UBC REB Retreat

Issues with Informed Consent
Perspectives on Change

Dr. Marc Levine
Dr. John Russell

Oct. 21, 2015

UBC REB Retreat

Outline

- What are perceived problems with informed consent?
- Is there evidence these affect the consent process?
- Do interventions improve the consent process?
- What type(s) of interventions might be beneficial?

- What **could** UBC REBs do?
- What **should** UBC REBs do?

Some perceived problems with **informed consent process** – supported by evidence

Participants often:

1. are **unaware** they are being enrolled in research
2. **do not understand the aim** of the study
3. experience **therapeutic misconception**
4. have **poor understanding of randomization**
5. have **poor understanding of benefits and risks**; misunderstand voluntarism
6. find **consent forms too long and complex**
7. have difficulty with **language level/literacy**

Some evidence for problems with informed consent:

Flory J, Emanuel E. Interventions to improve research participants' understanding of informed consent for research. **JAMA 292 (13): 1593-1601, 2004**

Falagas ME, et al. Informed consent: how much and what do patients understand? **Am J Surg 198: 420-35, 2009**

Nishimura A, et al. Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials. **BMC Med Ethics 14:28, 2013**

Kass NE et al. A pilot study of interventions to improve informed consent in clinical research: feasibility, approach and results. **Clin Trials 12 (1): 54-66, 2014**

The Moral Problem with ICFs

- They are not participant-centred.
  - Reflect stakeholders' interests and concerns
    - Sponsors, researchers, REBs, lawyers, ethicists, regulators, local hospitals, universities
  - Are ostensibly prepared to convey relevant information to potential participants
  - But really reflect a conversation among stakeholders about appropriate ethical standards for particular research

The Elephant in the Room

- Some Conclusions
  - Consent forms contain too much information
  - The information is not accessible
  - Important information is overwhelmed by *technical* and *formal* detail
  - The information is often too nuanced to be appreciated
  - Are well beyond the literacy (and stamina) of average readers
  - If fully explained, demand too much of researchers to communicate

More of the Elephant…

- ICFs are often made more complex by REB review
- Are a challenge to administer in light of practical realities
- Undermine participant and researcher commitments to a meaningful consent process

Does altering the informed consent process make a difference?

Nishimura *et al. BMC Medical Ethics* 2013, **14**:28
http://www.biomedcentral.com/1472-6939/14/28

BMC Medical Ethics

RESEARCH ARTICLE Open Access

Improving understanding in the research informed consent process: a systematic review of 54 interventions tested in randomized control trials

Adam Nishimura[1], Jantey Carey[2,4], Patricia J Erwin[2], Jon C Tilburt[2,3,5], M Hassan Murad[2,3,4] and Jennifer B McCormick[2,3,5*]

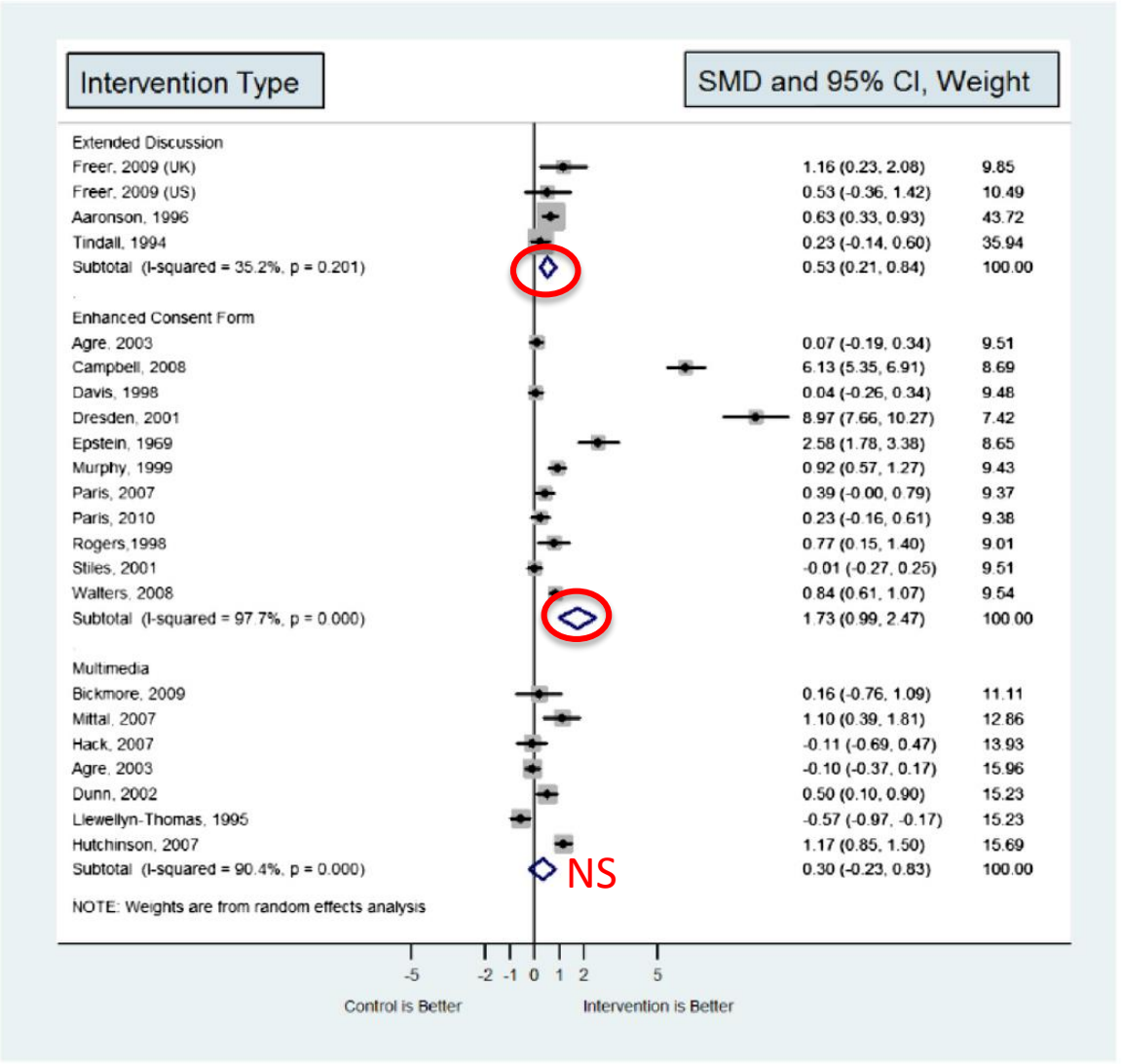
Conclusions: Enhanced consent forms and extended discussions were most effective in improving participant understanding. Interventions of all categories had no negative impact on participant satisfaction or study accrual. Identification of best practices for studies of informed consent interventions would aid future systematic comparisons.

Does altering the informed consent process make a difference?

Enhanced Discussion

Enhanced ICF

Multimedia



Nishimura A, et al. **BMC Med Ethics 14:28, 2013**

Types of enhancement of ICFs:

- Simplified paper document
- Grade 6-7 reading level
- Font type
- Font size
- Use of illustrations
- Colour

Types of extended discussion:

- Standardized **focus groups**
- Supplementary standardized discussion with **staff**
- Supplementary discussion with **nurse**
- Supplementary discussion with **enrolling physician**
- Uniform/standardized disclosure of information by **physicians**

Some limitations of the evidence:

- Use of simulation *vs* actual studies (altered effect)
- Substantial variability in assessment methods and other design features
- Assessing information retention *vs* understanding
- Most data from RCTs
- Substantial heterogeneity in meta-analyses
- Major differences in design of studies (standard approaches not developed)

What **could** UBC REBs do?

Consider piloting a simplified consenting process – with consideration of studies such as:

Clinical Trials
2015, Vol. 12(1) 54–66

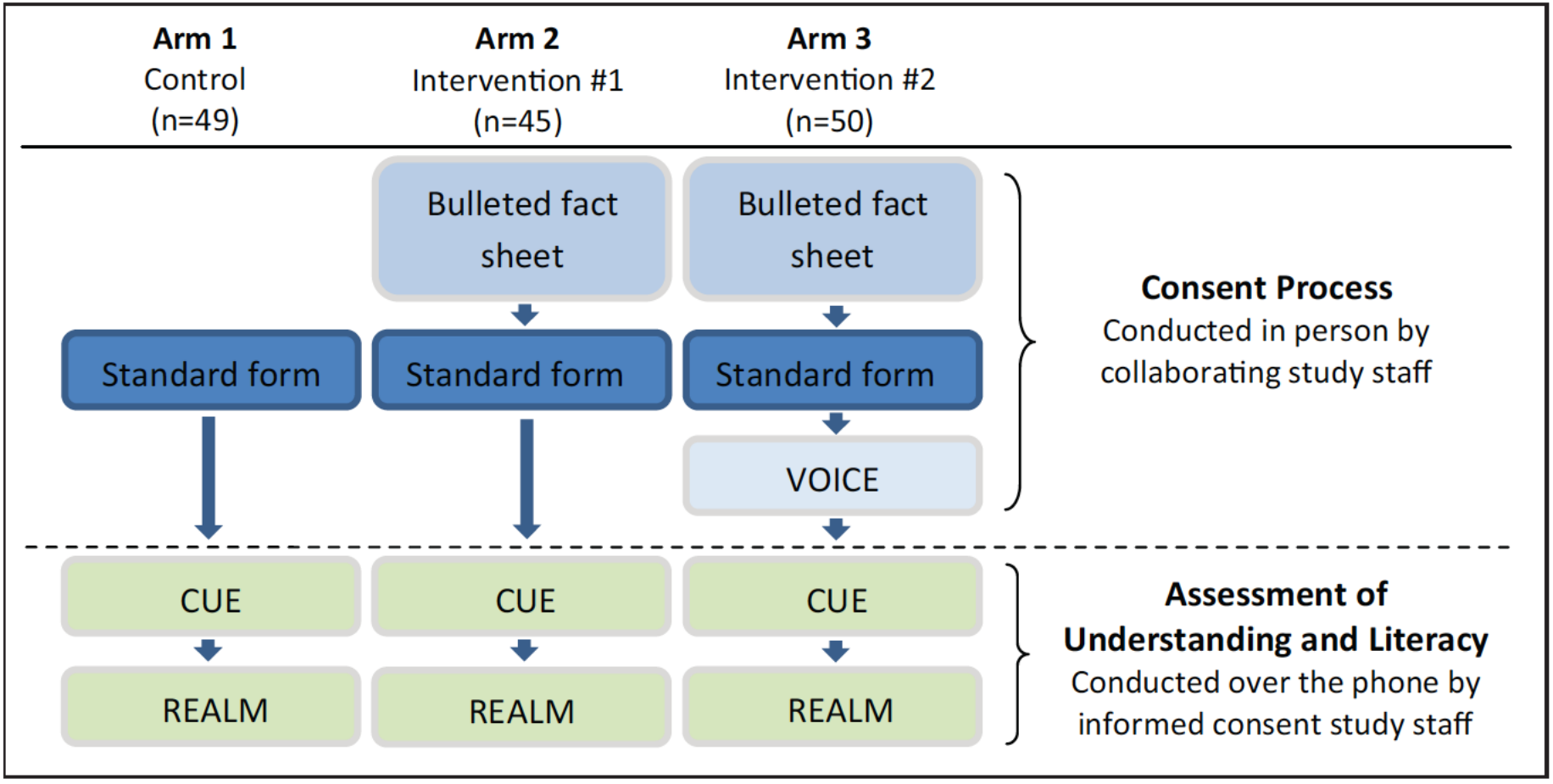
DOI: 10.1177/1740774514560831
ctj.sagepub.com
SAGE

A pilot study of simple interventions to improve informed consent in clinical research: Feasibility, approach, and results

Nancy E. Kass[1,2], Holly A. Taylor[1,2], Joseph Ali[1], Kristina Hallez[1] and Lelia Chaisson[3]

Conclusions: Our study supports the hypothesis that patients receiving both bulleted fact sheets and a Q&A session had higher understanding compared to standard consent. Fact sheets and short structured dialog are quick to administer and easy to replicate across studies and should be tested in larger samples.

Pilot study design



Clin Trials 12 (1): 54-66, 2014

Verbalization of informed consent essentials (VOICE)

Topic area	Question
Purpose	"If you were going to tell a friend what this study was about, what would you say?"
Procedures	"What are the main things you will do or will happen to you while you are in this study?"
Randomization	"Does everyone in this study have to do the same thing?"
	"Tell me in your own words how the researchers will decide whether you get the [intervention] or the [usual care]?"
Risks	"What are the risks, or bad things that might happen to you if or when you join this study?"
Benefits	"What are the benefits, or good things that might happen to you if or when you join this study?"
Voluntariness	"What will happen if you decide you don't want to be in the study?"
	"What can happen if you decide to be in the study but later change your mind?"

Figure 1. VOICE instrument.

Consent understanding evaluation (CUE)

CUE Question	Correct Response	Scoring
"What are the main things you will do or that will happen to you while you are in the research study they discussed with you today?"	• Tests (breathing/lung function, blood pressure, x-ray, CAT scan, questionnaire) • Multiple follow-up visits	Mentioning at least one type of test or need to come back for follow-up visits gets full credit
"What does the word 'placebo' mean to you?"	• Placebo = sugar pill, fake pill, pill that looks just like the medicine under study.	Must answer with any one of the correct responses (or equivalent) for full credit.
"How is it that the researchers decide whether you get the placebo or not?"	• Random assignment • Computer assignment	Must answer with one of the correct responses (or equivalent) for full credit.

Figure 4. Example of scoring criteria for open-ended CUE questions.

What **should** UBC REBs consider doing? (for discussion)

- Inform researchers of the current trend toward modifying consent forms and process
- Invite participation from interested PIs
- Pilot use of shortened, simplified consent form across a number of studies (**maximum 3 pages**)
- Use methods derived from some of the better, current studies
- Evaluate participant experience and understanding
- **Create a working group**

Issues to consider:

- Company-sponsored *vs* investigator-driven RCTs
- Observational studies *vs* RCTs
- Clinical *vs* behavioural studies
- Registries
- Tissue banks
- Mandatory/optional future uses of data &/or tissue

Dealing with complicating issues, e.g.:

- Vulnerable participants (children, disadvantaged, mentally ill, reduced literacy, etc.)
- Incidental findings
- Genetic research possibly affecting others

The Basic Elements (for discussion)

1. Reason for the study (combine background and purpose)
2. Procedures
3. Potential Risks and Benefits
4. Confidentiality
5. Transition out of study
6. Deviations from standard research ethics practice disclosed
7. Bulleted summary list with links to supplemental information

- Omitted
  - Voluntariness statements (entailed by IC process)
  - Exclusions
  - Most Potential Conflicts
  - Lengthy confidentiality disclosures
  - Alternative treatments
  - Participant responsibilities
  - Being asked to leave study
  - Reference to optional studies, including consent to be contacted for future studies
  - Others?
- Kass et al: “less is more’’...