From theory to implementation: attempting to reduce complexity in the development of a complex intervention

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Presentation outline

• Background
• An exemplar project
• Reflections
Background I

• **Challenges of medication use in older people**
  – Altered pharmacokinetics/pharmacodynamics
  – Multimorbidity
  – **Polypharmacy**
  – Potentially inappropriate prescribing

• **Changing perspectives on polypharmacy**
  – Many drugs (appropriate)
  – Too many drugs (inappropriate)
  – How to get the balance right (appropriate polypharmacy)
  – Intervention to promote appropriate polypharmacy?
Background II

• Developing interventions
  – Older people (community-dwelling)
  – Older people (nursing homes)
  – Heart failure
  – Asthma

• Basis of the intervention?
  – Pragmatism; literature; what we thought might work
  – ISLAGIATT
Medical Research Council Framework

Feasibility and Piloting
- Testing procedures, estimating recruitment, sample size

Evaluation
- Assessing effectiveness and cost-effectiveness, understanding change process

Development
- Evidence, theory, modelling

Implementation
- Dissemination, surveillance and monitoring, long-term follow-up
Interventions to improve the appropriate use of polypharmacy for older people (Patterson et al. 2014)

- Intervention development lacked detailed description.
- Evidence for effectiveness of identified interventions was weak.
Moving through the MRC framework

- **Development**
  - Evidence, theory, modelling

- **Feasibility and Piloting**
  - Testing procedures, estimating recruitment, sample size

- **Implementation**
  - Dissemination, surveillance and monitoring, long-term follow-up

- **Evaluation**
  - Assessing effectiveness and cost-effectiveness, understanding change process
Theory

A system of ideas or statements held as an explanation or account of a group of facts or phenomena

Allows researchers to generate testable hypotheses and explore potential causal mechanisms underlying an intervention’s effect
Theory-Theoretical Domains Framework

- 12 theoretical domains relevant to changing healthcare professionals’ behaviour.

<table>
<thead>
<tr>
<th>Theoretical domains</th>
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</thead>
<tbody>
<tr>
<td>Knowledge</td>
</tr>
<tr>
<td>Skills</td>
</tr>
<tr>
<td>Beliefs about capabilities</td>
</tr>
<tr>
<td>Emotion</td>
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<tr>
<td>Beliefs about consequences</td>
</tr>
<tr>
<td>Behavioural regulation</td>
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<tr>
<td>Motivation and goals</td>
</tr>
<tr>
<td>Social influences</td>
</tr>
<tr>
<td>Memory, attention and decision processes</td>
</tr>
<tr>
<td>Environmental context and resources</td>
</tr>
<tr>
<td>Social/professional role and identity</td>
</tr>
<tr>
<td>Nature of the behaviours</td>
</tr>
</tbody>
</table>
## Selected TDF domains

<table>
<thead>
<tr>
<th>Domain label</th>
<th>Domain content</th>
<th>Domain Constructs</th>
</tr>
</thead>
</table>
| Knowledge                                | Knowledge of the field (i.e. whether there is adequate evidence) and individuals’ knowledge of the evidence or of a guideline | Knowledge; Procedural knowledge  
Knowledge about condition/ scientific rationale  
Schemas + mindsets + illness representations |
| Skills                                   | Covers the possibility that new skills would be required by the staff who are required to implement a new procedure | Skills; Interpersonal skills  
Competence/ ability/ skill assessment  
Practice/ skill development  
Coping strategies |
| Social/professional role and identity    | The clinical thinking and norms of a particular profession                     | Identity  
Professional identity/ boundaries/role  
Group/social identity  
Social/ group norms  
Alienation/organisational commitment |
| Beliefs about capabilities               | How confident clinicians are that they could change their practice effectively | Self-efficacy  
Control-of behaviour and material and social environment  
Perceived competence  
Self-confidence/ professional confidence  
Empowerment; Self-esteem  
Perceived behavioural control  
Optimism/pessimism |
TDF-based interview studies

- Interview guides developed based around the domains
  - Identify domains which are perceived to act as barriers to, and facilitators of, behaviour change
  - ‘Mechanism of action’

- Used to guide intervention design, based on changing target behaviour(s)
Changing behaviour

- Target key domains as part of intervention using established **behaviour change techniques (BCTs)**
  - Can map from TDF domains to appropriate BCTs
- “An observable, replicable and irreducible component of an intervention designed to alter or redirect causal processes that regulate behaviour”
- BCTs are the basis of the intervention
  - ‘Active ingredients’
## Examples of BCTs

<table>
<thead>
<tr>
<th>BCT</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal-setting</td>
<td>Set or agree a goal defined in terms of the behaviour to be achieved</td>
<td>Set a goal with patients of taking all medicines as prescribed</td>
</tr>
<tr>
<td>Prompts and cues</td>
<td>Introduce or define environmental or social stimulus with the purpose of prompting or cueing the behaviour. The prompt or cue would normally occur at the time or place of performance</td>
<td>Place a Post-it® note on the door to remind patients to take medicines before leaving the house in the morning</td>
</tr>
<tr>
<td>Self-monitoring</td>
<td>Instruct self-recording of specified behaviour</td>
<td>Request patients to note each time they take their medicines in a diary</td>
</tr>
</tbody>
</table>
Link between TDF and BCTs

If the TDF provides a means of identifying the theoretical determinants of behaviour, i.e., the “mechanism of action” of a behaviour change intervention, BCTs represent the content of the intervention, i.e., its “active ingredients”
Overview of approach

An illustrative example

1. Who needs to do what differently?

- GPs’ compliance with guidelines
  1. Plain film x-ray ordering
  2. Advise patients to remain active

- Low awareness of key guideline messages
- Beliefs about consequences of complying

1. Awareness [Knowledge]
2. Beliefs

- Provide information
- Persuasive communication

Project aim and objectives

Aim
- To develop an intervention to improve appropriate polypharmacy in older patients in primary care.

Project phases and objectives
1. Update of Cochrane review
2. Qualitative interviews
3. Develop intervention
4. Test feasibility of intervention
Moving through the MRC framework

Feasibility and Piloting
Testing procedures, estimating recruitment, sample size

Development
Evidence, theory, modelling

Evaluation
Assessing effectiveness and cost-effectiveness, understanding change process

Implementation
Dissemination, surveillance and monitoring, long-term follow-up
Method

Series of systematic steps

1. Identify evidence (Cochrane review)

2. Specify target behaviour(s)
   Prescribing, dispensing....... (qualitative interviews)

3. Identify mediators of behaviour change through the TDF

4. Map theoretical domain to BCTs

5. Operationalise BCTs

6. Conduct feasibility screening

7. Undertake feasibility study
Qualitative interview phase

Aim

• To identify key theoretical domains that influenced the target behaviours (prescribing and dispensing)

• To map key domains to behaviour change techniques
Method (Steps 2 -4)

Sampling
• General practices and community pharmacies from each Health and Social Care Trust area (n=5) in Northern Ireland

Data collection
• Semi-structured interviews (TDF-based topic guides)
• Similarities between those used for GPs and community pharmacists
Sample interview questions

Knowledge

“What knowledge do you have as a GP/pharmacist that would help you to make the necessary changes to ensure that patients receive appropriate polypharmacy as opposed to inappropriate polypharmacy?”

Social/professional role and identity

“What would you consider your responsibilities to be as a GP/pharmacist in ensuring that older patients receive appropriate polypharmacy?”
Analysis and mapping

• Analysis: framework method and content analysis
  • Framework-mapping to the TDF domains
  • Content analysis of the framework analysis; identification of barriers and facilitators

• Selection of key domains
  • Based on analyses, identified domains most relevant to possible target behaviours; consensus within team

• Mapping of domains to BCTs
  • Based on Cane et al. (2015); demonstrated which BCTs mapped reliably to TDF
    – Some domains are associated with very few BCTs
# Results

<table>
<thead>
<tr>
<th>Gender</th>
<th>GPs</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>10</td>
<td>7</td>
</tr>
<tr>
<td>Female</td>
<td>5</td>
<td>8</td>
</tr>
</tbody>
</table>

**Professional experience**

<table>
<thead>
<tr>
<th>Years (range)</th>
<th>GPs</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 - 27</td>
<td></td>
<td>3 - 32</td>
</tr>
</tbody>
</table>

**Trust area**

<table>
<thead>
<tr>
<th>Trust area</th>
<th>GPs</th>
<th>Pharmacists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Belfast</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Southern</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>South-Eastern</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Northern</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Western</td>
<td>4</td>
<td>4</td>
</tr>
</tbody>
</table>
Results cont’d

Key domains

• Skills
• Beliefs about capabilities
• Beliefs about consequences
• Environmental context and resources
• Memory, attention and decision processes
• Social influences
• Social/professional role and identity
• Behavioural regulation

"...I would be confident about em... that I'd be able to pick up and have them on the right prescriptions, I think otherwise you shouldn't be working." GP4

"...it's a difficult thing to do, cos it's time consuming and there are time constraints." PCT2

"...something you have to keep an eye on where we’ve prescribed ..." GP1
Results cont’d

Mapping to BCTs

• Action planning
• Prompts/cues
• Modelling or demonstrating of behaviour
• Salience of consequences
Method

Series of systematic steps

1. Identify evidence (Cochrane review)

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   Prescribing, dispensing....... 

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6. Conduct feasibility screening

7. Undertake feasibility study
**Intervention development phase**

**Aim**

- To develop intervention approaches (using selected BCTs)
- To undertake feasibility screening
Method (Steps 5 & 6)

- Operationalise BCTs
  - Brainstorming exercise
  - What will the intervention look like?
  - Considered context, evidence and experience
- Conduct feasibility screening
  - APEASE criteria
    - Affordability
    - Practicability
    - Effectiveness and cost-effectiveness
    - Acceptability
    - Side-effects/safety
    - Equity
Results

• Three intervention approaches considered:
  – Patient-mediated intervention
  – GP-led intervention
  – Community pharmacist-led intervention

• Feasibility screening process:
  – Considered context, evidence and experience
  – Applied APEASE criteria
  – GP-led intervention selected for feasibility testing
The intervention and the target behaviour

• The intervention
  – Production of a video demonstrating a consultation between a GP and ‘older patient’
  – Actors (real GP!), script, filming
  – Video targeted at GPs
  – Made available through a secure web platform to be accessed by GPs

• The target behaviour
  – Prescribing (Medication review)
# BCTs embedded in the intervention

<table>
<thead>
<tr>
<th>BCT</th>
<th>Example of how the behaviour change technique is being operationalised as part of the intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action planning</strong></td>
<td>GPs will plan to perform medication reviews on the specified date when patients meeting inclusion criteria present at the practice for a scheduled appointment.</td>
</tr>
<tr>
<td><strong>Prompts and cues</strong></td>
<td>GPs will be prompted by the receptionist/practice manager to perform medication reviews with older patients meeting inclusion criteria when patients present for a scheduled appointment.</td>
</tr>
<tr>
<td><strong>Modelling or demonstrating of behaviour</strong></td>
<td>GPs will be provided with a video demonstration of how to perform a medication review with an older patient who is receiving polypharmacy.</td>
</tr>
<tr>
<td><strong>Salience of consequences</strong></td>
<td>As part of the video demonstration of how to perform a medication review, feedback will be included from the GP and ‘patient’ to emphasise the potentially positive consequences of performing the review.</td>
</tr>
</tbody>
</table>
Method

Series of systematic steps

1. Identify evidence (Cochrane review)
2. Specify target behaviour(s)
   Prescribing, dispensing......
3. Identify mediators of behaviour change through the TDF
4. Map theoretical domain to BCTs
5. Operationalise BCTs
6. Conduct feasibility screening
7. Undertake feasibility study
Feasibility study phase

Aim

• To undertake a short feasibility study using the developed intervention
Method (Step 7)

- Two general practices recruited
  - One rural, one urban
- Five patients per practice
- GPs viewed video
- Patients scheduled to attend an appointment
- GPs performed medication review
- Primary feasibility outcomes
  - Usability and acceptability of intervention
- Secondary feasibility outcomes
  - Data collection
  - Participant recruitment
Brief overview of results

- Recruited 4 GPs and 10 patients
- Intervention usable and acceptable
- Time issues in practice
- Patient feedback positive
- Did not lead to changes in prescribing polypharmacy or prescribing appropriateness
Strengths and limitations

**Strengths**

- Systematic approach to intervention development
- Analysis (rigorous-independent coding, health psychologist input)

**Limitations**

- Generalisability?
- Findings represent HCPs’ perceptions of influences on their clinical behaviour
Conclusions

• Have undertaken a systematic approach to intervention development

• Detailed, thorough, exhaustive (?)

• Time-consuming (but getting faster)
  – Balance between rigour and practical approach
  – Increasingly, funding bodies want to see this type of approach before supporting large studies

• **Important question**
  – Will this approach lead to a more effective intervention?
  – Moving to pilot phase in 2016
Research team

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