

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?

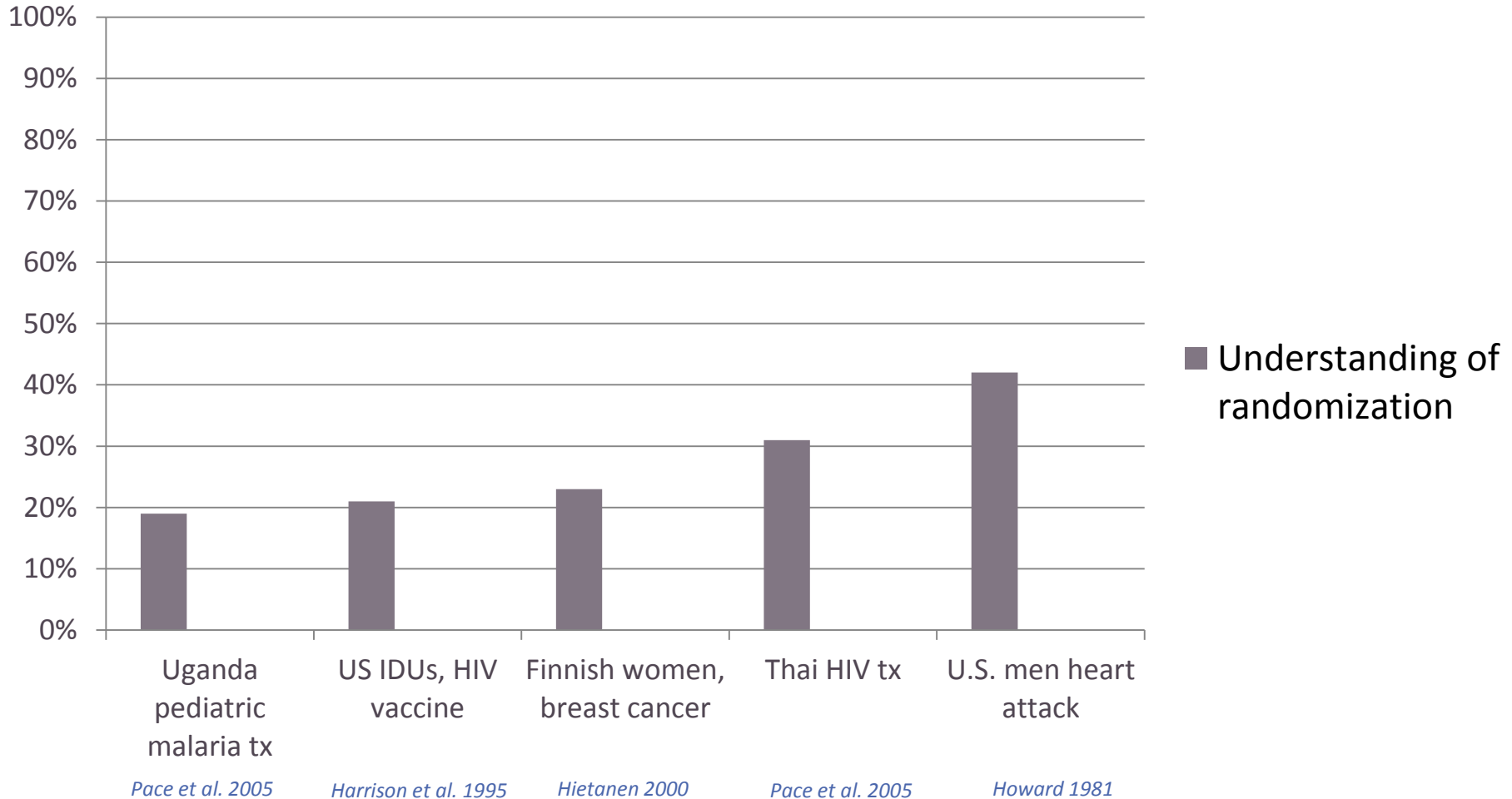
Can we think outside the box and do better?

How do we usually do this?



How have you seen randomization described?

How well do we usually do this?



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)

Minda ya alimi ndi mbewu zomwe anakolola



Slide showing results from different potato plots.

- 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

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

Questions/consultation/discussion

Any questions, consultation, or discussion from any part of the course?



Understanding of voluntariness



Study population	% who felt pressure	Cite
Cardiology and oncology studies in US (n=570)	2%	ACHRE 1996
Dutch parents in anticonvulsant study	25%	Van Stuijvenberg 1998
Ugandan parents in malaria tx trial	15% from others; 58% from child's illness	Pace et al. AJPB 2005

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

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

Abdool-Karim Q, et al. AJP 1998

Questions

