

# 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



Queen's University  
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- **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

Int J Clin Pharm  
DOI 10.1007/s11096-015-0180-6

COMMENTARY

## Development of a pharmacy practice intervention: lessons from the literature

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Received: 11 June 2015 / Accepted: 5 August 2015  
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**Abstract** The development of health interventions is receiving increasing attention within the scientific literature. In the past, interventions were often based on the ISLAGIATT principle: that is, 'It seemed like a good idea at the time'. However, such interventions were frequently ineffective because they were either delivered in part or not at all, demonstrating a lack of fidelity, or because little attention had been paid to their development, content, and mode of delivery. This commentary seeks to highlight the latest methodological advances in the field of intervention development, drawing on health psychology literature, together with guidance from key organisations and research consortia which are setting standards for development and reporting. Those working within pharmacy practice research can learn from the more systematic approach being advocated, and apply these methods to help generate evidence to support new services and professional roles.

**Keywords** Behaviour change · Intervention · Theoretical domains framework

### Impacts of practice

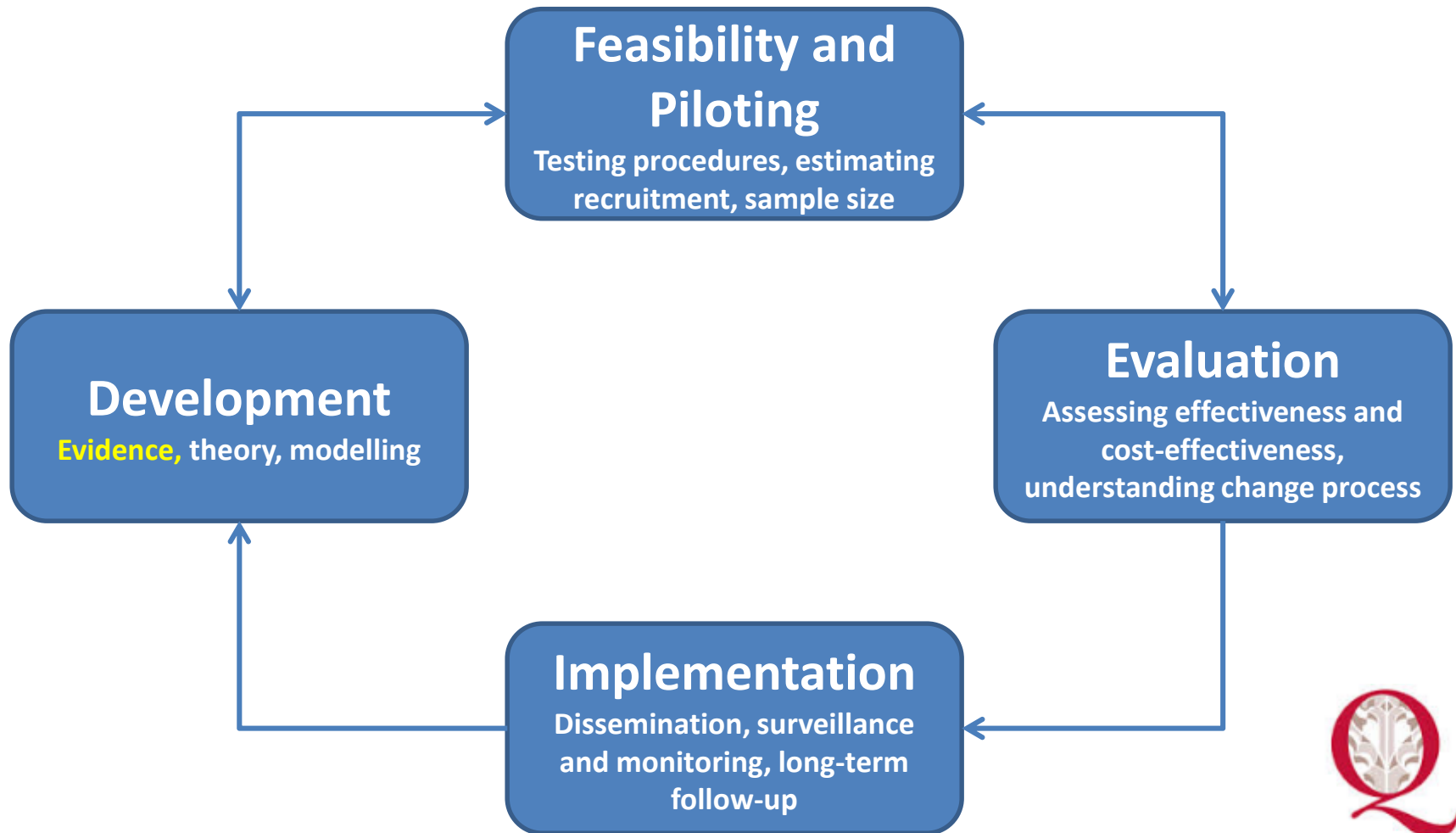
- There has been a lack of a systematic approach to the development of healthcare interventions, particularly in the use of theory.

- This paper describes how theory can be linked to behaviour change techniques, and how such techniques can be embedded in interventions.
- Developing interventions in this way may help to generate the evidence required to change healthcare and policy.

### Introduction

Increasingly, evidence is being sought by policymakers to support the commissioning and delivery of new health services [1]. Therefore, such services need to be underpinned by rigorous research that has produced the required evidence. Very often, the evidence will be generated through intervention studies. In the case of pharmacy practice, such interventions may be developed and evaluated by researchers, with the goal of producing evidence to support wide-scale implementation by practitioners working in clinical practice, most commonly in a community or hospital pharmacy setting. This is contingent on the intervention proving effective. To date, the end result of pharmacy practice-based intervention development and evaluation has been highly variable; some studies have shown positive effects, while others have demonstrated negative effects or no effect at all. In order to address the lack of intervention effect across studies, it is increasingly

# Medical Research Council Framework



# Evidence-Cochrane Review

## Interventions to improve the appropriate use of polypharmacy for older people (Patterson *et al.* 2014)

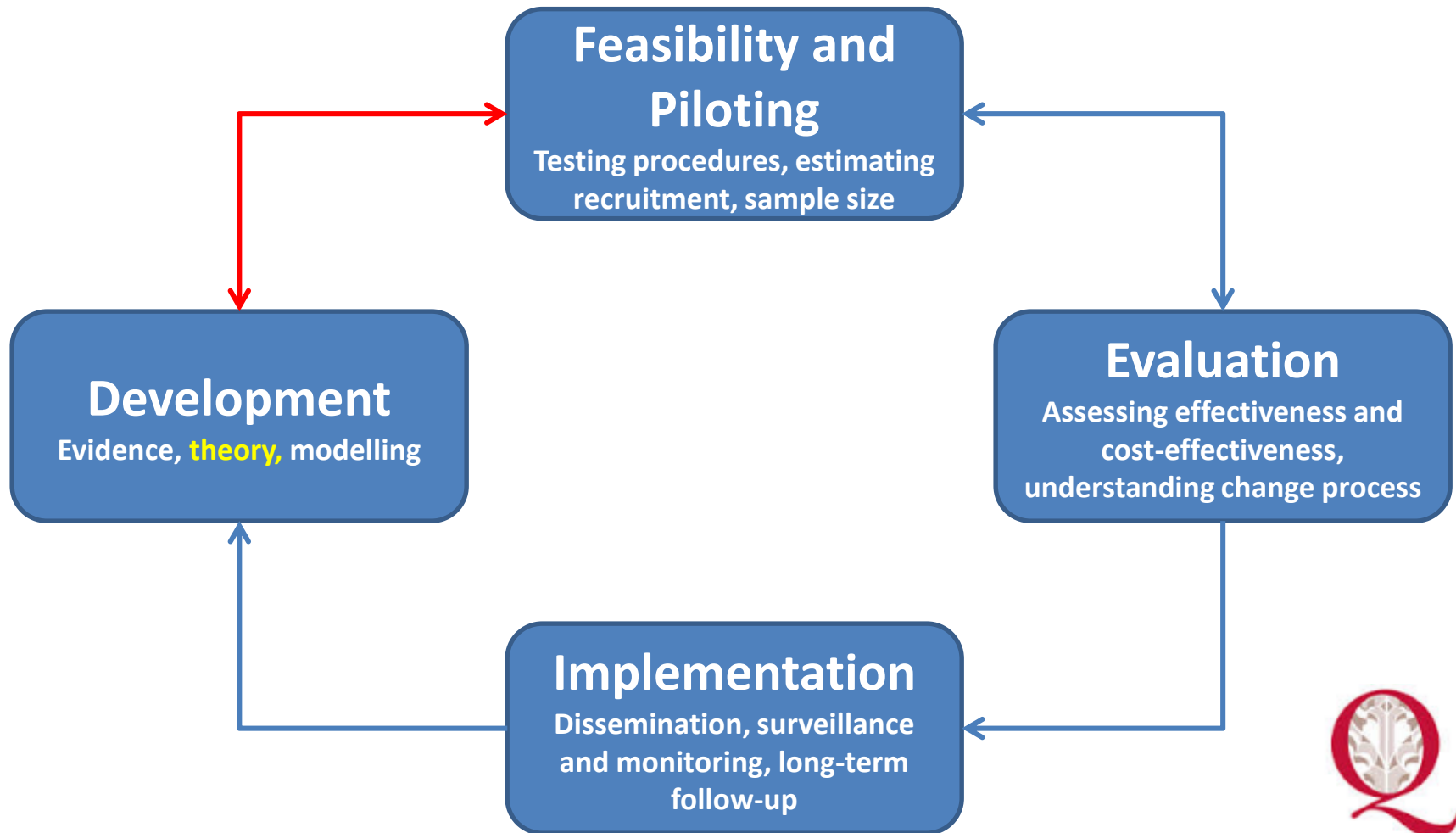
- Intervention development lacked detailed description.
- Evidence for effectiveness of identified interventions was weak.

Interventions to improve the appropriate use of polypharmacy for older people (Review)

Patterson SM, Cadogan CA, Kerse N, Cardwell CR, Bradley MC, Ryan C, Hughes C



# Moving through the MRC framework



# 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.

| Theoretical domains                      |                                     |
|--|-------------------------------------|
| Knowledge                                | Skills                              |
| Beliefs about capabilities               | Emotion                             |
| Beliefs about consequences               | Behavioural regulation              |
| Motivation and goals                     | Social influences                   |
| Memory, attention and decision processes | Environmental context and resources |
| Social/professional role and identity    | Nature of the behaviours            |

# Selected TDF domains

| Domain label                          | Domain content  | Domain Constructs  |
|---------------------------------------|---|--|
| 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

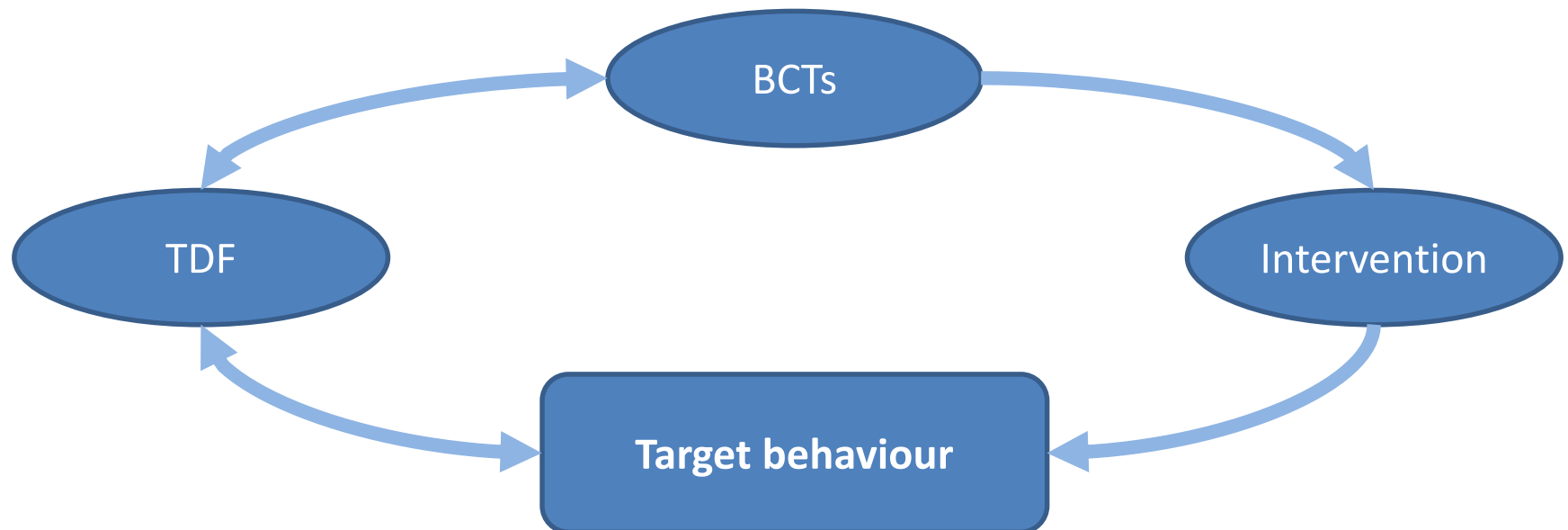
| BCT              | Definition   | Example  |
|------------------|--|--|
| Goal-setting     | Set or agree a goal defined in terms of the behaviour to be achieved   | Set a goal with patients of taking all medicines as prescribed   |
| Prompts and cues | Introduce or define environmental or social stimulus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

# Link between TDF and BCTs



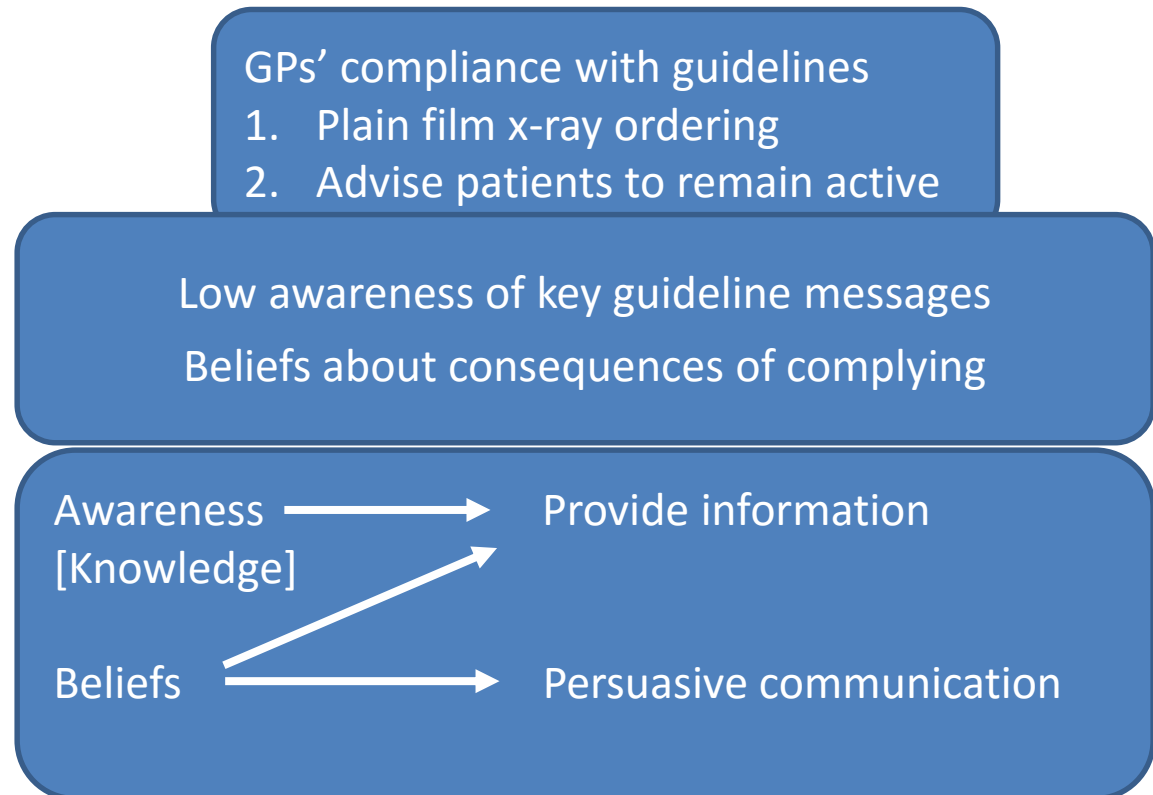
*If the TDF provides a means of identifying the theoretical determinants of behaviour, i.e., the “**mechanism of action**” of a behaviour change intervention, BCTs represent the content of the intervention, i.e., its “**active ingredients**”*

# Overview of approach



# An illustrative example

## 1. Who needs to do what differently?



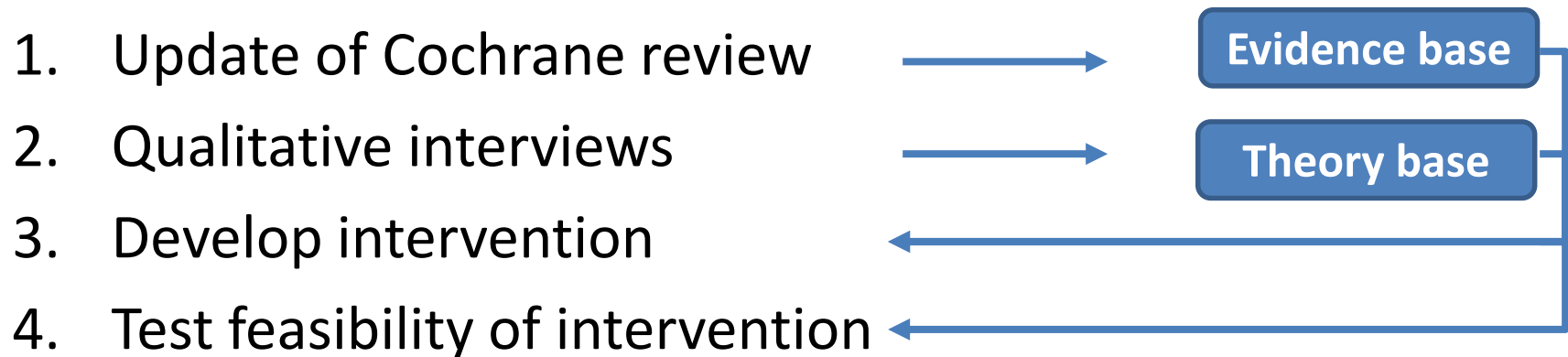


# Project aim and objectives

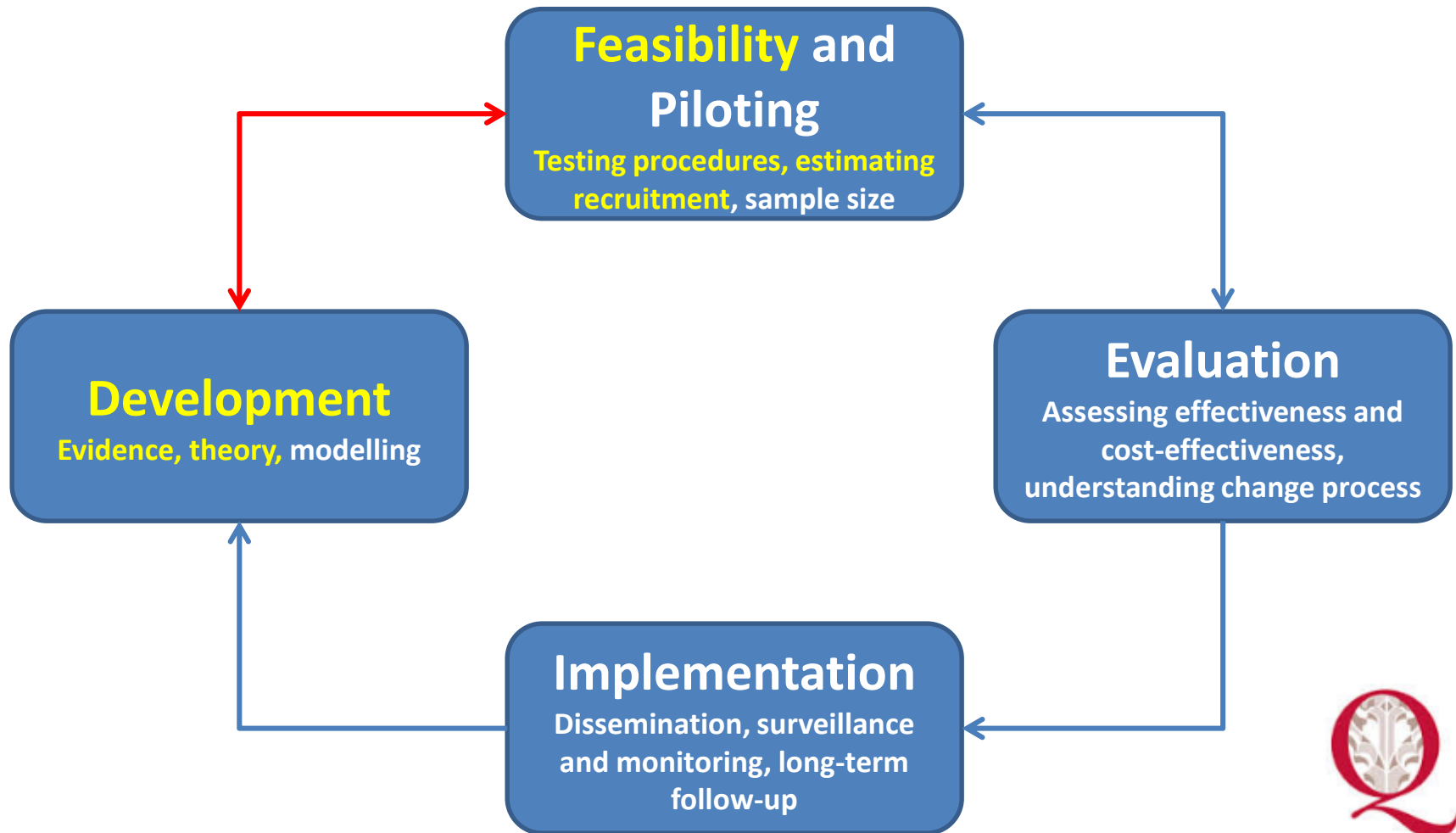
## Aim

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

## Project phases and objectives



# Moving through the MRC framework



# Method

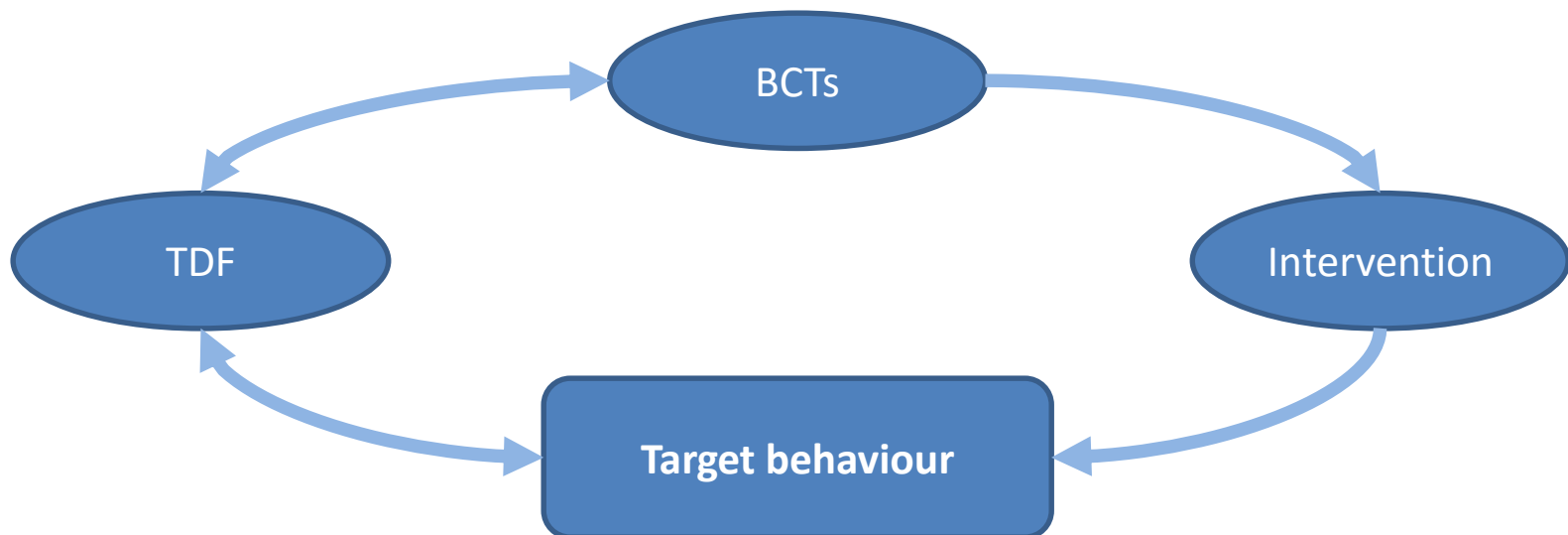
## Series of systematic steps

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

| Gender                  | GPs    | Pharmacists |
|-------------------------|--------|-------------|
| Male                    | 10     | 7           |
| Female                  | 5      | 8           |
| Professional experience |        |             |
| Years (range)           | 3 - 27 | 3 - 32      |
| Trust area              |        |             |
| Belfast                 | 4      | 4           |
| Southern                | 1      | 2           |
| South-Eastern           | 3      | 3           |
| Northern                | 3      | 2           |
| Western                 | 4      | 4           |



# Results *cont'd*

## Key domains

- Skills
- Beliefs about capabilities
- Beliefs about consequences
- Environmental
- Memory, attention
- Social influences
- Social/professional
- 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..."*

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

*some... go where we've prescribed ..." GP1*

# Results *cont'd*

## Mapping to BCTs

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

### RESEARCH

### Open Access



## Improving appropriate polypharmacy for older people in primary care: selecting components of an evidence-based intervention to target prescribing and dispensing

Cathal A. Cadogan<sup>1,2</sup>, Cristin Ryan<sup>1,2</sup>, Jill J. Francis<sup>3</sup>, Gerard J. Gormley<sup>4</sup>, Peter Passmore<sup>5</sup>, Ngairé Kerse<sup>6</sup> and Carmel M. Hughes<sup>1\*</sup>

### Abstract

**Background:** The use of multiple medicines (polypharmacy) is increasingly common in older people. Ensuring that patients receive the most appropriate combinations of medications (appropriate polypharmacy) is a significant challenge. The quality of evidence to support the effectiveness of interventions to improve appropriate polypharmacy is low. Systematic identification of mediators of behaviour change, using the Theoretical Domains Framework (TDF), provides a theoretically robust evidence base to inform intervention design. This study aimed to (1) identify key theoretical domains that were perceived to influence the prescribing and dispensing of appropriate polypharmacy to older patients by general practitioners (GPs) and community pharmacists, and (2) map domains to associated behaviour change techniques (BCTs) to include as components of an intervention to improve appropriate polypharmacy in older people in primary care.

**Methods:** Semi-structured interviews were conducted with members of each healthcare professional (HCP) group using tailored topic guides based on TDF version 1 (12 domains). Questions covering each domain explored HCPs' perceptions of barriers and facilitators to ensuring the prescribing and dispensing of appropriate polypharmacy to older people. Interviews were audio-recorded and transcribed verbatim. Data analysis involved the framework method and content analysis. Key domains were identified and mapped to BCTs based on established methods and discussion within the research team.

**Results:** Thirty HCPs were interviewed (15 GPs, 15 pharmacists). Eight key domains were identified, perceived to influence prescribing and dispensing of appropriate polypharmacy: 'Skills', 'Beliefs about capabilities', 'Beliefs about consequences', 'Environmental context and resources', 'Memory, attention and decision processes', 'Social/professional role and identity', 'Social influences' and 'Behavioural regulation'. Following mapping, four BCTs were selected for inclusion in an intervention for GPs or pharmacists: 'Action planning', 'Prompts/cues', 'Modelling or demonstrating of behaviour' and 'Salience of consequences'. An additional BCT ('Social support or encouragement') was selected for inclusion in a community pharmacy-based intervention in order to address barriers relating to interprofessional working that were encountered by pharmacists.

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# Method

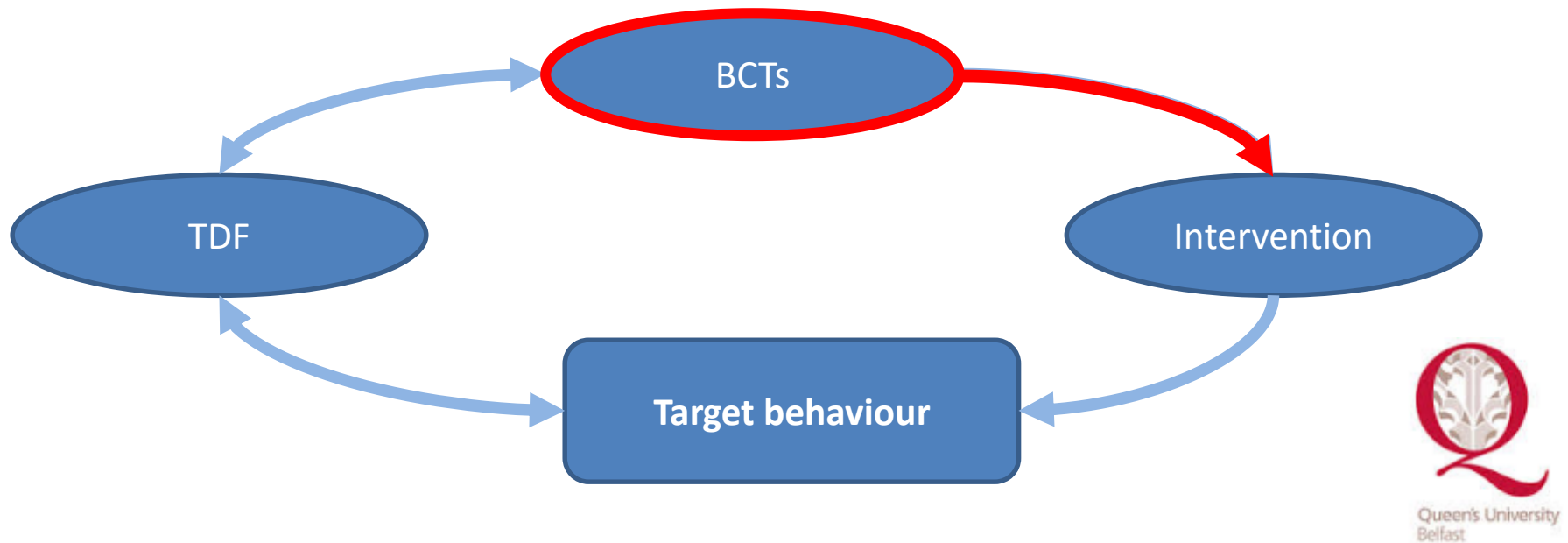
## Series of systematic steps

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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

# 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
    - Prac<sup>t</sup>icability
    - Effectiveness and cost-effectiveness
    - Acc<sup>e</sup>ptability
    - 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

| BCT                                     | Example of how the behaviour change technique is being operationalised as part of the intervention   |
|---|--|
| Action planning                         | GPs will plan to perform medication reviews on the specified date when patients meeting inclusion criteria present at the practice for a scheduled appointment.  |
| Prompts and cues                        | 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.                  |
| Modelling or demonstrating of behaviour | GPs will be provided with a video demonstration of how to perform a medication review with an older patient who is receiving polypharmacy.   |
| Salience of consequences                | 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. |



# Method

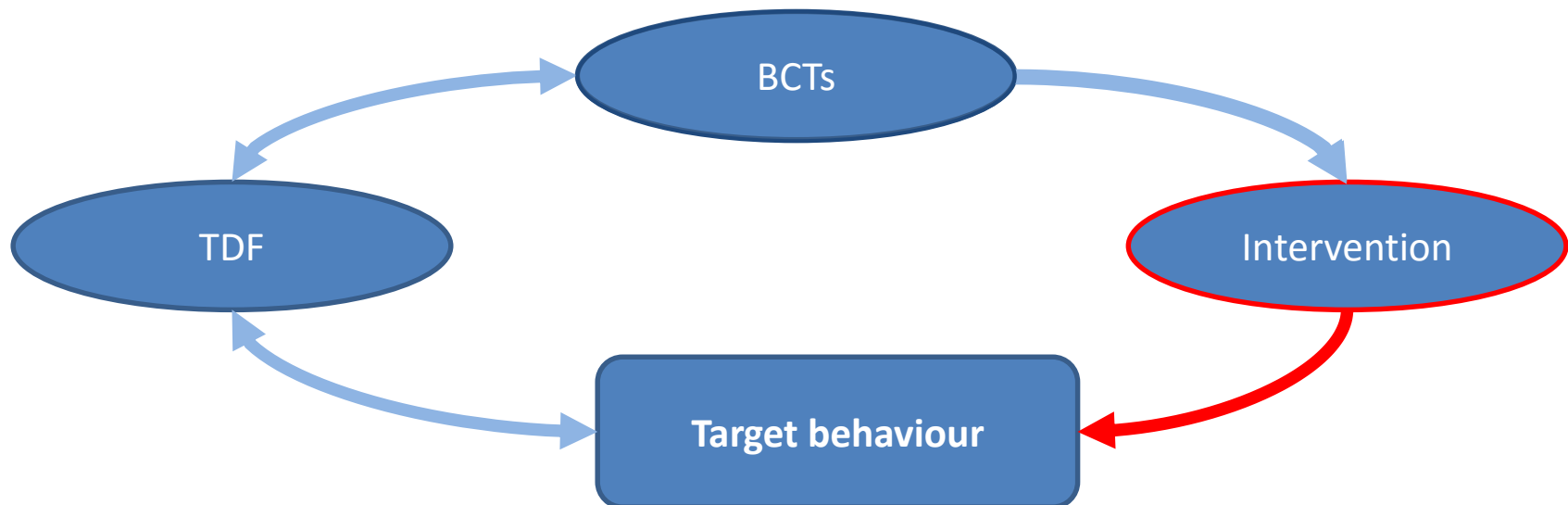
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6. Conduct feasibility screening
7. **Undertake feasibility study**

# 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

- Dr. Cathal Cadogan<sup>1</sup>
- Dr. Cristín Ryan<sup>1</sup>
- Dr. Gerry Gormley<sup>1</sup>
- Prof. Peter Passmore<sup>1</sup>
- Prof. Jill Francis<sup>2</sup>
- Prof. Ngaire Kerse<sup>3</sup>
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# Acknowledgements

- The Dunhill Medical Trust
- Northern Ireland Clinical Research Network

