women retained from the informed consent document, a simple test of comprehension was conducted. We asked a short series (1 to 8) of open-ended comprehension questions following the initial consent and six days after delivery. The overall mean score of total correct responses was 11 following delivery compared to 13 prior to delivery (p=0.0001). There was no significant effect of years of schooling on retention.

Table 1. IC retention study participant characteristics

| Variable | Total n=105 | n (%)
|----------|-------------|-------
| Age (y) | 27±4 (72) | 25±4 (77) |
| Ethnicity | Tibetan 97 (94) | Han Chinese 7 (7) |
| Urban 64 (61) | Rural 25 (24) |
| Preterm care 96 (94) | 100 (100)

Results of IC retention

- Of the subset of women (n=105) who were asked the same 16 questions 2 to 3 days following delivery, the overall mean score of total correct responses was 11 following delivery compared to 13 prior to delivery (p=0.0001).
- There was no significant effect of years of schooling on retention.

Discussion

Basic required elements of IC

According to regulations of the U.S. Office for Human Research Protections (OHRP), there are eight basic elements required in an informed consent document:

1. Study involves research and an explanation of the purpose of the study.
2. Description of risks or discomforts.
3. Description of any benefits.
4. Confidentiality of the subject.
5. Disclosure of alternatives to participating in the research.
6. For research involving more than minimal risk, an explanation must be given of whatever voluntary compensation or treatment will be provided.
7. Who to contact for questions about the research.
8. Participation is voluntary and refusal to participate will not affect patient care.

Informed consent documents developed by the National Institutes of Health (NIH) and the Bill and Melinda Gates Foundation have been used to model and assess the effectiveness of these consent documents. The development of these documents was based on the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1978) and the Belmont Report (1979). The content of these documents was intended to provide comprehensive information to persons participating in the research.

**Table 2. Pre- and post-delivery comprehension results by question**

<table>
<thead>
<tr>
<th>Question</th>
<th>Pre-delivery n=105</th>
<th>Post-delivery n=105</th>
<th>Paired t-test p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. What is the name of the Tibetan medicine?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>2. What is the purpose of the study?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>3. What is a placebo?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>4. Does the doctor know which green capsules she will get?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>5. Does the doctor know which white tablets the woman will get?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>6. Does the woman know which green capsule she will get?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>7. Does the woman know which white tablets the woman will get?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>8. Are there any risks to participating?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
<tr>
<td>9. Will you be paid to participate in this research?</td>
<td>13 (12.5)</td>
<td>13 (12.5)</td>
<td>0.42</td>
</tr>
</tbody>
</table>

**Table 1. IC retention study participant characteristics**

- Between August 2005 and September 2006 – 1,539 women have been screened.
- – 836 eligible and approached for consent
- – 105 women (of the 640 women participating in the study) were tested.
- – 69.9% (n=584) on the second attempt.
- – 16.1% (n=135) answered all questions correctly on the first attempt.
- – 13.2% (n=110) on the third attempt.
- – Less than 1% (n=7) proved ineligible to participate.
- – 77% (n=460) of women approached for consent agreed to participate in the study.
- – 105 women (of the 640 women participating in the study) were approached following delivery.

**Methods**

- In order to assess comprehension, a simple IC document developed over 2 years of iterative pilots was used to consent pregnant women presenting at three study hospitals in Lhasa, Tibet.
- All women meeting eligibility requirements were read the IC document in their primary language, by study trained providers. After each section of the IC document providers included in the informed consent document. Table 1 shows the four basic elements included in the informed consent document.

**Discussion (cont’d)**

- Women understood the information provided to them during the initial informed consent process, particularly the 8 OHRP required elements.
- Participants did not score as well two to three days following delivery. The mean score prior to delivery was 13 and only 11 following delivery.
- Women may not have scored as well 2 to 3 days following delivery because the retention questions tested memory as well as comprehension.
- One study which tested recall of informed consent information regarding analgesic risks given to women in labor found that only 50% were able to properly recall all risks one day following the initial consent. (Affleck P et al.)
- Other studies have found that patients undergoing cancer treatment, eye surgery, or cosmetic surgery scored similarly. (Cassileth et al., Moss et al., Prutch et al., and Lohr et al.)

**Conclusions**

Making an informed decision requires comprehension. Assessing comprehension questions following each section of the IC document helped to reinforce information and allowed researchers to determine women’s comprehension. While the participants did not score as well a few days following the initial consent, they demonstrated retention of those informed consent elements related to safety and to the voluntary nature of the research. It is evident that challenges still remain in achieving truly OHRP-style informed consent in settings with little experience of biomedic research.

This study was supported by the Global Network for Women’s Children’s Health Research (grant 135-00001) funded by the National Institutes of Health and the Bill and Melinda Gates Foundation.