Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Improving appropriate polypharmacy in older people in primary care

A thesis submitted for the degree of

Doctor of Philosophy

at the School of Pharmacy and Pharmaceutical Sciences,

Trinity College Dublin

By

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Appendix 1.1 Theories included in the Theoretical Domains Framework (adapted from Michie *et al.* 2005)

Type of theory	Name of theory
Psychological theories	Theory of planned behaviour (+ theory of reasoned action, protection motivation theory, health belief model)
	Social cognitive theory
	Locus of control theories
	Social learning theory
	Social comparison theory
	Cognitive adaptation theory
	Social identity theory
	Elaboration likelihood model
	Goal theories
	Intrinsic motivation theories
	Self-determination theory
	Attribution theory
	Decision making theories (e.g. social judgement theory, "fast and frugal" model, systematic versus heuristic decision making)
	Fear arousal theory
Action theories	Learning theory
	Operant theory
	Modelling
	Self-regulation theory
	Implementation theory/ automotive model
	Goal theory
	Volitional control theory
	Social cognitive theory
	Cognitive behaviour theory
	Transtheoretical model
	Social identity theory
Organisational theories	Effort-reward imbalance
	Demand-control model
	Diffusion theory
	Group theory (e.g. group minority theory)
	Decision making theory
	Goal theory
	Social influence
	Person situation contingency models

Appendix 2.1 The Theory Coding Scheme (Michie and Prestwich 2010)

Item No.	Item	Description	Yes/ No/ Don't know	List with location in paper (i.e. page number)
1	*Theory/model of behaviour mentioned*	Models/theories that specify relations among variables, in order to *explain* or *predict* behaviour (e.g., TPB, SCT, HBM) are mentioned, even if the intervention is not based on this theory.		
2	*Targeted construct mentioned as predictor of behaviour*	'Targeted' construct refers to a psychological construct that the study intervention is hypothesized to change). Evidence that the psychological construct relates to (correlates/predicts/causes) behaviour should be presented within the Introduction or Method (rather than the Discussion).		Location of evidence that construct relates to behaviour: Location that this predictor is targeted by the intervention:
3	*Intervention based on single theory*	The intervention is based on a single theory (rather than a combination of theories or theory + predictors).		
4	*Theory/predictors used to select recipients for the intervention*	Participants were screened/selected based on achieving a particular score/level on a theory-relevant construct/predictor.		Construct (Theory) Predictor
5	*Theory/predictors used to select/develop intervention techniques*	The intervention is explicitly based on a theory or predictor or combination of theories or predictors.		Theory Predictor
6	*Theory/predictors used to tailor intervention techniques to recipients*	The intervention differs for different sub-groups that vary on a psychological construct (e.g., stage of change) or predictor at baseline.		Construct Predictor
7	*All intervention techniques are explicitly linked to at least one theory-relevant construct/predictor*	Each intervention technique is explicitly linked to at least one theory-relevant construct/predictor.		Construct (list links) Predictor (list links)
8	*At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor*	At least one, but not all, of the intervention techniques are explicitly linked to at least one theory-relevant construct/ predictor.		Construct (list links) Predictor (list links)

Item no.	Item	Description	Yes/ No/ Don't know	List with location in paper (i.e. page number)
9	*Group of techniques are linked to a group of constructs/predictors*	A cluster of techniques is linked to a cluster of constructs/ predictors.		List clusters of techniques/constructs List clusters of techniques/predictors
10	*All theory-relevant constructs/predictors are explicitly linked to at least one intervention technique*	Every theoretical construct within a stated theory, or every stated predictor (see item 5), is linked to at least one intervention technique.		Construct (list links) Predictor (list links)
11	*At least one, but not all, of the theory relevant constructs/predictors are explicitly linked to at least one intervention technique*	At least one, but not all, of the theoretical constructs within a stated theory or at least one, but not all, of the stated predictors (see item 5) are linked to at least one intervention technique.		Construct (list links) Predictor (list links)
12	*Theory-relevant constructs/ predictors are measured*	a) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured post-intervention. b) At least one construct of theory (or predictor) mentioned in relation to the intervention is measured pre- and post-intervention.		Construct Predictor
13	*Quality of measures*	a) All of the measures of theory relevant constructs/predictors had some evidence for their reliability. b) At least one, but not all, of the measures of theory relevant constructs/predictors had some evidence for their reliability. c) All of the measures of theory relevant constructs/predictors have been previously validated. d) At least one, but not all, of the measures of theory relevant constructs/predictors have been previously validated. e) The behaviour measure had some evidence for its reliability. f) The behaviour measure has been previously validated.		Construct Predictor

Item no.	Item	Description	Yes/ No/ Don't know	List with location in paper (i.e. page number)
14	*Randomization of participants to condition*	a) Do the authors claim randomization? b) Is a method of random allocation to condition described (e.g., random number generator; coin toss). c) Was the success of randomization tested? d) Was the randomization successful (or baseline differences between intervention and control group statistically controlled)?		
15	*Changes in measured theory-relevant constructs/ predictor*	The intervention leads to significant change in at least one theory-relevant construct/predictor (vs. control group) in favour of the intervention.		Construct Predictor
16	*Mediational analysis of constructs/predictors*	In addition to 15, do the following effects emerge? a) Mediator predicts DV? (or change in mediator leads to change in DV) b) Mediator predicts DV (when controlling for IV)? c) Intervention does not predict DV (when controlling for mediator)? d) Mediated effect statistically significant?		Construct Predictor
17	*Results discussed in relation to theory*	Results are discussed in terms of the theoretical basis of the intervention.		
18	*Appropriate support for theory*	Support for the theory is based on appropriate mediation OR refutation of the theory is based on obtaining appropriate null effects (i.e. changing behaviour without changing the theory relevant constructs).		
19	*Results used to refine theory*	The authors attempt to refine the theory upon which the intervention was based by either: a) adding or removing constructs to the theory, or b) specifying that the interrelationships between the theoretical constructs should be changed and spelling out which relationships should be changed.		a) Constructs added or removed from theory: b) Interrelationships between the theoretical constructs to be changed:

TPB = Theory of Planned Behaviour SCT = Social Cognitive Theory HBM = Health Belief Model DV = dependent variable IV = independent variable

Construct = a key concept, excluding behaviour Theory-relevant construct = a construct within a theory/model upon which the intervention is based Predictor = a construct that is not explicitly linked to a theory by the authors, but is targeted for intervention (as a means to change behaviour) because it predicts behaviour Intervention technique = strategy used to change behaviour, theory-relevant construct, or predictor

Appendix 2.2 Completed PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	46
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	N/A for chapter
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	46-47
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	49
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address) and, if available, provide registration information including registration number.	49
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	49
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	50
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	343
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	50
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	50

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	50
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	52
Summary measures	13	State the principal summary measures (e.g., risk ration, difference in means).	N/A
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., $I^{2)}$) for each meta-analysis.	N/A
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting with studies).	N/A
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	54
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	59
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	65
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	N/A
Synthesis of results	21	Present the main results of the review. If meta-analyses are done, include for each, confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see item 15).	N/A

Additional analyses	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	66-70
Limitations	25	Discuss limitation at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	69
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	66-70
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	v

Appendix 2.3 Search strategies

CINAHL search strategy

S1. TI polypharmacy

S2. AB polypharmacy

S3. MH "polypharmacy+"

S4. polypharmacy OR polymedicine OR polypragmas* OR pharmacotherapy OR 'multiple pharmacotherapy' OR 'multiple medicines' OR 'many medicines' OR 'multiple medications' OR 'many medications' OR 'multiple drugs' OR 'many drugs' OR deprescrib* OR unprescrib* OR 'drug therapy' OR 'multi-drug therapy' OR multidrug therapy' OR 'multiple drug therapy' OR 'multiple drug treatment'

S5. S1 OR S2 OR S3 OR S4

S6. TI aged

S7. AB aged

S8. (MH "Aged+") OR (MH "Aged, 80 and Over+")

S9. old* OR geriatric OR elderly OR ageing OR 'senior citizen' OR senium

S10. S6 OR S7 OR S8 OR S9

S11. TI primary healthcare

S12. AB primary healthcare

S13. MH "Primary Health Care"

S14. S11 OR S12 OR S13

S15. S5 AND S10 AND S14

Cochrane Library search strategy

#1. MeSH descriptor: [Polypharmacy] explode all trees

#2. polypharmacy OR polymedicine OR polypragmas* OR pharmacotherapy OR 'multiple pharmacotherapy' OR 'multiple medicines' OR 'many medicines' OR 'multiple medications' OR 'many medications' OR 'multiple drugs' OR 'many drugs' OR deprescrib* OR unprescrib* OR 'drug therapy' OR 'multi-drug therapy' OR multidrug therapy' OR 'multiple drug therapy' OR 'multiple drug treatment'

#3. #1 OR #2

#4. MeSH descriptor: [Aged] in all MeSH products

#5. old* OR geriatric OR elderly OR ageing OR 'senior citizen' OR senium

#6. #4 OR #5

#7. MeSH descriptor: [Primary Health Care] explode all trees

#8. ‘primary care’ OR ‘primary medical care’ OR ‘primary health care’

#9. #7 OR #8

#10. #3 AND #6 AND #9

Embase search strategy

#1. ‘polypharmacy’/exp

#2. ‘polypharmacy’/exp OR polypharmacy OR polymedicine OR polypragmas* OR ‘pharmacotherapy’/exp OR pharmacotherapy OR ‘multiple pharmacotherapy’/exp OR ‘multiple pharmacotherapy’ OR ‘multiple medicines’ OR ‘many medicines’ OR ‘multiple medications’ OR ‘many medications’ OR ‘multiple drugs’ OR ‘many drugs’ OR deprescribe* OR unprescrib* OR ‘drug therapy’/exp OR ‘drug therapy’ OR ‘multi-drug therapy’/exp OR ‘multi-drug therapy’ OR ‘multidrug therapy’/exp OR ‘multidrug therapy’ OR ‘multiple drug therapy’/exp OR ‘multiple drug therapy’ OR ‘multiple drug treatment’:ab,ti

#3. #1 OR #2

#4. ‘aged’/exp

#5. Old* OR ‘geriatric’/exp OR geriatric OR ‘elderly’/exp OR elderly OR ‘ageing’/exp OR ageing OR ‘senior citizen’/exp OR ‘senior citizen’ OR senium:ab,ti

#6. #4 OR #5

#7. ‘primary health care’/exp

#8. ‘primary care’/exp OR ‘primary care’ OR ‘primary medical care’/exp OR ‘primary medical care’ OR ‘primary health care’:ab,ti

#9. #7 OR #8

#10. #3 AND #6 AND #9

MEDLINE search strategy

1. exp Polypharmacy/ (keyword, map term to subject heading)

2. (polypharmacy OR polymedicine OR polypragmas* OR pharmacotherapy OR ‘multiple pharmacotherapy’ OR ‘multiple medicines’ OR ‘many medicines’ OR ‘multiple medications’ OR ‘many medications’ OR ‘multiple drugs’ OR ‘many drugs’ OR deprescrib* OR unprescrib* OR ‘drug therapy’ OR ‘multi-drug therapy’ OR multidrug therapy’ OR ‘multiple drug therapy’ OR ‘multiple drug treatment’).mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

3. 1 OR 2

4. exp Aged/ (keyword, map term to subject heading)

5. (old* OR geriatric OR elderly OR ageing OR 'senior citizen' OR senium).mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

6. 4 OR 5

7. exp primary healthcare/ (keyword, map term to subject heading)

8. ('primary care' OR 'primary medical care' OR 'primary health care').mp. [mp = title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms]

9. 7 OR 8

10. 3 AND 6 AND 9

PsycInfo

S1. TI polypharmacy

S2. AB polypharmacy

S3. MM "polypharmacy"

S4. polypharmacy OR polymedicine OR polypragmas* OR pharmacotherapy OR 'multiple pharmacotherapy' OR 'multiple medicines' OR 'many medicines' OR 'multiple medications' OR 'many medications' OR 'multiple drugs' OR 'many drugs' OR deprescrib* OR unprescrib* OR 'drug therapy' OR 'multi-drug therapy' OR multidrug therapy' OR 'multiple drug therapy' OR 'multiple drug treatment'

S5. S1 OR S2 OR S3 OR S4

S6. TI aged

S7. AB aged

S8. DE "Gerontology"

S9. old* OR geriatric OR elderly OR ageing OR 'senior citizen' OR senium

S10. S6 OR S7 OR S8 OR S9

S11. TI primary healthcare

S12. AB primary healthcare

S13. DE "Primary Health Care"

S14. S11 OR S12 OR S13

S15. S5 AND S10 AND S14

Scopus

1. TITLE-ABS-KEY (Polypharmacy)
2. TITLE-ABS-KEY (polypharmacy OR polymedicine OR polypragmas* OR pharmacotherapy OR 'multiple pharmacotherapy' OR 'multiple medicines' OR 'many medicines' OR 'multiple medications' OR 'many medications' OR 'multiple drugs' OR 'many drugs' OR deprescrib* OR unprescrib* OR 'drug therapy' OR 'multi-drug therapy' OR multidrug therapy' OR 'multiple drug therapy' OR 'multiple drug treatment')
3. 1 OR 2
4. TITLE-ABS-KEY (Aged)
5. TITLE-ABS-KEY (old* OR geriatric OR elderly OR ageing OR 'senior citizen' OR senium)
6. 4 OR 5
7. TITLE-ABS-KEY (primary health care)
8. TITLE-ABS-KEY ('primary care' OR 'primary medical care' OR 'primary health care')
9. 7 OR 8
10. 3 AND 6 AND 9

Web of Science

#1. TI,AB=(Polypharmacy)

#2. TI,AB=(polypharmacy OR polymedicine OR polypragmas* OR pharmacotherapy OR 'multiple pharmacotherapy' OR 'multiple medicines' OR 'many medicines' OR 'multiple medications' OR 'many medications' OR 'multiple drugs' OR 'many drugs' OR deprescrib* OR unprescrib* OR 'drug therapy' OR 'multi-drug therapy' OR multidrug therapy' OR 'multiple drug therapy' OR 'multiple drug treatment')

#3. #1 OR #2

#4. TI,AB=(Aged)

#5. TI,AB=(old* OR geriatric OR elderly OR ageing OR 'senior citizen' OR senium)

#6. #4 OR #5

#7. TI,AB=(primary healthcare)

#8. TI,AB=('primary care' OR 'primary medical care' OR 'primary health care')

#9. #7 OR #8

#10. #3 AND #6 AND #9

Appendix 2.4 Data extraction form

Study characteristics		**Page number(s)**
Article title		
Authors		
Year of publication		
Journal published in		
Country of origin		
Clinical Trial registration number		
Study design		
Unit of randomisation (if required)		
Study aim		
Definition of polypharmacy		
Primary care setting		
Method of recruitment for primary care setting		
Inclusion criteria for primary care setting		
Exclusion criteria for primary care setting		
Primary outcome(s)		
Secondary outcome(s)		
Description of intervention		

Duration of participation (specify follow-ups if required)		
Study participants		
Method of recruitment		
Number of patients recruited		
Age (range, mean age)		
Gender		
Average number of medicines per participant		
Number of patients in follow-up(s)		
Inclusion criteria		
Exclusion criteria		
Validated tool		
Validated tool used		
Implicit or explicit validated tool		
How the validated tool was used		
Theory		
Theory used		
Description of theory		
Extent of theory used		
Intervention group		
No. randomized to group		

Description		
Duration of treatment		
Delivery		
Providers		
Resource requirements		
Control group (if required)		
No. randomized to group		
Description		
Duration		
Outcome 1		
Outcome name		
Time points measured		
Time points reported		
Definition and Methods		
Unit of measurement		
Outcome result		
Outcome 2		
Outcome name		
Time points measured		
Time points reported		
Definition and Methods		

Unit of measurement		
Outcome result		
(include other outcomes as required)		
Other information		
Key conclusions of study authors		
Other reports of this study (e.g. protocol, follow-up studies etc.)		
Reference to other relevant studies		
Comments from study reviewer		

Appendix 3.1 Ethical approval September 2018

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Prof. Cristín Ryan,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College Dublin,
Dublin 2.

Ref. 2018-07-01

29 September 2018

Dear Cristín,

Re: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)

I am pleased to inform you that the above project now has approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

You are reminded that any significant deviation from the research description in the application requires approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee before implementation.

Please also note the reporting requirements outlined on the Committee's website (http://pharmacy.tcd.ie/research/SoPPS_REC.php), in particular the need for:

- An immediate report in writing (by email to pharmacy.ethics@tcd.ie) of any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio as outlined in the application.
- Annual reports (report form on the Committee's website).
- An end of project report (report form on the Committee's website).

Please quote the reference number 2018-07-01 in any further correspondence.

We wish you success with your research.

Yours sincerely,

Sheila Ryder,
Chairperson,
School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

Sheila Ryder
Chairperson
Research Ethics Committee
School of Pharmacy and Pharmaceutical Sciences

Panoz Building, East End 4/5,
Trinity College,
Dublin 2, Ireland.

Tel. +353 1 896 2786
E-mail pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Síle Ní Mharcaigh
Cathaoirleach
Coiste um Eitic Thaighde
Scoil na Cógaisíochta agus na nEolaíochtaí Cogaisíochta

Foirgneamh Panoz, An Taobh Thoir 4/5,
Coláiste na Tríonóide,
Baile Átha Cliath 2, Éire.

Teil. +353 1 896 2786
R-phost pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Appendix 3.2 Research team information

PhD candidate, AG, female

The PhD candidate was employed as Research Assistant on the PolyPrime study (Chapter 3 and Chapter 4) whilst undertaking a PhD.

The PhD candidate has had numerous experiences conducting qualitative interviews prior to this study:

- Has MSc in Applied Social Research which included module on conducting qualitative interviews and submission of group research paper
- Conducted and analysed qualitative interviews as part of healthy eating and exercise programme with the Public Health Agency
- Conducted focus group research

Research Fellow, AR, female

The Research Fellow was employed in this position on the PolyPrime study.

The Research Fellow has had experience conducting qualitative interviews prior to this study:

- Rankin, A., Kuznesof, S.A., Frewer L.J., *et al.* 2016. Public perceptions of personalised nutrition through the lens of Social Cognitive Theory. *Journal of Health Psychology.* Doi: 10.1177/1359105315624750

Appendix 3.3 Ethical approval December 2018

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Prof. Cristín Ryan,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College,
Dublin 2.

Ref. 2018-07-01 (R01)

18 December 2018

Dear Cris,

Re: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)

I am happy to confirm that your recent application for amendment of the above project's approval (research team, subjects and methodology) has been agreed.

You are reminded that any further significant deviation from the research description in the application requires approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee before implementation.

Your attention is drawn to the reporting requirements outlined on the Committee's website (http://pharmacy.tcd.ie/research/SoPPS_REC.php), in particular the need for:

- An immediate report in writing (by email to pharmacy.ethics@tcd.ie) of any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio as outlined in the application.
- Annual reports (report form on the Committee's website).
- An end of project report (report form on the Committee's website).

The newly updated record for this study has been designated 2018-07-01 (R01), indicating it incorporates one approved revision. Please quote this reference number in any further correspondence.

Yours sincerely,

_____

Sheila Ryder,
Chairperson,
School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

Sheila Ryder
Chairperson
Research Ethics Committee
School of Pharmacy and Pharmaceutical Sciences

Panoz Building, East End 4/5,
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Dublin 2, Ireland.

Tel. +353 1 896 2786 Fax +353 1 896 2524
E-mail pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Síle Ní Mharcaigh
Cathaoirleach
Coiste um Eitic Thaighde
Scoil na Cógaisíochta agus na nEolaíochtaí Cogaisíochta

Foirgneamh Panoz, An Taobh Thoir 4/5,
Coláiste na Tríonóide,
Baile Átha Cliath 2, Éire.

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http://pharmacy.tcd.ie/research/SoPPS_REC.php

Appendix 3.4 Letter of access

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin

Date xx/xx/2018

Dear (insert Practice Managers name),

Re: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

I would like to invite you to assist the research team in conducting the above named study. Before you decide you need to understand why the research is being done and what it would involve for you and for the participants. Please take time to read the following information carefully.

Members of the research team have developed an intervention to improve appropriate polypharmacy (the use of multiple medicines) in older people in Northern Ireland (NI). The intervention consists of a short online video that demonstrates how a general practitioner (GP) prescribes appropriate polypharmacy during a typical consultation with an older patient. GPs then invite patients to attend for a consultation to review their medicines. The aim of the current study is to seek the views of GPs in the six border counties in the Republic of Ireland (ROI) about this intervention and if necessary, refine it further before testing it in a future study.

I am writing to ask for your assistance in inviting up to two general practitioners from [insert practice name] to participate in the above named study. This will involving confirming if the GP practice meets the inclusion criteria (i.e. GPs are involved in prescribing medicines for older people in primary care and not currently involved in another, similar prescribing

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Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

improvement research project). If these inclusion criteria are met, we would then seek your assistance in distributing study information and consent forms to each GP with the practice.

Each GP will be asked to participate in a semi-structured, audio-recorded interview with one of the researchers (Dr. Audrey Rankin/Ms. Ashleigh Gorman). The interview will last approximately one hour, although this may vary between individuals. The interview will be conducted at a time and date to suit each GP, at your practice. GP participants/practices will be asked to invoice us for room hire in order to facilitate the conduct of interviews (maximum €54 per room hire).

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the research group. Interviews with the GPs will be audio-recorded, all recordings will be anonymous and all identifiable information (i.e. GP name or the name of your practice) will be removed during transcription. Information gained from the study including identifiable information such as consent forms will be stored securely at the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin and Queen's University Belfast. When the study has been completed, hard copies of participant consent forms and transcripts stored at Queen's University Belfast will be transferred to Trinity College Dublin [in line with General Data Protection Regulation (GDPR 2018) for the transferring of data]. These will be kept for five years and then destroyed (shredded and disposed of in confidential waste bags), in line with GDPR 2018. Data may be published in academic journals and presented at conferences, but your name and the name of your practice will not appear in any publications. All data reported will be kept pseudonymised (i.e. any identifying data will be replaced with unique ID codes). You will be provided with a report of the results at the end of the study.

There is a risk that participants may disclose poor practice during interviews. In the unlikely event that this occurs, any cases will be reported to Professor Tom Fahey (RCSI) and Professor Cristín Ryan (TCD) who will take appropriate action on a case-by-case basis which may involve

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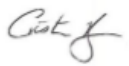
informing the appropriate professional regulatory body. Any disclosure of poor practice will be retained in the transcripts but not used in any formal output from the study.

Please find enclosed a copy of the Practice Manager consent form (which you will be asked to sign), along with a copy of the General Practitioner invitation letter, General Practitioner information leaflet, which provides further information about the study and a copy of the General Practitioner consent form, for your information purposes. If you have any queries, please do not hesitate to contact the Research Fellow/Assistant (Dr. Audrey Rankin/ Ms. Ashleigh Gorman), or any other member of the research team as detailed below. We appreciate the time you have taken to read this letter and the enclosed information leaflet.

This is a study run by the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, the Schools of Pharmacy and Medicine, Queen's University Belfast and the School of Pharmacy and Department of General Practice, Royal College of Surgeons in. The study has received ethical approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee (Reference Number: 2018-07-01).

Yours sincerely,



Prof. Cristín Ryan
Professor in Practice of Pharmacy,
Trinity College Dublin

Prof. Tom Fahey
Professor of General Practice,
Royal College of Surgeons in Ireland

On behalf of the research team:
Prof. Carmel Hughes, Dr. Heather Barry, Dr. Audrey Rankin, Ms. Ashleigh Gorman, Dr. Cathal Cadogan, Prof. Tom Fahey and Dr. Gerard Gormley

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Contact details for more information:

Dr. Audrey Rankin
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: +44 (0)28 9097 2348
Email: a.rankin@qub.ac.uk

Ms. Ashleigh Gorman
Research Assistant
School of Pharmacy and Pharmaceutical
Trinity College Dublin
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Dublin D02PN40
Telephone: 01 8962943
Email: gormanas@tcd.ie

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
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Queen's University Belfast
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Prof. Cristín Ryan
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Appendix 3.5 Practice manager consent form

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Practice Manager Consent Form

Title of study: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

- I voluntarily agree to help facilitate this research study.
- I understand that even if I agree to help now, I can withdraw at any time without any consequences of any kind.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study.
- I understand that I will assist the research team in inviting up to two general practitioners to participate in the above named study. This will involving confirming if the GP practice meets the inclusion criteria and distributing study information and consent forms to each GP within the practice.
- I understand that all data collected in this study is confidential and pseudonymous (i.e. any identifying data will be replaced with unique ID codes).
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

---------- ----------

Signature of practice manager [gate keeper] Date

---------- ----------

Signature of researcher Date

Contact details for more information:

Dr. Audrey Rankin
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: +44 (0)28 9097 2348
Email: a.rankin@qub.ac.uk

Ms. Ashleigh Gorman
Research Assistant
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin D02PN40
Telephone: 01 8962943
Email: gormanas@tcd.ie

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
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Practice Manager Consent Form

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Professor of Primary Care Pharmacy
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Appendix 3.6 Invitation letter

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin

Date xx/xx/2018

Dear (insert General Practitioner's name),

Re: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

I am writing to invite you to take part in the above named study. Members of the research team have developed an intervention to improve appropriate polypharmacy in older people in Northern Ireland (NI). The intervention consists of a short online video that demonstrates how a general practitioner (GP) prescribes appropriate polypharmacy during a typical consultation with an older patient. GPs then invite patients to attend for a consultation to review their medicines. The aim of the current study is to seek the views of GPs in the six border counties in the Republic of Ireland (ROI) about this intervention and if necessary, refine it further before testing it in a future study.

You have been approached to participate because you are involved in prescribing medicines for older people in your practice. Should you decide to participate, a researcher will arrange to meet with you to carry out the interview at your practice. During this interview, you will be asked about your views of polypharmacy in older people and your approach to prescribing for this age group. The intervention will then be described in more detail and you will be asked to comment on its content, mode of delivery, relevance to practice, and to suggest changes that you may feel would be required.

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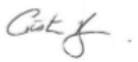
GP participants/practices will be asked to invoice us for room hire in order to facilitate the conduct of interviews (maximum €54 per room hire). A certificate of participation will also be provided. This is a study run by the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, the Schools of Pharmacy and Medicine, Queen's University Belfast, the School of Pharmacy and Department of General Practice, Royal College of Surgeons in Ireland and the School of Psychology, National University of Ireland Galway. This project is funded by the Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) which is a unique cross-border partnership between the Public Health Agency in Northern Ireland and the Health Research Board in the Republic of Ireland, to develop infrastructure and deliver Healthcare Intervention Trials (HITs). The study has received ethical approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee (Reference Number: 2018-07-01).

Please find enclosed a study information leaflet, which provides further information about the study. If you have any queries, please do not hesitate to contact the Research Fellow/Assistant *(Dr. Audrey Rankin/Ms. Ashleigh Gorman*), or any other member of the research team as detailed below. We appreciate the time you have taken to read this letter and the enclosed information leaflet. We will be in contact with you after 10 days to discuss if you would like to participate.

Yours sincerely,



Prof. Cristín Ryan
Professor in Practice of Pharmacy, Trinity College Dublin.

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The University of Dublin

On behalf of the research team:

Prof. Carmel Hughes, Dr. Heather Barry, Dr. Audrey Rankin, Ms. Ashleigh Gorman, Dr. Cathal Cadogan, Prof. Tom Fahey and Dr. Gerard Gormley

Contact details for more information:

Dr. Audrey Rankin
Research Fellow
School of Pharmacy
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97 Lisburn Road
Belfast BT9 7BL
Telephone: +44 (0)28 9097 2348
Email: a.rankin@qub.ac.uk

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Prof. Cristín Ryan
Professor in Practice of Pharmacy
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Email: cristin.ryan@tcd.ie

Appendix 3.7 General practitioner information leaflet

Title of study: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

You are being invited to take part in a research study, being run by Queen's University Belfast, Trinity College Dublin and the Royal College of Surgeons in Ireland. Before you decide whether or not you would like to take part, it is important that you take time to understand why this research is being completed and what will be asked of you should you agree to participate.

Please read the following information and contact the Research Fellow/Assistant (Dr. Audrey Rankin/Ms. Ashleigh Gorman), or any other member of the research team if you have any questions. Contact details can be found at the end of this information leaflet.

Introduction:

Historically, polypharmacy was viewed negatively (too many medicines), but the advent of multimorbidity and the plethora of treatment guidelines have led to prescribing of multiple medicines, particularly in the older population. The challenge is to obtain a balance between many medicines (appropriate polypharmacy) and too many medicines (inappropriate polypharmacy). Members of the research team have developed a theory-based intervention, targeting prescribing of appropriate polypharmacy in primary care, which has been tested for feasibility in two general practices in Northern Ireland (NI). The existing intervention package currently consists of two components: (a) a video incorporating behaviour change techniques (BCTs) demonstrating how general practitioners (GPs) can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review). The current study you are being

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General Practitioner Information Leaflet

invited to be involved in aims to refine the existing intervention package by undertaking semi-structured interviews with GPs. This will allow us to take into account any subtle cross-border differences in context and practice between NI and the Republic of Ireland (ROI) before testing the intervention in a future study.

Procedures:

You have been approached to participate in this study because you are a GP involved in prescribing medicines for older people in primary care within the ROI.

The Researcher Fellow/Assistant (Dr. Audrey Rankin/Ms. Ashleigh Gorman) will contact you ten days after you receive this information leaflet to discuss if you might be interested in participating in the study. If you are interested, you will be asked to take part in an interview with a researcher. Prior to the interview, you will be asked to provide informed consent for the interview to be audio-recorded. The interview will last approximately one hour, although this may vary between individuals. The interview will be conducted at a time and date to suit you, at your place of work. During the interview, you will be asked about how you usually manage the prescribing of polypharmacy for older people. The researcher will then describe the existing intervention which currently consists of two components: (a) a video incorporating behaviour change techniques (BCTs) demonstrating how general practitioners (GPs) can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review). You will then be asked to comment on its content, mode of delivery, relevance to practice, and to suggest any changes that you may feel would be required. After the interview, the audio-recording will be transcribed by the researcher. On completion of the interview, you will be offered a certificate of

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participation which could be added to your continuing professional development portfolio.

Benefits:

Participation in this study may be beneficial for you, as it will help to determine if the intervention needs to be refined before further evaluations can be undertaken to assess the effectiveness of the intervention in improving appropriate polypharmacy in older people. You will also receive a certificate of participation, which could be used as part of your ongoing continued professional development.

Risks:

There is a risk that poor practice may be identified during the interview. In the unlikely event that this occurs, any cases will be reported to Professor Tom Fahey (RCSI) and Professor Cristín Ryan (TCD) who will discuss the case and take appropriate action on a case-by-case basis which may involve informing the appropriate professional regulatory body. Any disclosure of poor practice will be retained in the transcripts but not used in any formal output from the study.

Exclusion from participation:

You cannot participate in this study if any of the following are true:

- You do not currently prescribe for older people
- You are currently involved in another, similar prescribing improvement research project

Confidentiality:

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the research group. Interviews will be audio-recorded, all recordings will be pseudonymised meaning that all identifiable information (i.e. your

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General Practitioner Information Leaflet

name or the name of your practice) will be replaced with unique ID codes during transcription. You will be given access to your transcript if you wish. Information gained from the study including identifiable information such as consent forms will be stored securely at the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin and Queen's University Belfast. When the study has been completed, participant consent forms and transcripts stored at Queen's University Belfast will be transferred to Trinity College Dublin [in line with General Data Protection Regulation (GDPR 2018) for the transferring of data]. These will be kept for five years and then destroyed (shredded and disposed of in confidential waste bags), in line with GDPR 2018. Data may be published in academic journals and presented at conferences, but your name and the name of your practice will not appear in any publications. All data reported will be kept pseudonymous. You will be provided with a report of the results at the end of the study.

There is a risk that participants may disclose poor practice during interviews. In the unlikely event that this occurs, any cases will be reported to Professor Tom Fahey (RCSI) and Professor Cristín Ryan (TCD) who will take appropriate action on a case-by-case basis which may involve informing the appropriate professional regulatory body. Any disclosure of poor practice will be retained in the transcripts but not used in any formal output from the study.

In order to ensure that studies involving human participants are carried out to a high standard, the University is required to monitor on-going research studies and as a result, staff from Trinity College Dublin may need to review the information collected as part of this research.

Compensation:

This study is covered by standard institutional indemnity insurance. Nothing in this document restricts or curtails your rights.

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Voluntary Participation:

If you decide to volunteer to participate in this study, you may withdraw at any time. If you decide not to participate, or if you withdraw, you will not be penalised and will not give up any benefits that you had before entering the study. Any data that you have provided up to the point of withdrawal will not be used in the research and your data will be destroyed immediately.

Stopping the study:

The investigators may withdraw your participation in the study at any time without your consent.

Permission:

The study has received ethical approval from the School of Pharmacy and Pharmaceutical Sciences (TCD) Research Ethics Committee.

Names of researchers:

Prof. Carmel Hughes,[1] Dr. Heather Barry,[1] Dr. Audrey Rankin,[1] Prof. Cristín Ryan,[2] Ms. Ashleigh Gorman,[2] Dr. Cathal Cadogan,[3] Prof. Tom Fahey,[4] and Dr. Gerard Gormley,[5]

[1]School of Pharmacy, Queen's University Belfast, [2]School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, [3]School of Pharmacy, Royal College of Surgeons in Ireland

[4]Department of General Practice, Royal College of Surgeons in Ireland, [5]School of Medicine Dentistry and Biomedical Sciences, Queen's University Belfast

Further information and how to take part

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from Dr. Audrey Rankin or Ms. Ashleigh

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The University of Dublin

General Practitioner Information Leaflet

Gorman who can be contacted on the details given below. If the study team learns of important new information that might affect your desire to remain in the study, you will be informed at once.

Contact details for more information:

Dr. Audrey Rankin
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
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Email: a.rankin@qub.ac.uk

Ms. Ashleigh Gorman
Research Assistant
School of Pharmacy and Pharmaceutical Sciences
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Telephone: 01 8962943
Email: gormanas@tcd.ie

Prof. Carmel Hughes
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School of Pharmacy
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Email: c.hughes@qub.ac.uk

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Appendix 3.8 General practitioner consent form

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

General Practitioner Consent Form

PROJECT TITLE: A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

PRINCIPAL INVESTIGATORS: Prof. Carmel Hughes (Queen's University Belfast) and Prof. Cristín Ryan (Trinity College Dublin).

BACKGROUND:

The aim of the current study is to refine an intervention focusing on appropriate polypharmacy in older people for use in the Republic of Ireland (ROI). Members of the research team have developed a theory-based intervention, targeting prescribing of appropriate polypharmacy in primary care, which has been tested for feasibility in two general practices in Northern Ireland (NI).

You will be asked to participate in an interview with a researcher (Dr. Audrey Rankin/Ms. Ashleigh Gorman). The interview will last approximately one hour, although this may vary between individuals. The interview will be conducted at a time and date to suit you, at your place of work. During the interview, you will be asked about how you usually manage the prescribing of polypharmacy for older people. The researcher will then describe the existing intervention which consists of two components: (a) a video incorporating behaviour change techniques (BCTs) demonstrating how general practitioners (GPs) can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review). You will then be asked to comment on its content, mode of delivery, relevance to practice, and to suggest any changes that you may feel would be required.

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Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

General Practitioner Consent Form

Your identity will remain confidential. Interviews will be audio-recorded, recordings will be pseudonymous and all identifiable information (i.e. your name or the name of your practice) will be replaced with unique ID codes during transcription. Information gained from the study including identifiable information such as consent forms will be stored securely at the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin or the School of Pharmacy, Queen's University Belfast. When the study has been completed, participant consent forms and transcripts stored at Queen's University Belfast will be transferred to Trinity College Dublin [in line with General Data Protection Regulations (GDPR 2018) for the transferring of data]. These will be kept for five years and then destroyed (shredded and disposed of in confidential waste bags). Data may be published in academic journals and presented at conferences but your name and the name of your practice will not appear in any publications.

DECLARATION:

I have read, or had read to me, the information leaflet for this project and I understand the contents. I have had the opportunity to ask questions and all my questions have been answered to my satisfaction. I freely and voluntarily agree to be part of this research study, though without prejudice to my legal and ethical rights. I understand that I may withdraw from the study at any time and I have received a copy of this agreement. I agree for the interview to be audio-recorded and will be given access to the transcript if I wish. I understand that my personal information (including consent forms) will be kept confidential and stored in a safe manner in the School of Pharmacy and Pharmaceutical Sciences, TCD or the School of Pharmacy, QUB. I understand that at the end of the study, my personal information (including consent forms) will be transferred to the School of Pharmacy and Pharmaceutical Sciences, TCD for storage. I understand that the data gathered during the study including my personal information will be transferred to the School of Pharmacy, QUB for analysis by named researchers involved in this project (which can be found below). I understand that my

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personal information will not be used in future unrelated studies without further specific permission being obtained.

PARTICIPANT'S NAME:

CONTACT DETAILS:

PARTICIPANT'S SIGNATURE:

Date:

Statement of investigator's responsibility: I have explained the nature and purpose of this research study, the procedures to be undertaken and any risks that may be involved. I have offered to answer any questions and fully answered such questions. I believe that the participant understands my explanation and has freely given informed consent.

INVESTIGATOR'S SIGNATURE: Date:

(Keep the original of this form in the investigator's file and give one copy to the participant).

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Appendix 3.9 Certificate of participation

Trinity College Dublin
The University of Dublin

School of Pharmacy and Pharmaceutical Sciences

Certificate of Participation

For

Title of Event: Interview to refine an intervention to improve appropriate polypharmacy in older people in primary care

Date of Event:

Name of Individual:

I hereby certify that the individual named above attended this event.

Signed: _____

Event Organiser: Professor Cristín Ryan

Professor in Practice of Pharmacy, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin

Appendix 3.10 Topic guide

GP interview schedule

Introduction

"Thank you very much for making the time to talk to me today.

Have you had a chance to read through the information leaflet that was sent out to you?

The aim of this interview is to explore your views of polypharmacy in older people (those aged 70 years and over), your approach to prescribing polypharmacy for this age group and your views on an intervention developed to improve appropriate polypharmacy for older patients in primary care. I'd like to focus specifically on older patients living within the community as opposed to those in nursing home or residential care home settings. The interview should last approximately/no more than [estimated duration] minutes.

Before we start, I just need to get written consent from you that you understand what the study involves; that you know that anything you say will be kept completely confidential; that you will not be identified in any way; that you know that we can stop at any time; and that you are happy for the interview to be recorded. If you wouldn't mind, can you read through this consent form, initial each of the boxes, and sign and date in the relevant section? During the interview, remember that there are no right or wrong answers, so please give your honest opinions to the questions. You are free to stop the interview and/or recording at any time.

[Turn recorder on]

Have you any immediate questions about the study before we start the interview?"

Demographics

- Could you tell me how long you have been practising as a GP?
- Approximately, what percentage of the patients in this practice are older patients (i.e. aged ≥70 years)?
- On a typical working day in your practice:
    - Approximately what percentage of your overall prescribing is for older patients?
    - What proportion of your prescribing would be issuing an acute prescription as opposed a repeat prescription for multiple medications to a typical older patient in your practice?
    - What proportion of your prescribing for older patients would be done during a face-to-face consultation?

- What would be the average number of medicines regularly prescribed per older patient?

Definitions

How would you define polypharmacy?

PROMPTS (depending on response):

- Do you think about polypharmacy in terms of the number of medicines?
- Do you ever think about polypharmacy in a different way?

There are several definitions of polypharmacy in the literature. For the purpose of this project, we are adopting a definition of polypharmacy which states that…

[Hand participant printed flashcard with definition of polypharmacy]

- **Polypharmacy** constitutes the co-prescribing of four or more regular medicines (Cochrane Review)

In the past, prescribing many medicines (polypharmacy) has been viewed negatively. However, more recently, because people are living longer, have a number of medical conditions at the same time, and medical guidelines recommend that a number of different medicines may need to be prescribed for these conditions, views on polypharmacy have changed. Consequently, use of the term 'appropriate polypharmacy', has been advocated which refers to…

[Hand participant printed flashcard with definition of appropriate polypharmacy]

- **Appropriate polypharmacy** is defined as prescribing for an individual for complex conditions or for multiple conditions in circumstances where medicines use has been optimised and where the medicines are prescribed according to best evidence.

The concept of appropriate polypharmacy is really about recognising that some patients may benefit from multiple medicines and highlights the importance of getting the balance right between 'many' and 'too many' drugs.

Current prescribing practices

Q. Could you describe your approach to issuing an acute prescription for multiple medications to a typical older patient in your practice?

Prompt: How would you start the prescribing process for an older person?

Potential generic prompts here (if appropriate)

- What would you do next?

- Anything else?
- [possibly] Would you always do these things in the same order?
- Can you think of any exceptions to this approach?

Prompt: Would the process differ if the patient was present at a consultation or not?
Prompt: On average how long would a face-to-face consultation with an older person last?

Q. Could you describe your approach to issuing a repeat prescription for multiple medications to a typical older patient in your practice?
Prompt: How would you start the repeat prescribing process for an older person?
Potential generic prompts here (if appropriate)

- What would you do next?
- Anything else?
- [possibly] Would you always do these things in the same order?
- Can you think of any exceptions to this approach?

Prompt: Would this differ if the patient was present at a consultation or not?
Prompt: Would you routinely recall patients who have not been seen for 6 months?

Q. A lot of changes to medicines are initiated in a hospital setting. How would this impact upon your current prescribing practices?
Prompt: How would you approach initiating these changes (stopping, starting, changing doses)?
Prompt: How would you address a patient's concerns about this?

Existing intervention package

Members of the research team have developed an intervention, targeting prescribing of appropriate polypharmacy in primary care. In a previous study, we interviewed GPs, community pharmacists and patients, and asked for their views on polypharmacy and how they thought it could be improved. From the information we obtained and after working with a health psychologist, we developed a new intervention which has already been tested for feasibility in two general practices in Northern Ireland (NI). The existing intervention consists of a short online video that demonstrates how a general practitioner (GP) prescribes appropriate polypharmacy during a typical consultation with an older patient. GPs then invite patients to attend for a consultation to review their medicines. The aim of the current study is to seek the views of GPs in the six border counties in the Republic of Ireland (ROI) about this intervention and if necessary, refine it further before testing it in a pilot trial in both NI and the ROI. This pilot trial will be conducted in 12 practices: six practices in NI and six practices in the six border counties in the ROI (Cavan, Donegal, Leitrim, Louth, Monaghan and Sligo).

The first component is a video demonstrating how GPs can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient. The video also includes feedback from both a practising GP and a simulated patient to emphasise the positive outcomes of the consultation.

I'm now going to show you the intervention video we prepared for the NI feasibility study.

[Play video]

Q. Do you have any immediate thoughts on the video?
Prompt: Do you have any comments on the content of the video?
Prompt: Do you have any thoughts on using a video in this way to demonstrate prescribing appropriate polypharmacy?

Q. Are there any aspects in particular you like about the video?
Prompt: Length of video; clinical scenario used; GP and patient interaction.
Q. Are there any aspects that you dislike about the video?
Prompt: Why did you dislike this?
Prompt: How could this been improved/overcome?
Q. Is there anything that you would change about the video?
Prompt: Anything else?

The second component of the intervention is a patient recall process, whereby patients attend the practice for their scheduled appointment to undertake medication review consultations with GPs. In order to facilitate this, GPs make a plan at weekly meetings with practice colleagues (i.e. reception staff, practice managers) of when and how they would ensure that older patients meeting the inclusion criteria (i.e. ≥70 years, receiving four or more regular medicines, not cognitively impaired, resident in the community) will be invited to the GP surgery for a medication review

Q. What do you think about this approach?
Prompt: How would you organise this in your practice?
Prompt: What would be the barriers to implementing this in your practice?
Prompt: What would help you to implement this in your practice?

Reception staff also assist in scheduling the consultations for patients. GPs are prompted by the receptionist/practice manager to perform medication reviews to address appropriate polypharmacy with older patients meeting certain inclusion criteria when these patients attend for a scheduled appointment.

Q. What do you think about this approach?
Prompt: How would you organise this in your practice?
Prompt: What would be the barriers to implementing this in your practice?
Prompt: What would help you to implement this in your practice?

General Questions

Q. Do you think this type of intervention would fit into your current practice?
Prompt: Think of when and how you would use this type of intervention in practice; do you think it would make it easier to perform medication reviews?

Q. How often do you think the video should be shown to the GPs involved in a future pilot study?
Prompt: Do you think once is enough?
Prompt: Do you think access to the video throughout the duration of the intervention would be useful?

Q. Overall, can you think of any potential barriers to implementing this type of intervention into practice?
Prompt: Lack of appropriate resources (e.g. staff); time constraints; financial constraints.
Prompt: Anything else?

Q. What might help to implement this type of intervention into practice?
Prompt: Adequate staff; incentives/rewards; professional recognition; education/skills training.
Prompt: Anything else?

Q. Can you think of any changes that you feel would be required?
Prompt: Anything else?

Concluding comments

That brings us to the end of the interview.

Is there anything else on the topic of appropriate polypharmacy in older people or the existing intervention package that you feel has not been covered?

Do you have any additional comments that you would like to make as to the content of the interview or how it went?

Thank you very much for giving up your time to talk to me today.

[Turn voice recorder off]

Appendix 3.11 Coding scheme

A qualitative study to refine a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)

Coding Scheme

	Coding categories / Codes	Definition
1	General Practitioners' (GPs) definitions of polypharmacy	
1.1	Polypharmacy definition	Data relating to the GPs definition of polypharmacy
2	Current prescribing practices	
2.1	Acute prescriptions	Data relating to the process of issuing an acute prescription
2.2	Repeat prescriptions	Data relating to process of issuing a repeat prescription
2.3	Patient recalls	Data relating to the process of routinely recalling patients for consultations
2.4	Prescriptions initiated by other prescribers	Data relating to the initiation of medicines prescribed by other medical professionals
3	Intervention component – video [a]	
3.1	Clinical scenario	Data relating to the clinical scenario addressed within the video component; to include data to the complexity of the patient discussed
3.2	Length of video	Data relating to the length of video; to include data on time constraints within primary care
3.3	GP/Patient interaction	Data relating to the interaction between the GP and the patient as shown within the video component
3.4	Engagement with video	Data relating to how often the GPs should be able to access the video during a future pilot study
3.5	Positive comments [video]	Data relating to the positive statements made surrounding the video component
3.6	Negative comments [video]	Data relating to the negative statements made surrounding the video component
3.7	Improvements required [video]	Data relating to statements made surrounding the potential improvements required (or additions) to the video component
4	Intervention component – explicit plans [b]	
4.1	Potential barriers [explicit plans]	Data relating to negative statements surrounding the use of making explicit plans at weekly meetings

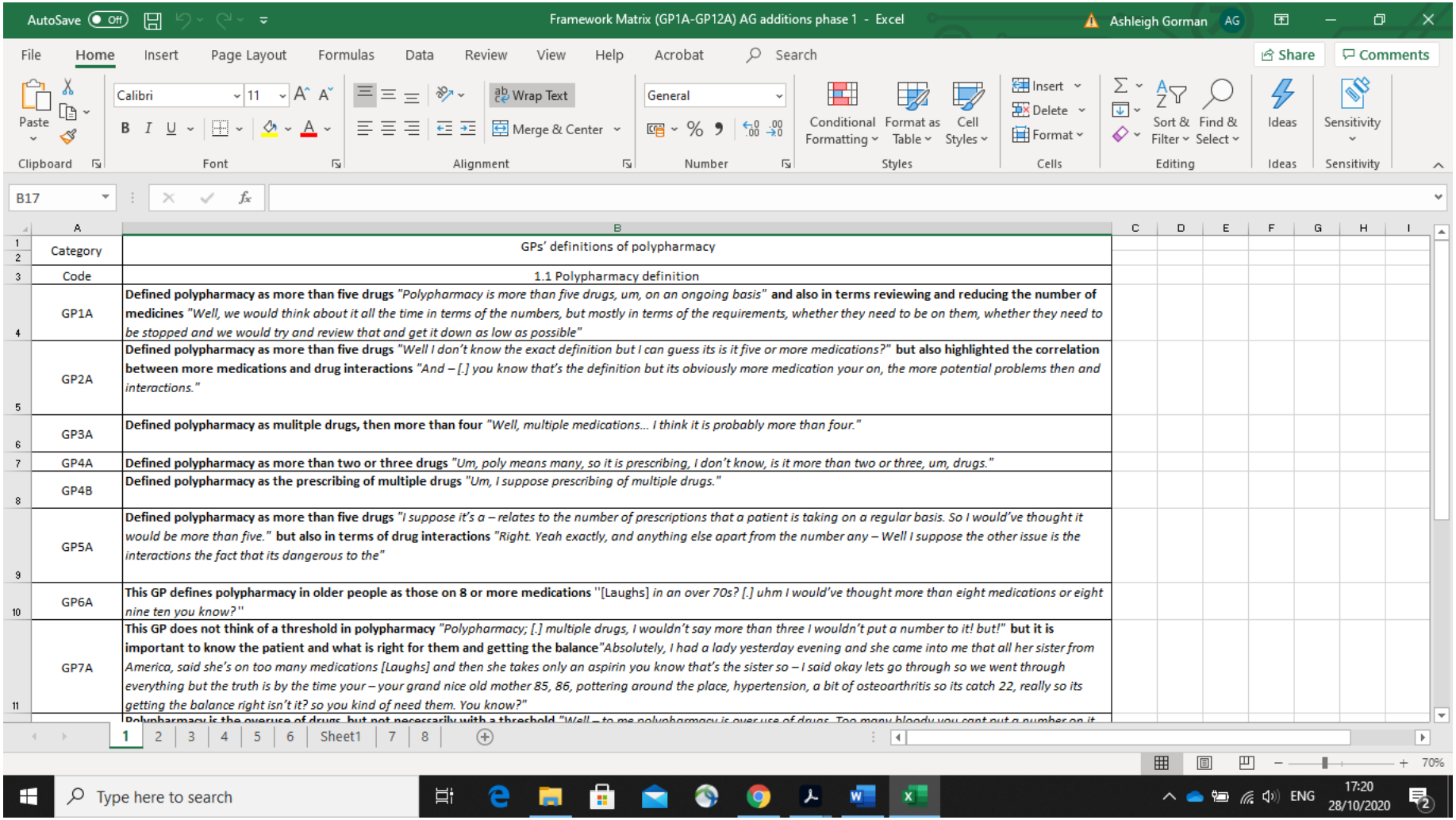
4.2	Potential enablers [explicit plans]	Data relating to positive statements surrounding the use of making explicit plans at weekly meetings
4.3	Improvements/ additions required [explicit plans]	Data relating to statements surrounding potential improvements required or additions to the use of making explicit plans at weekly meetings
5	Intervention component – prompts [c]	
5.1	Potential barriers [prompts]	Data relating to the factors preventing the use of prompts by the practice staff
5.2	Potential enablers [prompts]	Data relating to the factors which could facilitate the use of prompts by the practice staff
5.3	Improvements/ additions required [prompts]	Data relating to statements surrounding potential improvements required or additions to the use of prompts by the practice staff
6	GPs' views on the overall intervention package	
6.1	Potential barriers [overall]	Data relating to the factors preventing the uptake of the overall intervention package
6.2	Potential enablers [overall]	Data relating to the factors which could facilitate the uptake of the overall intervention package
6.3	Improvements/additions required [overall]	Data relating to statements surrounding potential improvements required or additions to the overall intervention package
7	Contextual factors	
7.1	Contextual information	Data relating to primary care contextual information

[a] Video demonstrating how GPs can prescribe appropriate polypharmacy.

[b] Explicit plans were made at weekly meetings with practice staff to ensure that target patients were prescribed appropriate polypharmacy.

[c] Reception staff scheduling the consultations for recruited patients and prompting GPs to review patients' medications.

Appendix 3.12 Framework matrix screenshot of 'GPs definition of polypharmacy



	A	B
1	Category	GPs' definitions of polypharmacy
2		
3	Code	1.1 Polypharmacy definition
4	GP1A	**Defined polypharmacy as more than five drugs** *"Polypharmacy is more than five drugs, um, on an ongoing basis"* **and also in terms reviewing and reducing the number of medicines** *"Well, we would think about it all the time in terms of the numbers, but mostly in terms of the requirements, whether they need to be on them, whether they need to be stopped and we would try and review that and get it down as low as possible"*
5	GP2A	**Defined polypharmacy as more than five drugs** *"Well I don't know the exact definition but I can guess its is it five or more medications?"* **but also highlighted the correlation between more medications and drug interactions** *"And – [.] you know that's the definition but its obviously more medication your on, the more potential problems then and interactions."*
6	GP3A	**Defined polypharmacy as mulitple drugs, then more than four** *"Well, multiple medications... I think it is probably more than four."*
7	GP4A	**Defined polypharmacy as more than two or three drugs** *"Um, poly means many, so it is prescribing, I don't know, is it more than two or three, um, drugs."*
8	GP4B	**Defined polypharmacy as the prescribing of multiple drugs** *"Um, I suppose prescribing of multiple drugs."*
9	GP5A	**Defined polypharmacy as more than five drugs** *"I suppose it's a – relates to the number of prescriptions that a patient is taking on a regular basis. So I would've thought it would be more than five."* **but also in terms of drug interactions** *"Right. Yeah exactly, and anything else apart from the number any – Well I suppose the other issue is the interactions the fact that its dangerous to the"*
10	GP6A	**This GP defines polypharmacy in older people as those on 8 or more medications** ''[Laughs] *in an over 70s? [.] uhm I would've thought more than eight medications or eight nine ten you know?''*
11	GP7A	**This GP does not think of a threshold in polypharmacy** *"Polypharmacy; [.] multiple drugs, I wouldn't say more than three I wouldn't put a number to it! but!"* **but it is important to know the patient and what is right for them and getting the balance***"Absolutely, I had a lady yesterday evening and she came into me that all her sister from America, said she's on too many medications [Laughs] and then she takes only an aspirin you know that's the sister so – I said okay lets go through so we went through everything but the truth is by the time your – your grand nice old mother 85, 86, pottering around the place, hypertension, a bit of osteoarthritis so its catch 22, really so its getting the balance right isn't it? so you kind of need them. You know?"*

Appendix 3.13 Consolidated criteria for reporting qualitative research (COREQ) checklist (adapted from Tong *et al.* 2007)

Number/ Item	Guide question/ description	Page number
Domain 1: Research team and reflexivity		
Personal characteristics		
1. Interviewer/facilitator	Which author/s conducted the interview or focus group?	90
2. Credentials	What were the researcher's credentials? E.g. PhD, MD	90
3. Occupation	What was their occupation at the time of the study?	352
4. Gender	Was the researcher male or female?	352
5. Experience and training	What experience or training did the researcher have?	352
Relationship with participants		
6. Relationship established	Was a relationship established prior to study commencement?	90
7. Participant knowledge of the interviewer	What did the participants know about the researcher? E.g. personal goals, reasons for doing the research	90
8. Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? E.g. bias, assumptions, reasons and interests in the topic	NR
Domain 2: Study design		
Theoretical framework		
9. Methodological orientation and theory	What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	N/A
Participant selection		
10. Sampling	How were participants selected? E.g. purposive, convenience, consecutive, snowball	84
11. Method of approach	How were participants approached? E.g. face-to-face, telephone, mail, email	84
12. Sample size	How many participants were in the study?	90
13. Non-participation	How many people refused to participate or dropped out? Reasons?	90
Setting		
14. Setting of data collection	Where was the data collected? E.g. home, clinic, workplace	85
15. Presence of non-participants	Was anyone else present besides the participants and researchers?	85
16. Description of sample	What are the important characteristics of the sample? E.g. demographic data, date	90
Data collection		
17. Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	85
18. Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A

19. Audio/ visual recording	Did the research use audio or visual recording to collect the data?	85
20. Field notes	Were field notes made during and/or after the interview or focus group?	N/A
21. Duration	What was the duration of the interviews or focus groups?	90
22. Data saturation	Was data saturation discussed?	105
23. Transcripts returned	Were transcripts returned to participants for comment and/or correction?	NR
Domain 3: Analysis and findings		
Data analysis		
24. Number of data coders	How many data coders coded the data?	86
25. Description of the coding tree	Did authors provide a description of the coding tree?	371
26. Derivation of themes	Were themes identified in advance or derived from the data?	86
27. Software	What software, if applicable, was used to manage the data?	86
28. Participant checking	Did participants provide feedback on the findings?	NR
Reporting		
29. Quotations presented	Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified? E.g. participant number	90
30. Data and findings consistent	Was there consistency between the data presented and the findings?	90
31. Clarity of major themes	Were major themes clearly presented in the findings?	90
32. Clarity of minor themes	Is there a description of diverse cases of discussion of minor themes?	90

Appendix 3.14 Research integrity and impact in an open scholarship era certificate

CERTIFICATE OF COMPLETION

IS AWARDED TO

Ashleigh Gorman

FOR SUCCESSFULLY PASSING ALL PARTS OF MODULE CA7000
'RESEARCH INTEGRITY AND IMPACT IN AN OPEN SCHOLARSHIP ERA.'

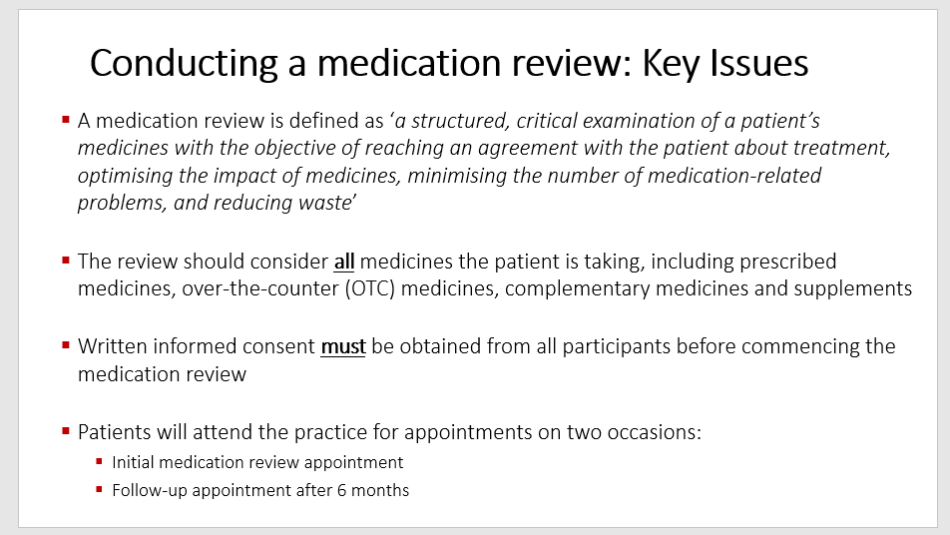
January 2020

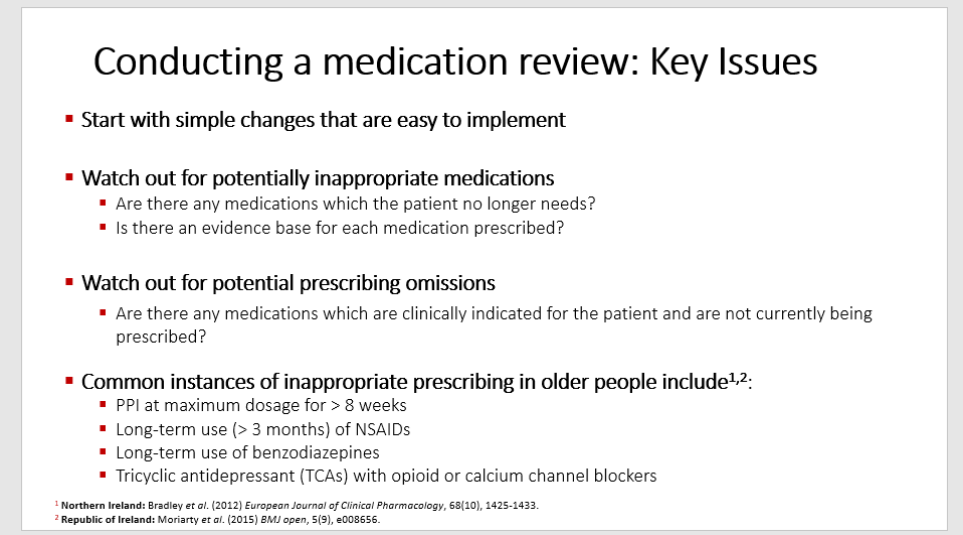
Trinity College Dublin
The University of Dublin

PROFESSOR NEVILLE COX
Dean of Graduate Studies

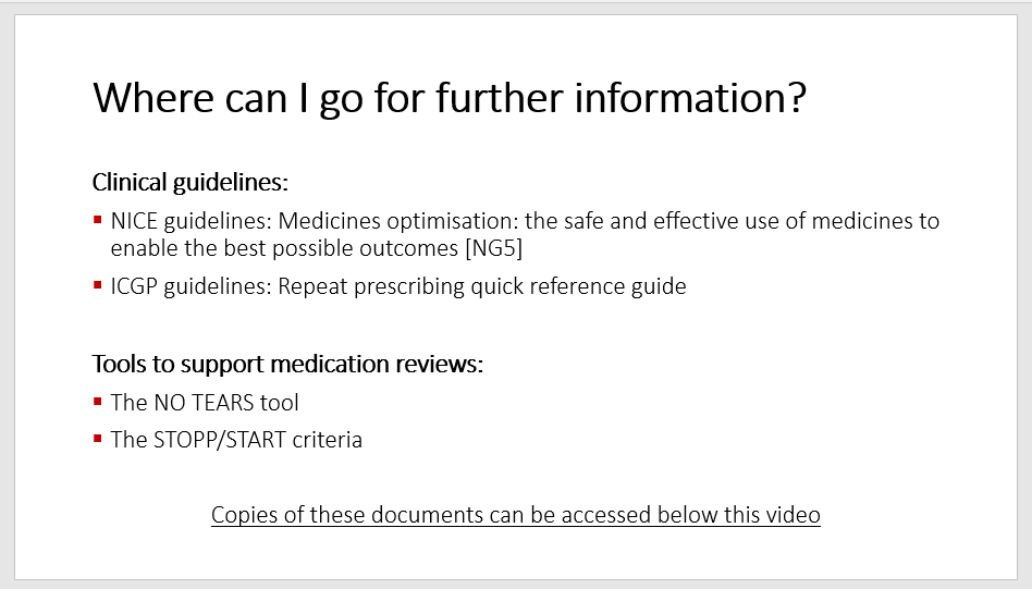
NIAMH BRENNAN
Course Coordinator

Appendix 3.15 Educational slides added to the video component





Appendix 3.16 Further information added to the video component including guidelines and validated assessment tools



Appendix 3.17 Information sheet for practice staff

PolyPrime

Practice Staff Information Leaflet

Screening GP records for eligible patients

- Practice staff will be asked to screen patients who are potentially eligible to take part in the study; a Research Nurse will be able to support you in doing this.
- The research team will provide patient information packs which will be posted to eligible patients in batches of 25; until ten patients confirm that they will take part in the study.

The study inclusion/exclusion criteria are as follows:

Inclusion criteria	Exclusion criteria
Aged 70 years or over	Care home residents
Receiving four or more regular medicines	Cognitively impaired
Resident in the community	Diagnosed with a terminal illness
In receipt of either a valid general medical services (GMS) card in the Republic of Ireland or registered for NHS primary care services	Involved in other Investigational Medicinal Product (IMP) or medicines management studies
Registered with and/or regularly attending the practice for a minimum of 12 months	

- Each practice will be assigned at random into one of two groups, the intervention group or the control group.
- If your practice is in the control group, patients will continue to be treated as usual.
- If your practice is in the intervention group, patients will attend the practice for medication reviews on two occasions. The practice staff will assist in the following components of the intervention: (1) scheduling patients to attend medication review appointments and (2) prompting GPs to conduct the review.

1. Scheduling patients' medication review appointments

- Practice staff will be given a list of patients who have agreed to take part in the study.
- Practice staff will then organise an appointment for the patient to attend the practice for their medication review with one of the GPs involved in the study.
- After 6 months, the practice staff will be contacted by the researchers and asked to schedule the patient's follow-up appointment with the same GP.

2. Prompting GPs to conduct medication reviews

- Practice staff will prompt GPs to conduct medication reviews with recruited patients when they present at the practice for their scheduled appointments.
- Practice staff will complete the Practice Staff Input Form for each patient when they attend the practice for their scheduled appointments.

Appendix 3.18 Patient recruitment poster

Appendix 4.1: Ethical approval letter July 2019

23 July 2019

Prof. Carmel Hughes
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast

PolyPrime trial: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

Dear Professor Hughes,

The ICGP Research Ethics Committee have reviewed your clarifications and are happy to grant the above named study ethical approval.

The following documents were reviewed and approved:

- Research Ethics Standard Application Form- 14.05.2019
- Study protocol v1-09.05.2019
- Declaration and Signatory Page
- DPIA Screening Form
- MRB-QoL tool v2- 19.06.2019
- Effective Ireland EQ-5D-5L Paper Self complete v1.0- 01.04.2019
- EQ-5D-5L Paper Interviewer Administration v1.1- 29.03.2019
- General Practitioner Information Sheet v2- 19.06.2019
- General Practitioner Consent Form v2- 20.06.2019
- Patient Participant Information Sheet v2- 19.06.2019
- Patient Participant Consent Form v2- 20.06.2019
- General Practitioner Invitation Letter v1-09.05.2019
- Patient Participant Invitation Letter v1- 09.05.2019
- Health Service Use Questionnaire v1- 08.05.2019
- PolyPrime Study Health Service Use Diary v1- 08.05.2019
- Certificate of Participation v1- 09.05.2019
- Recruitment Poster v1- 03.05.2019
- Pilot Study Overview v1- 03.05.2019
- Letter of Support (GP Practices)- 19.06.2019
- Patient Case Report Form v1- 05.07.2019
- Evidence of indemnity
- PI and co-investigator CVs

Please note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submit a one page follow-up report one year to the date that the application was approved.
2. Report unexpected adverse events, serious adverse events, or any ethical harms that may affect ethical acceptability of the study.
3. Submit any change to study documentation (minor or major) to ICGP REC for review and approval. Amendments must be submitted on the standard amendment form and revised study documents must clearly highlight the changes and include a new version number and date. Amendments cannot be implemented without written approval from ICGP REC.
4. Notify the ICGP REC if the study is discontinued.
5. Notify the ICGP REC of study completion using the study completion notification form.

If you have any further questions please contact Colleen O'Neil, colleen.oneil@icgp.ie.

Yours sincerely,

Sent on behalf of Dr. Claire Collins
Chair, Research Ethics Committee

Appendix 4.2: Brief overview of the PolyPrime study

School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin

xx/07/2019

Dear Practice Manager,

A randomised pilot study of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)

We would like to invite GP practices to express an interest in participating in a study which involves testing how an intervention to improve appropriate polypharmacy in older people works in practice.

A team of health care professionals, patient representatives and researchers have developed a novel theory-based intervention, targeting the prescribing of appropriate polypharmacy in older people in primary care (PolyPrime). The PolyPrime intervention package currently consists of two components: (a) a video demonstrating how general practitioners (GPs) can prescribe appropriate polypharmacy during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review). We hope this study will allow us to test and compare the delivery of the intervention across general practices in Northern Ireland and the border counties of the Republic of Ireland (ROI).

We have already tested this intervention in a feasibility study in NI and conducted interviews with GPs in the ROI border counties, which has helped us refine the details of the intervention. The current study will contribute to the development of the intervention further, through testing in a larger pilot study in six GP practices across NI and the border counties in ROI respectively.

GP practices selected to be part of the 'intervention group' would be asked to watch the PolyPrime intervention video and then perform medication reviews on two occasions with approximately 10 patients who are recruited into the study. GP practices selected to be part of the 'control group' will continue to treat the recruited patients as normal (i.e. usual care). However, at the end of the study, all 'control group' GP practices will be offered access to the PolyPrime intervention video.

The study was submitted for ethical approval in May 2019, but in the interim, we would very much like to receive Expressions of Interest from interested GP practices, to inform future

planning. If you are interested in taking part in the PolyPrime study, then please complete and return the attached Expression of Interest form using the envelope provided. We will then contact you to provide further information and to answer any questions you may have.

Many thanks in advance,

Yours sincerely,

Prof. Cristín Ryan

Professor in Practice of Pharmacy, Trinity College Dublin.

On behalf of the research team: Prof. Carmel Hughes, Dr. Heather Barry, Dr. Audrey Rankin, Ms. Ashleigh Gorman, Dr. Cathal Cadogan, Prof. Tom Fahey, Prof. Gerard Gormley and Dr. Gerry Molloy

Appendix 4.3 Expression of Interest form

PolyPrime

Expression of Interest Form

- I have read the enclosed 'Expression of Interest Letter' and have had the opportunity to consider the information.

- I understand that by completing this form I am expressing an interest and will be contacted by a member of the PolyPrime study team with further information and to discuss participation in the study.

- I understand that I am free to contact a member of the PolyPrime study team (see below for contact details) should I have any further questions.

- I understand that returning this form does not oblige me to participate.

Name: …… GP Practice name: …….

Phone number: …… Email address: …….

Date: ……

If your practice is in **Northern Ireland** please return this form to:
Dr. Audrey Rankin
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: +44 (0)28 9097 2348
Email: a.rankin@qub.ac.uk

If your practice is in the **Republic of Ireland** please return this form to:
Ms. Ashleigh Gorman
Research Assistant
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin D02PN40
Telephone: +353 86 608 9094
Email: gormanas@tcd.ie

Appendix 4.4 General practitioner invitation letter

On QUB or TCD headed notepaper

Date xx/xx/2019

Dear (insert General Practitioner's name),

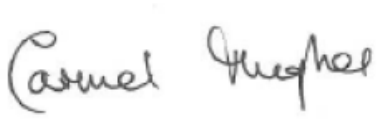
Re: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

I am writing to invite you to take part in the above named study. Members of the research team have developed a theory-based intervention, targeting prescribing of appropriate polypharmacy in primary care, which has been tested for feasibility in two general practices in Northern Ireland (NI). The existing intervention package currently consists of two components: (a) a video demonstrating how general practitioners (GPs) can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review). This study forms part of an ongoing research project in which we have conducted interviews with GPs in the border region of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim, Louth, Monaghan and Sligo). During the interviews the intervention package was described in more detail and GPs were shown the video component. GPs were then asked to comment on the content of the intervention package, mode of delivery, relevance to practice, and to suggest any changes that they felt would be required.

The current study will contribute to the development of the intervention further, through testing in a larger pilot study in six GP practices across NI and the border counties in ROI respectively. This will allow us to test and compare the delivery of the intervention across NI and the ROI and to decide whether to progress to a full-scale randomised trial at a later date.

Please find enclosed a study information sheet, which provides further information about the study. If you have any queries, please do not hesitate to contact the Research Fellow/Assistant (Dr. Audrey Rankin/Ms. Ashleigh Gorman), or any other member of the research team as detailed below. We appreciate the time you have taken to read this letter and the enclosed information sheet. We will be in contact with you over the next week to discuss if you would like to participate.

Yours sincerely,



Prof. Carmel Hughes

Professor of Primary Care Pharmacy, Queen's University Belfast.

On behalf of the research team:

Prof. Cristín Ryan, Dr. Heather Barry, Dr. Audrey Rankin, Ms. Ashleigh Gorman, Dr. Cathal Cadogan, Prof. Tom Fahey, Dr. Gerard Gormley and Dr. Gerry Molloy

If your practice is in **Northern Ireland**

Dr. Audrey Rankin
Research Fellow
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: +44 (0) 7391 730647
Email: a.rankin@qub.ac.uk

Prof. Carmel Hughes
Professor of Primary Care Pharmacy
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast BT9 7BL
Telephone: +44 (0)28 9097 2147
Email: c.hughes@qub.ac.uk

If your practice is in **Republic of Ireland**

Ms. Ashleigh Gorman
Research Assistant
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin D02PN40
Telephone: +353 (0) 86 608 9094
Email: gormanas@tcd.ie

Prof. Cristín Ryan
Professor in Practice of Pharmacy
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin D02PN40
Telephone: +353 (0) 1 896 8452
Email: cristin.ryan@tcd.ie

Appendix 4.5 Study information leaflet

Study Title: A pilot cluster randomised controlled trial of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)

Chief Investigator: Professor Carmel Hughes (Queen's University Belfast)

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important that you take time to understand why this research is being completed and what will be asked of you should you agree to participate. Please read the following information and contact the Research Fellow/Assistant (Dr. Audrey Rankin / Ms. Ashleigh Gorman), or any other member of the research team if you have any questions. Contact details can be found at the end of this information sheet.

Why is this research being done?

Polypharmacy (sometimes defined as the use of four or more medicines) is the new paradigm for prescribing in older people, largely driven by multimorbidity and evidence-based guidelines for the management of long-term conditions. The prescribing of appropriate polypharmacy is a well-documented challenge which faces healthcare professionals (HCPs), particularly general practitioners (GPs) who prescribe most of older people's medicines. Despite this, evidence of effective interventions to improve the appropriate prescribing of polypharmacy for older people is lacking, owing primarily to a lack of input from HCPs and patients when designing interventions. Members of the research team have developed a theory-based intervention, targeting prescribing of appropriate polypharmacy in primary care, which has been tested for feasibility in two general practices in Northern Ireland (NI). The existing intervention package currently consists of two components: (a) a video demonstrating how GPs can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review).

What is the purpose of this study?

This study forms part of an ongoing research project during which we have conducted interviews with GPs in the border region of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim,

Louth, Monaghan and Sligo). During these interviews the intervention package was described in more detail and GPs were shown the video component. GPs were then asked to comment on the content of the intervention package, mode of delivery, relevance to practice, and to suggest any changes that they felt would be required.

The current study will contribute to the development of the intervention further, through testing in a larger pilot study in six GP practices across NI and the border counties in ROI respectively. This will allow us to test and compare the delivery of the intervention across NI and the ROI and to decide whether to progress to a full-scale randomised trial at a later date.

Who is organising and funding this study?

This research is being organised by the Schools of Pharmacy and Medicine, Queen's University Belfast, the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, the School of Pharmacy and Department of General Practice, Royal College of Surgeons in Ireland and the School of Psychology, National University of Ireland Galway. This project is funded by the Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) which is a unique cross-border partnership between the Public Health Agency in Northern Ireland and the Health Research Board in the Republic of Ireland, to develop infrastructure and deliver Healthcare Intervention Trials (HITs). The study has received ethical approval from the North of Scotland Research Ethics Committee (Reference Number: 19/NS/0100) and the Irish College of General Practitioners (ICGP) Research Ethics Committee.

Why am I being asked to take part?

You have been approached to participate in this study because you are a GP who prescribes medicines for older patients.

What will happen to me if I agree to take part?

If you would like to take part, please return your completed consent form to the Research Fellow/Assistant (Dr. Audrey Rankin / Ms. Ashleigh Gorman) to confirm that you would like to take part in the study.

If you volunteer to take part in this study, several things may happen:

- Your practice will be asked to screen patients who will be eligible to take part in the study; a Research Nurse will be able to support your Practice Manager in doing this.
- Your practice will be assigned at random, that is, by a method of chance, into one of two groups. There will be an equal chance that your practice will be in the control arm

who will continue to treat the recruited patients as normal (i.e. usual care) or in the intervention arm who will be asked to perform medication reviews with patients who are recruited into the study.

- If your practice is in the intervention group, you will be asked to complete medication reviews with approximately 10 patients.
- Your practice (whether in the intervention or control group) will be asked to share data from recruited patients' medical records, subject to these patients providing written informed consent to the researchers.
- If your practice is in the intervention group, you may be asked to tape-record (audio-record) your discussions during a medication review with one of the patients.
- If your practice is in the intervention group, you may also be asked to participate in a feedback interview with one of the researchers at the end of the study, we may share the pseudonymised audio-recordings with a transcription company.

How many people will be in this study?

In total, we will recruit 12 GP practices (six in Northern Ireland and six in the border region of the Republic of Ireland) into this study. Each practice will recruit approximately 10 patients.

What will happen to any video/and or audio recordings?

If you are invited to take part in a feedback interview or record one of your medication reviews, these will be audio-recorded and all audio files will be pseudonymised meaning that any information that could identify you will be removed. Your name or the name of your practice will not appear and will be replaced with a unique code. We may share the pseudonymised audio-recordings with a transcription company. The transcription company will be asked to delete the audio-recordings when transcriptions have been received by the researchers.

What are the possible benefits for me and/or society?

Participation in this study may be beneficial for you, as it will help to determine if the intervention needs to be refined before further evaluations can be undertaken to assess the effectiveness of the intervention in improving appropriate polypharmacy in older people. You could potentially include the completed medication reviews as part of any existing performance assessments that your practice is subject to. Furthermore, you will receive a certificate of participation, which could be used as part of your ongoing continued professional development. The practice in which you work will also be offered an honorarium of £855/€1000 by way of compensation for the time and resources associated with study participation. An additional

£92/€108 (intervention arm) or £46/€54 (control arm) will be paid to GP practices for each patient who is successfully recruited into the study. Furthermore, GPs allocated to the intervention arm, will be asked to invoice us for room hire in order to facilitate the conduct of interviews (maximum £46/€54 per room hire).

Are there any risks or disadvantages of taking part in the study?

There is a risk that poor practice may be identified during the pilot study. In the unlikely event that this occurs, any cases will be reported to the Chief Investigator (Professor Carmel Hughes) who will take appropriate action on a case-by-case basis which may involve informing the appropriate professional regulatory body.

What information will be kept private?

Queen's University Belfast is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen's University Belfast will keep identifiable information about you for five years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw you have the choice of removing any data/information you have provided for the study. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at www.qub.ac.uk/privacynotice/.

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the research group. All identifiable information you provide to us such as your name or the name of your practice will be removed from the data and replaced with a unique ID code. Other identifiable information will be removed. A list linking your ID code with your name will be kept by the Research Fellow in QUB, in a secure place, separate from the information you provide. Information gained from the study including identifiable information such as consent forms will be stored securely at the School of Pharmacy, Queen's University Belfast or the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin in locked filing cabinets. If you are invited to take part in an interview or if you agree to record a medication review all audio files will be pseudonymised meaning that any information that could identify you or your practice will be removed during transcription, after which the audio-recordings will be deleted. When the study has been completed, participant consent forms and

transcripts stored at Trinity College Dublin will be transferred to Queen's University Belfast [in line with General Data Protection Regulation (GDPR 2018) for the transferring of data]. These will be kept for five years and then destroyed, in line with GDPR 2018.

Data may be published in academic journals and presented at conferences, but your name and the name of your practice will not appear in any publications. All data reported will be pseudonymised, meaning that any information that could identify you or your practice will be removed and/or replaced with a unique ID code. You will be provided with a report of the results at the end of the study.

In order to ensure that studies involving human participants are carried out to a high standard, the Queen's University Belfast's or Trinity College Dublin's Research Governance, Ethics and Integrity teams may examine the study data to ensure that we are complying with good practice. By consenting to take part in the study, you are authorising this access.

Can participation in the study end early?

You are free to withdraw from the study at any time. If you decide to withdraw you have the choice of removing any data/information you have provided for the study. The £92/€108 (intervention arm) or £46/€54 (control arm) honorarium will only be paid to the practice on condition that: ten patients who meet inclusion criteria are recruited into the study; medication reviews are completed during a consultation with these patients (intervention arm); the requested data are returned to the researchers.

If I have any questions or problems, whom can I call?

If your practice is in **Northern Ireland** and have any questions about the research, now or later, please contact:

Dr. Audrey Rankin, Research Fellow, School of Pharmacy, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL. Telephone: +44 (0) 7391 730647, Email: a.rankin@qub.ac.uk

If your practice is in the **Republic of Ireland** and have any questions about the research, now or later, please contact:

Ms. Ashleigh Gorman, Research Assistant, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Panoz Institute, Dublin, D02PN40. Telephone: +353 (0) 86 608 9094, Email: gormanas@tcd.ie

If you have concerns about how this research is being conducted, please contact:

Prof. Carmel Hughes, Head of School, School of Pharmacy, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL. Telephone: +44 (0)28 9097 2147, Email: c.hughes@qub.ac.uk

In the event that your concerns are not addressed, please contact:

Mrs Louise Dunlop, Head of Research Governance, Ethics and Integrity, Queen's University

Belfast, BT7 1NN. Tel +44 (0) 28 9097 2572, Email: l.h.dunlop@qub.ac.uk

If you have concerns about how your information is being used, please contact:

Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, D02 RD28, Ireland.

Telephone +353 761 104 800, Online https://forms.dataprotection.ie/contact

Appendix 4.6 Consent form

Study Title: A pilot cluster randomised controlled trial of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

Chief Investigator: Professor Carmel Hughes (Queen's University Belfast)

Please tick the appropriate boxes	Yes	No
1. Taking part in the study		
I have read and understood the information sheet dated [28.07.2020] (version 3.0). I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
I have been given a copy of the information sheet and this completed consent form for my records.	☐	☐
I am aware of the potential risks, benefits and alternatives of this research study.	☐	☐
I agree to patients from my practice being recruited into the study.	☐	☐
I understand that my practice will be one of two groups. If my practice is in the control arm I will continue to treat the recruited patients as normal (i.e. usual care). If my practice in the intervention arm I will be asked to perform medication reviews with patients who are recruited into the study.	☐	☐
If my practice is allocated to the intervention arm, I agree to perform medication reviews with patients who are recruited into the study.	☐	☐
I agree to share data with the researchers from recruited patients' medical records, subject to these patients providing written informed consent.	☐	☐
I understand that if my practice is allocated to the intervention arm, I may be asked to tape-record (audio-record) the discussion during a medication review	☐	☐

with a patient. I agree that the discussions can be recorded, subject to these patients providing written informed consent.		
I understand that if my practice is allocated to the intervention arm, I may be asked to take part in an interview towards the end of the study. I agree to take part in an interview and that the interview can be recorded.	☐	☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my legal rights.	☐	☐
I consent to take part in the study described in the information sheet, having been fully informed of the risks, benefits and alternatives.	☐	☐
2. Use of information in the study		
I understand that my personal information will be confidential and stored safely in Queen's University Belfast or Trinity College Dublin. I am aware that I will not be identified in any of the findings.	☐	☐
I understand that relevant sections of information collected during the study may be looked at by researchers involved in the study, or from Queen's University Belfast or Trinity College Dublin, for audit purposes. I understand that no other individuals will have access to my personal information.	☐	☐
I give my informed explicit consent to have my data to be processed as part of this research study.	☐	☐
I understand that an interview may be audio recorded and that anonymous quotations may be used in the reports or outputs from this study.	☐	☐
3. Future use of information and ongoing contact		
I understand that the research team will contact me at the end of the study to provide a summary of the results.	☐	☐

_____	_____	_____
Name of the participant (please print)	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

2 copies to be made: 1 for participant, 1 for PI.

Appendix 4.7 Patient invitation letter

ON GENERAL PRACTICES' HEADED NOTEPAPER

Date: xx/xx/2019

Dear Patient,

I am writing to invite you to take part in a research project. My GP colleagues and I in the practice are working with researchers from the Schools of Pharmacy and Medicine, Queen's University Belfast, the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, the School of Pharmacy and Department of General Practice, Royal College of Surgeons in Ireland and the School of Psychology, National University of Ireland Galway. The study aims to try and improve the care of patients who are taking at least four medicines every day. Within this information pack there is an information sheet that should hopefully answer any questions you may have about this research project. I would be grateful if you would take the time to read this.

The purpose of this study is to find out if it would be useful to have your regular medicines reviewed by one of the GPs here in the practice. In this study, one group of patients will receive a review of their medicines on two occasions from GPs in addition to their usual care. The other group will continue to receive usual care from their GP. Which group you are allocated to is totally random, and you will be told at a later date which group you will be in. Should you wish to take part, please return the enclosed consent form and questionnaires to the Research Fellow/Assistant (Dr. Audrey Rankin/Ms. Ashleigh Gorman) using the pre-paid envelope provided.

With your permission, the practice will also provide the researchers with some information from your medical records. The researchers will make sure that you are not identified in any report or paper that comes from the project.

If you wish to discuss any aspect of the project, please do not hesitate to contact one of the researchers who is organising the study (Dr. Audrey Rankin / Ms. Ashleigh Gorman) using the details given below.

Yours sincerely,

[insert GP's signature/name]

Researcher's contact details:

If you live in **Northern Ireland**

Dr. Audrey Rankin

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

Belfast BT9 7BL

Telephone: +44 (0) 7391 730647

Email: a.rankin@qub.ac.uk

If you live in the **Republic of Ireland**

Ms. Ashleigh Gorman

Research Assistant

School of Pharmacy and Pharmaceutical Sciences

Trinity College Dublin

Panoz Institute

Dublin D02PN40

Telephone: +353 (0) 86 608 9094

Email: gormanas@tcd.ie

Appendix 4.8 Patient information leaflet

Study Title: A study to improve the use of many medicines in older people (PolyPrime)

Chief Investigator: Professor Carmel Hughes (Queen's University Belfast)

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important that you understand why this research is being completed and what you will be asked to do. Please take time to read the following information and do not hesitate to ask questions about anything that might not be clear to you. Contact details for the researcher can be found at the end of this information sheet. Please take time to decide whether you would or would not like to take part in the study.

Why is this research being done?

Patients with medical conditions are often prescribed several medicines. We know from other research studies that some patients often find it difficult taking all their prescribed medicines which have been prescribed by their General Practitioner (GP) and dispensed by the community pharmacist. We have put together a plan to try and help patients who take several medicines.

What is the purpose of this study?

The purpose of this study is to find out if it would be useful to have your regular medicines reviewed by one of the GPs here in the surgery. In this study, one group of patients will receive a review of their medicines on two occasions from GPs in addition to their usual care. The other group will continue to receive usual care from their GP. Whether you will receive the service or not is totally random, and you will be told at a later date which group you will be in.

Who is organising and funding this study?

This research is being organised by the Schools of Pharmacy and Medicine, Queen's University Belfast, the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, the School of Pharmacy and Department of General Practice, Royal College of Surgeons in Ireland and the School of Psychology, National University of Ireland Galway. This project is funded by the Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) which is a unique cross-border

partnership between the Public Health Agency in Northern Ireland and the Health Research Board in the Republic of Ireland. The study has received ethical approval from the North of Scotland Research Ethics Committee (Reference Number: 19/NS/0100) and the Irish College of General Practitioners (ICGP) Research Ethics Committee. The study will run for 12 months.

Why am I being asked to take part?

You have been identified as a patient registered in a general practice, who is currently taking four or more prescribed medicines every day. Some of the GPs in your practice are also taking part in the study.

What will happen to me if I agree to take part?

If you volunteer to take part in this study, several things may happen:

- The information pack you have received from your GP practice contains three questionnaires to gather information on your quality of life and use of the health service (e.g. hospital admissions). You will be asked to complete these questionnaires and return them to the researchers using the prepaid envelope provided. You will also be asked to complete these three questionnaires again after six months and after one year and return these to the researchers. All identifiable information you provide to us such as your name, address, phone number, doctor's name will be removed from the information replaced with a unique ID code.
- In this study there will be two groups. There will be an equal chance that you will be in the group who receive their usual care or in another group who will be asked to attend appointments with a GP on two occasions to receive a review of their medicines.
- If you are in the group which will receive the review of medicines, your GP practice will contact you to arrange a date and time for an appointment. These appointments will be held either over the telephone or online, when a face-to-face consultation is not possible). During the appointment, the GP will talk to you about the medicines that you take every day to see if there are any changes that could be made to help with your overall health and wellbeing. An appointment for a second review of medicines will be arranged in approximately six months' time.
- With your permission, the GP will provide us with information from your medical record about the different medicines that you are receiving, your medical conditions and your use of the health service (e.g. hospital admissions). This information will be collected

three times so that we can see if there are any changes made to the medicines that you take every day.

- If you are in the group which will receive the review of medicines, your GP may ask you if they can tape-record (audio-record) the discussion during this review.
- If you are in the group which will receive the review of medicines, you will also be asked to complete a feedback questionnaire at the end of the study.
- With your permission, the information you supply on a questionnaire relating to your quality of life will be shared with our colleagues at the University of Sydney.

If you would like to take part, please return the enclosed consent form and questionnaires to the Research Fellow/Assistant (Dr. Audrey Rankin/Ms. Ashleigh Gorman) using the pre-paid envelope provided.

How many people will be in this study?

In total, we will recruit 120 participants into study.

What will happen to any video/and or audio recordings?

If you are invited to have your appointment recorded, these will be audio-recorded, and all recordings will be 'pseudonymised', meaning that any information that could identify you will be removed. Your name will not appear and will be replaced with a unique code. We may share the pseudonymised audio-recordings with a transcription company. The transcription company will be asked to delete the audio-recordings when transcriptions have been received by the researchers.

What are the possible benefits for me and/or society?

By taking part in this study you would be providing information which will help us to test our plan to help patients who take several medicines daily. If you are in the group which will receive the review of medicines, you may be asked to complete a feedback questionnaire at the end of the study.

Are there any risks or disadvantages of taking part in the study?

There is little risk to you if you take part in the study and you can withdraw at any time. It is possible that the medication review may make you think about upsetting aspects of your medicines and conditions for which you take your medicines. If you find this distressing, you may withdraw at any time.

If I do not want to take part in the study, are there other choices?

It is important for you to understand that you do not have to take part in this study. If you decide that you do not want to participate, that is fine. Deciding not to take part will not affect the care that you or your family receive from your GP or any other healthcare professionals.

What information will be kept private?

Queen's University Belfast is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen's University Belfast will keep identifiable information about you for five years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw you have the choice of removing any data/information you have provided for the study. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at www.qub.ac.uk/privacynotice/.

All identifiable information you provide to us such as your name, address, phone number, doctor's name will be removed from the information. Your name will be removed and replaced with a unique ID code. A list linking your ID code with your name will be kept by the Research Fellow in QUB in a secure place, separate from the information you provide. Any information you provide during this study will be kept securely in a locked filing cabinet in a secure floor of Queen's University Belfast, Trinity College Dublin or the Northern Ireland Clinical Trials Unit (NICTU). If you are invited to have the review of your medicines recorded, these will be audio-recorded and transcripts (typed word-for-word copies of the audio-recordings) will be pseudonymised meaning that any information that could identify you will be removed. When the study has been completed, participant consent forms, questionnaires and transcripts (typed word-for-word copies of the audio-recordings) stored at Trinity College Dublin or the Northern Ireland Clinical Trials Unit will be transferred to Queen's University Belfast [in line with General Data Protection Regulation (GDPR 2018) for the transferring of data]. These will be kept for five years and then destroyed, in line with GDPR 2018.

To ensure that we are carrying out this research properly and looking after your data, a member of Queen's University Belfast's or Trinity Colleges Dublin's Research Governance, Ethics and Integrity teams may examine the study data to ensure that we are following good practice. By consenting to take part in the study you are allowing this team to look at your information.

When the study is finished and we are making the results public, your name will not be used and no information that could identify you will be released or published. All the data/information collected for this study will be stored securely and destroyed after five years.

Can participation in the study end early?

Yes. If you volunteer to take part in this study, you may withdraw at any time and this will not affect the care you receive from your GP or any other healthcare provider. You are free to withdraw from the study without giving a reason. If you decide to withdraw you have the choice of removing any data/information you have provided for the study.

If I have any questions or problems, whom can I call?

If you live in **Northern Ireland** and have any questions about the research, now or later, please contact:

Dr. Audrey Rankin, Research Fellow, School of Pharmacy, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL. Telephone: +44 (0) 7391 730647, Email: a.rankin@qub.ac.uk

If you live in the **Republic of Ireland** and have any questions about the research, now or later, please contact:

Ms. Ashleigh Gorman, Research Assistant, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Panoz Institute, Dublin, D02PN40. Telephone: +353 (0) 86 608 9094, Email: gormanas@tcd.ie

If you have concerns about how this research is being conducted, please contact:

Prof. Carmel Hughes, Professor of Primary Care Pharmacy, School of Pharmacy, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL. Telephone: +44 (0)28 9097 2147, Email: c.hughes@qub.ac.uk

In the event that your concerns are not addressed, please contact:

Mrs Louise Dunlop, Head of Research Governance, Ethics and Integrity, Queen's University

Belfast, BT7 1NN. Tel +44 (0) 28 9097 2572, Email: l.h.dunlop@qub.ac.uk

If you have concerns about how your information is being used, please contact:

Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, D02 RD28, Ireland.

Online https://forms.dataprotection.ie/contact, Telephone +353 761 104 800

Appendix 4.9 Patient consent form

Study Title: A study to improve the use of many medicines in older people (PolyPrime)

Chief Investigator: Professor Carmel Hughes (Queen's University Belfast)

Please tick the appropriate boxes	Yes	No
1. Taking part in the study		
I have read and understood the information sheet dated [28.07.2020] (version 3.0). I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
I have been given a copy of the information sheet and this completed consent form for my records.	☐	☐
I am aware of the potential risks, benefits and alternatives of this research study.	☐	☐
I understand that I will be in one of two groups. One group of patients will receive a review of their medicines on two occasions from GPs in addition to their usual care. The other group will continue to receive usual care from their GP.	☐	☐
I understand that I may be asked to an appointment with my GP for a review of my medicines on two occasions.	☐	☐
I agree to allow my GP practice to share information from my medical records about my medicines, medical conditions and health service use with the researchers. I understand that this information will be pseudonymised meaning that any information that could identify me will be removed.	☐	☐

I agree to complete and return the three enclosed questionnaires to the researchers. I also agree to complete these three questionnaires again after six months and after one year and return these to the researchers.	☐	☐
I understand that if my GP does a review of medicines, I may be asked if the discussion about my medicines with the GP can be tape-recorded (audio-recorded). I agree that the discussion can be recorded.	☐	☐
I understand that if I have a review of my medicines as part of this study, I will be asked to complete a feedback questionnaire towards the end of the study.	☐	☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my future medical care.	☐	☐
I consent to take part in the study described in the information sheet, having been fully informed of the risks, benefits and alternatives.	☐	☐
2. Use of information in the study		
I understand that my personal information will be confidential and stored safely in Queen's University Belfast, Trinity College Dublin or the Northern Ireland Clinical Trials Unit (NICTU). I am aware that I will not be identified in any of the findings.	☐	☐
I understand that the information I have shared on a quality of life questionnaire will be shared with researchers from the University of Sydney.	☐	☐
I understand that relevant sections of information collected during the study may be looked at by researchers involved in the study, or from Queen's University Belfast or Trinity College Dublin, for audit purposes. I understand that no other individuals will have access to my personal information.	☐	☐
I give my informed explicit consent to have my data to be processed as part of this research study.	☐	☐
I understand that if I agree to the discussion about my medicines being tape-recorded that anonymous quotations may be used in the reports or papers from this study.	☐	☐
3. Future use of information and ongoing contact		

I understand that the research team will contact me at the end of the study to provide a summary of the results.	☐	☐

_____	_____	_____
Name of the participant (please print)	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

2 copies to be made: 1 for participant, 1 for PI.

Appendix 4.10 Health service use questionnaire

Health Service Use Questionnaire

This questionnaire asks about your contacts with the health service in the past **6 months** (e.g visits to your GP, hospital appointments).

You were given a Health Service Use Diary as a booklet to keep track of your service use in this period. You may wish to use this now to help with filling out this questionnaire.

Please complete the questionnaire as best you can. If nothing is entered next to a service, we will assume you did not use the service at all. If you run out of room or don't know where to record a service you have used, please use the Additional Information section at the end.

Please enter today's date

D	D	M	M	Y	Y	Y	Y

1. Contacts with a Doctor or Nurse from your GP practice / surgery

Service		How many times in the past 6 months?
Doctor	Appointment at GP practice	
	Spoke with GP on the phone	
	Home visit by GP	

	Visit to Out-of-Hours clinic	
Nurse	Appointment with nurse at GP practice	
	Spoke with nurse on the phone	

2. Contacts with other healthcare professionals

Health care professional	How many visits in the past 6 months <u>at your home</u>?	How many visits in the past 6 months <u>not at your home</u>?
District nurse		
Specialist nurse (e.g. diabetic nurse)		
Social worker		
Physiotherapist		
Occupational therapist/ Aids & Adaptions worker		
Dietician /Nutritionist		
Counselling / therapy		
Pharmacist / Chemist *(please use section 3 below)*		
Other (please specify)		
Other (please specify)		

3. Contacts with a Pharmacist / Chemist

Have you been to see a pharmacist / chemist in the past **6 months**? ☐YES ☐ NO

If Yes, please provide details below

Visit number	Was the purpose to collect one or more prescription items? *Please tick*	Was the purpose to discuss or review your medications? *Please tick*

1	☐YES If yes, how many items?	☐NO	☐YES	☐NO
2	☐YES If yes, how many items?	☐NO	☐YES	☐NO
3	☐YES If yes, how many items?	☐NO	☐YES	☐NO
4	☐YES If yes, how many items?	☐NO	☐YES	☐NO
5	☐YES If yes, how many items?	☐NO	☐YES	☐NO
6	☐YES If yes, how many items?	☐NO	☐YES	☐NO

4. Contacts with Hospital Services

Visits to Accident & Emergency

Have you attended Accident and Emergency in the past **6 months**? ☐YES ☐ NO

If Yes, please provide details below

Visit number	Did you use an ambulance? *Please tick*		Did the visit lead to a hospital admission? *Please tick*	
1	☐YES	☐NO	☐YES	☐NO
2	☐YES	☐NO	☐YES	☐NO
3	☐YES	☐NO	☐YES	☐NO

Hospital Clinics Attended

Have you attended any hospital clinics in the past **6 months**? ☐YES ☐ NO

If Yes, please provide details below

Name of Clinic (e.g. kidney, heart, lungs, surgery, cancer)		Total number of visits to this clinic in the past 6 months
Example	*Heart clinic*	*4*
1		
2		
3		
4		
5		

Admission to hospital or other unit

Have you been admitted to OR stayed at any of the units below in the past **6 months**?

☐YES ☐ NO

- Hospital
- Rehabilitation Unit
- Nursing Home
- Residential Care Home
- Respite Care

If yes, please provide the name of the hospital / residential unit and enter each admission or stay **separately**. For example, if you were admitted to hospital twice please use separate lines on the table.

Type of unit		Day case? *Please tick*	Length of stay *(number of nights / weeks)*
Example	*rehabilitation unit*	☐YES ☑NO	*3* nights ___ weeks
Admission 1		☐YES ☐NO	___ nights ___ weeks

Admission 2		☐YES ☐NO	___ nights ___ weeks
Admission 3		☐YES ☐NO	___ nights ___ weeks
Admission 4		☐YES ☐NO	___ nights ___ weeks

If you run out of space or you are not sure where to record something, use this space below

5. Additional Information

Appendix 4.11 EQ-5D-5L questionnaire

Health Questionnaire

English version for Ireland

Under each heading, please tick the ONE box that best describes your health TODAY.

MOBILITY

I have no problems in walking about ❑
I have slight problems in walking about ❑
I have moderate problems in walking about ❑
I have severe problems in walking about ❑
I am unable to walk about ❑

SELF-CARE

I have no problems washing or dressing myself ❑
I have slight problems washing or dressing myself ❑
I have moderate problems washing or dressing myself ❑
I have severe problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

PAIN / DISCOMFORT

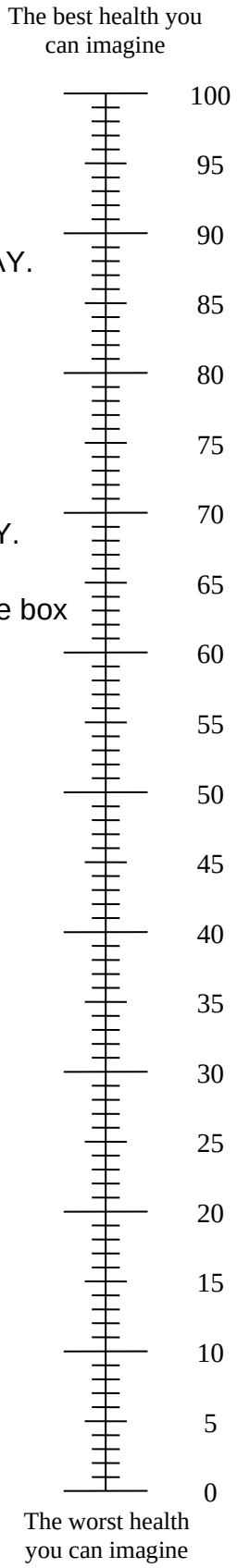
I have no pain or discomfort ❑
I have slight pain or discomfort ❑
I have moderate pain or discomfort ❑
I have severe pain or discomfort ❑
I have extreme pain or discomfort ❑

ANXIETY / DEPRESSION

I am not anxious or depressed ❑
I am slightly anxious or depressed ❑
I am moderately anxious or depressed ❑
I am severely anxious or depressed ❑
I am extremely anxious or depressed ❑

- We would like to know how good or bad your health is TODAY.
- This scale is numbered from 0 to 100.
- 100 means the <u>best</u> health you can imagine.
  0 means the <u>worst</u> health you can imagine.
- Mark an X on the scale to indicate how your health is TODAY.
- Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY = ☐



Appendix 4.12 Medication-related burden quality of life questionnaire

The Medication-Related Burden Quality of Life (MRB-QoL)
tool

Instructions

We are interested in knowing the impact of the medicines on health and wellbeing. You, as a consumer of health and medicine are the ideal person to know how medicine/s benefit or affect your health and wellbeing. Below is the list of statement that other people have said important. Answer every question by circling the appropriate number (1, 2, 3, 4, or 5) that best applies for you?

Section A: The following statements are about the burden associated with the medicine regimen and routines of taking medicines. Considering the past two weeks, indicate how much you agree or disagree with each statement?

		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
1	I find it difficult organizing my medicines	①	②	③	④	⑤
2	I find it hard keeping my medicines records	①	②	③	④	⑤
3	It is difficult for me to manage the routines associated with my medicine taking	①	②	③	④	⑤
4	Fitting medicine routines into my other life schedules is a difficult task for me	①	②	③	④	⑤
5	Taking medicine/s interferes with my physical activities	①	②	③	④	⑤
6	It is difficult to balance my daily life schedules with taking medicines	①	②	③	④	⑤
7	My current medication regimen is not simple for me to manage (e.g. injections, tablets, eye drops)	①	②	③	④	⑤
8	Understanding the instructions on my medicine/s is challenging at times	①	②	③	④	⑤
9	My current medicine/s are not in a convenient form for me to take (e.g difficult to swallow, unpleasant taste/smell)	①	②	③	④	⑤
10	Sometimes I have to cancel my daily schedules because of my medicines	①	②	③	④	⑤
11	Opening the package of my medicines is sometimes a difficult task for me (eg child-proof caps)	①	②	③	④	⑤

Section B: The following statements are about the impact of medicines associated burden on psychological wellbeing. Considering the past two weeks, indicate how much you agree or disagree with each statement?

		Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
12	It bothers me that I have to take medicines for the long term	①	②	③	④	⑤
13	I am concerned about the number of medicines I am on	①	②	③	④	⑤
14	I worry about the long term effects of medicines on my health	①	②	③	④	⑤
15	Taking medicines on a regular basis reminds me of my health problems	①	②	③	④	⑤
16	I am concerned that my medicines may interact with each other	①	②	③	④	⑤
17	My medicines signify me as being not healthy	①	②	③	④	⑤

Section C: The following statements are about the impact of medicines associated burden on physical wellbeing.

Considering the past two weeks, indicate how much you agree or disagree with each statement?

18	I am sometimes sexually frustrated because of my medicine/s	①	②	③	④	⑤
19	I am unable to relax and enjoy sex because of my medicine/s	①	②	③	④	⑤
20	Some of medicines slow down my physical health	①	②	③	④	⑤
21	I often have a bad night's sleep because of my medicine/s	①	②	③	④	⑤
22	Because of my medicine/s I feel too tired to perform physical activities	①	②	③	④	⑤
23	I work less than usual because of the effect of my medicine/s	①	②	③	④	⑤
24	Some of my medicine make me feel uncomfortable due to side effects	①	②	③	④	⑤

Section D: The following statements are about medicine burden related to health care services. Considering the past two weeks, indicate how much you agree or disagree with each statement?

25	I am not treated with respect and dignity as a patient	①	②	③	④	⑤
26	My doctor doesn't take into account the health of my body, mind, and spirit	①	②	③	④	⑤
27	My doctor/s talk about my medicine/s as if I am not there	①	②	③	④	⑤

Section E: The following statements are about the impact of medicines associated burden on social wellbeing.

Considering the past two weeks, indicate how much you agree or disagree with each statement?

28	I would rather not tell others that I am taking medicines regularly	①	②	③	④	⑤
29	I get embarrassed using my medicines in public	①	②	③	④	⑤
30	I feel stigmatized because of what people say about the medicine/s I take	①	②	③	④	⑤
31	If people found out I was on medicines they would see me as weak	①	②	③	④	⑤

Appendix 4.13 ethical approval letter August 2020

13 August 2020

Prof. Carmel Hughes
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast

PolyPrime trial: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

Dear Professor Hughes,

I wish to confirm that the proposed amendments submitted on the 31st July 2020 for the above study were reviewed by the Research Ethics Committee and the amendments have been approved.

The following documents have also been reviewed and approved:

- PolyPrime Protocol_Final 3.0_30.07.2020
- Appendix 8: General Practitioner information sheet_Final 3.0_28.07.2020
- Appendix 14: Patient participant information sheet_Final 3.0_28.07.2020
- Appendix 16: Patient participant consent form [ROI]_Final 3.0_28.07.2020
- Appendix 21: Letter informing patients of study changes_Final 1.0_28.07.2020
- Appendix 22: Patient opt-in or opt-out reply slip_Final 1.0_28.07.2020
- Appendix 23: Practice Staff information sheet_Final 1.0_28.07.2020
- Appendix 24: Practice Staff consent form_Final 1.0_28.07.2020
- Appendix 25: SAE reporting form_Final 1.0_28.07.2020
- Appendix 26: SAE reporting form guidance_Final 1.0_28.07.2020

Please note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submit a one page follow-up report one year to the date that the application was originally approved.
2. Report unexpected adverse events, serious adverse events, or any ethical harms that may affect ethical acceptability of the study.
3. Submit any change to study documentation (minor or major) to ICGP REC for review and approval. Amendments must be submitted on the standard amendment form and revised study documents must clearly highlight the changes and include a new version number and date. Amendments cannot be implemented without written approval from ICGP REC.
4. Notify the ICGP REC if the study is discontinued.
5. Notify the ICGP REC of study completion using the study completion notification form.

If you have any further questions please contact Colleen O'Neil at research@icgp.ie.

Yours sincerely,

Sent on behalf of Dr. Akke Vellinga
Chair, Research Ethics Committee

Appendix 4.14 Letter to patients regarding changes to study

To be printed on practice headed paper

Date: 2021

Dear patient

I am writing to you in relation to a research project, called PolyPrime, that you agreed to take part in. This research project focused on your regular medicines and you may remember completing questionnaires as part of this study. Due to the ongoing public health emergency caused by COVID-19 and the increased workload the practice needs to deal with, the practice has taken the difficult decision to withdraw from the study. This means you will no longer be receiving a review of your medicines from Dr McNamee as part of the study, although, normal review of your medicines will continue as part of your health care.

However, the PolyPrime team is inviting you to continue to take part in the study by completing questionnaires at two later dates (June and September 2021). The questionnaires will be sent to your home address, accompanied with a pre-paid envelope.

The PolyPrime team would be grateful if you could complete and return the reply slip enclosed, letting them know if you want to complete these questionnaires, or if you no longer want to take part in the study altogether.

If you wish to discuss any aspect of this project, please do not hesitate to contact the practice or Ashleigh Gorman (gormanas@tcd.ie; +353 86 608 9094), Research Assistant on the project, using the details given below.

Yours sincerely,

[practice sign-off]

Researcher's contact details:
Ashleigh Gorman, Research Assistant
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Dublin D02PN40
Telephone: +353 (0) 86 608 9094
Email: gormanas@tcd.ie

Appendix 4.15 Opt-in/opt-out form

PolyPrime

Patient Reply Slip

Please tick the appropriate boxes	Yes	No
I have read the enclosed letter informing me of [insert GP practice name] withdrawal from the study and have had the opportunity to consider the information	☐	☐
I would like to continue taking part in the study by completing questionnaires that will be sent to me	☐	☐

Name: …….

Address……..

……
……

Date……

If you wish to discuss any aspect of the project, please do not hesitate to contact Ashleigh Gorman, the Research Assistant on the project, using the details given below.

Please return this form in the envelope provided to:
Ms. Ashleigh Gorman
Research Assistant
School of Pharmacy and Pharmaceutical Sciences
Trinity College Dublin
Panoz Institute
Dublin D02PN40
Telephone: +353 86 608 9094
Email: gormanas@tcd.ie

Appendix 4.16 Ethical approval letter November 2020

25 November 2020

Prof. Carmel Hughes
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast

PolyPrime trial: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

Dear Professor Hughes,

I wish to confirm that the proposed amendments submitted on the 20th November 2020 for the above study were reviewed by the Research Ethics Committee and the amendments have been approved.

The following documents have also been reviewed and approved:

- PolyPrime Protocol_Final 4.0_20.11.2020
- Appendix 27_Polyprime Health service use Q at 9-months_Final 1.0 04.11.2020
- Appendix 28_Polyprime Health Service Use Diary at 6-months_Final 1.0 04.11.2020
- Appendix 29_Six month follow-up letter to all patients_Final 1.0 10.11.2020
- Appendix 30_Nine month follow-up letter to control arm patients_Final 1.0 10.11.2020
- Appendix 31_Nine month follow-up letter to intervention arm patients_Final 1.0 10.11.2020
- Appendix 32_General Practitioner Topic Guide_Final 1.0 10.11.2020
- Appendix 33_Patient feedback questionnaire_Final 1.0 10.11.2020
- Appendix 34_Patient feedback questionnaire letter to patients_Final 1.0 10.11.2020
- Appendix 35_Practice Staff Topic Guide_Final 1.0 10.11.2020
- Appendix 36_ Letter to patients for MRB-QoL re-test_ Final 1.0 20.11.2020

Please note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submit a one page follow-up report one year to the date that the application was originally approved.
2. Report unexpected adverse events, serious adverse events, or any ethical harms that may affect ethical acceptability of the study.
3. Submit any change to study documentation (minor or major) to ICGP REC for review and approval. Amendments must be submitted on the standard amendment form and revised study documents must clearly highlight the changes and include a new version number and date. Amendments cannot be implemented without written approval from ICGP REC.
4. Notify the ICGP REC if the study is discontinued.
5. Notify the ICGP REC of study completion using the study completion notification form.

If you have any further questions, please contact Colleen O'Neil at research@icgp.ie.

Yours sincerely,

Sent on behalf of Dr. Akke Vellinga
Chair, Research Ethics Committee

Appendix 4.17 Ethical approval letter April 2021

21 April 2021

Prof. Carmel Hughes
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast

PolyPrime trial: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

Dear Professor Hughes,

I wish to confirm that the proposed amendment submitted on 30 March 2021 for the above study was reviewed by the Research Ethics Committee and the amendment has been approved.

The following documents have also been reviewed and approved:

- PolyPrime Protocol_Final 5.0_30.03.2021
- Appendix 37 – Letter informing patients of practice withdrawal_Final 1.0_30.03.2021
- Appendix 38 – Patient opt-in or opt-out reply slip_Final 1.0_30.03.2021

Please note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submit a one page follow-up report one year to the date that the application was originally approved.
2. Report unexpected adverse events, serious adverse events, or any ethical harms that may affect ethical acceptability of the study.
3. Submit any change to study documentation (minor or major) to ICGP REC for review and approval. Amendments must be submitted on the standard amendment form and revised study documents must clearly highlight the changes and include a new version number and date. Amendments cannot be implemented without written approval from ICGP REC.
4. Notify the ICGP REC if the study is discontinued.
5. Notify the ICGP REC of study completion using the study completion notification form.

If you have any further questions, please contact Colleen O'Neil at research@icgp.ie.

Yours sincerely,

Vellinga

Sent on behalf of Dr. Akke Vellinga
Chair, Research Ethics Committee

Appendix 4.18 Ethical approval letter June 2021

21 June 2021

Prof. Carmel Hughes
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast

PolyPrime trial: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

Dear Professor Hughes,

I wish to confirm that the proposed amendment submitted on 15 June 2021 for the above study was reviewed by the Research Ethics Committee and the amendment has been approved.

The following documents have also been reviewed and approved:

- Appendix 37 – Letter informing patients of practice withdrawal_Final 2.0_15.06.2021

Please note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submit a one page follow-up report one year to the date that the application was originally approved.
2. Report unexpected adverse events, serious adverse events, or any ethical harms that may affect ethical acceptability of the study.
3. Submit any change to study documentation (minor or major) to ICGP REC for review and approval. Amendments must be submitted on the standard amendment form and revised study documents must clearly highlight the changes and include a new version number and date. Amendments cannot be implemented without written approval from ICGP REC.
4. Notify the ICGP REC if the study is discontinued.
5. Notify the ICGP REC of study completion using the study completion notification form.

If you have any further questions, please contact Colleen O'Neil at research@icgp.ie.

Yours sincerely,

Vellinga

Sent on behalf of Dr. Akke Vellinga
Chair, Research Ethics Committee

Appendix 4.19 Ethical approval letter July 2021

9 July 2021

Prof. Carmel Hughes
School of Pharmacy
Queen's University Belfast
97 Lisburn Road
Belfast

PolyPrime trial: A pilot cluster randomised controlled trial (cRCT) of a theory-based intervention to improve appropriate polypharmacy in older people in primary care

Dear Professor Hughes,

I wish to confirm that the proposed amendment submitted on 7 July 2021 for the above study was reviewed by the Research Ethics Committee and the amendment has been approved.

The following documents have also been reviewed and approved:

- PolyPrime Protocol_Final 7.0_05.07.2021
- Appendix 23 – Practice Staff information leaflet_Final 2.0_05.07.2021

Please note that ethical approval will lapse if you do not adhere to the following conditions:

1. Submit a one page follow-up report one year to the date that the application was originally approved.
2. Report unexpected adverse events, serious adverse events, or any ethical harms that may affect ethical acceptability of the study.
3. Submit any change to study documentation (minor or major) to ICGP REC for review and approval. Amendments must be submitted on the standard amendment form and revised study documents must clearly highlight the changes and include a new version number and date. Amendments cannot be implemented without written approval from ICGP REC.
4. Notify the ICGP REC if the study is discontinued.
5. Notify the ICGP REC of study completion using the study completion notification form.

If you have any further questions, please contact Colleen O'Neil at research@icgp.ie.

Yours sincerely,

Vellinga

Sent on behalf of Dr. Akke Vellinga
Chair, Research Ethics Committee

Appendix 4.20 Patient registration form

Patient ID G P P _ _ P T _ _ **Site Number** G P P _ _ **Date of Collection** D D / M M / Y Y Y Y

Patient Registration Form

1a.	Is the patient aged 70 years or over?	☐	Yes
		☐	No
1b.	Is the patient receiving four or more regular medicines?	☐	Yes
		☐	No
1c.	Is the patient resident in the community?	☐	Yes
		☐	No
1d.	Is the patient in receipt of GMS card (ROI) or registered for NHS primary care services (NI)?	☐	Yes
		☐	No
1e.	Is the patient registered with and/or regularly attending the practice for a minimum of 12 months?	☐	Yes
		☐	No
If any part of question 1 is marked **'NO'**, the subject is **NOT ELIGIBLE** to participate in the study.			
2a.	Is the patient a care home resident?	☐	Yes
		☐	No
2b.	Is the patient cognitively impaired?	☐	Yes
		☐	No
2c.	Does the patient have a terminal illness?	☐	Yes
		☐	No
2d.	Is the patient involved in other IMP or medicines management studies?	☐	Yes
		☐	No
If any part of question 2 is marked **'YES'**, the subject is **NOT ELIGIBLE** to participate in the study.			
3.	Is the patient eligible to take part in the PolyPrime Trial?	☐	Yes
		☐	No
4.	Has patient consent been obtained?	☐	Yes
		☐	No
5.	Date of consent	D D / M M / Y Y Y Y	
6.	Date of recruitment	D D / M M / Y Y Y Y	
7.	Is the patient in the control or intervention arm of the study?	☐	Control
		☐	Intervention
8.	Date of birth	D D / M M / Y Y Y Y	
9.	Gender	☐	Male
		☐	Female
10.	Educational status (Please select highest attained)	☐	Less than primary education
		☐	Primary education
		☐	Lower secondary education
		☐	Upper secondary education

Patient ID G P P _ _ P T _ _ **Site Number** G P P _ _ **Date of Collection** D D / M M / Y Y Y Y

		☐	Post secondary non-tertiary education (e.g. vocational training)
		☐	Short cycle tertiary education (e.g. diploma of higher education)
		☐	Bachelor's degree or equivalent level
		☐	Master's degree or equivalent level
		☐	Doctorate or equivalent level
		☐	Not available

Appendix 4.21 Diagnoses details

Patient ID G P P P T

Site Number G P P

Time Point Baseline ☐ 6 month ☐ 12 month ☐

Date of Collection D D / M M / Y Y Y Y

Section 1: Diagnoses Details

CVS								
Does the patient have……?	**Condition Status**			**Type**	**Frequency (Over past 5 years)**	**Stage**	**Date of diagnosis**	**Further Details**
	Yes Current	**Previously (In last 5 years)**	**No**					
Heart failure	☐	☐	☐	**Class 1** ☐ **Class 2** ☐ **Class 3** ☐ **Class 4** ☐				
Heart block	☐	☐	☐					
Bradycardia	☐	☐	☐					Heart Rate (bpm)
Ischaemic heart disease	☐	☐	☐					
Stent insertion (in previous 12 month)	☐	☐	☐					
Acute coronary syndrome	☐	☐	☐					
High grade symptomatic carotid arterial stenosis	☐	☐	☐					
Stable coronary arterial disease	☐	☐	☐					
Stable cerebrovascular arterial disease	☐	☐	☐					

Patient ID G P P P T

Site Number G P P

Time Point Baseline ☐ 6 month ☐ 12 month ☐

Date of Collection D D / M M / Y Y Y Y

Does the patient have……?	**Condition Status**			**Type**	**Frequency (Over past 5 years)**	**Stage**	**Date of diagnosis**	**Further Details**
	Yes current	**Previously (In last 5 years)**	**No**					
Stable peripheral arterial disease	☐	☐	☐					
Supraventricular tachyarrhythmias	☐	☐	☐					
Deep Vein Thrombosis (DVT)	☐	☐	☐				/ /	
Pulmonary Embolism (PE)	☐	☐	☐				/ /	
Hypertension	☐	☐	☐					
Ankle oedema	☐	☐	☐					
Atrial fibrillation	☐	☐	☐				/ /	
Risk of bleeding e.g. bleeding diathesis, recent non-trivial spontaneous bleeding	☐	☐	☐					
Symptomatic orthostatic hypotension	☐	☐	☐					

Patient ID: G P P _ _ P T _ _

Site Number: G P P _ _

Time Point: Baseline ☐ 6 month ☐ 12 month ☐

Date of Collection: D D / M M / Y Y Y Y

Central Nervous System								
Does the patient have.....?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In last 5 years)	No					
Dementia	☐	☐	☐					
Parkinsonism	☐	☐	☐					
Lewy body disease	☐	☐	☐					
Benign essential tremor	☐	☐	☐					
Depression	☐	☐	☐					
Anxiety	☐	☐	☐					
Sleep disorders	☐	☐	☐					

Patient ID: G P P _ _ P T _ _

Site Number: G P P _ _

Time Point: Baseline ☐ 6 month ☐ 12 month ☐

Date of Collection: D D / M M / Y Y Y Y

Gastro-intestinal (GI) System								
Does the patient have.....?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Current	Previously (In last 5 years)	No					
Chronic Constipation (Duration > 1 month)	☐	☐	☐					
Peptic ulcer disease (PUD)	☐	☐	☐					
Other upper GI Disease (i.e. dysphagia, oesophagitis, gastritis, duodenitis, or peptic ulcer disease)	☐	☐	☐					
History of GI Bleed	☐	☐	☐					
Diverticulitis	☐	☐	☐					

Patient ID	Site Number	Time Point	Date of Collection
G P P P T	G P P	Baseline ☐ 6 month ☐ 12 month ☐	D D / M M / Y Y Y Y

Respiratory System								
Does the patient have……?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In last 5 years)	No					
COPD	☐	☐	☐	Mild ☐ Moderate ☐ Severe ☐ V. Severe ☐				
Asthma	☐	☐	☐	Mild ☐ Moderate ☐ Severe ☐				
Asthma/ COPD exacerbations	☐	☐	☐		__ Per day/week/ month/year (Delete as appropriate)			
Acute or chronic respiratory failure	☐	☐	☐	Type 1 ☐ Type 2 ☐				

Patient ID	Site Number	Time Point	Date of Collection
G P P P T	G P P	Baseline ☐ 6 month ☐ 12 month ☐	D D / M M / Y Y Y Y

Ocular System								
Does the patient have……?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In the last 5 years)	No					
Narrow angle glaucoma	☐	☐	☐					
Open angle glaucoma	☐	☐	☐					

Urogenital System								
Does the patient have……?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In last 5 years)	No					
Chronic prostatism	☐	☐	☐					
History of urinary retention	☐	☐	☐					
Bladder outflow obstruction	☐	☐	☐					
Hysterectomy	☐	☐	☐					
Micturition syncope	☐	☐	☐					
Symptomatic atrophic vaginitis	☐	☐	☐					
Urinary incontinence	☐	☐	☐					

Patient ID: G P P _ _ P T _ _ | Site Number: G P P _ _ | Time Point: Baseline ☐ 6 month ☐ 12 month ☐ | Date of Collection: D D / M M / Y Y Y Y

Endocrine System								
Does the patient have.....?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In last 5 years)	No					
Diabetes Mellitus	☐	☐	☐	Type 1 ☐ Type 2 ☐				
Hypoglycaemic attacks	☐	☐	☐		__ Per day/ week/ month / year (Delete as appropriate)			
Primary or secondary hypogonadism	☐	☐	☐					

Musculoskeletal System								
Does the patient have.....?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In last 5 years)	No					
Rheumatoid disease	☐	☐	☐					
Osteoporosis	☐	☐	☐					
Previous fracture	☐	☐	☐					
Gout	☐	☐	☐		__ Per day/week/ month/year (Delete as appropriate)			

Patient ID: G P P _ _ P T _ _ | Site Number: G P P _ _ | Time Point: Baseline ☐ 6 month ☐ 12 month ☐ | Date of Collection: D D / M M / Y Y Y Y

Other								
Does the patient have.....?	Condition Status			Type	Frequency (Over past 5 years)	Stage	Date of diagnosis	Further Details
	Yes Currently	Previously (In last 5 years)	No					
Breast Cancer	☐	☐	☐					
Falls	☐	☐	☐		__ Per day/week/ month / year (Delete as appropriate)			
Restless leg syndrome	☐	☐	☐					
Liver Failure	☐	☐	☐					
Nephrotic syndrome	☐	☐	☐					
Renal Failure	☐	☐	☐					
Other: _____	☐	☐	☐					
Other: _____	☐	☐	☐					
Other: _____	☐	☐	☐					
Other: _____	☐	☐	☐					

Patient ID	Site Number	Time Point	Date of Collection
G P P _ _ P T _ _	G P P _ _	Baseline ☐ 6 month ☐ 12 month ☐	D D / M M / Y Y Y Y

Section 2: Allergies

Does the patient have any known drug allergies or documented contraindications to medicines? Yes ☐ No ☐

If yes, please list in the table below.

Please note if this is the 6 month or 12 month review, only record new drug allergies identified since baseline.

	Allergy/Intolerance	Date of Diagnosis
1.		D D / M M / Y Y Y Y
2.		D D / M M / Y Y Y Y
3.		D D / M M / Y Y Y Y
4.		D D / M M / Y Y Y Y
5.		D D / M M / Y Y Y Y
6.		D D / M M / Y Y Y Y

Patient ID	Site Number	Time Point	Date of Collection
G P P _ _ P T _ _	G P P _ _	Baseline ☐ 6 month ☐ 12 month ☐	D D / M M / Y Y Y Y

Section 3: Biochemical Data

Does the patient have any blood results recorded in the last 12 months? Yes ☐ **No** ☐

If yes, please record in the table below.

Blood	Blood Result (most recent)	Date of Blood Result	Not Available
Urea	_____ mmol/L	D D / M M / Y Y Y Y	☐
Sodium	_____ mmol/L	D D / M M / Y Y Y Y	☐
Potassium	_____ mmol/L	D D / M M / Y Y Y Y	☐
Creatinine	_____ µmol/L	D D / M M / Y Y Y Y	☐
eGFR	_____ mL/min	D D / M M / Y Y Y Y	☐
Protein creatinine ratio (PCR)	_____ mg/mmol	D D / M M / Y Y Y Y	☐
Albumin creatinine ratio (ACR)	_____ mg/mmol	D D / M M / Y Y Y Y	☐
Calcium	_____ mmol/L	D D / M M / Y Y Y Y	☐
Haemoglobin	_____ g/L	D D / M M / Y Y Y Y	☐
Mean corpuscular volume (MCV)	_____ fL	D D / M M / Y Y Y Y	☐
Ferritin	_____ µg/L	D D / M M / Y Y Y Y	☐

Patient ID	Site Number	Time Point	Date of Collection
G P P P T	G P P	Baseline ☐ 6 month ☐ 12 month ☐	D D / M M / Y Y Y Y

Section 4: Clinical Parameters

Has the patient's blood pressure been recorded in the last 12 months? Yes ☐ No ☐

If yes, please record the last 3 readings in the table below.

Blood Pressure (mm Hg)			Date of BP Reading	Not Available
1.	Systolic / Diastolic		D D / M M / Y Y Y Y	☐
2.	Systolic / Diastolic		D D / M M / Y Y Y Y	☐
3.	Systolic / Diastolic		D D / M M / Y Y Y Y	☐

	Result	Date of result	Not Available
FEV_1	_____ %	D D / M M / Y Y Y Y	☐

	Result	Date of result	Not Available
Bone Mineral Density T-scores	_____	D D / M M / Y Y Y Y	☐
	_____	D D / M M / Y Y Y Y	☐
	_____	D D / M M / Y Y Y Y	☐

Arterial Blood Gas	Result	Date of result	Not Available
pO_2	_____ kPa	D D / M M / Y Y Y Y	☐
SaO_2	_____ %	D D / M M / Y Y Y Y	☐

Appendix 4.22 Health service use

Patient ID: G P P _ _ P T _ _ | Site Number: G P P _ _ | Time Point: Baseline ☐ 6 month ☐ 12 month ☐ | Date of Collection: D D / M M / Y Y Y Y

Patient Health Service Use- GP record

Please record patients' use of the Health Service as recorded in their GP notes.
If you run out of room or don't know where to record a service, please use the Additional Information section at the end.

1. Contacts with a Doctor or Nurse from the GP practice / surgery

Service		In notes?		How many times in the past 6 months?
Doctor	Appointment at GP practice	☐YES	☐NO	
	Spoke with GP on the phone	☐YES	☐NO	
	Home visit by GP	☐YES	☐NO	
	Visit to Out-of-Hours clinic	☐YES	☐NO	
Nurse	Appointment with nurse at GP practice	☐YES	☐NO	
	Spoke with nurse on the phone	☐YES	☐NO	

2. Contacts with other healthcare professionals

Health care professional	In notes?		How many times in the past 6 months		
			at patient's home	other location e.g. clinic	location not stated
District nurse	☐YES	☐NO			
Specialist nurse	☐YES	☐NO			
Social worker	☐YES	☐NO			
Physiotherapist	☐YES	☐NO			
Occupational therapist	☐YES	☐NO			
Dietician /Nutritionist	☐YES	☐NO			
Counselling / therapy	☐YES	☐NO			
Pharmacist	☐YES	☐NO			
Other (please specify)	☐YES	☐NO			
Other (please specify)	☐YES	☐NO			

Patient ID: G P P _ _ P T _ _ | Site Number: G P P _ _ | Time Point: Baseline ☐ 6 month ☐ 12 month ☐ | Date of Collection: D D / M M / Y Y Y Y

3. Medication reviews

For the past **6 months** - does the patient have any medication reviews recorded in their notes? ☐YES ☐ NO

If yes, please provide the details below

Review number	Who conducted it?		Date (DD/MM/YYYY)	
1		☐not in notes		☐not in notes
2		☐not in notes		☐not in notes
3		☐not in notes		☐not in notes
4		☐not in notes		☐not in notes
5		☐not in notes		☐not in notes

4. Contacts with Hospital Services

Visits to Accident & Emergency

For the past **6 months** - does the patient have any Accident and Emergency visits recorded in their notes? ☐YES ☐ NO

If Yes, please provide details below

Visit number	Did they use an ambulance? *Please tick*			Did the visit lead to a hospital admission? *Please tick*		
Visit 1	☐YES	☐NO	☐not in notes	☐YES	☐NO	☐not in notes
Reason for visit:						☐not in notes
Visit 2	☐YES	☐NO	☐not in notes	☐YES	☐NO	☐not in notes
Reason for visit:						☐not in notes
Visit 3	☐YES	☐NO	☐not in notes	☐YES	☐NO	☐not in notes
Reason for visit:						☐not in notes

Patient ID: G P P _ _ P T _ _ | Site Number: G P P _ _ | Time Point: Baseline ☐ 6 month ☐ 12 month ☐ | Date of Collection: D D / M M / Y Y Y Y

Hospital Clinics Attended

For the past **6 months** - does the patient have any hospital clinics recorded in their notes?
☐YES ☐ NO

If Yes, please provide details below

	Name of Clinic (if stated) (e.g. kidney, heart, lungs, surgery, cancer)	Total number of visits to this clinic recorded in the past 6 months
Example	*Heart clinic*	*4*
1		
2		
3		
4		
5		

Admission to hospital

For the past **6 months** - does the patient have any hospital admissions recorded in their notes? ☐YES ☐ NO

If yes, please provide details below

Admission number	Day case? *Please tick*			Length of stay *(number of nights / weeks)*				
Admission 1	☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Reason for admission*:								☐not in notes
Admission 2	☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Reason for admission*:								☐not in notes
Admission 3	☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Reason for admission*:								☐not in notes
Admission 4	☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Reason for admission*:								☐not in notes

* Please record if it was planned or unplanned here

Patient ID: G P P _ _ P T _ _ | Site Number: G P P _ _ | Time Point: Baseline ☐ 6 month ☐ 12 month ☐ | Date of Collection: D D / M M / Y Y Y Y

Admission to other units

For the past **6 months** - does the patient have any admissions /stays at any of the units below recorded in their notes? ☐YES ☐ NO

- Rehabilitation Unit
- Nursing Home
- Residential Care Home
- Respite Care

If yes, please list the type of unit in the table below and enter each admission or stay **separately**. For example, if the patient was admitted to the same unit twice please use separate lines on the table.

Admission number	Type of unit	Day case? *Please tick*			Length of stay *(number of nights / weeks)*				
Example	*rehabilitation unit*	☐YES	☑NO	☐not in notes	*3*	nights	__	wks	☐not in notes
Admission 1		☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Admission 2		☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Admission 3		☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes
Admission 4		☐YES	☐NO	☐not in notes	__	nights	__	wks	☐not in notes

If you run out of space or you are not sure where to record something, use this space below

5. Additional information

Appendix 4.23 Medications

Patient ID	Site Number	Date of Baseline data collection	Date of 6 month data collection	Date of 12 month data collection
G P P _ _ P T _ _	G P P _ _	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

Medications:

Full Name of Medication *Please record the drug name as prescribed and formulation*	Date drug first prescribed	Strength	Medication Unit *(See Key on page 5)*	Dose	Frequency *(See Key on page 5)*	Indication	On drug at 6-month follow-up? *If 'no', complete 'Date Stopped' column* Yes	No	On drug at 12-month follow-up? *If 'no', complete 'Date Stopped' column* Yes	No	Date Stopped
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY

Medications Form
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Patient ID	Site Number	Date of Baseline data collection	Date of 6 month data collection	Date of 12 month data collection
G P P _ _ P T _ _	G P P _ _	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

Medications:

Full Name of Medication *Please record the drug name as prescribed and formulation*	Date drug first prescribed	Strength	Medication Unit *(See Key on page 5)*	Dose	Frequency *(See Key on page 5)*	Indication	On drug at 6-month follow-up? *If 'no', complete 'Date Stopped' column* Yes	No	On drug at 12-month follow-up? *If 'no', complete 'Date Stopped' column* Yes	No	Date Stopped
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY

Medications Form
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Patient ID	Site Number	Date of Baseline data collection	Date of 6 month data collection	Date of 12 month data collection
G P P _ _ P T _ _	G P P _ _	DD / MM / YYYY	DD / MM / YYYY	DD / MM / YYYY

Acute Medications

Full Name of Medication *Please record the drug name as prescribed and formulation*	Date drug first prescribed	Strength	Medication Unit *(See Key on page 5)*	Dose	Frequency *(See Key on page 5)*	Indication	On drug at 6-month follow-up? *If 'no', complete 'Date Stopped' column*		On drug at 12-month follow-up? *If 'no', complete 'Date Stopped' column*		Date Stopped
							Yes	No	Yes	No	
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY

Patient ID	Site Number	Date of Baseline data collection	Date of 6 month data collection	Date of 12 month data collection
G P P _ _ P T _ _	G P P _ _	DD / MM / YYYY	DD / MM / YYYY	DD / MM / YYYY

Full Name of Medication *Please record the drug name as prescribed and formulation*	Date drug first prescribed	Strength	Medication Unit *(See Key on page 5)*	Dose	Frequency *(See Key on page 5)*	Indication	On drug at 6-month follow-up? *If 'no', complete 'Date Stopped' column*		On drug at 12-month follow-up? *If 'no', complete 'Date Stopped' column*		Date Stopped
							Yes	No	Yes	No	
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY
	DD / MM / YYYY						☐	☐	☐	☐	DD / MM / YYYY

Patient ID	Site Number	Date of Baseline data collection	Date of 6 month data collection	Date of 12 month data collection
G P P _ _ P T _ _	G P P _ _	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

Key for completing Medication Unit and Frequency columns:

Medication Unit			
1	Milligram (mg)	6	Drops
2	Microgram (µg)	7	Spray(s)
3	Gram (g)	8	International Units (IU)
4	Millilitre (ml)	99	Other
5	Puffs		

Frequency			
1	Once daily	7	Once a week
2	Twice daily	8	Once every two weeks
3	Three times daily	9	Once every three weeks
4	Four times daily	10	Once every four weeks
5	Three times a week	11	Once every five weeks
6	Twice a week	12	Once every six months
		88	As required / "PRN"

Patient ID	Site Number	Date of Baseline data collection	Date of 6 month data collection	Date of 12 month data collection
G P P _ _ P T _ _	G P P _ _	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y	D D / M M / Y Y Y Y

Additional details:

Data Collector at Baseline: Name: _____

Data Collector at 6-months: Name: _____

Data Collector at 12-months: Name: _____

Appendix 4.24 Queries in relation to specific medications prescribed

Patient ID	Site Number	Time Point	Date of Collection
G P P _ _ P T _ _	G P P _ _	Baseline ☐ 6 month ☐ 12 month ☐	D D / M M / Y Y Y Y

Queries relating to specific medications

1a.	Is the patient prescribed centrally acting antihypertensives (e.g. methyldopa, clonidine, moxonidine)?	☐	Yes
		☐	No
1b.	If 'Yes', please record if intolerant of other classes of antihypertensives.		
2a.	Is the patient prescribed Quetiapine or clozapine?	☐	Yes
		☐	No
2b.	If 'Yes', please note indication.		
3.	Is the patient prescribed Phenothiazines e.g. chlorpromazine, levomepromazine, promazine hydrochloride, pericyazine, fluphenazine decanoate, perphenazine, prochlorperazine, trifluoperazine	☐	Yes
		☐	No
4a.	Is the patient prescribed NSAID e.g. ibuprofen, diclofenac, naproxen, fenoprofen, flurbiprofen, ketoprofen, dexketoprofen, desibuprofen, tiaprofenic acid, etodolac, indomethacin, mefanamic acid, meloxicam, tenoxicam, sulindac, piroxicam, celecoxib, etoricoxib for osteoarthritis?	☐	Yes
		☐	No
4b.	If 'Yes', was paracetamol tried first?	☐	Yes
		☐	No
5a.	Is the patient prescribed corticosteroids (e.g. prednisolone, methylprednisolone, triamcinolone, dexamethasome?	☐	Yes
		☐	No
5b.	If 'Yes', please note indication.		
6a.	Has the patient received the seasonal trivalent influenza vaccine?	☐	Yes
		☐	No
6b.	If 'Yes' please note date last given	D D / M M / Y Y Y Y	
7a.	Has the patient received the pneumococcal vaccine?	☐	Yes
		☐	No
7b.	If 'Yes' please note date last given	D D / M M / Y Y Y Y	

Appendix 4.25 STOPP/START

Screening Tool of Older Persons' Prescriptions (STOPP)

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
A1.	Any drug prescribed without an evidence-based clinical indication Esomeprazole	☐	☐
A2.	Any drug prescribed beyond the recommended duration, where treatment duration is well defined	☐	☐
A3.	Any duplicate drug class prescription, e.g. two concurrent NSAIDs, SSRIs, loop diuretics, ACE inhibitors, anticoagulants (optimisation of monotherapy within a single drug class should be observed prior to considering a new agent)	☐	☐
B1.	Digoxin for heart failure with normal systolic ventricular function (no clear evidence of benefit)	☐	☐
B2.	Verapamil or diltiazem with NYHA Class III or IV heart failure (may worsen heart failure)	☐	☐
B3.	Beta-blocker in combination with verapamil or diltiazem (risk of heart block)	☐	☐

B4.	Beta blocker with bradycardia (<50 beats/min), type II heart block or complete heart block (risk of complete heart block, asystole)	☐	☐
Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
B5.	Amiodarone as first-line antiarrhythmic therapy in supraventricular tachyarrhythmias (higher risk of side-effects than beta-blockers, digoxin, verapamil or diltiazem)	☐	☐
B6.	Loop diuretic as first-line treatment for hypertension (safer, more effective alternatives available)	☐	☐
B7.	Loop diuretic for dependent ankle oedema without clinical, biochemical evidence or radiological evidence of heart failure, liver failure, nephrotic syndrome or renal failure (leg elevation and/or compression hosiery usually more appropriate)	☐	☐
B8.	Thiazide diuretic with current significant hypokalaemia (i.e. serum K+ <3.0mmol/l), hyponatraemia (i.e. serum Na+ <130mmol/l) hypercalcaemia (i.e. corrected serum calcium >2.65mmol/l) or with a history of gout (hypokalaemia, hyponatraemia, hypercalcaemia and gout can be precipitated by thiazide diuretic)	☐	☐
B9.	Loop diuretic for treatment of hypertension with concurrent urinary incontinence (may exacerbate incontinence)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
B10.	Centrally-acting antihypertensives (e.g. methyldopa, clonidine, moxonidine, rilmenidine, guanfacine), unless clear intolerance of, or lack of efficacy with, other classes of antihypertensives (centrally-active antihypertensives are generally less well tolerated by older people than younger people)	☐	☐
B11.	ACE inhibitors or Angiotensin Receptor Blockers in patients with hyperkalaemia	☐	☐
B12.	Aldosterone antagonists (e.g. spironolactone, eplerenone) with concurrent potassium-conserving drugs (e.g. ACEIs, ARBs, amiloride, triamterene) without monitoring of serum potassium (risk of dangerous hyperkalaemia i.e. >6.0mmol/l – serum K should be monitored regularly, i.e. at least every 6 months)	☐	☐
B13.	Phosphodiesterase type-5 inhibitors (e.g. sildenafil, tadalafil, vardenafil) in severe heart failure characterised by hypotension, i.e. systolic BP <90mmHg, or concurrent nitrate therapy for angina (risk of cardiovascular collapse)	☐	☐
C1.	Long-term aspirin at doses greater than 160mg per day (increased risk of bleeding, no evidence for increased efficacy)	☐	☐
C2.	Aspirin with a past history of peptic ulcer disease without concomitant PPI (risk of recurrent peptic ulcer)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
C3.	Aspirin, clopidogrel, dipyridamole, vitamin K antagonists, direct thrombin inhibitors or factor Xa inhibitors with concurrent significant bleeding risk, i.e. uncontrolled severe hypertension, bleeding diathesis, recent non-trivial spontaneous bleeding) (high risk of bleeding)	☐	☐
C4.	Aspirin plus clopidogrel as secondary stroke prevention, unless the patient has a coronary stent(s) inserted in the previous 12 months or concurrent acute coronary syndrome or has a high grade symptomatic carotid arterial stenosis (no evidence of added benefit over clopidogrel monotherapy)	☐	☐
C5.	Aspirin in combination with vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in patients with chronic atrial fibrillation (no added benefit from aspirin)	☐	☐
C6.	Antiplatelet agents with vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in patients with stable coronary, cerebrovascular or peripheral arterial disease (no added benefit from dual therapy)	☐	☐
C7.	Ticlopidine in any circumstances (clopidogrel and prasugrel have similar efficacy, stronger evidence and fewer side-effects)	☐	☐
C8.	Vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors for first deep venous thrombosis without continuing provoking risk factors (e.g. thrombophilia) for >6 months, (no proven added benefit)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
C9.	Vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors for first pulmonary embolus without continuing provoking risk factors (e.g. thrombophilia) for >12 months (no proven added benefit)	☐	☐
C10.	NSAID and vitamin K antagonist, direct thrombin inhibitor or factor Xa inhibitors in combination (risk of major gastrointestinal bleeding)	☐	☐
C11.	NSAID with concurrent antiplatelet agent(s) without PPI prophylaxis (increased risk of peptic ulcer disease)	☐	☐
D1.	Tricyclic Antidepressants (TCAs) with dementia, narrow angle glaucoma, cardiac conduction abnormalities, prostatism, or prior history of urinary retention (risk of worsening these conditions)	☐	☐
D2.	Initiation of Tricyclic Antidepressants (TCAs) as first-line antidepressant treatment (higher risk of adverse drug reactions with TCAs than with SSRIs or SNRIs)	☐	☐
D3.	Neuroleptics with moderate-marked antimuscarinic/anticholinergic effects (chlorpromazine, clozapine, flupenthixol, fluphenzine, pipothiazine, promazine, zuclopenthixol) with a history of prostatism or previous urinary retention (high risk of urinary retention)	☐	☐
D4.	Selective serotonin re-uptake inhibitors (SSRIs) with current or recent significant hyponatraemia, i.e. serum Na <130mmol/l (risk of exacerbating or precipitating hyponatraemia)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
D5.	Benzodiazepines for ≥4 weeks (no indication for longer treatment; risk of prolonged sedation, confusion, impaired balance, falls, road traffic accidents; all benzodiazepines should be withdrawn gradually if taken for more than 4 weeks as there is a risk of causing a benzodiazepine withdrawal syndrome if stopped abruptly)	☐	☐
D6.	Antipsychotics (i.e. other than quetiapine or clozapine) in those with parkinsonism or Lewy Body Disease (risk of severe extra-pyramidal symptoms)	☐	☐
D7.	Anticholinergics/antimuscarinics to treat extra-pyramidal side-effects of neuroleptic medications (risk of anticholinergic toxicity)	☐	☐
D8.	Anticholinergics/antimuscarinics in patients with delirium or dementia (risk of exacerbation of cognitive impairment)	☐	☐
D9.	Neuroleptic antipsychotic in patients with behavioural and psychological symptoms of dementia (BPSD) unless symptoms are severe and other non-pharmacological treatments have failed (increased risk of stroke)	☐	☐
D10.	Neuroleptics as hypnotics, unless sleep disorder is due to psychosis or dementia (risk of confusion, hypotension, extra-pyramidal side effects, falls)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)

		Yes	No
D11.	Acetylcholinesterase inhibitors with a known history of persistent bradycardia (<60 beats/min), heart block or recurrent unexplained syncope or concurrent treatment with drugs that reduce heart rate such as beta-blockers, digoxin, diltiazem, verapamil (risk of cardiac conduction failure, syncope and injury)	☐	☐
D12.	Phenothiazines as first-line treatment, since safer and more efficacious alternatives exist (phenothiazines are sedative, have significant anti-muscarinic toxicity in older people, with the exception of prochlorperazine for nausea/vomiting/vertigo, chlorpromazine for relief of persistent hiccoughs and levomepromazine as an anti-emetic in palliative care)	☐	☐
D13.	Levodopa or dopamine agonists for benign essential tremor (no evidence of efficacy)	☐	☐
D14.	First-generation antihistamines (safer, less toxic antihistamines now widely available)	☐	☐
E1.	Digoxin at a long-term dose greater than 125µg/day if eGFR <30ml/min/1.73m^2 (risk of digoxin toxicity if plasma levels not measured)	☐	☐
E2.	Direct thrombin inhibitors (e.g. dabigatran) if eGFR <30ml/min/1.73m^2 (risk of bleeding)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)

		Yes	No
E3.	Factor Xa inhibitors (e.g. rivaroxaban, apixaban) if eGFR <15ml/min/1.73m^2 (risk of bleeding)	☐	☐
E4.	NSAIDs if eGFR <50ml/min/1.73m^2 (risk of deterioration in renal function)	☐	☐
E5.	Colchicine if eGFR <10ml/min/1.73m^2 (risk of colchicine toxicity)	☐	☐
E6.	Metformin if eGFR <30ml/min/1.73m^2 (risk of lactic acidosis)	☐	☐
F1.	Prochlorperazine or metoclopramide with Parkinsonism (risk of exacerbating Parkinsonian symptoms)	☐	☐
F2.	PPI for uncomplicated peptic ulcer disease or erosive peptic oesophagitis at full therapeutic dosage for >8 weeks (dose reduction or earlier discontinuation indicated)	☐	☐
F3.	Drugs likely to cause constipation (e.g. antimuscarinic/anticholinergic drugs, oral iron, opioids, verapamil, aluminium antacids) in patients with chronic constipation where non-constipating alternatives are available (risk of exacerbation of constipation)	☐	☐
F4.	Oral elemental iron doses greater than 200mg daily (e.g. ferrous fumarate >600mg/day, ferrous sulphate >600mg/day, ferrous gluconate >1800mg/day; no evidence of enhanced iron absorption above these doses)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No

G1.	Theophylline as monotherapy for COPD (safer, more effective alternative; risk of adverse effects due to narrow therapeutic index)	☐	☐
G2.	Systemic corticosteroids instead of inhaled corticosteroids for maintenance therapy in moderate-severe COPD (unnecessary exposure to long-term side-effects of systemic corticosteroids and effective inhaled therapies are available)	☐	☐
G3.	Antimuscarinic bronchodilators (e.g. ipratropium, tiotropium) with a history of narrow angle glaucoma (may exacerbate glaucoma) or bladder outflow obstruction (may cause urinary retention)	☐	☐
G4.	Benzodiazepines with acute or chronic respiratory failure, i.e. pO_2 <8.0kPa ± pCO_2 >6.5kPa (risk of exacerbation of respiratory failure)	☐	☐
H1.	Non-steroidal anti-inflammatory drug (NSAID) other than COX-2 selective agents with history of peptic ulcer disease or gastrointestinal bleeding, unless with concurrent PPI or H_2 antagonist (risk of peptic ulcer relapse)	☐	☐
H2.	NSAID with severe hypertension (risk of exacerbation of hypertension) or severe heart failure (risk of exacerbation of heart failure)	☐	☐
H3.	Long-term use of NSAID (>3 months) for symptom relief of osteoarthritis pain where paracetamol has not been tried (simple analgesics preferable and usually as effective for pain relief)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No

H4.	Long-term corticosteroids (>3 months) as monotherapy for rheumatoid arthritis (risk of systemic corticosteroid side-effects)	☐	☐
H5.	Corticosteroids (other than periodic intra-articular injections for mono-articular pain) for osteoarthritis (risk of systemic corticosteroid side-effects)	☐	☐
H6.	Long-term NSAID or colchicine (>3 months) for chronic treatment of gout where there is no contraindication to a xanthine-oxidase inhibitor (e.g. allopurinol, febuxostat) (xanthine-oxidase inhibitors are first choice prophylactic drugs in gout)	☐	☐
H7.	COX-2 selective NSAIDs with concurrent cardiovascular disease (increased risk of myocardial infarction and stroke)	☐	☐
H8.	NSAID with concurrent corticosteroids without PPI prophylaxis (increased risk of peptic ulcer disease)	☐	☐
H9.	Oral bisphosphonates in patients with a current or recent history of upper gastrointestinal disease, i.e. dysphagia, oesophagitis, gastritis, duodenitis, or peptic ulcer disease, or upper gastrointestinal bleeding (risk of relapse/exacerbation of oesophagitis, oesophageal ulcer, oesophageal stricture)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No

I1.	Antimuscarinic drugs with dementia, or chronic cognitive impairment (risk of increased confusion, agitation) or narrow-angle glaucoma (risk of acute exacerbation of glaucoma), or chronic prostatism (risk of urinary retention)	☐	☐
I2.	Selective alpha-1 alpha blockers in those with symptomatic orthostatic hypotension or micturition syncope (risk of precipitating recurrent syncope)	☐	☐
J1.	Sulphonylureas with a long duration of action (e.g. glibenclamide, chlorpropamide, glimepiride) with type 2 diabetes mellitus (risk of prolonged hypoglycaemia)	☐	☐
J2.	Thiazolidenediones (e.g. rosiglitazone, pioglitazone) in patients with heart failure (risk of exacerbation of heart failure)	☐	☐
J3.	Beta-blockers in diabetes mellitus with frequent hypoglycaemic episodes (risk of suppressing hypoglycaemic symptoms).	☐	☐
J4.	Oestrogens with a history of breast cancer or venous thromboembolism (increased risk of recurrence)	☐	☐
J5.	Oral oestrogens without progestogen in patients with intact uterus (risk of endometrial cancer)	☐	☐
Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
J6.	Androgens (male sex hormones) in the absence of primary or secondary hypogonadism (risk of androgen toxicity; no proven benefit outside of the hypogonadism indication).	☐	☐

K1.	Benzodiazepines (sedative, may cause reduced sensorium, impair balance)	☐	☐
K2.	Neuroleptic drugs (may cause gait dyspraxia, Parkinsonism)	☐	☐
K3.	Vasodilator drugs (e.g. alpha-1 receptor blockers, calcium channel blockers, long-acting nitrates, ACE inhibitors, angiotensin II receptor blockers) with persistent postural hypotension, i.e. recurrent drop in systolic blood pressure ≥20mmHg (risk of syncope, falls)	☐	☐
K4.	Hypnotic Z-drugs, e.g. zopiclone, zolpidem, zaleplon (may cause protracted daytime sedation, ataxia)	☐	☐
L1.	Use of oral or transdermal strong opioids (morphine, oxycodone, fentanyl, buprenorphine, diamorphine, methadone, tramadol, pethidine, pentazocine) as first line therapy for mild pain (WHO analgesic ladder not observed)	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
L2.	Use of regular (as distinct from PRN) opioids without concomitant laxative (risk of severe constipation)	☐	☐

L3.	Long-acting opioids without short-acting opioids for break-through pain (risk of persistence of severe pain)	☐	☐
M1.	Concomitant use of two or more drugs with antimuscarinic/ anticholinergic properties (e.g. bladder antispasmodics, intestinal antispasmodics, tricyclic antidepressants, first generation antihistamines) (risk of increased antimuscarinic/anticholinergic toxicity)	☐	☐

		Number of medicines (n)
Q1.	How many medicines were involved in the identification of the instances of potentially inappropriate prescribing?	

Screening Tool to Alert to Right Treatment (START)

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
A1.	Vitamin K antagonists or direct thrombin inhibitors or factor Xa inhibitors in the presence of chronic atrial fibrillation	☐	☐

A2.	Aspirin (75mg – 160mg once daily) in the presence of chronic atrial fibrillation, where Vitamin K antagonists or direct thrombin inhibitors or factor Xa inhibitors are contraindicated	☐	☐
A3.	Antiplatelet therapy (aspirin or clopidogrel or prasugrel or ticagrelor) with a documented history of coronary, cerebral or peripheral vascular disease	☐	☐
A4.	Antihypertensive therapy where systolic blood pressure consistently >160mmHg and/or diastolic blood pressure consistently >90mmHg; if systolic blood pressure >140mmHg and /or diastolic blood pressure >90mmHg, if diabetic	☐	☐
A5.	Statin therapy with a documented history of coronary, cerebral or peripheral vascular disease, unless the patient's status is end-of-life or age is >85 years	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
A6.	Angiotensin Converting Enzyme (ACE) inhibitor with systolic heart failure and/or documented coronary artery disease	☐	☐
A7.	Beta-blocker with ischaemic heart disease	☐	☐
A8.	Appropriate beta-blocker (bisoprolol, nebivolol, metoprolol or carvedilol) with stable systolic heart failure	☐	☐

B1.	Regular inhaled β_2 agonist or antimuscarinic bronchodilator (e.g. ipratropium, tiotropium) for mild to moderate asthma or COPD	☐	☐
B2.	Regular inhaled corticosteroid for moderate-severe asthma or COPD, where FEV_1 <50% of predicted value and repeated exacerbations requiring treatment with oral corticosteroids	☐	☐
B3.	Home continuous oxygen with documented chronic hypoxaemia (i.e. pO_2 <8.0kPa or 60mmHg or SaO_2 <89%)	☐	☐
C1.	L-DOPA or a dopamine agonist in idiopathic Parkinson's disease with functional impairment and resultant disability	☐	☐
C2.	Non-TCA antidepressant drug in the presence of persistent major depressive symptoms	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
C3.	Acetylcholinesterase inhibitor (e.g. donepezil, rivastigmine, galantamine) for mild-moderate Alzheimer's dementia or Lewy Body dementia (rivastigmine)	☐	☐
C4.	Topical prostaglandin, prostamide or beta-blocker for primary open-angle glaucoma	☐	☐
C5.	Selective serotonin reuptake inhibitor (or SNRI or pregabalin if SSRI contraindicated) for persistent severe anxiety that interferes with independent functioning	☐	☐

C6.	Dopamine agonist (ropinirole or pramipexole or rotigotine) for Restless Legs Syndrome, once iron deficiency and severe renal failure have been excluded	☐	☐
D1.	Proton Pump Inhibitor with severe gastro-oesophageal reflux disease or peptic stricture requiring dilatation	☐	☐
D2.	Fibre supplements (e.g. bran, ispaghula, methylcellulose, sterculia) for diverticulosis with a history of constipation	☐	☐
E1.	Disease-modifying anti-rheumatic drug (DMARD) with active, disabling rheumatoid disease	☐	☐
E2.	Bisphosphonates and vitamin D and calcium in patients taking long-term systemic corticosteroid therapy	☐	☐
Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
E3.	Vitamin D and calcium supplement in patients with known osteoporosis and/or previous fragility fracture(s) and/or (Bone Mineral Density T-scores more than -2.5 in multiple sites)	☐	☐
E4.	Bone anti-resorptive or anabolic therapy (e.g. bisphosphonate, strontium ranelate, teriparatide, denosumab) in patients with documented osteoporosis, where no pharmacological or clinical status contraindication exists (Bone Mineral Density T-scores ->2.5 in multiple sites) and/or previous history of fragility fracture(s)	☐	☐

E5.	Vitamin D supplement in older people who are housebound or experiencing falls or with osteopenia (Bone Mineral Density T-score is >-1.0 but <-2.5 in multiple sites)	☐	☐
E6.	Xanthine-oxidase inhibitors (e.g. allopurinol, febuxostat) with a history of recurrent episodes of gout	☐	☐
E7.	Folic acid supplement in patients taking methotrexate	☐	☐
F1.	ACE inhibitor or Angiotensin Receptor Blocker (if intolerant of ACE inhibitor) in diabetes with evidence of renal disease i.e. dipstick proteinuria or microalbuminuria (>30mg/24 hours) with or without serum biochemical renal impairment.	☐	☐

Section	Criteria	Decision (Is this potentially inappropriate)	
		Yes	No
G1.	Alpha-1 receptor blocker with symptomatic prostatism, where prostatectomy is not considered necessary	☐	☐
G2.	5-alpha reductase inhibitor with symptomatic prostatism, where prostatectomy is not considered necessary	☐	☐
G3.	Topical vaginal oestrogen or vaginal oestrogen pessary for symptomatic atrophic vaginitis	☐	☐

H1.	High-potency opioids in moderate-severe pain, where paracetamol, NSAIDs or low-potency opioids are not appropriate to the pain severity or have been ineffective	☐	☐
H2.	Laxatives in patients receiving opioids regularly	☐	☐
I1.	Seasonal trivalent influenza vaccine annually	☐	☐
I2.	Pneumococcal vaccine at least once after age 65 according to national guidelines	☐	☐

		Number of medicines (n)
Q2.	How many medicines were involved in the identification of the instances of prescribing omissions?	

Appendix 4.26 Schedule of Medication Review Form

Schedule of Medication Reviews Form

1a.	Initial medication review attended	☐	Yes (if yes, please complete Q1c.)
		☐	No (if no, please complete Q1b. and Protocol Deviation Form)
1b.	Reason(s) for not attending initial review		
1c.	Date of initial medication review	D D / M M / Y Y Y Y	
1d.	How was the patient's initial medication review held?	☐	Face-to-face
		☐	Telephone
		☐	Online
2a.	Has the patient consented to having their initial medication review recorded?	☐	Yes (if yes, please complete Q2b.)
		☐	No (if no, please complete Q3a.)
2b.	Has the patient's initial medication review been recorded?	☐	Yes (if yes, please complete Q2c.)
		☐	No (if no, please complete Q3a.)
2c.	Length of initial medication review (taken from audio recording)	m m m	minutes

3a.	6-month follow-up medication review attended	☐	Yes (if yes, please complete Q3c.)
		☐	No (if no, please complete Q3b. and Protocol Deviation Form)
3b.	Reason(s) for patient not attending 6-month follow-up medication review		
3c.	Date of 6-month follow-up medication review	D D / M M / Y Y Y Y	
3d.	How was the patient's 6-month follow-up medication review held?	☐	Face-to-face
		☐	Telephone
		☐	Online
4a.	Has the patient consented to having their 6-month follow-up medication review recorded?	☐	Yes (if yes, please complete Q4b.)
		☐	No
4b.	Has the patient's 6-month follow-up medication review been recorded?	☐	Yes (if yes, please complete Q4c.)
		☐	No
4c.	Length of 6-month follow-up medication review (taken from audio recording)	m m m	minutes

Appendix 4.27 GP practice and General practitioner eligibility form

PolyPrime

GP Practice and GP Eligibility, Recruitment/Demographics Form

1a.	Has the practice provided written informed consent?	☒	Yes
		☐	No
1b.	Has the practice provided Research Governance sign-off?	☒	Yes
		☐	No
1c.	Does the practice have a stable internet service in order to access the video?	☒	Yes
		☐	No
If any part of question 1 is marked **'NO',** the practice is **NOT ELIGIBLE** to participate in the study.			
2.	Is the practice participating in other studies related to medicines management in older people?	☐	Yes
		☒	No
If question 2 is marked **'YES',** the practice is **NOT ELIGIBLE** to participate in the study.			
3.	Is the practice eligible to take part in PolyPrime Trial?	☒	Yes
		☐	No
4.	Has practice consent been obtained?	☒	Yes
		☐	No
5.	Date of Consent	1 0 / 1 0 / 2 0 1 9	
6.	Date of Recruitment	1 0 / 1 0 / 2 0 1 9	

7.	Is the practice in the control or intervention arm of the study?	☐	Control
		☒	Intervention
8.	Number of GPs in the practice	n n n	number
9.	Number of other staff members	Administrative and support staff	n n
		Nurses	n n
		Pharmacists	n n
		Other, please state: _____	n n
		Other, please state: _____	n n
		Other, please state: _____	n n
10.	Number of weekly meetings (at which explicit plans were made to recall patients for medication reviews)	n n n	number
11.	In terms of current practice, please give a brief description of how this GP practice typically prescribes for older patients (aged 70 years or over) receiving polypharmacy [four or more regular medicines (i.e. prescribed for more than three months)]		
12.	Are medication reviews conducted for older patients receiving polypharmacy [four or more regular medicines (i.e. prescribed for more than three months)]?	☐	Yes (if yes, please complete Q12a. & b.)
		☐	No
12a.	How often are medications reviews conducted for older patients receiving polypharmacy [four or more regular medicines (i.e. prescribed for more than three months)]?	☐	Every 3 months
		☐	Every 6 months
		☐	Once per year
		☐	Other, please state: _____
12b.	Who is conducting medication reviews for older patients receiving polypharmacy [four or more regular medicines (i.e. prescribed for more than three months)]? Please tick all that apply	☐	General Practitioners
		☐	Nurses
		☐	Pharmacists
		☐	Other, please state: _____

13.	Geographical area	☒	Republic of Ireland
		☐	Northern Ireland
14.	Number of GPs recruited	☒	1 (if ticked please complete Q15)
		☐	2 (if ticked please complete Q15 & Q16)
		☐	3 (if ticked please complete Q15 to Q17)
		☐	4 (if ticked please complete Q15 to Q18)
		☐	5 (if ticked please complete Q15 to Q19)
Please complete the following section with details of each GP recruited onto the study			
15a.	General Practitioner ID	G P P 2 4 G P 0 1	
15b.	Gender	☒	Male
		☐	Female
15c.	Years practising as a GP	y y	years
Please complete if “Intervention” was ticked for Q7			
15d.	Number of times the GP accessed the online video (taken from online server)	n n n	views
16a.	General Practitioner ID	G P P G P 0 2	
16b.	Gender	☐	Male
		☐	Female
16c.	Years practising as a GP	y y	years
Please complete if “Intervention” was ticked for Q7			
16d.	Number of times the GP accessed the online video (taken from online server)	n n n	views

17a.	General Practitioner ID	G P P [ ] [ ] G P 0 3
17b.	Gender	☐ Male ☐ Female
17c.	Years practising as a GP	y y years
Please complete if “Intervention” was ticked for Q7		
17d.	Number of times the GP accessed the online video (taken from online server)	n n n views
18a.	General Practitioner ID	G P P [ ] [ ] G P 0 4
18b.	Gender	☐ Male ☐ Female
18c.	Years practising as a GP	y y years
Please complete if “Intervention” was ticked for Q7		
18d.	Number of times the GP accessed the online video (taken from online server)	n n n views
19a.	General Practitioner ID	G P P [ ] [ ] G P 0 5
19b.	Gender	☐ Male ☐ Female
19c.	Years practising as a GP	y y years
Please complete if “Intervention” was ticked for Q7		
19d.	Number of times the GP accessed the online video (taken from online server)	n n n views

Appendix 4.28 Practice staff input form

Practice Staff Input Form

We would like to find out the level of practice staff involvement in the tasks undertaken for the PolyPrime study.

We would like you to complete this form for each patient taking part in the PolyPrime study. Please estimate the time you spent on each task as you completed it so that it is as accurate as possible. If there are any other tasks you undertook, then please record this under 'Other activity' in the table. Please also briefly summarise the activities involved in completing each task and which member(s) of practice staff were responsible for completing these activities.

Please complete this section of the form for each of the tasks associated with the patient's initial medication review

Task	Activities involved	Time input
Scheduling the patient's initial medication review appointment	Please record the job title of practice staff completing this activity: _____	mins
Prompting the GP to conduct the patient's initial medication review	Please record the job title of practice staff completing this activity: _____ Please record the number of prompts made to the GP: _____ Please indicate how these prompts were given: Computerised system: Yes ☐ No ☐ If Yes, please record the number of electronic prompts made to the GP ____ Verbally: Yes ☐ No ☐ If Yes, please record the number of verbal prompts made to the GP _____	mins
Other activity, please state:	Please record the job title of practice staff completing this activity: _____	mins
Other activity, please state:	Please record the job title of practice staff completing this activity: _____	mins

Please complete this section of the form for each of the tasks associated with the patient's 6-month follow-up medication review

Task	Activities involved	Time input

Scheduling the patient's 6-month follow-up medication review appointment	Please record the job title of practice staff completing this activity: _____	mins
Prompting the GP to conduct the patient's 6-month follow-up medication review	Please record the job title of practice staff completing this activity: _____ Please record the number of prompts made to the GP: _____ Please indicate how these prompts were given: Computerised system: Yes ☐ No ☐ If Yes, please record the number of electronic prompts made to the GP ____ Verbally: Yes ☐ No ☐ If Yes, please record the number of verbal prompts made to the GP _____	mins
Other activity, please state:	Please record the job title of practice staff completing this activity: _____	mins
Other activity, please state:	Please record the job title of practice staff completing this activity: _____	mins

This form will be collected from you by a researcher at the end of the study.

Appendix 4.29 Practice staff participant information leaflet and consent form

Study Title: A pilot cluster randomised controlled trial of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime)

Chief Investigator: Professor Carmel Hughes (Queen's University Belfast)

You are being invited to take part in a research study. Before you decide whether or not you would like to take part, it is important that you take time to understand why this research is being completed and what will be asked of you should you agree to participate. Please read the following information and contact the Research Fellow/Assistant (Dr. Audrey Rankin / Ms. Ashleigh Gorman), or any other member of the research team if you have any questions. Contact details can be found at the end of this information sheet.

Why is this research being done?

Polypharmacy (sometimes defined as the use of four or more medicines) is the new paradigm for prescribing in older people, largely driven by multimorbidity and evidence-based guidelines for the management of long-term conditions. The prescribing of appropriate polypharmacy is a well-documented challenge which faces healthcare professionals (HCPs), particularly general practitioners (GPs) who prescribe most of older people's medicines. Despite this, evidence of effective interventions to improve the appropriate prescribing of polypharmacy for older people is lacking, owing primarily to a lack of input from HCPs and patients when designing interventions. Members of the research team have developed a theory-based intervention, targeting prescribing of appropriate polypharmacy in primary care, which has been tested for feasibility in two general practices in Northern Ireland (NI). The existing intervention package currently consists of two components: (a) a video demonstrating how GPs can prescribe appropriate polypharmacy (primarily focusing on reducing unnecessary/inappropriate medicines) during a typical consultation with an older patient; and (b) a patient recall process (appointment with GP for a medication review).

What is the purpose of this study?

This study forms part of an ongoing research project during which we have conducted interviews with GPs in the border region of the Republic of Ireland (ROI; Cavan, Donegal, Leitrim,

Louth, Monaghan and Sligo). During these interviews the intervention package was described in more detail and GPs were shown the video component. GPs were then asked to comment on the content of the intervention package, mode of delivery, relevance to practice, and to suggest any changes that they felt would be required.

The current study will contribute to the development of the intervention further, through testing in a larger pilot study in six GP practices across NI and the border counties in ROI respectively. This will allow us to test and compare the delivery of the intervention across NI and the ROI and to decide whether to progress to a full-scale randomised trial at a later date.

Who is organising and funding this study?

This research is being organised by the Schools of Pharmacy and Medicine, Queen's University Belfast, the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, the School of Pharmacy and Department of General Practice, Royal College of Surgeons in Ireland and the School of Psychology, National University of Ireland Galway. This project is funded by the Cross-border Healthcare Intervention Trials in Ireland Network (CHITIN) which is a unique cross-border partnership between the Public Health Agency in Northern Ireland and the Health Research Board in the Republic of Ireland, to develop infrastructure and deliver Healthcare Intervention Trials (HITs). The study has received ethical approval from the North of Scotland Research Ethics Committee (Reference Number: 19/NS/0100) and the Irish College of General Practitioners (ICGP) Research Ethics Committee.

Why am I being asked to take part?

You have been approached to participate in this study because you are currently involved in the implementation of the PolyPrime intervention within the GP practice in which you work.

What will happen to me if I agree to take part?

If you would like to take part, please return your completed consent form to the Research Fellow/Assistant (Dr. Audrey Rankin / Ms. Ashleigh Gorman) to confirm that you would like to take part in the study.

If you volunteer to take part in this study, you will be asked to participate in a feedback interview with one of the researchers at the end of the study. Prior to the interview, you will be asked to provide informed consent for the interview to be audio-recorded. The interview will last approximately 30 minutes, although this may vary between individuals. The interviews will be conducted over the phone at a time which is convenient to you.

How many people will be in this study?

In total, we will recruit 6 members of practice staff currently involved in the implementation of the PolyPrime intervention (three in Northern Ireland and three in the border region of the Republic of Ireland) into this study.

What will happen to any video/and or audio recordings?

Interviews will be audio-recorded and all audio files will be pseudonymised meaning that any information that could identify you will be removed. Your name or the name of the practice you work in will not appear and will be replaced with a unique code. We may share the pseudonymised audio-recordings with a transcription company. The transcription company will be asked to delete the audio-recordings when transcriptions have been received by the researchers.

What are the possible benefits for me and/or society?

Participation in this study may be beneficial for you, as it will help to determine if the intervention needs to be refined before further evaluations can be undertaken to assess the effectiveness of the intervention in improving appropriate polypharmacy in older people.

Are there any risks or disadvantages of taking part in the study?

There is a risk that poor practice may be identified during the pilot study. In the unlikely event that this occurs, any cases will be reported to the Chief Investigator (Professor Carmel Hughes) who will take appropriate action on a case-by-case basis which may involve informing the appropriate professional regulatory body.

What information will be kept private?

Queen's University Belfast is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen's University Belfast will keep identifiable information about you for five years after the study has finished. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you decide to withdraw you have the choice of removing any data/information you have provided for the study. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information at www.qub.ac.uk/privacynotice/.

Your identity will remain confidential. Your name will not be published and will not be disclosed to anyone outside the research group. All identifiable information you provide to us such as your name or the name of the practice you work in will be removed from the data and replaced with a unique ID code. Other identifiable information will be removed. A list linking your ID code with your name will be kept by the Research Fellow in QUB, in a secure place, separate from the information you provide. Information gained from the study including identifiable information such as consent forms will be stored securely at the School of Pharmacy, Queen's University Belfast or the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin in locked filing cabinets. If you are invited to take part in an interview or if you agree to record a medication review all audio files will be pseudonymised meaning that any information that could identify you or the practice you work in will be removed during transcription, after which the audio-recordings will be deleted. When the study has been completed, participant consent forms and transcripts stored at Trinity College Dublin will be transferred to Queen's University Belfast [in line with General Data Protection Regulation (GDPR 2018) for the transferring of data]. These will be kept for five years and then destroyed, in line with GDPR 2018.

Data may be published in academic journals and presented at conferences, but your name and the name of the practice you work in will not appear in any publications. All data reported will be pseudonymised, meaning that any information that could identify you or your practice will be removed and/or replaced with a unique ID code. You will be provided with a report of the results at the end of the study.

In order to ensure that studies involving human participants are carried out to a high standard, the Queen's University Belfast's or Trinity College Dublin's Research Governance, Ethics and Integrity teams may examine the study data to ensure that we are complying with good practice. By consenting to take part in the study, you are authorising this access.

Can participation in the study end early?

You are free to withdraw from the study at any time. If you decide to withdraw you have the choice of removing any data/information you have provided for the study.

If I have any questions or problems, whom can I call?

If the practice you work is in **Northern Ireland** and have any questions about the research, now or later, please contact:

Dr. Audrey Rankin, Research Fellow, School of Pharmacy, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL. Telephone: +44 (0) 7391 730647, Email: a.rankin@qub.ac.uk

If the practice you work in is in the **Republic of Ireland** and have any questions about the research, now or later, please contact:

Ms. Ashleigh Gorman, Research Assistant, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Panoz Institute, Dublin, D02PN40. Telephone: +353 (0) 86 608 9094, Email: gormanas@tcd.ie

If you have concerns about how this research is being conducted, please contact:

Prof. Carmel Hughes, Professor of Primary Care Pharmacy, School of Pharmacy, Queen's University Belfast, 97 Lisburn Road, Belfast, BT9 7BL. Telephone: +44 (0)28 9097 2147, Email: c.hughes@qub.ac.uk

In the event that your concerns are not addressed, please contact:

Mrs Louise Dunlop, Head of Research Governance, Ethics and Integrity, Queen's University

Belfast, BT7 1NN. Tel +44 (0) 28 9097 2572, Email: l.h.dunlop@qub.ac.uk

If you have concerns about how your information is being used, please contact:

Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, D02 RD28, Ireland.

Telephone +353 761 104 800, Online https://forms.dataprotection.ie/contact

Study Title: A pilot cluster randomised controlled trial of a theory-based intervention to improve appropriate polypharmacy in older people in primary care (PolyPrime).

Chief Investigator: Professor Carmel Hughes (Queen's University Belfast)

Please tick the appropriate boxes	Yes	No
1. Taking part in the study		
I have read and understood the information sheet dated [05.07.2021] (version 2.0). I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
I have been given a copy of the information sheet and this completed consent form for my records.	☐	☐
I am aware of the potential risks, benefits and alternatives of this research study.	☐	☐
I agree to take part in an interview.	☐	☐
I agree for the interview to be audio-recorded.	☐	☐
I understand that I don't have to take part in this study and that I can opt out at any time. I understand that I don't have to give a reason for opting out and I understand that opting out won't affect my legal rights.	☐	☐
I consent to take part in the study described in the information sheet, having been fully informed of the risks, benefits and alternatives.	☐	☐
2. Use of information in the study		
I understand that my personal information will be confidential and stored safely in Queen's University Belfast or Trinity College Dublin. I am aware that I will not be identified in any of the findings.	☐	☐
I understand that relevant sections of information collected during the study may be looked at by researchers involved in the study, or from Queen's University Belfast or Trinity College Dublin, for audit purposes. I understand that no other individuals will have access to my personal information.	☐	☐
I give my informed explicit consent to have my data to be processed as part of this research study.	☐	☐

I understand that an interview may be audio recorded and that anonymous quotations may be used in the reports or outputs from this study.	☐	☐
3. Future use of information and ongoing contact		
I understand that the research team will contact me at the end of the study to provide a summary of the results.	☐	☐

_____	_____	_____
Name of the participant (please print)	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

2 copies to be made: 1 for participant, 1 for PI.

Appendix 4.30 General practitioner topic guide

PolyPrime

General Practitioner Topic Guide

Good morning/afternoon and thank you for agreeing to take part in this feedback interview. The aim of this interview is to find out about your experience of taking part in the PolyPrime study. During the interview you will be asked about the intervention package, the practicality of the study procedures and delivering this type of intervention in your everyday practice and your overall experience with it. There are no right or wrong answers. It is about your own views and opinions, both positive and negative. Your honest feedback will be very important in refining this intervention for future testing and so we are very open to hearing what aspects you think could be improved upon.

The interview should last approximately 45 minutes depending on how much you have to say. As previously mentioned, the interview will be audio-recorded and we may wish to include selected extracts in our reports. However, any quotes that we do use will be completely anonymised and therefore cannot be attributed to you. You can stop the interview at any time, or if you would prefer not to answer a question, then please let me know and we can move onto the next one.

Do you have any immediate questions before we begin?

[Turn on digital recorder]

<u>Part 1 – Acceptability of study procedures including patient screening and recruitment and support provided by the research team</u>

In this first set of questions, I'd like you to reflect upon specific aspects of the study procedures including the process of screening and recruiting patients and the level of support provided by the research team.
As you will recall, your practice staff were asked to screen patients who met the study inclusion criteria in order to select patients who would receive invitation letters. Interested patients then returned completed consent forms to the research team.

Q1. What did you think about the approach taken to recruiting patients?
Prompt: *Did this work well in your practice? Was there anything you think we should have done differently?*

During the patient screening procedure, research nurses were on site at your practice to support the practice staff. The researchers on the team also had regular contact with the practice during the study and were available if you or the practice staff had any queries.

Q2. What do you think about the level of support you received from the research team?

Q3. Is there anything else that the research team could have done to support you and your practice over the course of the study?
Prompt: *What else could the research team have done to support you and your practice over the course of the study?*

Q4. Is there any additional support that the research team could have provided that would have helped you in implementing this study within your practice?

Part 2 – Intervention delivery and experience of delivering the PolyPrime intervention
We will now move on to the implementation of the PolyPrime intervention. In this second set of questions, I will ask you to reflect upon specific aspects of the intervention such as the online video, the patient recall process, prompts received from practice staff and weekly meetings.

Firstly, you were given access to the PolyPrime online video which demonstrated how general practitioners can prescribe appropriate polypharmacy during a typical consultation with an older patient.

Q5. What did you think about the video generally?

Prompt: *Do you have any comments on the content of the video?*

Prompt: *Do you have any thoughts on using a video in this way to demonstrate prescribing appropriate polypharmacy?*

Prompt: *What did you think of the clinical scenario used?*

Q6. What aspects did you like about the video?

Prompt: *Why did you like this?*

Prompt: *Length of video; GP and patient interaction.*

Q7. What aspects did you dislike about the video?

Prompts: *Why did you dislike this? How could this been improved/overcome?*

Q8. Is there anything that you would change about the video?

Prompt: *Anything else?*

Q9. Did you use any of the supporting documents that were highlighted in the video?

Prompts: *Did you find them useful? Are there any other resources we should consider adding?*

After watching the online video, you were asked to undertake a patient recall process. In order to facilitate the patient medication review appointments, you were asked to make a plan at weekly meetings with practice colleagues (i.e. reception staff, practice managers) of when and how you would ensure that older patients meeting the inclusion criteria would be invited to the GP surgery for a medication review.

Q10. What did you think about this approach?

Prompts: *How did you organise the meetings in your practice? Were there any barriers to implementing this in your practice?*

Prompt: *Did you find holding practice meetings useful in organising patient medication review appointments?*

Reception staff were also asked to assist in scheduling the consultations for patients. You were prompted by the receptionist/practice manager to perform medication reviews to address appropriate polypharmacy with older patients recruited to the study when these patients attended for a scheduled appointment.

Q11. What did you think about this approach?

Prompts: *How did you organise the prompts in your practice? Were these prompts verbal or electronic? Were there any barriers to implementing this in your practice?*

Prompt: *Did you find the prompts useful?*

After being prompted by the practice staff, you then conducted medication review consultations with the patients.

Q12. Can you tell me about your experience of delivering medication reviews for PolyPrime?

Prompt: *How did you deliver the medication reviews (face-to-face, via telephone or via video call)?* ***Prompt: IF VIA TELEPHONE OR VIDEO CALL:*** *Do you think delivering the medication reviews in this way had any impact on the quality of the medication reviews you were able to conduct? If so, in what way(s)?*

Prompt: *Did you make a plan of what you wanted to discuss with each patient before their appointment?*

Part 3: Acceptability of the overall intervention (TFA based questions)

In this next set of questions, I want to ask you about the acceptability of the intervention as a whole/overall. These questions may appear repetitive, but they are just to recap on some of the issues you have already raised in the context of the overall intervention.

Q13. What did you **like** about the overall intervention?
Prompt: *Why did you **like** X?*

Q14. What did you **dislike** about the overall intervention?
Prompt: *Why did you **dislike** X?*

Q15. Did you have to **deprioritise anything important** to be able to deliver the intervention?
Prompts: *other work tasks, time*

Q16. How **demanding** was it to deliver the overall intervention?
Prompts: *time commitment, communication skills, mental effort (e.g. prolonged concentration)*

Q17. Did you understand **how** the overall intervention was supposed to help improve the use of multiple medication in older people?
Prompts: *How do you think the intervention was* supposed to help improve the use of multiple medication in older people? *Did the intervention make sense?*

Q18. In your opinion do you think the overall intervention was **effective** at improving the prescribing of appropriate polypharmacy in older people?
Prompt: *why? / why not?*

Q19. After watching the online video how **confident** were you that you could perform a medication review to improve the prescribing of appropriate polypharmacy in older people?

Prompts: *How confident were you when you thought the patient was at LOW risk because of the medicines prescribed for them? How confident were you when you thought the patient may be at HIGH risk because of the medicines prescribed for them?*

Q20. Overall, was the intervention acceptable *Y/N?*

Prompt: *Why? / why not?*

Q21. Could anything be changed to improve the overall intervention?

Finally, as you know the coronavirus pandemic has had, and continues to have, a dramatic impact upon primary care services in NI and the ROI. Not only has the pandemic affected how GP practices provide usual care to patients, it has also affected the way in which medication reviews can be delivered.

Q22. How did the coronavirus pandemic affect the implementation of the PolyPrime intervention in your practice?

Round up

That brings us to the end of this interview.

Is there anything that you feel has not been covered? Do you have any further comments that you would like to make?

Thank you very much for participating in the PolyPrime study and for all of your feedback on the intervention.

[Turn off digital recorder]

Appendix 4.31 Practice staff topic guide

Practice Staff Topic Guide

Good morning/afternoon and thank you for agreeing to take part in this feedback interview. The aim of this interview is to find out about your experience of taking part in the PolyPrime study. During the interview you will be asked about the practicality of the study procedures and implementing this type of intervention in practice and your overall experience with it. There are no right or wrong answers. It is about your own views and opinions, both positive and negative. Your honest feedback will be very important in refining this intervention for future testing and so we are very open to hearing what aspects you think could be improved upon.

The interview should last approximately 30 minutes depending on how much you have to say. As previously mentioned, the interview will be audio-recorded and we may wish to include selected extracts in our reports. However, any quotes that we do use will be completely anonymised and therefore cannot be attributed to you. You can stop the interview at any time, or if you would prefer not to answer a question, then please let me know and we can move onto the next one.

Do you have any immediate questions before we begin?

[Turn on digital recorder]

Part 1 – Acceptability of the study procedures including patient screening and recruitment and support provided by the research team

In this first set of questions, I'd like you to reflect upon specific aspects of the study procedures, including the process of screening and recruiting patients and level of support provided by the research team.

As you will recall, you were asked to screen patients who met the study inclusion criteria in order to select patients who would receive invitation letters. Interested patients then returned completed consent forms to the research team.

Q1. What did you think about the approach taken to recruiting patients?
Prompt: *Did this work well in your practice? Was there anything you think we should have done differently?*

During the patient screening procedure, research nurses were on site to support you through the process. The researchers on the team also had regular contact with the practice during the study and were available if you or the GP had any queries.

Q2. What do you think about the level of support you received from the research team?

Q3. Is there anything else that the research team could have done to support you and your practice over the course of the study?

Q4. Is there any additional support that the research team could have provided that would have helped you in implementing this study within your practice?

Part 2 – Intervention delivery and experience of implementing the PolyPrime intervention

We will now move on to the implementation of the PolyPrime intervention. I will ask you to reflect upon specific aspects of the intervention such as scheduling the medication reviews, weekly meetings and delivering prompts to the GPs.

After GPs had watched the online video, you were asked to schedule patient appointments. In order to facilitate this, GPs were asked to hold weekly meetings with practice colleagues (i.e. reception staff, practice managers) to plan when and how they would ensure that older patients meeting the inclusion criteria would be invited to their medication review appointments.

Q5. What did you think about this approach?

Prompts: *How did you organise the meetings in your practice? Where there any barriers to implementing this in your practice?*

Prompt: *Did you find holding practice meetings useful in organising patient medication review appointments?*

When this plan was in place, you were asked to schedule appointments where medication review consultations would be undertaken with the patients.

Q6. Can you tell me about your experience of scheduling the medication reviews for PolyPrime?

Prompt: *How did this work in your practice?*

You were also asked to prompt GPs to perform medication reviews to address appropriate polypharmacy with older patients meeting certain inclusion criteria when these patients attended for a scheduled appointment.

Q7. What did you think about this approach?

Prompts: *How did you organise the prompts in your practice? Where these prompts verbal or electronic? Where there any barriers to implementing this in your practice?*

Prompt: *Did you think the GPs found the prompts useful?*

Part 3: Acceptability of the overall intervention (TFA based questions)

In this next set of questions, I want to ask you about the acceptability of the intervention as a whole/overall. These questions may appear repetitive, but they are just to recap on some of the issues you have already raised in the context of the overall intervention.

Q8. What did you **like** about the overall intervention?

Prompt: *Why did you **like** X?*

Q9. What did you **dislike** about the overall intervention?

Prompt: *Why did you **dislike** X?*

Q10. Did you have to **deprioritise anything important** to be able to help implement the intervention?

Prompts: *Other work tasks, time*

Q11. How **demanding** was it to implement the overall intervention?

Prompts: *Time commitment, communication skills, mental effort (e.g. prolonged concentration)*

Q12. Overall, was the intervention acceptable*: Y/N?*

Prompt: *why? / why not?*

Q13. Could anything be changed to improve the overall intervention?

Finally, as you know the coronavirus pandemic has had, and continues to have, a dramatic impact upon primary care services in NI and the ROI. Not only has the pandemic affected how GP practices provide usual care to patients, it has also affected the way in which medication reviews can be delivered.

Q14. How did the coronavirus pandemic affect the implementation of the PolyPrime intervention in your practice?

Round up

That brings us to the end of this interview.

Is there anything that you feel has not been covered? Do you have any further comments that you would like to make?

Thank you very much for participating in the PolyPrime study and for all of your feedback on the intervention.

[Turn off digital recorder]

Appendix 4.32 Patient feedback questionnaire

Patient feedback questionnaire

We would like to hear your thoughts about the PolyPrime study that you took part in, so that we can continue to improve our research, and help support people who take many medicines. We want to know your honest thoughts about the study, and we would welcome any feedback that you may have. We have developed a short questionnaire that asks for your views about the study, the medication reviews that you received from your general practitioner (GP), and your overall experience of being involved in the PolyPrime study.

Once you have completed the questionnaire, you can use the return envelope provided to send it straight back to a member of the research team.

Your GP will not see your answers to these questions.

If you have any questions about this questionnaire, you can get in touch using the contact details below.

If you live in **Northern Ireland**

Dr. Audrey Rankin

Research Fellow

School of Pharmacy

Queen's University Belfast

97 Lisburn Road

If you live in the **Republic of Ireland**

Ms. Ashleigh Gorman

Research Assistant

School of Pharmacy and Pharmaceutical Sciences

Trinity College Dublin

Panoz Institute

Belfast BT9 7BL
Telephone: +44 (0) 7391 730647
Email: a.rankin@qub.ac.uk

Dublin D02PN40
Telephone: +353 (0) 86 608 9094
Email: gormanas@tcd.ie

Part 1 – Study procedures				
1. Think about the first time you were contacted about this study through the post. Did you like or dislike the way you were contacted? ***Please circle one of the following:***				
Strongly like	Like	No opinion	Dislike	Strongly dislike
2. If you circled 'Dislike' or 'Strongly dislike' to Question 1, please briefly explain your reasons for doing this:				
3. If you circled 'Dislike' or 'Strongly dislike' to Question 1, what would have been a better way to contact you about getting involved in this study?				
4. During the study you were asked to complete questionnaires on three occasions about your quality of life and how you used health services. Were you happy with the number of questionnaires you were asked to complete during the study? ***Please tick the appropriate box:***				
Yes	☐			
No	☐			

5. Please briefly explain your reasons for stating this:	
6. Were you happy with the support provided by members of the research team (i.e. the members of the research team listed on page 1)? ***Please tick the appropriate box:***	
Yes	☐
No	☐
7. Please briefly explain your reasons for stating this:	

Part 2 – Your medication reviews during the PolyPrime study	
8. What did you hope <u>would happen</u> as a result of having your medicines reviewed by your GP? ***Please tick all that apply:***	
The number of medicines I take would decrease	☐
The number of medicines I take would increase	☐
The number of times I take my medicines each day would decrease	☐
The number of times I take my medicines each day would increase	☐
I would have a better understanding about the medicines I take	☐
I would feel happier about my medicines I take	☐
I would feel reassured that my medicines have been reviewed	☐
Nothing, please briefly explain why:	☐

If you thought something else would happen, please briefly explain:	☐
In the following questions, we would like you to think about the <u>first</u> medication review appointment you received as part of the PolyPrime study.	
9. How did your <u>first</u> medication review take place? ***Please tick the appropriate box:***	
During a face-to-face appointment	☐
By telephone	☐
By video call	☐
10. Did you like or dislike the way you received your <u>first</u> medication review (i.e. face-to-face, over the telephone or video call)? ***Please circle one of the following:***	
Strongly like Like No opinion Dislike Strongly dislike	
11. Please briefly explain your reasons for stating this:	
12. Did the doctor recommend any changes to the medicines that you were taking at the time of the <u>first</u> medication review? ***Please tick the appropriate box:***	
Yes (If YES to Question 12, please complete Questions 13 & 14)	☐
No (If NO to Question 12, please go to Question 15)	☐
13. Did you agree with the doctor's recommended change(s) to the medicines that you were taking at the time of the <u>first</u> review? ***Please tick the appropriate box:***	
Yes	☐
No	☐
14. Please briefly explain your reasons for agreeing/not agreeing with the change(s) that the doctor recommended:	

In the following questions we would like you to think about the <u>second</u> medication review appointment you received as part of the PolyPrime study.
15. How did your <u>second</u> medication review take place? ***Please tick the appropriate box:***

During a face-to-face appointment	☐
By telephone	☐
By video call	☐

16. Did you like or dislike the way you received your <u>second</u> medication review (i.e. face-to-face, over the telephone or video call)? ***Please circle one of the following:***
Strongly like Like No opinion Dislike Strongly dislike
17. Please briefly explain your reasons for stating this:
18. Did the doctor recommend any more changes to the medicines that you were taking at the time of the <u>second</u> medication review? ***Please tick the appropriate box:***

Yes (If YES to Question 18, please complete Questions 19 & 20)	☐
No (If NO to Question 18, please go to Question 21)	☐

19. Did you agree with the doctor's recommended change(s) to the medicines that you were taking at the time of the <u>second</u> review? ***Please tick one of the following:***

Yes	☐
No	☐

20. Please briefly explain your reasons for agreeing/not agreeing with the change(s) that the doctor recommended:
In the following questions, we would like you to think about <u>both</u> medication review appointments you received as part of the PolyPrime study.

21. Did you like or dislike attending the medication review appointments? ***Please circle one of the following:***				
Strongly like	Like	No opinion	Dislike	Strongly dislike
22. How much do you agree with the following statement? Based on my experience, the PolyPrime intervention is likely to improve how many medicines are prescribed for older people. ***Please circle one of the following:***				
Strongly agree	Agree	No opinion	Disagree	Strongly disagree

23. What has been the effect of having your medicines reviewed by your GP? ***Please tick all that apply:***	
The number of medicines I take has decreased	☐
The number of medicines I take has increased	☐
I have a better understanding about the medicines I take	☐
The number of times I take my medicines each day has decreased	☐
The number of times I take my medicines each day has increased	☐
I am happier about my medicines	☐
I feel reassured that my medicines have been reviewed	☐
I am still concerned about my medicines	☐
It has made no difference, please briefly explain:	☐
If there have been other effects, please briefly explain:	☐

Part 3 – Your overall experience of the PolyPrime study				
24. How would you sum up your experience of the PolyPrime study? ***Please circle one of the following:***				
Very good	Good	Average	Poor	Very poor

25. Please briefly explain your reasons for stating this:

26. How much effort was required for you to take part in the PolyPrime study? ***Please circle one of the following:***

No effort at all	A little effort	No opinion	A lot of effort	Huge effort

27. Please briefly explain your reasons for stating this:

28. What would have improved your overall experience of being involved in the PolyPrime study? ***Please tick all that apply:***

Being sent an appointment letter for my medication review appointments	☐
Longer appointment(s)	☐
Shorter appointment(s)	☐
Nothing, I was happy with the overall experience	☐
Improvements could be made but have not been listed above. I have the following suggestions that might lead to improvements:	☐

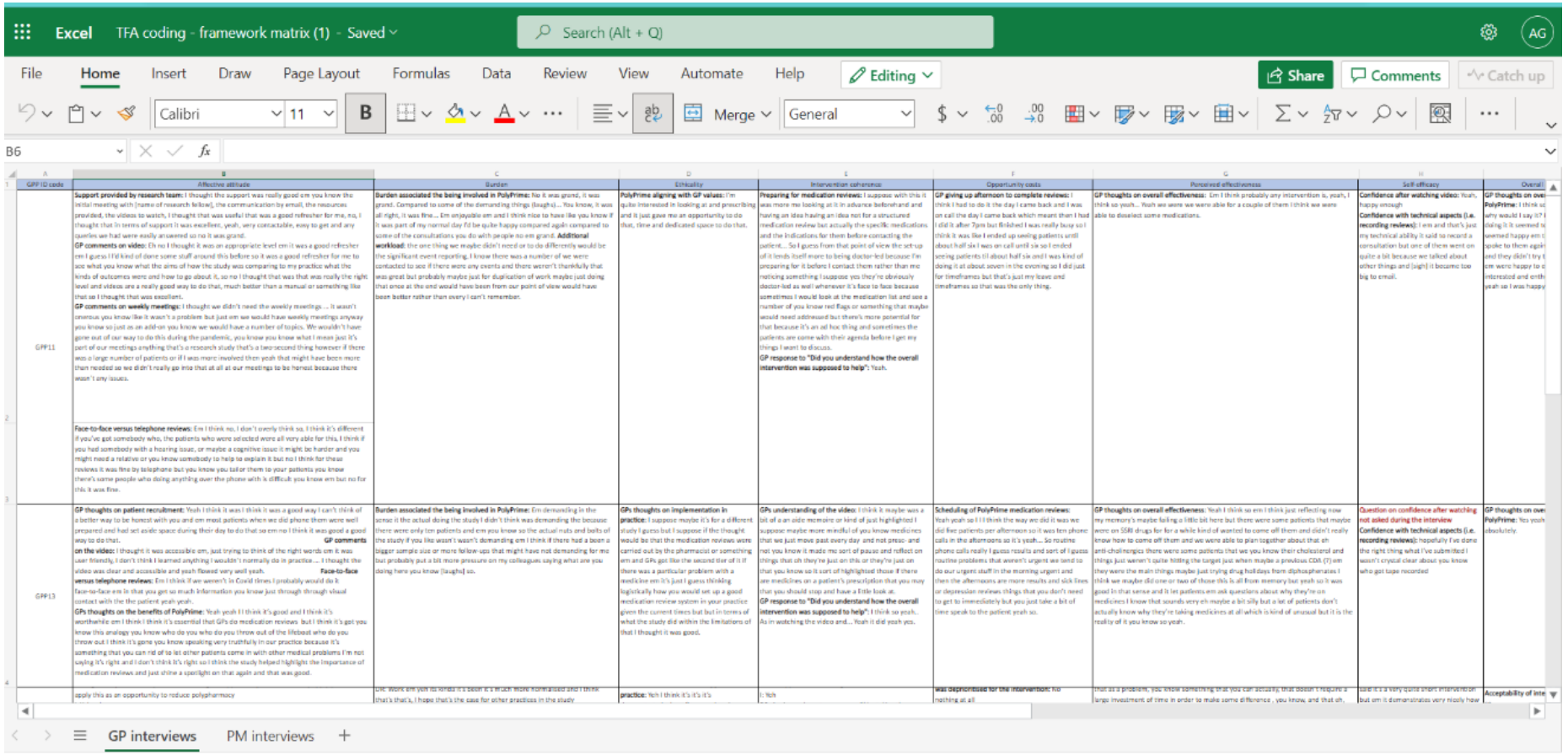
29. Would you recommend being involved in the PolyPrime study to a friend or family member? ***Please tick one of the following:***

Yes	☐
No	☐

Please use the return addressed envelope provided (or the address on Page 1) to send the questionnaire back to the research team. If you

would like to speak further to the research team about your experience, then please contact them using the details on Page 1.

Appendix 4.33 Framework matrix



Appendix 4.34 BCT online training certificate

Appendix 4.35 Consolidated Standards of Reporting Trials (CONSORT) Checklist (adapted from Schulz *et al.* 2010)

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	**109**
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	**Viii**
Introduction			
Background and objectives	2a	Specific background and explanation of rationale	110
	2b	Specific objectives or hypotheses	114
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	121
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	123
Participants	4a	Eligibility criteria for participants	121
	4b	Settings and locations where the data were collected	125
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	125
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	132
	6b	Any changes to trial outcomes after the trial commenced, with reasons	132
Sample size	7a	How sample size was determined	125
	7b	When applicable, explanation of any interim analyses and stopping guidelines	125
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	125
	8b	Type of randomisation; details of any restriction (such as clocking and block size)	125
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	125
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	121,122,125
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	132
	11b	If relevant, description of the similarity of interventions	N/A

Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	132
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	132
Results			
Participant flow	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	141
	13b	For each group, losses and exclusions after randomisation, together with reasons	141
Recruitment	14a	Dates defining the periods of recruitment and follow-up	144
	14b	Why the trial ended or was stopped	123
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	143,144
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	145
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	145
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses an adjusted analyses, distinguishing pre-specified from exploratory	N/A
Harms	19	All important harms or unintended effects in each group	N/A
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	181
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	181
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	168
Other information			
Registration	23	Registration number and name of trial registry	115
Protocol	24	Where the full trial protocol can be accessed, if available	115
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	v

Appendix 4.36 Good Clinical Practice certificate

HEALTH RESEARCH BOARD
Primary Care CTNI
CLINICAL TRIALS NETWORK IRELAND

CERTIFICATE OF ATTENDANCE

This is to certify that

Ashleigh Gorman

completed the

Good Clinical Practice (GCP) Programme

available online from the

HRB Primary Care Clinical Trials Network Ireland at:

https://training.primarycaretrials.ie

Date: 9 July 2019

Signed:

Prof Andrew Murphy,
Director,
HRB Primary Care Clinical Trials Network Ireland

This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma, Inc. as necessary to enable mutual recognition of GCP training among trial sponsors.

The course qualifies for 2 external CPD credit(s) under the Professional Competence Scheme as approved by the Irish College of General Practitioners – Ref. 152918.

Appendix 5.1 Ethical approval letter August 2021

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Ashleigh Gorman,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College Dublin,
Dublin 2.

Ref. 2021-05-01 (A01)

28 October 2021

Dear Ashleigh,

Re: Community pharmacists' role in the management of appropriate polypharmacy for older adults

I am happy to confirm that your recent application for amendment of the above project's approval (recruitment methodology) has been approved.

You are reminded that any further significant deviation from the research description in the application requires approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee before implementation.

Your attention is drawn to the reporting requirements outlined on the Committee's website (http://pharmacy.tcd.ie/research/SoPPS_REC.php), in particular the need for:

- An immediate report in writing (by email to pharmacy.ethics@tcd.ie) of any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio as outlined in the application.
- Annual reports (report form on the Committee's website).
- An end of project report (report form on the Committee's website).

The newly updated record for this study has been designated 2021-05-01 (A01), indicating it incorporates one approved amendment. Please quote this reference number in any further correspondence.

Yours sincerely,

Sheila Ryder,
Chairperson,
School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

Sheila Ryder
Chairperson
Research Ethics Committee
School of Pharmacy and Pharmaceutical Sciences

Panoz Building, East End 4/5,
Trinity College,
Dublin 2, Ireland.

Tel. +353 1 896 2786
E-mail pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Síle Ní Mharcaigh
Cathaoirleach
Coiste um Eitic Thaighde
Scoil na Cógaisíochta agus na nEolaíochtaí Cogaisíochta

Foirgneamh Panoz, An Taobh Thoir 4/5,
Coláiste na Tríonóide,
Baile Átha Cliath 2, Éire.

Teil. +353 1 896 2786
R-phost pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Appendix 5.2 Twitter advertisement

Tweet that will be sent from School of Pharmacy, Trinity College Dublin Twitter account

Are you a community pharmacist in the ROI and provide care to older adults who take multiple medicines? Would you be interested in taking part in a virtual interview on this topic? See our study <here> {'here' will be a link to the relevant TCD pharmacy website page} Interested pharmacists can contact Ashleigh (gormanas@tcd.ie) We are looking for a range of pharmacists from chain/independent pharmacies and urban/rural locations.

Image for Tweet:

Please RT ~COMMENT UNDERNEATH FIRST TWEET~

@IrishPharmacy	@thinkPharmacy
@PSIRegualtor	@IPSA_Ireland
@Irish_PharmNews	@Pharm_Forum_IE
@APPEL_Pharmacy	@LloydsPharmIre
@IIOPharmacy	@CarePlusIreland
@irishpharmacist	@AllcareIreland
@DuleekPharmacy	@McCabesPharmacy
@daltonspharmacy	@McCauleyPharmacy
@totalhealthIRL	

Appendix 5.3 Brief overview of the study

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Summary

Community pharmacist's role in the management of appropriate polypharmacy for older adults

We would like to invite community pharmacists to express an interest in participating in a study which involves a one-to-one interview, conducted online or by telephone at a date and time suitable for you. The research study which explores community pharmacists' role in managing appropriate polypharmacy for older adults in primary care in the Republic of Ireland (RoI), is being conducted by the School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin, in conjunction with the School of Pharmacy, Queen's University Belfast.

During the interview you will be asked about your experiences of managing appropriate polypharmacy for older adults, your views on how to improve the management of appropriate polypharmacy for older adults and the barriers and facilitators associated with how this could be done. The interview should last approximately one hour. You will be provided with acertificate of participation which could be added to your continuing professional development folder.

If you are interested in participating, please contact Ashleigh Gorman (gormanas@tcd.ie; PhD candidate supervised by Prof Cristín Ryan). You will be asked a small number of screening questions to confirm you meet the inclusion criteria (registered as a community pharmacist in the RoI, employed full-time or part-time or as a locum, and provide care to older adults prescribed polypharmacy) and to ensure representation from independent/chain pharmacies and urban/rural locations. Community pharmacists will be purposively selected and formally invited to participate. At this point you will receive a Participant Information Leaflet and consent form.

All study data will be processed in compliance with the General Data Protection Regulations, 2018, and the Health Research Regulations, 2018. The study has been approved by the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee in TCD; approval was granted on 27/08/2021.

If you have any queries please do not hesitate to contact Ashleigh (gormanas@tcd.ie). We appreciate the time you have taken to read this summary.

Research team:

Ashleigh Gorman, Prof. Cristín Ryan, Asst. Prof. Máire O'Dwyer, Assoc. Prof. Cathal Cadogan (School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin) and Prof. Carmel Hughes (School of Pharmacy, Queen's University Belfast)

Appendix 5.4 Screening questions

Screening questions	
Are you currently registered as a community pharmacist in the Republic of Ireland?	
Are you currently employed full-time, part-time or as a locum in a community pharmacy in the Republic of Ireland?	
Do you currently provide care to older adults (those aged 65 years or over) prescribed four or more medicines?	
Sampling questions	
Do you work in a chain pharmacy or an independent pharmacy?	
Is your pharmacy located in an urban or rural location?	

Appendix 5.5 Sampling matrix

	Name and email address	Registered as community pharmacist	Full/part-time or locum	Provides care to older adults with ≥4 medicines	Urban or rural location	Chain or independent pharmacy
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13.						
14.						
15.						
16.						
17.						
18.						
19.						
20.						

Appendix 5.6 Email invitation

Email subject heading: Management of Polypharmacy in Older Adults – formal invitation

Dear [insert community pharmacist's name]

Thank you for your interest in our study on the management of appropriate polypharmacy for older adults.

I am contacting you to formally invite you to participate in the study. Please find attached the Participant Information Leaflet which provides information on the study and what is involved.

I would be grateful if you could complete and return the attached consent form, via email (an electronic signature will suffice).

Please let me know of two possible times (and date/s) that would be suitable for you to participate in an interview. The interview should last approximately one hour but you will be free to stop the interview at any time.

If you have any questions, please do not hesitate to contact me.

Kind regards,

Ashleigh Gorman

Appendix 5.7 Participant Information Leaflet

[On TCD headed paper]

Study Title: Community pharmacists' role in the management of appropriate polypharmacy for older adults

Participant Information Leaflet

You are being invited to take part in a research study conducted by the School of Pharmacy and Pharmaceutical Sciences in Trinity College Dublin (TCD), in conjunction with the School of Pharmacy, Queen's University Belfast. Before you decide whether or not you would like to take part, it is important that you take time to understand why this research is being conducted and what will be asked of you should you agree to participate. Please read the following information and contact the Research Assistant (Ms. Ashleigh Gorman gormanas@tcd.ie), or the Principal Investigator (Prof. Cristín Ryan cristin.ryan@tcd.ie), if you have any questions. Contact details can be found at the end of this information leaflet.

Why is this study being conducted?
The population of Ireland is ageing. As people age, they are more likely to develop long-term conditions and be prescribed multiple medicines (polypharmacy). This study aims to explore community pharmacists' current involvement in the management of appropriate polypharmacy for older adults and their views on how their current role in the management of appropriate polypharmacy could be enhanced.

Why have I been invited to take part?
You have been invited to participate in this study because you are a community pharmacist working in the Republic of Ireland, on a full-time or part-time basis or as a locum, and who provides care for patients prescribed polypharmacy (i.e. four or more medicines) who are aged 65 years or over.

Do I have to take part?
Participation in the study is completely voluntary and the decision to not take part in the study will have no adverse consequences. If you decide to take part, you do not have to answer any questions that you do not wish to answer. If you decide to withdraw, you will not be penalised. Any data that you have provided up to the point of withdrawal will not be used in the research and your data will be destroyed immediately. You are free to withdraw from the study, including post-interview, up to the point when your data has been analysed.

How will the study be carried out?
Having contacted Ashleigh Gorman and expressed your interest in participating, you answered a small number of screening questions to ensure you meet the inclusion criteria
and to ensure that the study has a range of community pharmacists from chain and independent pharmacies and urban and rural locations. This Participant Information Leaflet accompanies a formal invite to participate in the study. When you have read this document and returned the consent form to Ashleigh Gorman, a date and time will be agreed to conduct the interview. The

interview will last approximately one hour, although this may very between individuals and will be conducted via telephone (recorded using a dictaphone) or Microsoft Teams (recorded via Microsoft Teams). During the interview, you will be asked questions on your current management of appropriate polypharmacy for older adults and how you would like your role to evolve and to be enhanced. Interviews conducted via telephone will be transcribed (typed word-for-word) by AG and for interviews conducted via Microsoft Teams (a virtual video platform), the transcribe function will be turned on to allow transcriptions to be carried out. These will be checked for accuracy. Identifiers (such as the name of a pharmacy or your name) will be removed and replaced with another name (i.e. pseudonymise the data). You will be offered the opportunity to review and comment on your pseudonymised transcript. On completion of the interview, you will be provided with a certificate of participation which could be added to your continuing professional development portfolio.

What will happen to my data?

Answers to the screening questions will be entered into a password protected Excel file and stored on the research Assistant's TCD OneDrive, accessed via their TCD double encrypted laptop. After completing and returning the consent form, you will be assigned a unique ID code. This code will identify your pseudonymised transcript as yours so your rights to access, change or move your information from the study are not affected. You can withdraw from the study, including post-interview, up until the point when your data has been analysed. Recordings from Microsoft Teams will be downloaded onto the Research Assistant's TCD OneDrive account and stored securely, then deleted from Microsoft Teams as soon as possible after the interview. All pseudonymised transcripts and consent forms will also be stored on the Research Assistant's TCD OneDrive account, each in a password protected document. Once transcription has been completed, interview recordings will be destroyed, however, pseudonymised transcripts will be stored securely for seven years and then destroyed, in accordance will current GDPR and Health Research Regulations. Any published research will not be attributable to you or the community pharmacy you are affiliated with. As TCD is the sponsor for this study, they will act as the data controller.

Are there any benefits to taking part in this research?

Participation in this study may be beneficial for you, as you will receive a certificate of participation, which could be used as part of your ongoing professional development. By taking part in this study you will help us understand how community pharmacists manage appropriate polypharmacy which may be a useful resource for future research.

Are there any risks to taking part in this research?

There is a risk that poor practice may be identified during the interview. In the unlikely event that this occurs, any cases will be reported to Professor Cristín Ryan (TCD) who will take appropriate action on a case-by-case basis which may involve informing the Pharmaceutical Society of Ireland, or other relevant body. Any disclosure of poor practice will be retained in the transcripts but not used in any formal research output from the study.

Will I be told of the outcome of this study?

You will be given access to your transcript, provided with a short overview of study findings and can be informed of any publications if you wish.

What information about me will be used as part of the study?
Your name and contact information will be gathered in order to conduct the interview. Once you agree to participate, you will be assigned a unique ID code and this will be used for the remainder of the study. All interview recording will be pseudonymised meaning that all identifiable information will be replaced during transcription.

What will happen to my personal data?
The data collected in this study will be processed only as necessary to achieve the objective of the study. Consent and pseudonymised transcripts will be kept for seven years in line with 2018 Health Research Regulations. After this, the responses will be destroyed. Data collected in this study will not be used for any future studies.

Who will access and use my personal data as part of the study?
Only the Research Assistant (Ms Ashleigh Gorman) and the Principal Investigator (Prof. Cristín Ryan) will have access to your name and other personal information. When you agree to participate in the study you will be assigned a unique ID code and this will be used for the remainder of the study. All interview recordings will be pseudonymised. Should any indication of poor practice arise, the researcher will provide the transcript to Prof. Cristín Ryan and if further action is required, she will receive the name and work location of the community pharmacist. In order to ensure that studies involving human participants are carried out to a high standard, the University is required to monitor on-going research studies and as a result, staff from Trinity College Dublin may need to review the information collected as part of this research.

Will my personal data be kept confidential? How will be data be kept safe?
Your identity will remain confidential. Transcripts will be assigned a unique ID code and will be pseudonymised. Information gained from the study including identifiable information such as consent forms/emails will be stored securely the Research Assistant's secure TCD OneDrive account. Consent and transcripts will be securely stored for seven years and then destroyed, in line with current GDPR and Health Research Regulations 2018.

What is the lawful basis to use my personal data?
By law[1], we can use your personal information for scientific research[2] (in the public interest[3]). We will also ask for your consent to use your data as a requirement of the Irish Health Research Regulations.

[1] The European General Data Protection Regulation (GDPR)
[2] Article 9(2) (i)
[3] Article 6(1) (e)

What are my rights?
You are entitled to:

- The right to access your data and receive a copy of it
- The right to restrict or object to processing of your data
- The right to object to any further processing of the information we hold about you
- The right to have inaccurate information about you corrected or deleted
- The right to receive your data in a portable format and to have it transferred to another data controller
- The right to request deletion of your data

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting the study Principal Investigator [Prof. Cristín Ryan, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin, Dublin 2, Ireland. Email: cristin.ryan@tcd.ie] or the Trinity College Data Protection Officer, Secretary's Office, Trinity College Dublin, Dublin 2, Ireland. Email: dataprotection@tcd.ie. Website: www.tcd.ie/privacy.

Has this study been approved by a research ethics committee?
This study has been approved by the School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin Research Ethics Committee. Approval was granted on 27/08/21.

Will it cost me anything if I agree to take part?

It will not cost you anything to participate in this study. You will not receive any renumeration for taking part in this study.

Will my personal data be used in future studies?
Data collected during the course of this study will only be used for the current study.

Who should I contact for further information?
If you have any questions about the research, now or later, please contact the Research Assistant (Ms. Ashleigh Gorman) or the Principal Investigator (Prof. Cristín Ryan).

Ms. Ashleigh Gorman
School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin
Dublin 2
Email: gormanas@tcd.ie
Tel: +353 86 608 9094

Prof. Cristín Ryan
School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin
Dublin 2
Email: cristin.ryan@tcd.ie

If you wish to make a complaint about the research, you can contact Prof. Cristín Ryan or the Data Protection Office, Trinity College Dublin.
Data Protection Officer,

Secretary's Office,
Trinity College Dublin,
Dublin 2
Email: dataprotection@tcd.ie
Website: www.tcd.ie/privacy

On behalf of the research team:
Asst. Prof. Máire O'Dwyer (School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin), Prof. Carmel Hughes (School of Pharmacy, Queen's University Belfast) and Assoc. Prof. Cathal Cadogan (School of Pharmacy and Pharmaceutical Sciences, Trinity.

Appendix 5.8 Consent form

Trinity College Dublin
Coláiste na Tríonóide, Baile Átha Cliath
The University of Dublin

Study Title: Community pharmacists' role in the management of appropriate polypharmacy for older adults

Principal Investigator: Prof. Cristín Ryan, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin

Participant consent form

There are 2 sections in this form. Each section has a statement and asks you to initial if you agree. The end of this form is for the researcher to complete. Please initial the box if you agree with the statement. Please feel free to contact Ashleigh Gorman (gormanas@tcd.ie) if there is something you do not understand. Thank you for participating.	
General	*Initials*
I confirm that I have read and understood the information leaflet for the above study. The information has been fully explained to me and I have been able to ask questions, all of which have been answered to my satisfaction.	
I understand that this study is entirely voluntary, and if I decide that I do not want to take part, I can stop taking part in this study at any time without giving a reason.	
I understand that I will not be paid for taking part in this study.	
I know how to contact the research team if I need to.	
I agree to take part in this research study having been fully informed of the risks, benefits and alternatives which are set out in full in the information leaflet which I have been provided with.	
I agree to being contacted by researchers by email as part of this research study.	
Data processing	
I understand that personal information about me will be protected in accordance with the General Data Protection Regulation.	
I understand that there are no direct benefits to me from participating in this study.	
I understand that I can request a copy of the text of my interview if I wish to do so from the research team to review before data analysis has begun.	
I understand that my personal information will be confidential and stored safely. I am aware that I will not be identified in any of the findings.	
I understand that an interview will be recorded (including both visual and audio) and that anonymous quotations may be used in the reports or outputs from this study.	
I understand that any disclosure of poor practice during the interview may result in notification to the Pharmaceutical Society of Ireland, or other relevant body.	

I understand that I can stop taking part in this study, up until the point when my data has been analysed, without giving a reason.	

…… …… ……

Participant Name Participant Signature Date

…… …… ……

Researcher Name Researcher Signature Date

To be completed by the Principal Investigator or nominee.

I, the undersigned, have taken the time to fully explain to the above participant the nature and purpose of this study in a way that they could understand. I have explained the risks and possible benefits involved. I have invited them to ask questions on any aspect of the study that concerned them.
I have given a copy of the information leaflet and consent form to the participant with contacts of the study team.

Researcher name

Title and qualifications

Signature

Date

Appendix 5.9 Ethical approval letter October 2021

Coláiste na Tríonóide, Baile Átha Cliath
Trinity College Dublin
Ollscoil Átha Cliath | The University of Dublin

Ashleigh Gorman,
School of Pharmacy and Pharmaceutical Sciences,
Trinity College Dublin,
Dublin 2.

Ref. 2021-05-01 (A01)

28 October 2021

Dear Ashleigh,

Re: Community pharmacists' role in the management of appropriate polypharmacy for older adults

I am happy to confirm that your recent application for amendment of the above project's approval (recruitment methodology) has been approved.

You are reminded that any further significant deviation from the research description in the application requires approval from the School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee before implementation.

Your attention is drawn to the reporting requirements outlined on the Committee's website (http://pharmacy.tcd.ie/research/SoPPS_REC.php), in particular the need for:

- An immediate report in writing (by email to pharmacy.ethics@tcd.ie) of any serious or unexpected adverse events on participants, or unforeseen events that might affect the benefits/risks ratio as outlined in the application.
- Annual reports (report form on the Committee's website).
- An end of project report (report form on the Committee's website).

The newly updated record for this study has been designated 2021-05-01 (A01), indicating it incorporates one approved amendment. Please quote this reference number in any further correspondence.

Yours sincerely,

Sheila Ryder,
Chairperson,
School of Pharmacy and Pharmaceutical Sciences Research Ethics Committee.

Sheila Ryder
Chairperson
Research Ethics Committee
School of Pharmacy and Pharmaceutical Sciences

Panoz Building, East End 4/5,
Trinity College,
Dublin 2, Ireland.

Tel. +353 1 896 2786
E-mail pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Síle Ní Mharcaigh
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Coiste um Eitic Thaighde
Scoil na Cógaíochta agus na nEolaíochtaí Cogaíochta

Foirgneamh Panoz, An Taobh Thoir 4/5,
Coláiste na Tríonóide,
Baile Átha Cliath 2, Éire.

Teil. +353 1 896 2786
R-phost pharmacy.ethics@tcd.ie
http://pharmacy.tcd.ie/research/SoPPS_REC.php

Appendix 5.11 Topic guide

Appendix 13 Topic guide

Introduction:

"Hello, thank you very much for making the time to talk to me today. I'm Ashleigh Gorman, a PhD student in the School of Pharmacy and Pharmaceutical Sciences, at Trinity College Dublin and this study is part of my PhD thesis on managing multiple medications in older people in primary care.

The aim of this interview is to explore your current involvement in the management of appropriate polypharmacy for older adults (those aged **65 years** and over) and your views on how your current role in the management of appropriate polypharmacy for older adults living within the community could be enhanced. The interview should last approximately1 hour.

Before we start, I would like to check if you had a chance to read the information leaflet that was emailed to you? And you understand what the study involves? I also want to check that you know that anything you say will be kept completely confidential; you will not be identified in any way; you know that we can stop at any time; and you are happy for the interview to be recorded. I can see you have sent your completed consent form, signed and dated to me.

During the interview, remember that there are no right or wrong answers so please give honest responses to the questions. You are free to stop the interview and/or recording at any time.

Have you any immediate questions about the study before we start the interview?

So, if it is OK, I will start the recording now?

[Start recording interview]

I'd like to start by asking you some questions about you and your current work.

General questions:

1. Approximately, how long have you been practising as a pharmacist?
2. What is your current position in the community pharmacy?

Polypharmacy:

I'd now like to ask you some question about your understanding of some of the terms we are using in the project. Again, there are no right or wrong answers.

3.What is your understanding of the term 'polypharmacy'?

- Prompt – would you use a numerical threshold? How many?

4.What is your understanding of the term 'appropriate polypharmacy'?

There are definitions of polypharmacy and 'appropriate polypharmacy' in the literature. For the purposes of this study and to ensure we can compare our study with others, we are adopting a definition of polypharmacy that states that:

Polypharmacy constitutes the co-prescribing of **four or more regular** medicines

And the phrase 'appropriate polypharmacy' is being defined as: the importance of getting the balance right between 'many' and 'too many' medicines.

Experiences of managing appropriate polypharmacy:

So now I would just like to move on to discuss your experiences of managing appropriate polypharmacy (again, getting the balance right between 'many' and 'too many' medicines) for older adults in the pharmacy that you work in.

5. Tell me about the process you undertake when you dispense a prescription containing multiple medicines (polypharmacy) to an older adult

- PROMPTS: walk me through it, step-by-step; consider drug-drug interactions, contact prescriber, discuss prescription with patient, check patient medical record

6. What do you see is the role of the community pharmacist within the healthcare team in managing appropriate polypharmacy in older adults?

- Prompts: regular interventions/ discussion with patient; interaction with other healthcare professionals: who, how often, why?
- Is it a priority for you to manage appropriate polypharmacy in older adults?

7. Currently, how confident are you in identifying appropriate polypharmacy in an older adult? (Beliefs about capabilities)

8. Do you use resources to help you in managing appropriate polypharmacy in older adults?

8a *If yes:* Can you tell me about the resources you use to help you in managing appropriate polypharmacy in older adults? (Environmental context and resources)

- PROMPT: use a validated assessment tool (i.e. a judgement-based or criterion-based tool that you can use to assess inappropriate prescribing), specific guidelines, check with the patient their medical conditions

9. Can you describe any issues you may have experienced in **managing appropriate polypharmacy** for older adults?

- PROMPTS: inappropriate medicine prescribed, inappropriate dose, inappropriate duration of medicine/prescription, drug-drug interactions, drug-disease interactions
  - Patient: non-adherence, lack of understanding, lack of interest
  - Lack of suitable resources available (such as?)

Views on how the management of appropriate polypharmacy for older adults could be improved:

10. How could you as a community pharmacist contribute more to managing appropriate polypharmacy for older adults?

- PROMPTS: Undertaking Medication Use Reviews, being allowed to qualify and practise as an independent prescriber, use of screening tools in your everyday practice, having increased access to patients' clinical information
  - Government funded programmes – such as?
  - services paid for by the patient – what type of services/ focus on certain conditions?

Barriers and facilitators to improving the management of appropriate polypharmacy in older adults (TDFv1 based):

11. Thinking of what you suggested could help you enhance the management of appropriate polypharmacy in older adults, what would the one most important change/improvement be? Please take your time to think about what you think is the one most important change/improvement as I will be asking questions in relation to this throughout the rest of the interview.

Now, I just want to explore more about {what pharmacist mentioned as way to improve management of appropriate polypharmacy} and potential barriers and facilitators, to improving the management of appropriate polypharmacy in older adults (i.e. those 65 years and older) using this strategy.

For these next questions I want you to remember *{most important suggestion to improving the management of appropriate polypharmacy}* and to answer the questions in relation to doing that.

12. Can you describe the knowledge you have as a community pharmacist that would help implement {*most important suggestion to improving the management of appropriate polypharmacy*} to enhance the management of appropriate polypharmacy in older adults? (knowledge)

- PROMPT: clinical knowledge; prescribing guidelines; knowledge of polypharmacy; knowledge of patient and their medical conditions

13. Are the resources available to help you use *{most important suggestion to improving the management of appropriate polypharmacy}* in managing appropriate polypharmacy? (Environmental context and resources)

- PROMPT - Staffing, room/ quiet space in the pharmacy

educational resources/ training, incentives

14. What resources do you think should be developed to help you with {improvement of appropriate polypharmacy} in the management of appropriate polypharmacy in older adults? (Environmental context and resources)

- CPD, webinar, online course, information booklet; online, face-to-face; concentrated time etc
    - What information should it include? Revision of principles of drug metabolism in older age/ interpreting biochemical data/ any specific evidence-based guidelines

Note: *may not be applicable to every participant*

Still thinking of *{most important suggestion to improving the management of appropriate polypharmacy}*

15. What skills do you currently have to use *{most important tool to improving the management of appropriate polypharmacy}* in older adults with polypharmacy? (skills)

- PROMPT: patient-focused communication skills
    - Prescriber-focused communication skills

Note: *may not be applicable to every participant*

16. Are there any skills-based training you think would help with *{most important suggestion to improving the management of appropriate polypharmacy} in* the management of appropriate polypharmacy in older adults? (skills)

- PROMPT: Communication/ IT / Interpretation of biochemical test results

You mentioned earlier that you think the role of the community pharmacist (overview of how they answered question 6)

17. If *{most important suggestion to improving the management of appropriate polypharmacy}* was regularly implemented/ conducted in community pharmacy do you think more emphasis would be placed on the community pharmacist as part of the healthcare team in managing appropriate polypharmacy? (Social/professional role and identity)

18. If *{most important suggestion to improving the management of appropriate polypharmacy}* was implemented in your community pharmacy, is there anything in your daily practice that might change? (Nature of the behaviours)

Thinking back again to *{most important tool to improving the management of appropriate polypharmacy}*

19. What do you think the benefits would be of *{most important tool to improving the management of appropriate polypharmacy}* for older adults with polypharmacy? (Beliefs about consequences)

- For the patient
- For the community pharmacist

- For other healthcare professionals
- For the Government

20. Can you describe any risks that might be associated with *{most important tool to improving the management of appropriate polypharmacy}? (*Beliefs about consequences*)*

- For the patient
- For the community pharmacist
- For other healthcare professionals
- For the Government

21. What would motivate community pharmacists to use *{most important suggestion to improving the management of appropriate polypharmacy}* in the management of polypharmacy? (Motivation and goals)

- PROMPT – government funded scheme; patient paid service; adequate training; part of a CPD programme

22. How frequently should community pharmacists use *{most important suggestion to improving the management of appropriate polypharmacy}* to manage appropriate polypharmacy for older adults? (Memory, attention and decision processes)

23. What would influence your decision to use *{most important suggestion to improving the management of appropriate polypharmacy}?* (Social influences)

- PROMPT - patient, carers, colleagues/ other healthcare professionals
    - good existing relationship(s), business of pharmacy [taken from Beliefs about capabilities question that I've removed]

24. How would your own feelings affect how you use *{most important suggestion to improving the management of appropriate polypharmacy}* to enhance the management of appropriate polypharmacy (Emotion)

- PROMPT – stress, fear, burn-out, tiredness, job satisfaction, work overload

25. Are there any work environment conditions that would prevent you from using *{most important suggestion to improving the management of appropriate polypharmacy}* in managing appropriate polypharmacy? (Environmental context and resources)

- PROMPT – workload/ time available, staff shortages, room/quiet space available in the pharmacy, work culture

26. What are the necessary steps to ensure you use *{most important suggestion to improving the management of appropriate polypharmacy}* in managing appropriate polypharmacy in older adults? (Behavioural regulation)

- PROMPT – Think of organizational steps: audits, external/ internal management
    - Think of individual steps: personal goal/ target setting, patient feedback
    - Can you think of any barriers and facilitators to these?

PolyPrime intervention

So this is the last section of the interview. Here, I'm going to ask you about a theory-based intervention that members of this research team have designed. It is targeted towards GPs to help them improve the prescribing of appropriate polypharmacy in older adults in primary care, but we are interested to know if something similar could potentially be developed and delivered to community pharmacists in Ireland.

Online video

The first component of the intervention we have developed for GPs consists of a short online video that demonstrates how a GP prescribes appropriate polypharmacy during a typical consultation with an older patient. The video also includes feedback from both a practising GP and a simulated patient to emphasis the positive outcomes of the consultation.

I'm now going to show you the intervention video

[play video]

27. What are your initial thoughts on the video?

28. Is there anything in this video that you think would be of benefit to community pharmacists in managing appropriate polypharmacy for older adults?

- PROMPT – patient/GP engagement; patient counselling
    -

29. Do you have any views on using a video in this way to demonstrate managing appropriate polypharmacy for community pharmacists?

30. Are there any aspects of this video you would like to see included in a video targeted at community pharmacists to demonstrate how to manage appropriate polypharmacy?

Can you recommend any other aspects that you would like to see included in a video targeted at community pharmacists to demonstrate how to manage appropriate polypharmacy?

If video does not play:

The video is around 13 minutes long and shows a older adult arriving at their GP practice for a scheduled medication review. During the consultation, the viewer is informed of the patients current medications. The GP goes through the medications and provides their point of view on why they should be stopped or the dose altered for example. The consultation also presents the patient showing some reluctance to the suggestion of a medication being stopped and presents how the GP dealt with this. The video also includes links to validated assessment tools and prescribing guidance which might be of use to the viewer when managing appropriate polypharmacy in an older adult.

27 a. From my short overview there, is there anything in the video that might be of benefit to community pharmacists in managing appropriate polypharmacy for older adults?

27 b. Do you have any views on using a video in this way to demonstrate managing appropriate polypharmacy for community pharmacists?

27 c. Can you recommend any other aspects that you would like to see included in a video targeted at community pharmacists to demonstrate how to manage appropriate polypharmacy?

Scheduled medication review

The second component of the intervention is a patient recall process, whereby patients attend the practice for their scheduled appointment to undertake a medication review consultation with their GP, as shown in the video. In order to facilitate this, GPs make a plan at weekly meetings with practice colleagues (i.e. reception staff, practice managers) of when and how they would ensure that older patients meeting the inclusion criteria (i.e. ≥70 years, receiving four or more regular medicines, not cognitively impaired, resident in the community) will be invited to the GP surgery for a medication review.

32. Do you think your community pharmacy could facilitate a community pharmacist conducting a medication review?

- How would you organise this in your community pharmacy?
- Do you think your pharmacy could schedule and conduct medication reviews?
- What would be the barriers to implementing this in your community pharmacy?
- What would be the facilitators to you implementing this in your community pharmacy?
- Who could schedule the medication reviews in your community pharmacy?

Intervention as a whole

33. Do you think an intervention, showing community pharmacists an online video and having community pharmacists conduct a medication review, could be implemented in your pharmacy?

34. Can you think of any barriers to implementing such an intervention in your pharmacy?

- Can you think of any facilitators to implementing such an intervention in your pharmacy?

Do you think it would help community pharmacists manage appropriate polypharmacy in older adults?

- PROMPT: what would be required? I.e. access to medical records; education resources: training, computer tools.
    - Who would be required? i.e. other healthcare professionals, patients

Concluding comments

That brings us to the end of the interview.

Is there anything else you would like to add about managing appropriate polypharmacy in older adults?

Do you have any comments that you would like to make about the content of the interview?

Thank you very much for taking the time to speak to me today.

[Stop recording]

Appendix 5.11 the Theoretical Domains Framework version 1 (adapted from Michie *et al.* 2005)

Domain	Constructs	Interview questions
1. Knowledge	Knowledge Knowledge about condition/scientific rationale Schemas+ mindsets+ illness representations Procedural knowledge	Do they know about the guideline? What do they think the guideline says? What do they think the evidence is? Do they know they should be doing *x*? Do they know why they should be doing *x*?
2. Skills	Skills Competence/ ability/ skill assessment Practice/ skills development Interpersonal skills Coping strategies	Do they know how to do *x*? How easy or difficult do they find performing *x* to the required standard in the required context?
3. Social/professional role and identity	Identity Professional identity/ boundaries/ role Group/ social identity Social/ group norms Alienation/ organisational commitment	What is the purpose of the guidelines? What do they think about the credibility of the source? Do they think guidelines should determine their behaviour? Is doing *x* compatible or in conflict with professional standards/identity? (prompts: moral/ethical issues, limits to autonomy) Would this be true for all professional groups involved?
4. Beliefs about capabilities	Self-efficacy Control - of behaviour and material and social environment Perceived competence Self-confidence/ professional confidence Empowerment Self-esteem Perceived behavioural control Optimism/ pessimism	How difficult or easy is it for them to do *x*? (prompt re internal and external capabilities/ constraints) What problems have they encountered? What would help them? How confident are they that they can do *x* despite the difficulties? How capable are they of maintaining *x*? How well equipped/comfortable do they feel to do *x*?
5. Beliefs about consequences	Outcome expectancies Anticipated regret Appraisal/ evaluation/ review Consequents Attitudes Contingencies	What do they think will happen if they do *x*? (prompt re themselves, patients, colleagues and the organisation; positive and negative, short term and long term consequences)

	Reinforcement/ punishment/ consequences Incentives/rewards Beliefs Unrealistic optimism Salient events/ sensitisation/ critical incidents Characteristics of outcome expectancies-physical, social, emotional; Sanctions/ rewards, proximal/ distal, valued/ not valued, probable/ improbable, salient/ not salient, perceived risk/ threat	What are the costs of *x* and what are the costs of the consequences of *x*? What do they think will happen if they don't do *x*? (prompts) Do benefits of doing *x* outweigh the costs? How will they feel if they do/don't so *x*? (prompts) Does the evidence suggest that doing *x* is a good thing?
6. Motivation and goals	Intention; stability of intention/ certainty of intention Goals (autonomous/controlled) Goal target/ setting Goal priority Intrinsic motivation Commitment Distal and proximal goals Transtheoretical model and stages of change	How much do they want to do *x*? How much do they feel they need to do *x*? Are there other things they want to do or achieve that might interfere with *x*? Does the guideline conflict with others? Are their incentives to do *x*?
7. Memory, attention and decision processes	Memory Attention Attention control Decision making	Is x something they usually do? Will they think to do *x*? How much attention will they have to pay to do *x*? Will they remember to do *x*? How? Might they decide not to do *x*? Why? (prompt: competing tasks, time constraints)
8. Environmental context and resources	Resources/ material resources (availability and management) Environmental stressors Person x environment interaction Knowledge of task environment	To what extent do physical or resource factors facilitate or hinder *x*? Are there competing tasks and time constraints? Are the necessary resources available to those expected to undertake *x*?
9. Social influences	Social support Social/ group norms Organisational development Leadership Team working	To what extent do social influences facilitate or hinder *x*? (prompts: peers, managers, other professional groups, patients, relatives) Will they observe others doing *x*? (i.e. have role models?)

	Group conformity Organisational climate/ culture Social pressure Power/ hierarchy Professional boundaries/ roles Management commitment Supervision Inter-group conflict Champions Social comparisons Identity: group/ social identity Organisational commitment/ alienation Feedback Conflict-competing demands, conflicting roles Change management Crew resource management Negotiation Social support: personal/ professional/ organisational, intra/ interpersonal, society/ community Social/ group norms: subjective, descriptive, injunctive norms Learning and modelling	
10. Emotion	Affect Stress Anticipated regret Fear Burn-out Cognitive overload/ tiredness Threat Positive/ negative effect Anxiety/ depression	Does doing *x* evoke an emotional response? If so, what? To what extent does emotional factors facilitate or hinder *x*? How does emotion affect *x*?
11. Behavioural regulation	Goal/ target setting Implementation intention Action planning Self-monitoring Goal priority Generating alternatives Feedback Moderators of intention-behaviour gap	What preparatory steps are needed to do *x*? (prompt re individual and organisational) Are there procedures or ways of working that encourage *x*?

	Project management Barriers and facilitators	
12. Nature of the behaviours	Routine/ automatic/ habit Breaking habit Direct experience/ past behaviour Representation of tasks Stages of change model	What is the proposed behaviour (*x*)? Who needs to do what differently when, where, how, how often and with whom? How do they know whether the behaviour has happened? What do they currently do? Is this a new behaviour or an existing behaviour that needs to become a habit? Can the context be used to prompt the new behaviour? (prompts: layout, reminders, equipment) How long are changes going to take? Are there systems for maintaining long term change?

Appendix 5.12 Certificate of participation

Trinity College Dublin
The University of Dublin

School of Pharmacy and Pharmaceutical Sciences

Certificate of Participation

For

Title of Event: Interview to establish community pharmacists' role in the management of appropriate polypharmacy for older adults

Date of Event:

Name of Individual:

I hereby certify that the individual named above attended this event.

Signed:

Event Organiser: Professor Cristín Ryan

Professor in Practice of Pharmacy, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin

Appendix 5.13 Coding scheme

Community pharmacists' role in the management of appropriate polypharmacy for older adults

Coding Scheme

	Coding categories/ Codes	Definition
1	**Demographics**	
1.1	Position in pharmacy	Data relating to the interviewee's job title in the pharmacy
1.2	Number of years practicing	Data relating to the number of years the interviewee has been practicing as a pharmacist
2	**Definitions**	
2.1	Polypharmacy	Data relating to the interviewee's definition of polypharmacy
2.2	Appropriate polypharmacy	Data relating to the interviewee's definition of appropriate polypharmacy
3	**Experiences managing polypharmacy**	
3.1	Dispense multiple medicines	Data relating to the process involved when dispensing a prescription containing multiple medicines
3.2	Role of community pharmacist in healthcare team	Data relating to statements made surrounding the community pharmacist's current role in the healthcare team
3.3	Issues in managing appropriate polypharmacy	Data relating to statements made surrounding any issues experienced in managing appropriate polypharmacy for older adults
3.4	Resources used	Data relating to statements made regarding resources currently used in identifying appropriate polypharmacy
3.5	Confidence in identifying appropriate polypharmacy	Data relating to statements surrounding the interviewee's confidence in identifying appropriate polypharmacy
3.6	Effective communication	Data relating to statements made regarding communicating effectively with patients or healthcare professionals
4	**How management of appropriate polypharmacy could be improved**	
4.1	Improvement idea	Data relating to ideas that could enable community pharmacists to contribute more to managing appropriate polypharmacy
4.2	Improvement idea discussed	The idea the interviewee believes will be the most helpful in helping community pharmacists manage appropriate polypharmacy for older adults

4.3	General comments	Data relating to statements made surrounding general comments about the idea discussed
	TDF Domains*	
5	**Knowledge**	
5.1	Clinical knowledge	Data relating to interviewee's knowledge of clinical practice in relation to the idea discussed
5.2	Patient knowledge	Data relating to interviewee's knowledge of the patient in relation to the idea discussed
6	**Skills**	
6.1	Communication skills	Data relating to the interviewee's communication skills in relation to the idea discussed
6.2	Skills required to implement idea	Data relating to new skills that will be needed to utilise the idea
7	**Social/professional role and identity**	
7.1	Ensuring medicines are prescribed appropriately	Data relating to the interviewee's role to ensure medication safety in relation to the idea discussed
7.2	Contacting other prescribers to ensure correct medication	Data relating to the interviewee's responsibility to contact other healthcare professionals with medication queries/concerns in relation to the idea discussed
7.3	Recognition of community pharmacist	Data relating to the tasks of community pharmacist being recognised by other healthcare professionals and government in relation to the idea discussed
8	**Beliefs about capabilities**	
8.1	Communicating with other healthcare professionals	Data relating to statements surrounding the interviewee's ability/confidence in communicating with other healthcare professionals in relation to the idea discussed
8.2	Identifying appropriate polypharmacy	Data relating to statements surrounding the interviewee's confidence in identifying appropriate polypharmacy in relation to the idea discussed
9	**Beliefs about consequences**	
9.1	Anticipated outcome(s)	Data relating to statements surrounding what might occur because of the idea, e.g., decreased hospitalisations as a result of the idea discussed
9.2	Communication with other healthcare professionals	Data relating to statements surrounding how the communication with other health professionals could change as a result of the idea discussed
9.3	Patient response	Data relating to how patients might respond to the idea discussed
9.4	Medication safety	Data relating to enhanced medication safety as a result of the idea discussed
10	**Motivation and goals**	

10.1	Improved patient safety	Data relating to improved patient safety as a result of the idea
10.2	Time saving	Data relating to the idea and how it could save time for healthcare professionals
10.3	Incentives	Data relating to possible incentives for community pharmacists to use idea e.g., government policy
11	**Memory, attrition and decision processes**	
11.1	Communication with other healthcare professionals	Data relating to statements surrounding communication from other healthcare professionals for the pharmacist to provide the correct care in relation to the idea discussed
12	**Environmental context and resources**	
12.1	Clinical resources	Data relating to the clinical resources that the pharmacists have access to or require access to, e.g. patient health records in order to use the idea
12.2	Pharmacy resources	Data relating to the resources available in the pharmacy, such as consultation room, computer, staffing (pharmacist/technician etc.), in order to use the idea
12.3	Time constraints/ time available	Data relating to the pharmacist's schedule in relation to the idea
12.4	Operational processes	Data relating to governmental policies/ regulatory bodies influence regarding idea discussed
13	**Social influences**	
13.1	Social structure within pharmacy	Data relating to the influences of colleagues in relation to the idea discussed
14	**Emotion**	
14.1	Emotions affecting community pharmacist on idea	Data relating to the emotions/feelings that might impact on how/if a community pharmacist uses the idea discussed
15	**Behavioural regulation**	
15.1	Managing community pharmacist behaviour	Data relating to managing/changing community pharmacist actions surrounding the idea e.g., regulatory bodies
16	**Nature of the Behaviours**	
16.1	Changing routine	Data relating to changes in current role that might occur due to the idea
	PolyPrime	
17	**Intervention component - video**	
17.1	Clinical Scenario	Data relating to the clinical scenario addressed within the video component
17.2	Engagement with video	Data relating to how community pharmacists could access the video and if they believe others would watch it

17.3	Positive comments	Data relating to positive statements made surrounding the video component
17.4	Negative comments	Data relating to negative statements made surrounding the video component
17.5	Current video aspects useful in community pharmacist video	Data relating to statements made surrounding existing aspects of the GP video that could be included in video targeted at community pharmacists?
17.6	Changes required	Data relating to statements made surrounding potential changes required to the video to be suitable for community pharmacists
18	**Intervention component – scheduled medication review**	
18.1	Scheduling and conducting of medication reviews	Data relating to statements made surrounding the scheduling and conducting of medication reviews in the pharmacy
18.2	Barriers to scheduling and conducting of medication reviews	Data relating to statements made surrounding the barriers to scheduling and conducting medication reviews in the pharmacy
18.3	Facilitators to scheduling and conducting medication reviews	Data relating to statements made surrounding the facilitators to scheduling and conducting medication reviews in the pharmacy
19	**Intervention as a whole**	
19.1	Barriers to implementing similar intervention in pharmacy	Data relating to statements made surrounding the barriers to implementing a similar intervention to PolyPrime in the pharmacy
19.2	Facilitators to implementing similar intervention in pharmacy	Data relating to statements made surrounding the facilitators to implementing a similar intervention to PolyPrime in the pharmacy
19.3	Positive comments	Data relating to statements made surrounding positive comments about the intervention as a whole
19.4	Negative comments	Data relating to statements made surrounding negative comments about the intervention as a whole
19.5	Changes required	Data relating to statements made surrounding potential changes required to the intervention as a whole to be suitable for community pharmacists
20	**Contextual factors**	
20.1	Contextual information	Data relating to community pharmacy contextual information

*type ‘B’ or ‘F’ beside each TDF code to distinguish if a barrier (B) or facilitator (F)

Appendix 5.14 Consolidated criteria for reporting qualitative research (COREQ) checklist (adapted from Tong *et al.* 2007)

Number/ Item	Guide question/ description	Page number
Domain 1: Research team and reflexivity		
Personal characteristics		
1.Interviewer/facilitator	Which author/s conducted the interview or focus group?	190
2.Credentials	What were the researcher's credentials? E.g. PhD, MD	352
3.Occupation	What was their occupation at the time of the study?	352
4.Gender	Was the researcher male or female?	352
5.Experience and training	What experience or training did the researcher have?	352
Relationship with participants		
6.Relationship established	Was a relationship established prior to study commencement?	190
7.Participant knowledge of the interviewer	What did the participants know about the researcher? E.g. personal goals, reasons for doing the research	500
8.Interviewer characteristics	What characteristics were reported about the interviewer/facilitator? E.g. bias, assumptions, reasons and interests in the topic	NR
Domain 2: Study design		
Theoretical framework		
9.Methodological orientation and theory	What methodological orientation was stated to underpin the study? E.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	189
Participant selection		
10.Sampling	How were participants selected? E.g. purposive, convenience, consecutive, snowball	189
11.Method of approach	How were participants approached? E.g. face-to-face, telephone, mail, email	189
12.Sample size	How many participants were in the study?	195
13.Non-participation	How many people refused to participate or dropped out? Reasons?	195
Setting		
14.Setting of data collection	Where was the data collected? E.g. home, clinic, workplace	190
15.Presence of non-participants	Was anyone else present besides the participants and researchers?	190
16.Description of sample	What are the important characteristics of the sample? E.g. demographic data, date	196
Data collection		
17.Interview guide	Were questions, prompts, guides provided by the authors? Was it pilot tested?	190
18.Repeat interviews	Were repeat interviews carried out? If yes, how many?	N/A

19.Audio/ visual recording	Did the research use audio or visual recording to collect the data?	190
20.Field notes	Were field notes made during and/or after the interview or focus group?	N/A
21.Duration	What was the duration of the interviews or focus groups?	195
22.Data saturation	Was data saturation discussed?	229
23.Transcripts returned	Were transcripts returned to participants for comment and/or correction?	190
Domain 3: Analysis and findings		
Data analysis		
24.Number of data coders	How many data coders coded the data?	191
25.Description of the coding tree	Did authors provide a description of the coding tree?	521
26.Derivation of themes	Were themes identified in advance or derived from the data?	191
27.Software	What software, if applicable, was used to manage the data?	191
28.Participant checking	Did participants provide feedback on the findings?	N/A
Reporting		
29.Quotations presented	Were participant quotations presented to illustrate the themes/ findings? Was each quotation identified? E.g. participant number	195
30.Data and findings consistent	Was there consistency between the data presented and the findings?	195
31.Clarity of major themes	Were major themes clearly presented in the findings?	195
32.Clarity of minor themes	Is there a description of diverse cases of discussion of minor themes?	195

Appendix 6.1 Involving the public in the design and conduct of research: building research partnerships certificate

CPM project has been funded by the EU's INTERREG VA Programme, managed by the Special EU Programmes Body (SEUPB)

Certificate of Attendance

Ashleigh Gorman

attended the course

Involving the Public in the Design and Conduct of Research: Building Research Partnerships

held in

C-TRIC, Altnagelvin Area Hospital

8 November 2019

Margaret Grayson
Facilitator

Personal and Public Involvement (PPI)

Involving you, improving care