

# A Case Study of Democratic Deliberation in Bioethics: Surrogate Consent for Dementia Research

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# Outline

- One way of using democratic deliberation (DD) in bioethics: consulting the public's moral opinions.
- Brief case study: Surrogate consent for dementia research

# Normative opinion survey

- Premise: the public's values should, in some way, be reflected in policies
  - i.e., public's moral views have normative weight
- But how do you measure public's views on morally complex issues?

# Normative Opinion Surveys: Challenges

- ***Informational*** challenges:
  - Complex scientific, legal, historical and ethical dimensions
  - Need for unbiased, accurate, reasonably comprehensive information
- Eliciting quality judgments
  - How can we obtain ***considered*** moral opinions?

# Surrogate Consent for Dementia Research

- An excellent topic for using DD methods:
  - Unsettled policy, but with very large public health implications
  - Complex scientific, ethical, social, and historical issues
  - Public has not been engaged in the specific ethics debate

# Our framework for using DD

- Pair with a nationally representative survey (Kim et al. Neurology 2009; Tomlinson et al 2015)
- Experimental design to measure effect of democratic deliberation (Kim et al., JERHRE 2009)
- Both quantitative (Kim et al Neurology 2011, PLOS One 2013) and qualitative outcomes. (DeVries et al, AJGP 2013)
- Assess and report quality of deliberation (De Vries et al 2010, 2011)

# Brief overview of DD study

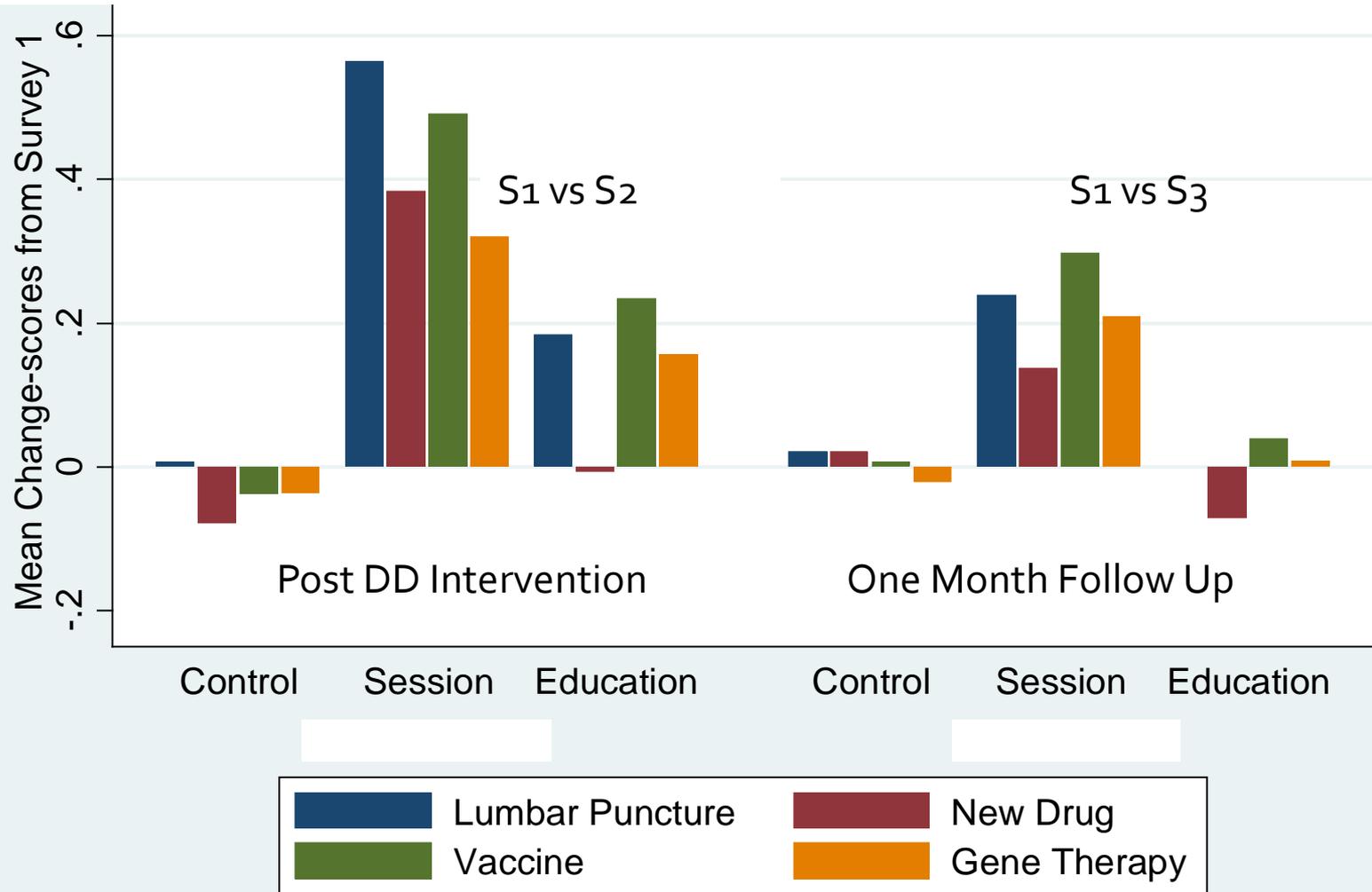
- Opinions on 4 research scenarios: Lumbar Puncture, Drug RCT, Vaccine, Gene Transfer
  - "...should our society allow their families to make the decision in their place?"
- General public, aged 51 or over within about 60 mile radius of Ann Arbor, Michigan, USA
- 3 arms, randomized: N=503
  - Control group: surveys only
  - Education group: educational materials + surveys
  - DD group: participate in deliberation session + surveys
- Surveyed 3 times
  - S1: One month before DD session day; before randomization
  - S2: End of DD session (approx for Control and Education groups)
  - S3: About one month after DD session day

**Knowledge Questionnaire:** 17 item “quiz” regarding AD, AD clinical research, and ethical issues in AD research.

|          | Control group, Mean (SD) | Education only, Mean (SD) | DD group, Mean (SD) | Between-groups, ANOVA p-value |
|----------|--------------------------|---------------------------|---------------------|-------------------------------|
| Survey 1 | 11.4 (2.5)               | 11.3 (2.7)                | 11.5 (2.6)          | .855                          |
| Survey 2 | 11.5 (2.5)               | 14.4 (2.6)                | 14.5 (2.3)          | <.001                         |
| Survey 3 | 11.5 (2.9)               | 13.3 (2.9)                | 14.1 (2.6)          | <.001                         |

**Both the education group and the DD group improved their understanding of issues; effect is seen even one month after DD session.**

# Change in Willingness to Allow Family Consent for Dementia Research



Scale: 1=definitely not allow, 2=probably not allow, 3=probably allow, 4=definitely allow

S1=baselines survey; S2=survey post DD or education; S3=one month follow up

# DD participants have a positive view of their experience (N=160)

|   | Mean (SD) |
|---|-----------|
| Do you feel that your opinions were <b>respected</b> by your group?   | 9.4 (1.1) |
| Do you feel you were <b>listened to by your facilitator</b> ?   | 9.7 (0.7) |
| Do you feel that the process that led to your groups' responses was <b>fair</b> ?                                 | 9.7 (0.7) |
| How willing are you to <b>abide by the group's final position</b> , even if you personally have a different view? | 8.8 (2.3) |

(Response scale: 1=Not at all, 10= Very Much)

# Key Limitations

- External validity (overall response rate 21%)
  - Participation takes full day commitment
    - Compared with decliners:
      - younger (63 vs 66),
      - related to/friends with person with dementia (71% v 43%)
      - caregiver/decision-maker for someone w dementia (23% vs 17%)
  - Especially important for bioethics issues that engage institutional trust (e.g., biobanking)?
- Expensive, with many moving parts!

# Conclusions

- Democratic deliberation has a strong effect on views regarding surrogate consent for research.
- Effect is not due to mere increase in knowledge.
- Process seen as fair and trustworthy by participants.
- Qualitative analysis generally validates high quality of deliberation and reasoning.

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  - David Knopman
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  - Ian Wall





# Change in Attitude toward Surrogate Consent for Research: DD Group

|                        | Survey 1<br>(n=212) | Survey 2<br>(n=173) | Survey 3<br>(n=168) | Survey<br>1v2 | Survey<br>1v3 |
|------------------------|---------------------|---------------------|---------------------|---------------|---------------|
| <b>Lumbar Puncture</b> | %                   | %                   | %                   | p-value       | p-value       |
| Definitely Not Allow   | 5.2                 | 0.6                 | 3.0                 | <0.001        | 0.001         |
| Probably Not Allow     | 9.4                 | 3.5                 | 5.4                 |               |               |
| Probably Allow         | 50.9                | 19.1                | 41.1                |               |               |
| Definitely Allow       | 33.0                | 76.3                | 50.6                |               |               |
| <b>New Drug RCT</b>    | %                   | %                   | %                   | p-value       | p-value       |
| Definitely Not Allow   | 1.9                 | 0.6                 | 1.8                 | <0.001        | 0.008         |
| Probably Not Allow     | 3.8                 | 2.3                 | 2.4                 |               |               |
| Probably Allow         | 56.1                | 21.4                | 42.9                |               |               |
| Definitely Allow       | 37.7                | 75.7                | 53.0                |               |               |
| <b>Vaccine</b>         | %                   | %                   | %                   | p-value       | p-value       |
| Definitely Not Allow   | 9.9                 | 7.5                 | 7.1                 | <0.001        | <0.001        |
| Probably Not Allow     | 24.5                | 12.7                | 13.7                |               |               |
| Probably Allow         | 46.2                | 28.3                | 45.2                |               |               |
| Definitely Allow       | 18.9                | 50.9                | 33.9                |               |               |
| <b>Gene Transfer</b>   | %                   | %                   | %                   | p-value       | p-value       |
| Definitely Not Allow   | 17.5                | 16.2                | 14.9                | <0.001        | 0.002         |
| Probably Not Allow     | 26.4                | 16.8                | 17.9                |               |               |
| Probably Allow         | 38.7                | 26.6                | 36.9                |               |               |
| Definitely Allow       | 17.0                | 40.5                | 29.8                |               |               |