Right for Me
A hybrid effectiveness-implementation trial to embed contraception shared decision-making in routine care

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Disclosures

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What is shared decision making?
Shared decision making

Patient decision aids can support people in making complex choices

1. Explicitly state the decision that needs to be considered;

2. Provide evidence-based information about a health condition, the options, associated benefits, harms, probabilities, and scientific uncertainties;

3. Help patients to recognize the values-sensitive nature of the decision and to clarify, either implicitly or explicitly, the value they place on the benefits and harms.

Stacey et al, Cochrane Library 2017
Patient decision aids

Compared to usual care, decision aids improve patient-centred outcomes:

- Higher knowledge****
- Reduced decisional conflict****
- More accurate risk perceptions***
- Being more active in decisions***
- Better match between values and choices**
- Reduced over- and under-use of elective surgery

**** High quality evidence
*** Moderate
** Low

Stacey et al, Cochrane Library 2017
Hybrid Trial Type 2 Design

Co-primary question
Will an intervention work in this setting/these patients?

Co-primary question
Does the implementation method show promise (either alone or in comparison with another method) in facilitating implementation of an intervention?

Curran “Effectiveness-implementation Hybrid Designs” (2012)
**Methods**

**Design & Setting**

- 2 x 2 factorial cluster randomized trial
- 16 primary care and family planning clinics in New England
- 4 clinics per trial arm

**Arm 1**
- Video + Prompt Card

**Arm 2**
- Decision Aids + Training

**Arm 3**
- Video + Prompt Card
- Decision Aids + Training

**Arm 4**
- Usual Care
### Types of Birth Control Methods

This decision aids you and your health care provider talk about methods of birth control and choose what's right for you. Most people can safely use these methods. Your health care provider can tell you whether these methods are safe for you.

#### What are they?
- Birth control methods that are placed by a health care provider and last between 3 and 10 years.
- Birth control methods that are used every day, every week, every 2 weeks, or every 3 months.
- Birth control methods that are used every time you have sex.
- Birth control methods that do not involve any hormones or devices.
- Birth control methods that involve a procedure to close off the tubes that carry eggs or sperm.
- Birth control methods that are used after unprotected sex.

#### What are the options?

<table>
<thead>
<tr>
<th>Long-Acting</th>
<th>Short-Acting</th>
<th>Barrier</th>
<th>Natural</th>
<th>Permanent</th>
<th>Emergency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant</td>
<td>Injection</td>
<td>Condom</td>
<td>Male Condom</td>
<td>Withdrawal Method</td>
<td>Female Sterilization</td>
</tr>
<tr>
<td>Hormonal IUD</td>
<td>Intrauterine Progestin Pill</td>
<td>Female Condom</td>
<td>Female Condom</td>
<td>Female Sterilization</td>
<td>By Laparoscopy</td>
</tr>
<tr>
<td>Copper IUD</td>
<td>IUD</td>
<td>Spreads</td>
<td>Female Condom</td>
<td>Female Sterilization</td>
<td>By Hysterectomy</td>
</tr>
<tr>
<td></td>
<td>Patch</td>
<td>Sponge</td>
<td>Female Condom</td>
<td>Female Sterilization</td>
<td>Male Sterilization</td>
</tr>
<tr>
<td></td>
<td>Ring</td>
<td>Contraceptive Cap</td>
<td>Female Condom</td>
<td>Female Sterilization</td>
<td>Vasectomy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DepoProvera</td>
<td>Female Condom</td>
<td>Female Sterilization</td>
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</table>

#### Who might choose them?

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<tbody>
<tr>
<td>People who want or are comfortable with:</td>
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<td>People who want or are comfortable with:</td>
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<tr>
<td>Almost no chance of pregnancy (fewer than 1 in 100 people become pregnant in the first year)</td>
<td>Some chance of pregnancy (1 in 10 people become pregnant in the first year)</td>
<td>A higher chance of pregnancy (3 in 10 people become pregnant in the first year)</td>
<td>A method they need to remember</td>
<td>A method that does not involve birth control devices</td>
<td></td>
</tr>
<tr>
<td>A method they can use</td>
<td>A method they need to remember</td>
<td>A method they need to remember</td>
<td>A method that does not involve birth control devices</td>
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<td></td>
</tr>
<tr>
<td>A procedure to start and also using the method</td>
<td>A non-hormonal method</td>
<td>A method that does not involve birth control devices</td>
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<tr>
<td>Almost no chance of pregnancy (fewer than 1 in 100 people become pregnant in the first year)</td>
<td>A method they can forget about</td>
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<tr>
<td>A procedure</td>
<td>A method that does not involve birth control devices</td>
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<td>Uterine TIP</td>
<td>Vasectomy</td>
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<td>Male Sterilization</td>
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<td>Progestin-Emergency Pill</td>
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When defining implementation science, some non-scientific language can be helpful

**INTERVENTION**
The intervention/practice/innovation is **the thing**

**EFFECTIVENESS**
Effectiveness research looks at whether **the thing works**

**IMPLEMENTATION**
Implementation research looks at how best to help people/places **do the thing**

**STRATEGIES**
Implementation strategies are **the stuff we do** to try to help people/places **do the thing**

**OUTCOMES**
Main implementation outcomes are **how much and how well** they do the thing

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| 1. Video + prompt card | Do the tools improve shared decision-making for contraceptive choices? | What helps care providers and administrators to use the tools? | • Educational materials  
• Champions  
• Essential vs. adaptable components | • Acceptability  
• Feasibility  
• Sustainability |
| 2. Decision aids + training | | | | |

Outcomes

Effectiveness Outcomes

*Primary*
- Shared decision-making about contraceptive methods in the health care visit using the CollaboRATE measure

*Secondary*
- Contraceptive conversation
- Satisfaction with conversation
- Contraceptive method(s) used
- Decisional regret
- Contraceptive satisfaction
- Contraceptive adherence
- Unintended pregnancy & more

Implementation Outcomes

*Primary*
- Acceptability, feasibility, and sustainability of two shared decision-making interventions in contraception counselling, using the **Theoretical Domains Framework**

What strategies would clinics use, in what circumstances, why, and to what effect?
Design
Qualitative study embedded within a 2x2 factorial cluster randomized controlled trial.

Participants
Clinical and administrative staff (n=29) who worked in one of the 12 intervention arm clinics in the northeastern United States.

Data Collection and Analysis
Semi-structured phone interviews following completion of intervention implementation.

Theoretical Approach
The Theoretical Domains and COM-B informed data collection and thematic analysis.
Key factors that facilitated implementation among clinicians and staff (n=29) included:

**Capability**
- Being aware of the intervention(s)
- Knowing how to use them correctly through training and/or practice
- Forming a plan to implement them

**Opportunity**
- Clinic workflow, time, and physical space
- Integrating the intervention(s) with other counseling resources
- Having a supportive organizational culture for shared decision-making

**Motivation**
- Believing that using the interventions enhances shared decision-making with patients
- Seeing a positive impact from patients and clinical and administrative staff engaging with the interventions

Analysis suggests that these factors informed participant perceptions that the decision aids were more acceptable, feasible, and sustainable than the video and prompt cards.
RESULTS: Feasibility and Acceptability

Changing one’s behaviour to engage in the new practice of using the interventions

“I mean I think the biggest challenge is just changing the behavior of the people who are interacting with [patients] to incorporate one more thing.”

Participant 19, Clinic 5, Clinical role, Video + prompt card
RESULTS: Feasibility and Acceptability

Social influence of interpersonal processes with patients

“I would say that the majority of [patients] that come into the waiting room are on their own phones and computers and are not really looking around.”

Participant 27, Clinic 5, Clinical role, Video + prompt card
KEY TAKEAWAYS

• The implementation study provided critical information on the factors that impacted the effectiveness of the tools in different settings – what works, for whom, and in what contexts.

• These data helped us to identify:
  • The video and prompt card need structured implementation strategies in order to be effective (e.g. introduce by email)
  • The paper-based decision aids fit the norms of routine workflow for contraception decision making (e.g. Planned Parenthood)

• Trial designers should consider hybrid designs as a strategy to accelerate implementation
Investigation of factors influencing the implementation of two shared decision-making interventions in contraceptive care: a qualitative interview study among clinical and administrative staff

Sarah Munro1,2, Ruth Manski3, Kyla Z. Donnelly4, Daniela Agusti5, Gabrielle Stevens4, Michelle Banach6, Maureen B. Boardman4, Pearl Brady7, Chrissy Colón Bradt8, Tina Foster9, Deborah J. Johnson4, Judy Norsigian10, Melissa Nothnagle11, Heather L. Shepherd12, Lisa Stern13, Lyndal Trevena12, Glyn Elwyn4 and Rachel Thompson12
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Future work

How do we support shared decision-making in the context of free prescription contraception?
Thank you!

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