BREAK OUT SESSION:
Comprehension and the Informed Consent Discussion

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Learning Objectives

I. Difficult concepts
Review difficult informed consent concepts for individuals to understand

II. How are we doing?
Discuss how these concepts are typically presented in the informed consent conversation

II. How can we do better?
Work with a small group to develop, practice, and test innovative strategies to present difficult concepts from real consent forms
Understanding of randomization

Randomization is a particularly hard concept for people to understand.

How do we usually do this?

How well do we usually do this?

Can we think outside the box and do better?
How do we usually do this?

How have you seen randomization described?
How well do we usually do this?

- Uganda pediatric malaria tx
  - Pace et al. 2005

- US IDUs, HIV vaccine
  - Harrison et al. 1995

- Finnish women, breast cancer
  - Hietanen 2000

- Thai HIV tx
  - Pace et al. 2005

- U.S. men heart attack
  - Howard 1981

Understanding of randomization
Understanding of placebo

10% of Gambian mothers understood placebo design for vaccine trial

Leach et al. 1999

67% of US participants in rheumatoid arthritis trial knew some people would get a placebo

- 50% knew they may not get active drug
- 53% knew treatment would not be decided based on symptoms

Criscione et al. 2003
Doing better: Some strategies

- Clarify what is not happening
- Use examples that are more realistic
- Incorporate visuals
Doing better: Some strategies

Study in Malawi randomized women to intervention to improve understanding (n=36)

- Vignettes
- Asking patients to repeat in their own words, explain to others
- Neutral team to present

Results:

- 13/18 women in intervention arm obtained above 75%
- No one in the control arm obtained this level

Ndebele et al. 2012
Your turn

Small groups

Get in groups of 2-3

30-minute sample case

Using sample consent randomization language, discuss how to present it and how to test it

Optional sample case

If you have extra time, test your strategy using the next numbered sample randomization language

Share back

Each group shares their strategy for the sample language and what they did with it
Conclusions

I. Randomization and placebo are difficult concepts to understand

II. Creating strategies to better describe these strategies as part of the consent conversation promotes comprehension
Any questions, consultation, or discussion from any part of the course?
## Understanding of voluntariness

<table>
<thead>
<tr>
<th>Study population</th>
<th>% who felt pressure</th>
<th>Cite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiology and oncology studies in US (n=570)</td>
<td>2%</td>
<td>ACHRE 1996</td>
</tr>
<tr>
<td>Dutch parents in anticonvulsant study</td>
<td>25%</td>
<td>Van Stuijvenberg 1998</td>
</tr>
<tr>
<td>Ugandan parents in malaria tx trial</td>
<td>15% from others; 58% from child’s illness</td>
<td>Pace et al. AJPH 2005</td>
</tr>
</tbody>
</table>
**Case about voluntariness**

**TABLE 3—Perceptions of Consent Given for Participation in Informed Consent Study: Evaluation Study Group vs Sensitization Control Group of Antenatal Clinic Attenders in Durban, South Africa**

<table>
<thead>
<tr>
<th>Question</th>
<th>Study Group (n = 56)</th>
<th>Controls (n = 56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Did you agree to have an HIV antibody test?</td>
<td>88</td>
<td>93</td>
</tr>
<tr>
<td>Do you want to know your HIV test result?</td>
<td>86</td>
<td>91</td>
</tr>
<tr>
<td>Did you feel you were compelled to participate in the study?</td>
<td>84</td>
<td>93</td>
</tr>
<tr>
<td>Will care be compromised if you do not participate?</td>
<td>32</td>
<td>23</td>
</tr>
<tr>
<td>Having agreed to participate in the study, do you think that you have the freedom to quit the study at any time?</td>
<td>93</td>
<td>88</td>
</tr>
<tr>
<td>Will the hospital allow you to quit?</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

*Abdoool-Karim Q, et al. AJPH 1998*
Questions

What could **explain** these responses?

What should the research team in this study **have done** with these findings?

How could you **explain** voluntariness better?

What does this suggest about doing **research** on informed consent in general?