Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

SHORT STUDY TITLE / ACRONYM:

My Medicines Journey: Assessment of a Toolkit

ASSESSING THE FEASIBILITY AND IMPLEMENTATION OF THE 'MY MEDICINES JOURNEY' INTERVENTION: A MULTI-METHODS EVALUATION

MY MEDICINES JOURNEY: ASSESSING THE FEASIBILITY AND IMPLEMENTATION OF A TOOLKIT

- **This protocol has regard to the HRA guidance and order of content**

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My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

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My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

SIGNATURE PAGE

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Medicines for Human Use (Clinical Trials) Regulations 2004 (SI 2004/1031), amended regulations (SI 2006/1928) and any subsequent amendments of the clinical trial regulations, GCP guidelines, the Sponsor's (and any other relevant) SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies and serious breaches of GCP from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date: ...../...../.....

.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date: **07/1/2025**

.....

Name: (please print):

Justine Tomlinson

.....

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

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i. LIST of CONTENTS

GENERAL INFORMATION	Page No.
TITLE PAGE	2
RESEARCH REFERENCE NUMBERS	4
SIGNATURE PAGE	5
KEY STUDY CONTACTS	6
i. LIST of CONTENTS	8
ii. LIST OF ABBREVIATIONS	9
iii. STUDY SUMMARY	10
iv. FUNDING	12
v. ROLE OF SPONSOR AND FUNDER	12
vi. ROLES & RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES, GROUPS AND INDIVIDUALS	12
vii, PROTOCOL CONTRIBUTERS	13
viii. KEYWORDS	14
ix. STUDY FLOW CHART	15
SECTION	
1. BACKGROUND	16
2. RATIONALE	17
3. OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS	18
4. STUDY DESIGN	18
5. STUDY SETTING AND METHODS OF DATA COLLECTION AND DATA ANALYSIS	21
6. STATISTICS AND DATA ANALYSIS	23
7. PARTICIPANT ELIGIBILITY CRITERIA	25
7. STUDY PROCEDURES	25
9. DATA MANAGEMENT	28
10. MONITORING, AUDIT & INSPECTION	28
11. ETHICAL AND REGULATORY CONSIDERATIONS	29
12. DISSEMINATION POLICY	34
13. REFERENCES	35
14. APPENDICES	37

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

ii. LIST OF ABBREVIATIONS

BTHFT	Bradford Teaching Hospital NHS Foundation Trust
BRI	Bradford Royal Infirmary
CI	Chief Investigator
CRN	Clinical Research Network
DMS	Discharge Medicine Service
GCP	Good Clinical Practice
HRA	Health Research Authority
ICF	Informed Consent Form
ISRCTN	International Standard Randomised Controlled Trials Number
NHS R&D	National Health Service Research & Development
NIHR	National Institute for Health Research
NMS	New Medicines Service
PI	Principal Investigator
PCN	Primary Care Network
PIS	Participant Information Sheet
PPIEP	Patient & Public Involvement, Engagement & Participation
PREM	Patient-Reported Experience Measure
PSRC	Patient Safety Research Collaborative
QoL	Quality of Life
RCT	Randomised Control Trial
RfPB	Research for Patient Benefit
REC	Research Ethics Committee
WHO	World Health Organisation
WP	Work Package

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

iii. STUDY SUMMARY

Study Title	Assessing the feasibility and implementation of the 'My medicines journey' intervention: A multi-methods evaluation	
Internal ref. no. (or short title)	My Medicines Journey: Assessing the feasibility and implementation of a Toolkit.	
Clinical Phase		
Study Design	Feasibility study	
Study Participants	Older people living with frailty and one or more long-term conditions and who have had one or more changes to their medicines during admission. Family carers Hospital staff (pharmacy teams) and community pharmacists implementing the intervention.	
Planned Size of Sample (if applicable)	**Phase 2:** 168 older people (84 to receive intervention; 84 to act as 'control' to determine if it is feasible to collect outcome measures from a non-trial group) 20 Older people/informal carers for qualitative interviews 12 Hospital staff for qualitative interviews Up to 8 Hospital Staff for the Focus group/feedback sessions.	
Treatment duration	2 weeks post-discharge	
Follow up duration	3 months post-discharge	
Planned Study Period	24 months	
	Objectives	Outcome Measures (feasibility)
Primary	Validate a PREM Explore the acceptability of implementation of the PREM from the perspectives of patient participants and staff	▪ Rate of recruitment ▪ Loss of follow-up at 2 months ▪ Intervention delivery ▪ Participation engagement with the intervention ▪ Evidence of feasibility to collect outcome measures
Secondary	Consolidate RCT protocol and refine outcome measures.	
	Create a multi-site trial protocol	

v. **FUNDING AND SUPPORT IN KIND**

FUNDER(S) (Names and contact details of ALL organisations providing funding and/or support in kind for this study)	**FINANCIAL AND NON-FINANCIAL SUPPORT GIVEN**
NIHR	£244,861.00 ▪ Staff costs ▪ Travel, Subsistence & Conference Costs ▪ Equipment Costs ▪ Consumables ▪ PPIEP Costs ▪ Dissemination costs
University of Bradford	▪ Venues for meetings

v. ROLE OF STUDY SPONSOR AND FUNDER

The study funder will provide financial support for all study aspects, including Staff Travel, Subsistence and conference Costs, Equipment Costs, Consumables, PPIEP Costs, and Dissemination costs. The study sponsor, on the other hand, will provide administrative support, including indemnity for the study and managing study data. However, the sponsor and funder do not have any role in the study design, conduct, data analysis and interpretation, and dissemination of results.

vi. ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITTEES/GROUPS & INDIVIDUALS

Study Management Committees

1. Patient & Public Involvement Group

Our PPI group will:

- Provide expert patient opinion during project design, especially ethical considerations, protocol development, recruitment strategy, and piloting data collection tools.
- Co-design participant documentation.
- Co-facilitate hospital and community pharmacy staff focus groups to review findings (with training).
- Produce newsletters reporting project progress for participants and sites.
- Help to problem-solve issues as they arise.
- Develop ideas for dissemination.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

vii. Protocol contributors

This protocol has been developed with input from an experienced team with an appropriate mix of academic, clinical, and research delivery skills who have worked successfully on medicines optimisation and older people research programmes. These include;

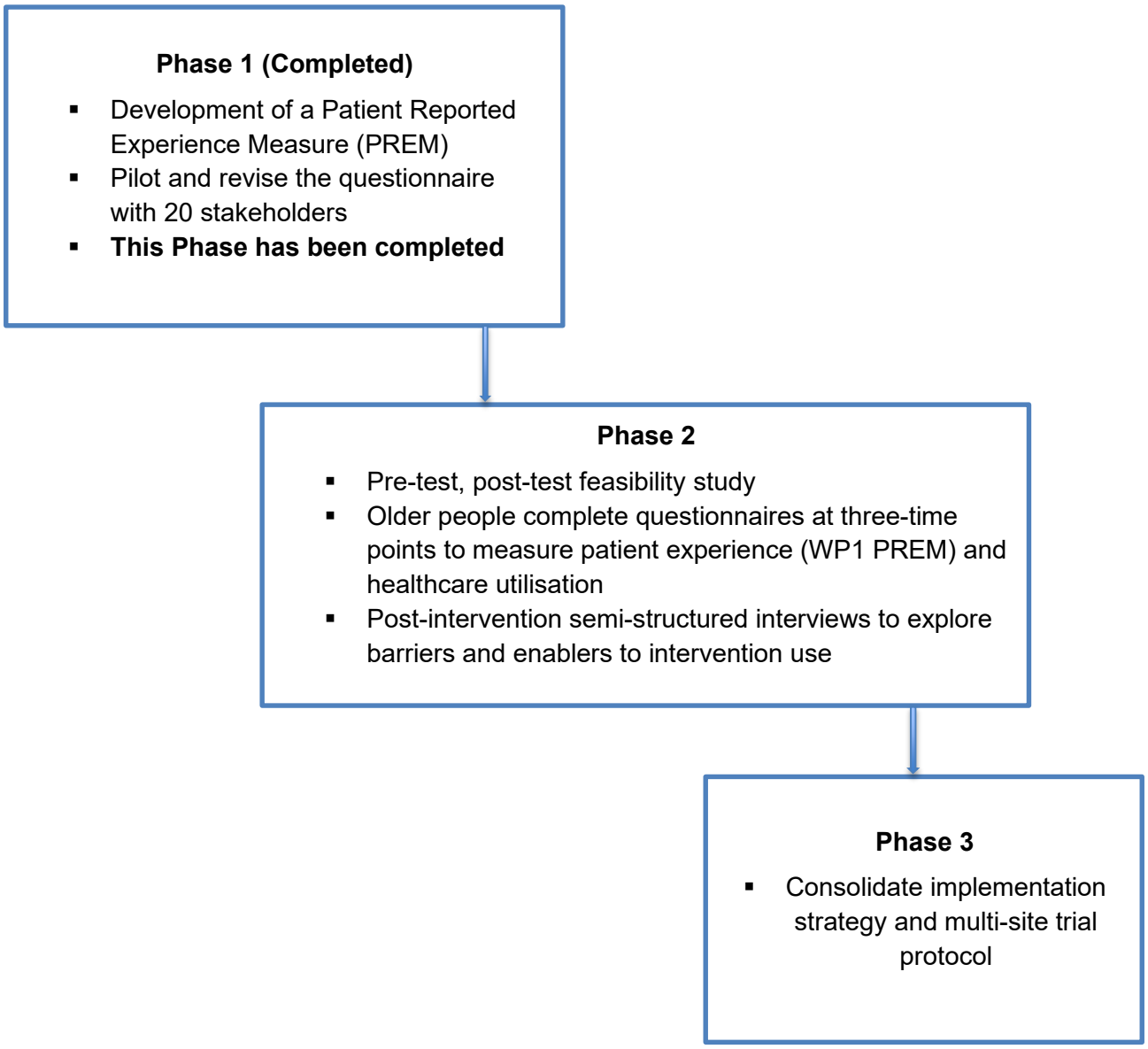
- Dr Justine Tomlinson who is the study Chief Investigator and grant Lead Applicant. She contributed to developing the grant application, which is the basis of this study protocol.
- Professor Beth Fylan
- Dr Adam Nyende
- Mrs Nazreen Butt (PPI representative)
- Professor Rebecca Lawton
- Professor Gerry Richardson
- Dr Jonathan Silcock
- Mrs Heather Smith
- In addition, the protocol and other study documents, such as the PIS, ICF, and data collection tools, benefited from the input of members of the public, who provided feedback on different aspects, such as the terminology used through the PPIEP. The PPIEP members also provided patient opinions on ethical considerations and risk assessment.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

viii. KEYWORDS:	Older people
	Medicines
	Management
	Intervention
	Feasibility
	Multi-methods

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

ix. STUDY FLOW CHART



My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

1 BACKGROUND

Harm from medicines during care transitions is a significant patient safety issue globally. The World Health Organisation (WHO) has set a target to reduce medicines-related harm by 50% by 2022, prioritising medicines safety for high-risk individuals and complex situations (Donaldson et al., 2017). While various methods exist to address medicines-related problems, only a few have been implemented in routine clinical practice (Liew et al., 2020). Despite the availability of professional services such as medicines reconciliation and medication reviews, medicines-related harm continues to be a widespread concern (WHO, 2024).

Older people, particularly those with long-term conditions, multiple medicines (polypharmacy), and frailty, are at a high risk of experiencing harm from medicines during transitions in care. Examples include adverse drug reactions and medicine errors, resulting in hospital readmission. Research indicates that 1 in 3 older people experience medicines-related harm within eight weeks of hospital discharge, amounting to an estimated cost of £396 million annually for the NHS (Parekh et al., 2018). Furthermore, studies involving older patients and their family caregivers have highlighted various gaps in the care received, including inadequate verbal and written communication about medicines, insufficient support for developing self-management skills, and a lack of person-centred follow-up. These challenges have been linked to a lack of knowledge, confidence, and capability for safe and effective post-discharge medicines management among patients, including older people (Fylan et al., 2018; Tomlinson et al., 2020a).

Ryan et al. (2014) argue that appropriately designed, theory-driven, complex interventions, such as medication self-monitoring and self-management programmes, can improve medicine use, adherence, and clinical outcomes and reduce adverse events. Additionally, a scoping review found evidence suggesting that pharmacist interventions within multidisciplinary teams provide greater clinical and economic benefits compared to standard care (Delgado-Silveira et al., 2021). There were significant reductions in emergency department attendance, primary care visits, hospital readmission rates, and length of hospital stay. Despite this compelling evidence, more work is needed in this area.

This feasibility study is based on our previous NIHR RfPB-funded project (PB-PG-0317-20010), which examined the patient experience of managing medicines after hospital discharge. We co-designed an intervention named ‘My Medicines Journey’, using the Theoretical Domains Framework to address medicines-related problems for older individuals with long-term conditions. This pharmacy-led intervention involves better quality medicines conversations, increased knowledge, skills, and self-management to ensure continuity of medicines-related care. It begins during hospital admission, led by the hospital pharmacy team, and continues after discharge with the community pharmacy-led Discharge Medicines Service (DMS). The multi-component intervention includes a patient information resource (paper-based), video, medicines support reviews, self-management planning, and patient-held checklists.

Our primary focus is on older people as they are a public health and NHS priority, frequent service users, and susceptible to deficiencies in medicines management. After conducting a systematic review of 24 studies that promoted continuity of medicines management (Tomlinson et al. 2020b), we found that interventions were more likely to reduce hospital readmission rates if they bridged the care transition and included components of self-management, medicines reconciliation, and telephone follow-up. Our intervention incorporates these important elements. Our review also highlighted that outcome measures typically focused on healthcare utilisation, quality of life, and medicines-related problems.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

However, no patient-reported experience measure (PREM) is currently associated with post-discharge medicines management, making it difficult to establish whether an intervention improves patient/carer experiences. This study will focus on developing and validating a PREM as a candidate primary outcome for subsequent trials. We will also test the use of other more routinely collected and validated measures that could be used as primary outcomes.

Community pharmacies could perform an important role in securing medicines continuity after hospital discharge, but few previous studies have actively involved them, and in most, they have been passive recipients of discharge medicines lists (Lussier et al. 2020). In England, community pharmacies offer NHS services, such as the DMS and the new medicines service (NMS), to support post-discharge medicines management, but this provision is challenging due to the lack of integration of community pharmacy into NHS information systems and poor patient engagement (Lam et al. 2019, Nazar et al. 2021). Our intervention includes a community pharmacy-led follow-up component (via DMS), and our study will generate evidence about the uptake of community pharmacy services. As part of the DMS, community pharmacies can refer to PCN pharmacists. Where PCN or practice pharmacy staff reconcile medicines post-discharge, there is a risk of duplication with the DMS, and we will explore how the interaction between community pharmacy and primary care pharmacy works during our study.

2 RATIONALE

It is an NHS priority to support people to age well, and for many people the focus should be to help them and their carers access tools to self-manage their conditions (NHS England, 2021). Better-managed medicines will optimise health and quality of life and reduce adverse outcomes. This, in turn, should reduce avoidable hospital readmissions and delay requirements for assisted living. The NHS has estimated that £530 million/year could be saved by improving healthcare utilisation due to avoidable medicines-related harm (NICE, 2015). This project also aligns with the 'supporting safe care in the home' theme of our Yorkshire and Humber NIHR Patient Safety Research Collaborative (PSRC).

As mentioned above, this feasibility study builds on NIHR RfPB-funded work (PB-PG-0317-20010), which explored post-discharge medicine management and co-designed an intervention. The intervention, called 'My Medicines Journey,' is pharmacy-led and multi-component. It promotes continuity of medicine-related care for older people living with long-term conditions through better-quality medicine conversations, increased knowledge, skills, and self-management.

2.1 Research aims and objectives

This multi-method study aims to assess the feasibility of implementing our intervention within the current NHS provision and explore how contextual factors influence its uptake. This will inform the development of a subsequent multi-site randomised controlled trial (RCT) to test the intervention's effectiveness and cost-effectiveness.

2.2 Specific objectives:

Although the project has three phases, this protocol and ethics application specifically relates to phase two, which aims to:

i) Explore the acceptability of implementation from the perspectives of patient participants and staff

ii) Develop materials for estimating the healthcare resource use of participants, the costs of the intervention, and the subsequent resources in both arms of a RCT
iii) Assess the feasibility of collecting a range of outcome measures
iv) Identify local individual/ organisational barriers and enablers to intervention delivery

3 OBJECTIVES AND OUTCOME MEASURES/ENDPOINTS

3.1 Primary objective

This study aims to assess the feasibility of implementing our intervention within the current NHS provision and to explore how contextual factors influence its uptake.

Objectives:

i) Validate a Patient-Reported Experience Measure (PREM) (developed in Phase 1 of our work)

ii) Explore the acceptability of implementation

iii) Assess the feasibility of collecting a range of outcome measures

iv) Identify local individual/ organisational barriers and enablers to intervention delivery

v) Consolidate and refine intervention components and implementation plan

3.2 Secondary objectives

To develop a subsequent protocol for a multicentre RCT.

3.3 Outcome measures

The primary outcome of this phase is the PREM validation and an understanding of the feasibility of implementing the intervention (i.e., are progression criteria met). However, the study has several outcome measures, including healthcare utilisation, medicine-related problems, self-efficacy, quality of life, and adherence.

4 PHASE TWO STUDY DESIGN

This is a feasibility study of a co-designed intervention called the ‘My Medicines Journey’ toolkit. The aim is to support older people to better manage their medicines after being discharged from hospital. The intervention will be initiated in the hospital and continued after discharge with the patient’s community pharmacy.

The intervention will be led by the pharmacy team and is designed to optimise existing processes rather than add more tasks for the team. However, both older people and pharmacy teams will play crucial roles in implementing the intervention.

- For the patient: They will be provided with information resources to prepare them to discuss their medicines with the pharmacist. They will also receive a checklist of what they need to know before discharge.

- For the pharmacy team: They will be expected to ask the patient about their medicines management/support needs at home, complete a short action plan with the patient for managing their new medicines at home, and, if possible, allow the patient to self-administer one or two doses before going home so they can practice, and transfer information to the community pharmacy to initiate DMS.

A non-intervention arm (n=84) will be recruited to explore whether the outcome measures can be collected from a 'control' group (n=84) to inform the future trial and boost our questionnaire sample size to enable PREM validation. This arm will receive usual care for that hospital ward but will additionally be asked to complete outcome measure questionnaires (e.g., baseline data, PREM, EQ-5D-5L, healthcare utilisation).

This feasibility study aims to test if the pharmacy team can incorporate the intervention into their regular work, assess the positive and negative impacts of doing so, and determine whether progression criteria (see page 24 for more details) are met, which would indicate a move to full trial. We will ask four NHS sites, including Bradford Teaching Hospitals NHS Trust, Hull University Teaching Hospitals NHS Trust, Leeds Teaching Hospitals NHS Trust, and Calderdale and Huddersfield NHS Trust, to each recruit approximately 21 older people over a span of 12-16 weeks period, which averages out to approximately 2 older people per week (n= 84), but with attrition, we predict a smaller final sample size. Based on previous feasibility studies, such as Teare et al. (2014) who determined that 70 measurable subjects are required when outcomes are continuous, we believe this is an appropriate sample size to determine feasibility.

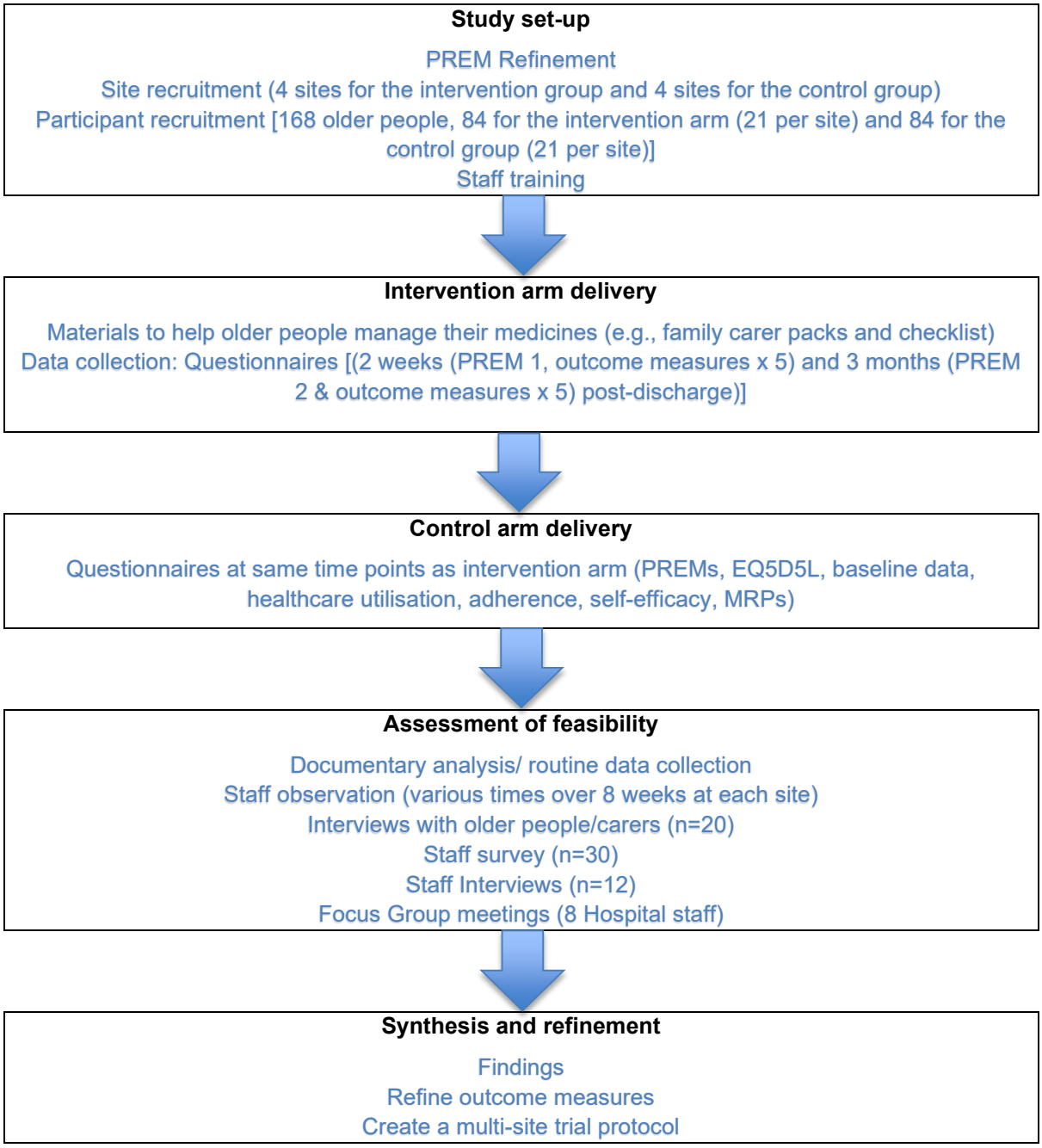
We will also conduct observations with the team, distribute staff questionnaires, and conduct semi-structured interviews with individuals who have used the intervention.

In summary, phase two of the study will involve:

- Administering the PREM questionnaire, developed in phase one, to assess post-discharge medicine experiences with older people, carers, and health professionals and to test its usefulness.
- We will work with approximately 4 local hospitals and participants' community pharmacists to use our Toolkit with older people and their carers. We will assess how well it works and its acceptability by using questionnaires, observations and interviews. In addition, we shall work with 4 other local hospitals to recruit a control group that will be asked to complete patient surveys, including PREMs, EQ5D5L, baseline data, healthcare utilisation, adherence, self-efficacy, and DRPs.
- Finally, we will use the findings to enhance the intervention Toolkit and implementation strategy and develop a proposal for a large-scale multi-site trial.

The workflow chart below summarises all components of the study design for the second phase of my medicines journey project.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit



My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

STUDY SETTING AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

5.1. STUDY SETTING

This feasibility study involves four diverse hospitals in Bradford, Leeds, Hull and Calderdale which are our intervention sites. We will also recruit four sites that will act as our 'control' to determine if it is possible to collect data from a non-intervention arm. The selection of sites considered population profiles, organisation size and access. We have established support from senior management and will work with the CRN to support coordination. Appropriate site training (in-person or online as preferred) will be provided.

5.2. DATA COLLECTION

5.2.1 Methods of data collection

This feasibility study will utilise a multi-methods approach guided by the Systems Engineering Initiative for Patient Safety (SEIPS) 3.0 Framework (Carayon et al. 2020) across the data collection phase.

5.2.1.1 Intervention arm delivery

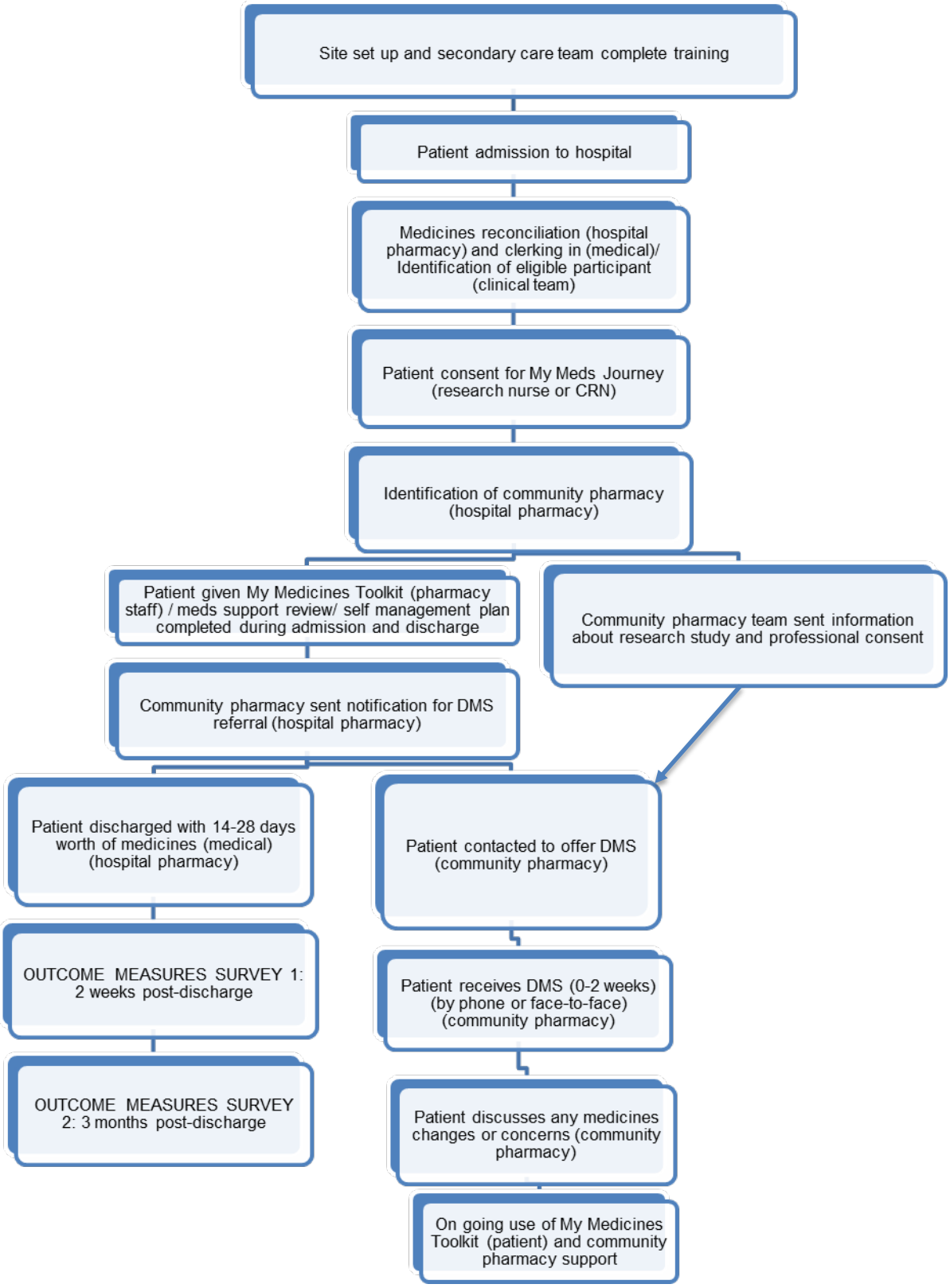
This will involve the clinical team identifying suitable participants and research nurses consenting participants and administering a patient survey to collect baseline characteristics data. This phase will also include clinical teams providing older people with materials to help them manage their medicines (e.g., family carer packs and medicine management checklists). As part of our intervention implementation guide, we have developed a customised eight-step checklist to support delivery. Staff will be asked to complete this checklist, and we will use it, along with other data sources such as patient-reported and community pharmacy-reported information, to ascertain the level of fidelity. We will calculate the percentage of intervention each participant receives and use this to establish our progression criteria for future definitive trials (intervention delivery >50% on the fidelity rating scale). We will also use this information to further refine the intervention and implementation guide.

In addition, as part of the intervention arm delivery, the research team will administer questionnaires two (2) weeks after discharge to collect data on five (5) outcome measures (PREM1, EQ5D5L, healthcare utilisation, adherence, self-efficacy, and medicines-related problems (MRPs). Depending on the participants' preferences, these questionnaires will be administered either by post, telephone, or online (via a link provided to MS Forms).

Furthermore, the research team will administer a PREM 2 questionnaire (Appendix 9) and collect data on the five outcome measures from the same sample 3 months post-discharge. These questionnaires will be administered via post, telephone or online (Microsoft Teams or Zoom). Below is a flowchart illustrating the patient journey through the project/intervention.

As part of this feasibility study, we will explore what routine data can be collected, with the participants' consent, to aid with our analysis. Presently, we envisage that this will be routinely data about the participant's number of hospital readmissions and data from community pharmacy reporting systems about whether the Discharge Medicine Service was delivered to the participant.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit



5.2.1.2 Control arm delivery

In addition to the intervention group, the clinical/ research team will recruit 84 older people to form the control group. This sample will be asked to complete patient surveys at the same time points, including PREMs, EQ5D5L, baseline data, healthcare utilisation, adherence, self-efficacy, and MRPs.

5.2.1.3 Assessment of feasibility

To evaluate the feasibility of the intervention, we will use various data collection methods. Along with the patient surveys above, our research team will conduct an online survey using a questionnaire (Appendix 12) with a maximum of 30 hospital staff members.

We will also undertake document analysis of intervention manuals to see if staff have completed the required details and conduct staff observations at various times over 8 weeks at each site. We will request ward-level permission to observe staff members delivering the intervention at the point of delivery. This will help us understand how the toolkit is being implemented and the overall care context in which the intervention is implemented. We will collect focused and general observation data using a structured observation tool or checklist (Appendix 13) and take field notes.

Additionally, we will invite up to 12 hospital staff members and up to 20 older people/carers to take part in semi-structured interviews. These interviews will be conducted face-to-face or online (via Microsoft Teams or Zoom) depending on the participants' convenience and will be facilitated by the research team. The interview topic guides for hospital staff and older people have been included as Appendices 10 and 11, respectively. Interviews will be audio recorded with consent, and anonymised transcripts will be produced from the recording. The analysis will use the framework method to help us explore the experiences, barriers, and facilitators of intervention use.

5.2.2 Data Analysis

We will provide an in-depth understanding of how usable and acceptable the intervention is in practice, as well as barriers and facilitators to delivery underpinned by the SEIPS 3.0 framework. Qualitative data will be analysed using the Framework method (Gale et al., 2013). Descriptive statistics will be employed to analyse survey data. The findings from the study will be used to refine the outcome measures and inform a multi-site trial protocol.

Following our analysis, we will hold dissemination workshops with key stakeholders from the participating organisations. We will present our findings and encourage stakeholders to suggest ways to overcome any challenges or refine our intervention in preparation for a future trial (if indicated from the progression criteria).

5.3 STATISTICS AND DATA ANALYSIS

5.3.1 Sample size calculation

We plan to recruit a diverse sample of 168 older people across 4 intervention sites and 4 control sites during hospital admission, plus hospital staff involved in delivering the intervention across the sites.

There are four varying sample size estimates for this study:

A. To determine feasibility against the progression criteria (n=84 intervention participants)
The sample size is based on the need to understand whether it is possible to consistently recruit 2 participants a week for up to 16 weeks per site and account for attrition. Based on previous feasibility studies, such as Teare et al. (2014) who determined that 70 measurable subjects are required when outcomes are continuous, we believe this is an appropriate sample size to determine feasibility against our progression criteria.

B. To determine if data can be collected from a 'control' arm (n=84 control participants)
Sample size is determined based on A, and contributes to C.

C. To validate the PREM (n=168 patient participants)
For validation studies, a widely used rule of thumb suggests 10 responses per item in the instrument.

The PREM contains 15 to 18 items, leading to a sample size in the range of 150 to 180.

The intended sample size is 168.

If this is achieved, the margin of error (for responses to each item) will be:

A) +/- 7.5% assuming a proportion of 50% at the 95% confidence level
B) +/- 5% assuming a proportion of 50% at the 80% confidence level

We consider this to be acceptable.

Extreme responses to the items (proportions higher or lower than 50%) will reduce the margin of error.

D. To collect in-depth qualitative data from a smaller sample of patient and staff participants (n=12-30 depending on methods)

5.3.2 Planned recruitment rate

We have worked with sites to understand what is realistic, given current workforce pressures and research timelines. Therefore, the planned recruitment rate is 2 participants per week for up to 16 weeks.

5.3.3 Statistical Analysis Plan

5.3.3.1 Analysis of the reliability and validity of the PREMs

- We will conduct initial analyses in SPSS to check for normality, outliers, and missing values.
- Our goal is to assess the validity and reliability of the two PREMS. This will involve exploratory factor analysis, a reliability test (Cronbach's alpha coefficient), and a construct validity test.
- We will evaluate the reliability of the PREMs using the composite reliability values for each dimension.

- To assess reliability, we will test for internal consistency using Cronbach's alpha coefficient.
- To determine construct validity, we will examine convergent, discriminant, and predictive validity using a Student's t-test, correction and regression analysis, and an analysis of covariance.

5.3.3.2 Analysis of the Intervention Outcome Measures

We shall focus on descriptive statistics such as percentages, means and standard deviations to understand the key features of the data from the outcome measures (Healthcare utilisation, Medicine-Related Problems, Self-efficacy, QoL, and Adherence) and the staff survey.

Criteria to determine if the intervention should proceed to RCT will be refined in agreement with our project advisory board. We will apply 'Red', 'Amber', and 'Green' (RAG) criteria (Young et al., 2019), which we have previously applied in our work (ISCOMAT programme RP-PG-0514-20009). Key criteria will be based on recruitment, intervention delivery, and participant engagement:

Criteria	Green	Amber	Red
Rate of recruitment	2 participants per week per site	1 participant per week per site	0 participant per week per site
Loss to follow up at 2 months	<20%	21-35%	>35%
Intervention delivery >50% on fidelity rating scale	100%	50-99%	<50%
Participant engagement with intervention (use of checklist, self-management plan and engages with DMS)	>75%	40-74%	<40%
Evidence of feasibility to collect outcome measures	>75%	35-75%	<35%

We will regularly review progress against the RAG progression criteria at project meetings and assess whether these are achievable within a full trial. Where progress is 'amber', barriers to implementation should be resolvable and we will work with our project advisory group (PAG) to review and adapt methods within the feasibility study. If more than 50% of our RAG criteria result in 'red' scores, we will not progress to a further full trial.

6 PARTICIPANT ELIGIBILITY CRITERIA

The clinical team will identify eligible participants using the following inclusion and exclusion criteria.

6.1 Inclusion criteria

- Aged 75 plus
- Living with frailty (based on clinical judgement of the ward geriatrician)
- Living with one or more long-term condition(s)
- Using five or more regular medicines
- Returning to a domiciliary setting
- At least one medicines change during inpatient stay
- Manage medicines without a formal social care package, i.e., the patient does not rely on formal paid carers for the administration of all medicines

6.2 Exclusion criteria

- Are on the End-of-Life pathway
- Are discharged to a temporary care setting
- Reside in a care home
- All medicines are administered by formal paid care providers
- Lack capacity (assessed by the care team and/or research nurse)

7 STUDY PROCEDURES

7.1 Recruitment

We will use a staggered approach to recruitment and check at various points in time to ensure maximum variation within our sample. We will coordinate with recruitment sites to assist the external research team in achieving diversity in the sample without disclosing any identifiable information until we receive consent from older people living with frailty and family carers to share this information.

We will recruit participants using purposeful sampling based on the above mentioned inclusion and exclusion criteria. Our recruitment strategy has been developed with input from older people and the public through PPIE. All study participants will be recruited through the study site, and clinicians (pharmacy staff) at these sites, who have frequent daily interactions with older people, will act as gatekeepers. Once eligible participants have been identified, research nurses at the sites will carry out consent procedures.

Key staff members within the pharmacy teams at the sites, who have frequent, daily contact with older people, will drive recruitment screening using the sites' electronic system.

Screening, recruitment, and intervention components are all designed to integrate seamlessly with the regular workflow. To assist with this, the researcher will spend dedicated time at each site to facilitate informed consent processes. Additionally, research nurse support for recruitment will be requested via the CRN. Any issues will be addressed during site support visits, and solutions will be sought.

7.1.2 Size of sample

We aim to recruit a diverse sample of 168 older people from eight hospitals. We will recruit 84 older people for the intervention group from 4 sites and another 84 for the control group from 4 different sites. We aim to recruit 21 participants from each site, with a goal of enrolling two older people per week. This sample will yield sufficient data to meet the objectives of this phase. The hospital staff involved in the intervention delivery will be recruited across the four hospital sites. We aim to recruit up to 30 diverse staff members across all sites for the survey work and 12 for subsequent interviews.

7.1.3 Sampling technique

We will use a purposive sampling strategy to recruit a diverse population, considering factors such as socioeconomic background, age, gender, and ethnicity for individuals living with frailty and family carers. We will select professionals to deliver the intervention based on their specific job roles.

7.1.4 Sample identification

The NIHR CRN will send Expressions of Interest to different sites for participation in our 'control arm'. We have already identified our intervention sites. The research team will also contact relevant organisations identified via networking and searches.

The clinicians, in this case, the pharmacy team responsible for implementing the intervention, will identify older people living with frailty (and family carers if possible) using the eligibility criteria. The clinicians/pharmacy team will screen or review the patient records of the potential participants to identify those who meet the inclusion/eligibility criteria. Once the older people who meet the inclusion criteria have been identified, they will be asked by someone from their usual care team if they wish to discuss more about the study and if they wish to have their contact details, such as telephone numbers or email addresses, passed on to the research team. Alternatively, the clinical team will hand out a PIS and consent form to the older people as part of their treatment packs. At this stage, the researcher will request the gatekeepers to get verbal permission from potential participants (once screened) to give their contact numbers to the research nurses so that they can expedite recruitment. If the potential participant consents to the research nurses having access to their identifiable information, this will be noted in their medical notes. The research nurses will then contact the older people through initiation letters to find out if they are interested in learning more about and taking part in the study and then provide them with the PIS. The research team will not access confidential patient information without the patient's consent. If the potential participants consent to share their personal identification with the research team, this will only be done by the clinical team at the study sites. Therefore, the identification and initial approach to older people/carers will always only be done by someone from their usual care team with access to this information. We will also give older people a family carer pack to give to anyone who helps with their medicines at home. When obtaining baseline characteristics, we will ask if they have any carers and leave them packs.

The site PI, acting as the gatekeepers, will send out information and ask the pharmacy team that will implement the intervention if they are interested in taking part in the semi-structured interviews. In addition, we will seek the opinion of the PPI group on how to optimise our recruitment strategy. We will also train the site clinicians in recruitment to ensure that a diverse sample is considered.

7.1.5 Screening

The clinical teams will use the sites' electronic systems to screen potential participants who meet the inclusion criteria. Recruitment screening will be driven by key clinicians within the pharmacy teams at the sites, who have frequent, daily contact with older people. The pharmacy team will identify older people taking five or more regular medicines and living with long-term conditions and frailty in their routine work. Therefore, the screening, recruitment, and intervention components are all designed to fit into the usual workflow.

We will ensure diversity is a key consideration in our sample recruitment process, guided by the NIHR (2020) INCLUDE framework and guidance. All our research team members have completed or will complete the NIHR Learn e-learning course on Improving the inclusion of under-served groups in health research. The geographic area where the research will be conducted has diverse populations, and we aim to involve individuals from different age groups with various comorbidities, genders, and ethnicities.

7.1.6 Payment

Study interview participants (n=20 older people/ family carers) will be paid £20 in vouchers to reimburse for their time. This amount has been decided upon through discussion with the PPIE group and aims to support recruitment for the interview element of the study.

7.2 Consent

The site research nurses at the sites will be responsible for obtaining their initial informed consent. At the stage of obtaining informed consent, the research nurses will inform all

eligible participants that the research team will contact them to participate in aspects of the study, e.g. interview. Therefore, the research nurses will ask for permission from the eligible participants to be contacted by the research team and to share their contact information, including telephone numbers, email addresses, and postcodes, with the research team. This information has been included in the participant information sheet and consent forms. Please note that the PIS and consent forms for the intervention and control sites are slightly different as activity is different between sites.

Since the research nurses will seek consent for all the study aspects involving older people at once, informed consent will be obtained before the participants are involved in any aspect of the study, including obtaining their identifiable data. The right of a participant to refuse participation without giving reasons will be respected. The participant will be informed that they are free to withdraw from the study at any time without giving reasons and without prejudicing their further treatment. They will also be provided with a contact point where they may obtain further information about the study. If a participant chooses to withdraw from the study, the data collected after withdrawal will only be used if the participant has consented to this, and the intention to utilise such data will be outlined in the participant consent form.

We shall use hospital interpreters to support the consent process by verbally translating the participant information sheet and consent form for participants who cannot use English. This translation will be done in person or via telephone depending on the participant's situation. Similarly, we shall provide translated materials, such as the intervention patient guide in Urdu, which will be translated locally. We have arrangements in place to confirm the accuracy of the translation, such as back translation.

The consent process will involve a discussion between the research nurses and the potential participants about the study objectives and the possible risks associated with their participation. The research nurses will also provide potential participants with PIS (Appendix 1) and the consent form (Appendix 4) approved by the REC, which will give details on the study and their participation. The potential participants will be allowed the opportunity to ask any questions. If the potential participants agree to take part, they will be asked by the research nurses to sign the informed consent form. Each participant will sign the consent form on the date they receive the intervention.

All the included participants will be capable of providing consent themselves. This means that the participants will be able to understand the purpose and nature of the research, what the study involves, its benefits (or lack of benefits), risks, and burdens, understand the alternatives to taking part, retain the information long enough to make an effective decision, make a free choice, and be capable of making this decision at the time it needs to be made.

The research team will obtain consent for study aspects involving staff. Staff will initially be approached about the study elements by the site PI, who will act as gatekeepers. The staff survey will not require written consent because all the data we intend to collect through the survey questionnaires will be fully anonymised. However, we shall obtain individual written consent for the staff observations and interviews. For the hospital staff observations, we will provide ward managers (senior sister/senior charge nurse) with a notification letter introducing the study and informing them that the research team will observe some of their staff as they deliver the intervention on the ward. The staff that will agree to be observed will be provided with an information sheet (Appendix 3) and asked to sign a consent form (Appendix 6) by the research team. Similarly, staff taking part in semi-structured interviews will be provided with an information sheet (Appendix 2) and asked to sign a consent form (Appendix 5). Once consented, the staff participant will introduce the research team as they talk to others who are not observed to get verbal assent that we can observe that interaction.

8 DATA MANAGEMENT

8.1 Data handling and record keeping

The sponsor will ensure that the data management system is validated, maintain SOPs for the use of the system, maintain an audit trail of data changes ensuring that there is no deletion of entered data, maintain a security system to protect against unauthorised access, maintain a list of the individuals authorised to make data changes, maintain an adequate backup of the data, safeguard the blinding of the study and archiving of any source data (i.e., hard copy and electronic). If data are transformed during processing, then care will be taken to ensure that it is possible to compare the original data and observations with the processed data. We will use an unambiguous participant identification code to identify all the data reported for each participant.

8.2 Access to Data

Direct access will be granted to authorised representatives from the Sponsor, host institution, and regulatory authorities to permit study-related monitoring, audits, and inspections in line with participant consent.

9 MONITORING, AUDIT & INSPECTION

The research team and the sponsor will develop and agree upon a study monitoring plan based on the study risk assessment, including on-site monitoring. The sponsor will undertake one site-visit monitoring exercise across the study sites during the course of the study. The monitoring will include face-to-face meetings between the researcher and the sponsor's representative to discuss and review processes related to participant recruitment, consent, eligibility, adherence to interventions and policies to protect participants, including reporting of harm and completeness, accuracy, and timeliness of data collection. The monitoring team will also review any (potential) challenges impacting the study timelines and agree on mitigation measures. The sites will be expected to host the site visits, provide any information for remote monitoring, and implement procedures to monitor the study internally.

10 ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Assessment and management of risk

Potential risks of taking part in the study:

The Declaration of Helsinki highlights that the purpose of research must not take precedence over the rights, interests, and well-being of research participants (WMA 2013). In planning this study, we carefully assessed the potential risks against the potential burdens for the participants involved. In terms of potential risks, this study can be categorised as Type A, implying that the risks involved are no higher than the risks of standard medical care. Some of the risks and burdens that might occur during the study include the following.

- We have considered that some older individuals may experience fatigue while answering the questionnaires and engaging in the interview process. To address this concern, we have designed the interview schedules to be concise and have incorporated breaks to allow for rest during the interviews. The PPI team has provided feedback on how to design the study documents to ensure that the tasks involved in the study are appropriate to the individuals involved. In addition, interviews will be scheduled at a time and location chosen by the participant to

ensure their comfort and reduce any inconvenience. Having a consistent research team member will help build rapport with participants and improve retention. We will also use telephone or postal reminders for data collection to encourage the retention of the participants.

Potential safeguarding issues during the study

- During the study, there might be instances where safeguarding concerns arise. For example, participants may witness inappropriate care processes or potential harm from medicines errors, or they may mention concerns about potential harm to themselves or others. In such cases, the researcher will first speak to the participant and then escalate the issue to the appropriate person in consultation with the research team, which includes qualified pharmacists (see flowchart Appendix 13). These procedures have been explained in the PIS and will be discussed with the participant at the beginning of the data collection process.
- Other measures to ensure the safety of the participants in their homes will include including the researcher's photograph on the PIS form so that the participants know what the person coming into their homes looks like and to ensure that the researcher always wears identification when visiting the participants.
- Since the interviews with older people will be undertaken in their homes, there are safety risks for the research team. Following the NHS Lone Working Policy, we have minimised such risks. Some lone working measures to ensure the researcher's safety in the participants' homes include the buddy system, not undertaking interviews late in the evening, and ensuring that they move with their photographic identification documents at all times during the data collection process.
- Risk assessments will be completed for each research phase to ensure that all potential risks are assessed and mitigation measures are implemented as the study evolves.

Potential benefits of taking part in the study

- Participating in this study will provide value to the participants, particularly older people living with frailty or other long-term conditions who are often excluded from research studies. They will feel invested in a common cause and may also hope to derive personal benefits from it. By taking part in this research, participants will provide valuable real-life experiences of managing medicines. These findings will be used to directly enhance future care for older patients' medicines, ultimately improving patients' quality of life and reducing unnecessary harm. The research team will feedback a summary of the findings to those who take part.
- Each older person taking part in the study will receive £20 in vouchers to reimburse them for their time as a token of gratitude. This amount was decided after discussions with the PPI group. It is meant to reflect the burden of participation without seeming coercive.
- Intervention facilitators will benefit from additional training in self-management of medicines for people living with frailty and family carers.

Support for participants with additional needs

Where it is identified that a participant requires support to take part in the study e.g. visual, hearing or speech impairments, this will be highlighted to the study team and reasonable adjustments will be made where possible. For example, participants can be supported by family and friends to complete documentation (this is included in the patient PIS), or a

member of the research team can complete outcome measure questionnaires with patients over the telephone.

Non-English speaking patients can be supported through the consenting process with the use of NHS translation services from the standard care pathway. Written study material can be translated into other languages as appropriate.

Documentation of any additional needs will be via the baseline characteristics form.

10.2 Research Ethics Committee (REC) review & reports

This study will receive ethical review and approval from the relevant HRA/NHS REC. Before the start of the study, approval will be sought from a REC for the study protocol, informed consent forms, and other relevant documents, e.g., PIS and GP information letters. In addition, substantial amendments that require review by the REC will not be implemented until the REC grants a favourable opinion for the study. All correspondence with the REC will be retained in the Study Master File/Investigator Site File. An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination. Similarly, within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

10.3 Peer review

This protocol has been peer-reviewed by experienced clinical/healthcare researchers and academics from the Universities of Bradford and Leeds. Two academics from the University of Bradford and the University of Leeds, who are independent of the study, provided the external review.

10.4 Public and Patient Involvement

The study actively involved members of the public in several aspects, including the Design of the research, where expert patients provided feedback on aspects related to the protocol, including potential risks and benefits of the study, terminology, and layout of the study documents such as the PIS and consent forms through PPIE meetings. In addition, members of the public and service users will also be involved in the dissemination stage, where they will be invited to attend workshops, meetings, and conferences, and the study findings will be disseminated.

Our PPI group will:

- Provide expert patient opinion during project design, especially ethical considerations, protocol
- Contribute to refining the PREM
- Develop and pilot data collection tools.
- Co-design participant documentation.
- Co-analyse interview data (with training).
- Co-facilitate hospital and community pharmacy staff focus groups to review findings (with training).
- Produce newsletters reporting project progress for participants and sites.
- Help to problem-solve issues as they arise.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

- Develop ideas for dissemination, co-present at conferences and co-author publications.

10.5 Regulatory Compliance

The study will not commence until a Favourable REC opinion is obtained. In addition, the protocol and study conduct will comply with the Medicines for Human Use (Clinical Trials) Regulations 2004 and any relevant amendments.

Before any site can enrol older people into the study, the Chief Investigator/or designee will ensure that appropriate approvals from participating organisations are in place. The Chief Investigator has had preliminary discussions with the R&D staff of the three/four participating NHS sites and shared with them a draft protocol to determine if they have the potential to participate in the study by assessing their 'capacity and capability' to participate in the study. Once the sponsor receives the HRA Approval initial assessment letter (or HRA Approval letter in cases where no initial assessment letter is issued), the research team will contact the R&D staff of the participating NHS sites to obtain the 'local information pack' and finalise discussions around confirming capacity and capability. This will also involve the research team providing the R&D office of these sites with all the necessary information and documentation needed to set up the study and confirm management permission. Arranging capacity and capability will also include organising training sessions with the clinical team (pharmacy teams). Therefore, before commencing any aspect of the study at the participating sites, the research team will obtain a 'Letter of Access' from all the participating NHS sites as confirmation of management permission.

For any amendment to the study, the Chief Investigator or designee, in agreement with the sponsor, will submit information to the appropriate body in order for them to issue approval for the amendment. The Chief Investigator or designee will work with sites (R&D departments at NHS sites as well as the study delivery team) so they can put the necessary arrangements in place to implement the amendment and confirm their support for the study as amended.

10.6 Protocol compliance

The study will be conducted in full compliance with the approved protocol. Any accidental protocol deviations that may occur at any time will be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.

10.7 Notification of Serious Breaches to GCP and/or the Protocol

A "serious breach" is a breach that is likely to affect to a significant degree the safety or physical or mental integrity of the participants of the study and/or the scientific value of the study. The sponsor will be notified immediately of cases where the above definition applies during the study conduct phase. The sponsor of a study will notify the licensing authority in writing of any serious breach of the conditions and principles of GCP in connection with that study and/or the protocol relating to that study, as amended from time to time, within 7 days of becoming aware of that breach.

10.8 Data protection and patient confidentiality

All the investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

The research team will be the custodian of the data generated from the study and will ensure that all the data obtained from the research is not used for any purpose other than that outlined in this protocol and the Participant Information Sheets.

All the personal information, including participant contact information and signed consent forms, will be securely stored electronically in password-protected folders on the BTHFT secure drive.

All the data collected in the form of questionnaires and interview transcripts will not include participants' names or other identifiable information. Instead, we shall use codes in the place of personal information to anonymise or depersonalise data and preserve the participants' privacy.

After data collection/interviews, the data in the form of questionnaires and interview transcripts will be securely stored at the research centre at the BTHFT in a secure cabinet. This data will then be transferred into electronic format as soon as possible.

The data collected for the study and other documents containing personal information will be accessed only by the research team. The only people outside the study team with access to the study documents containing personal information, such as consent forms, will be the monitoring team, which will be done for audit/monitoring purposes.

When the data are transmitted to sponsors and co-investigators, the confidentiality of the participants will be preserved by using encrypted emails to prevent unauthorised access to this data.

The data collected from questionnaires will be immediately transferred into electronic format, and the paper copies will be securely destroyed immediately afterwards. Similarly, interview data will be audio-recorded and transcribed as soon as possible. For interviews, we will use the Microsoft Teams computer application, which has an option for automatic recording and transcription. These virtual recordings will be securely stored on a BTHFT server and deleted once the transcript is checked by the research team for accuracy. The anonymised data sets will be electronically stored for five years after the study, while the audio recordings will be securely overwritten as soon as the in-house transcription process is completed. Similarly, the electronic version of the consent forms will be stored for five years for monitoring/audit purposes. Consequently, all paper documents will be destroyed, and electronic files will be deleted at the end of their retention period in a confidential manner in accordance with BTHFT policy and the dates documented in departmental records.

10.9 Financial and other competing interests for the chief investigator, PIs at each site and committee members for the overall study management

There are no competing interests for the chief investigator to disclose.

10.10 Indemnity

The study is being sponsored by BTHFT. BTHFT holds Public Liability insurance to cover the legal liability of the Trust as a Research Sponsor in the eventuality of harm to a research participant arising from the management of the research by the Trust. This does not in any way affect an NHS Trust's responsibility for any clinical negligence on the part of its staff.

Furthermore, BTHFT holds Professional Indemnity insurance to cover the legal liability of the Trust as Research Sponsor and/or as the employer of staff engaged in the research for harm to participants arising from the design of the research, where the Trust designed the research protocol.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Additionally, BTHFT's Public Liability and Professional Indemnity insurance policies indemnify its employees for their potential liability for harm to participants during the research. This does not in any way affect an NHS Trust's responsibility for any clinical negligence on the part of its staff.

10.11 Amendments

If a substantial amendment to the REC application, study authorisation, or the documents supporting the original application for the study is required, the sponsor will submit a valid notice of the amendment to the licencing authority for consideration.

Working with the sponsor, the research team will determine whether a substantial or non-substantial amendment to the REC authorisation or study documents is required. The protocol amendments will be submitted to the Sponsor for approval before submission to the REC committee.

The substantial amendment process will commence with the sponsor submitting a valid notice of amendment to the REC for consideration. The amendments will also be electronically notified to the national coordinating function of the UK country where the lead NHS R&D office is based and communicated to the participating organisations (R&D office and local research team) departments of participating sites to assess whether the amendment affects the NHS permission for that site. In addition, some amendments that may be considered non-substantial for the purposes of REC will still be notified to NHS R&D (e.g., a change to the funding arrangements).

The details of all the protocol amendments will be included in the Amendment History table (Appendix 14) whenever a new protocol version is produced.

10.12 Post-study care

The researchers will ensure that safeguards are put in place to protect the welfare and safety of participants after the study. In addition to the NHS Safeguarding of Adults Policy to protect the welfare and safety of the participants.

The research team will provide participants with information to signpost them to the available support services, including details on the **Patient Advisory Liaison Service (PALS)** [https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/], the **local AgeUK** "Relieving Loneliness: Community Connections" services [https://www.ageuk.org.uk/bournemouthpooleeastdorset/our-services/visiting-and-befriending/] and the **Silver Line** [https://www.thesilverline.org.uk/what-we-do/]. The research team will print out copies of the webpages/leaflets of the above-mentioned organisations and take them with him. A draft leaflet has been submitted for REC approval.

10.13 Access to the final study dataset

Only the researcher and the project team will be able to access the complete data set throughout the study to prevent any individual study site from disclosing the overall results before the main publication. After the study concludes, the anonymised data will be securely stored at a BTHFT server and later deposited in the Connected Bradford repository. This will ensure that the anonymised data is available for future use by other researchers in line with the NIHR Open Access Policy.

Connected Bradford uses anonymised (de-personalised) data where the information that identifies people has been removed or replaced. The data will be used in new and innovative ways to determine how ill the population is in the area, whether the services meet needs and to explore how they can be improved. Connected Bradford is committed to protecting privacy

at all times and will only use data ethically and lawfully. More information can be found here: https://bradfordresearch.nhs.uk/connected-bradford/connected-bradford-privacy-notice/

11 DISSEMINATION POLICY

11.1 Dissemination policy

The BTHFT will own the data arising from the study. Upon completion, the data will be analysed and tabulated, and a final study report will be prepared. The full study report will be accessed online on the BTHFT website. The participating investigators will have the right to publish study data. All the publications arising from the data will be peer-reviewed through high-quality journals. The publications, such as journal articles, will acknowledge the funding of the NIHR.

The research team will email a copy of the approved study results to all the participating sites. In addition, the study participants will be notified that they can request a copy of the study report or publications from the research team/CI. The research report or publications will be emailed to the interested participants after the Final Study Report has been compiled or after the results have been published.

The research team plans to make the study protocol, full study report, anonymised participant-level dataset, and statistical code for generating the results publicly available.

11.2 Authorship eligibility guidelines and any intended use of professional writers

The success of the project depends on the collaboration of all participants. Consequently, credit for the main results will be attributed to all those who have collaborated on the project through authorship and contributorship. Authorship decisions will be guided by uniform requirements for manuscripts submitted to medical journals. These requirements specify that authorship credit should be based on the following criteria:

a) Substantial contributions to the conception or design of the work or the acquisition, analysis, or interpretation of data for the work.
b) Drafting the work or revising it critically for important intellectual content.
c) Final approval of the version to be published.
d) Agreement to be accountable for all aspects of the work to ensure that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved (see www.icmje.org).

A final study report will be developed and agreed upon by all co-applicants for the funder, as well as interested organisations and stakeholders.

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16. APPENDICES

Appendix 1: Participant Information Sheet-Older people

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Participant Information Sheet-Older people [INTERVENTION SITE]

Invitation to take part in a research project on your medicines management

We, at Bradford Teaching Hospitals NHS Foundation Trust, would like to invite you to take part in our research project. Before you say 'yes' or 'no' to the project, we would like you to know why the research is being done and what would happen if you were to take part.

1. What is the research about?

As people get older, they usually have to take a lot of different medicines and often have one or more of their medicines changed. This can be hard to manage, especially when they leave the hospital. Sometimes, they might take the wrong dose or have trouble getting their medicines, which can be harmful and cause anxiety.

In the past, we worked with older people, their families, and healthcare professionals to create an intervention called 'My Medicines Journey' to help older people manage their medicines after leaving the hospital. This intervention is meant to be used by healthcare professionals while the person is in the hospital and after they leave. It includes resources, reviews, planning, and checklists to help people manage their medicines safely at home.

This research project aims to test how useful this intervention is in supporting older people in safely managing their medicines at home. If it works well, it could help reduce medicines-related harm and make it easier for older people to manage their medicines.

2. Who is organising and funding the research?

The research project is funded by the National Institute of Health and Social Research and is sponsored by Bradford Teaching Hospitals NHS Foundation Trust.

3. Who has reviewed and approved this project?

A research ethics committee has examined and approved this research. This committee is not involved in the project but is there to ensure your safety and rights are respected.

4. Why have I been chosen?

You have been invited to participate in the study because we believe you possess the characteristics of people we wish to include. This study targets individuals aged 75 and over who are clinically assessed as living with one or more long-term conditions, using five or more regular medications, having undergone at least one medication change, having been medically optimised for discharge, and returning home after hospital discharge. Only those who fulfil this criteria will be able to take part.

5. What will taking part in the project involve?

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

- Being provided with the 'My Medicines Journey' intervention (The researcher may wish to observe the professional supporting you with managing your medicines).
- Complete a questionnaire in the 2 weeks and then in 3 months following your discharge from the hospital. These questionnaires are about your experiences in managing medicines, quality of life, and communication with health, as well as social and voluntary professionals. Each questionnaire will take approximately 30 minutes to complete. **These questionnaires can be completed face-to-face, via a video call, or post, depending on what is convenient for you. You can also ask a family member or friend to help you.**
- We will collect information about your health from your health records and healthcare professionals, including which professionals you have visited during the study.
- You may also be asked to participate in a face-to-face interview about your experience with the 'My Medicines Journey' toolkit and how you manage your medicines with a research team member. This could take about 40 minutes at a time and place convenient for you.
- We shall also inform your GP that you are taking part in this study.

6. Do I have to take part?

No, you do not have to take part. Your participation in this project is completely voluntary. If you agree to participate, you do not have to answer any questions you do not want to for whatever reason. If you do not wish to participate, it will not affect your treatment or care in any way.

7. What are the potential benefits of taking part?

You will potentially help people living with long-term conditions and their family/friends manage their medication in the future. This will also help healthcare professionals understand patients' medicines management experiences.

8. Are there any risks to taking part?

You may become tired when answering the questions. If you become tired when answering the questionnaire or interview questions, please let the researcher know, and you can either take a break or re-schedule for another time. If you feel any distress, you can take a break, re-schedule activities, end activities, or withdraw from the study.

9. How will you use information about me?

We will need to use information from you, your medical records, and your GP for this research project.

This information will include your

- Initials
- NHS number
- Name
- Contact details
- Health condition(s) you live with
- Number and type of medicines
- Living alone or with family
- Socioeconomic background
- Age
- Gender
- Ethnicity

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

- Capacity to consent
- Whether you are on an end-of-life pathway
- Communication ability

People will use this information to undertake the research or check their records to ensure the research is done properly.

People who do not need to know who you are will not be able to see your name or contact details. Instead, your data will have a code number.

We will keep all information about you safe and secure following UK data protection laws.

10. What are my choices about how my information is used?

- You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to participate in this study, you may have the option to take part in future research using your data saved from this study.

11. What will happen to my information?

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor and data controller for this study. This means that we are responsible for looking after your information and using it properly.

All the information we collect from you will be securely stored at the Yorkshire Quality and Safety Research Group at Bradford Royal Infirmary for processing and analysis. It will remain confidential. However, if we have concerns that you or someone else is at risk of harm, we may break confidentiality and tell the relevant health services.

Bradford Teaching Hospitals NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished, and then the information will be securely destroyed.

In addition, the information collected may be used in an anonymous form to support other research publications in the future, and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. To enable this use, anonymised data will be added to an online Research Data Repository and accessible to the public after the study.

12. Where can I find out more about how my information is used?

- By asking one of the research team members
- You can contact us by emailing the Trust Data Protection Officer (DPO) at dataprotectionofficer@bthft.nhs.uk or the Information Governance team at Information.Governance@bthft.nhs.uk.
- By finding visiting: www.hra.nhs.uk/information-about-patients/ or from https://www.bradfordhospitals.nhs.uk/privacy-statement/

13. Confidentiality and ID numbers

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

We will keep your personal information (name and date of birth) separate from other information we collect. We will use an ID number to ensure any additional information we collect about you cannot be linked to your name. You will not be identified in any reports or academic papers we write.

If you participate in a face-to-face interview, the interview will be recorded using an audio device. The audio file will be transcribed by the research team, and a transcript of the interview created. Direct quotes from transcripts for use in reports, presentations, and academic papers will be used with your consent, and you will not be identified.

We will store all information securely, enabling future researchers to continue to analyse the information we gather in this project. In the unlikely event that we discover serious issues of concern regarding your well-being, we will have to break patient confidentiality and inform the medical or social care authorities for your safety.

14. What will happen to the results of the research project?

We will present the results at meetings and write about them as academic papers. No individual will be identified in any publication or meeting.

15. How can I find out about the results of the study?

The researcher will be happy to email or post you a summary of the approved research findings and a full research report.

16. What will happen if I do not want to carry on with the project?

You can withdraw from the project at any time. This will not affect your care in any way. If you wish to do so, we will use the information collected up to the time of your withdrawal unless you tell us that you want all information to be destroyed.

17. How do I raise a concern?

- If you are concerned, wish to know more, or make a complaint about any aspect of this project, please contact Dr Justine Tomlinson at Tel: +44 (0) 1274 23238 or email j.e.c.tomlinson@bradford.ac.uk.
- If you feel you need to make a formal complaint, please contact our Patient Experience team on 01274 364810, and they will be able to advise and assist you. Formal complaints should (where possible) be made to us in writing. We would recommend that you use our downloadable complaint form (doc) (go to www.bradfordhospitals.nhs.uk/patients-and-visitors/compliments-concerns-complaints/ as it sets out all the information that we need to investigate your complaint. If you are unable to access the form or do not want to use it, you can write to us directly by letter or email. You will need to provide details of your complaint, the department involved, yours and the patient's contact details (if not you), including their date of birth. You can use the following details to send your complaint to us:
  Patient Experience – Formal Complaint
  Bradford Teaching Hospitals
  Duckworth Lane
  Bradford
  BD9 6RJ

  Email: patient.experience@bthft.nhs.uk

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

18. What do I do now?

Thank you for taking the time to consider the project and for reading this information. If you decide that you would like to take part, you will be given this information sheet to keep and asked to sign a consent form.

Once you consent to the study, the research nurse will assess your eligibility for participation.

20. Who do I contact for information or advice?

If you would like further information, please contact:

Dr Justine Tomlinson

Assistant Professor in Medical Education

University of Bradford

Richmond Rd

Bradford

BD7 1DP

Tel: +44 (0) 1274 232381

Email: j.e.c.tomlinson@bradford.ac.uk

Thank you for reading this information sheet.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Participant Information Sheet--Older people [CONTROL SITE]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Invitation to take part in a research project on your medicines management

We, at Bradford Teaching Hospitals NHS Foundation Trust, would like to invite you to take part in our research project. Before you say 'yes' or 'no' to the project, we would like you to know why the research is being done and what would happen if you were to take part.

1. **What is the research about?**

As people get older, they usually have to take a lot of different medicines and often have one or more of their medicines changed. This can be hard to manage, especially when they leave the hospital. Sometimes, they might take the wrong dose or have trouble getting their medicines, which can be harmful and cause anxiety.

This research project aims to collect information about your experiences with medicines and involves the completion of two questionnaires after you have returned home from hospital; one questionnaire after two weeks and one after three months. Your hospital is being compared to others where a different type of patient information is being tested as part of a wider research study.

2. Who is organising and funding the research?

The research project is funded by the National Institute of Health and Social Research and is sponsored by Bradford Teaching Hospitals NHS Foundation Trust.

3. Who has reviewed and approved this project?

A research ethics committee has examined and approved this research. This committee is not involved in the project but is there to ensure your safety and rights are respected.

4. Why have I been chosen?

You have been invited to participate in the study because we believe you possess the characteristics of people we wish to include. This study targets individuals aged 75 and over who are clinically assessed as living with one or more long-term conditions, using five or more regular medications, having undergone at least one medication change, having been medically optimised for discharge, and returning home after hospital discharge. Only those who fulfil this criteria will be able to take part.

5. What will taking part in the project involve?

- Complete a questionnaire in the 2 weeks and then in 3 months following your discharge from the hospital. These questionnaires are about your experiences in managing medicines, quality of life, and communication with health, as well as social and voluntary professionals. Each questionnaire will take approximately 30 minutes to complete. **These questionnaires can be completed face-to-face, via a video call, or post, depending on what is convenient for you. You can also ask a family member or friend to help you.**
- We will collect information about your health from your health records and healthcare professionals, including which professionals you have visited during the study.

6. Do I have to take part?

No, you do not have to take part. Your participation in this project is completely voluntary. If you agree to participate, you do not have to answer any questions you do not want to for whatever reason. If you do not wish to participate, it will not affect your treatment or care in any way.

7. What are the potential benefits of taking part?

You will potentially help people living with long-term conditions and their family/friends manage their medication in the future. This will also help healthcare professionals understand patients' medicines management experiences.

8. Are there any risks to taking part?

You may become tired when answering the questions. If you become tired when answering the questionnaires, please let the researcher know, and you can either take a break or re-schedule for another time. If you feel any distress, you can take a break, re-schedule activities, end activities, or withdraw from the study.

9. How will you use information about me?

We will need to use information from you, your medical records, and your GP for this research project.

This information will include your

- Initials
- NHS number
- Name
- Contact details
- Health condition(s) you live with
- Number and type of medicines
- Living alone or with family
- Socioeconomic background
- Age
- Gender
- Ethnicity
- Capacity to consent
- Whether you are on an end-of-life pathway
- Communication ability

People will use this information to undertake the research or check their records to ensure the research is done properly.

People who do not need to know who you are will not be able to see your name or contact details. Instead, your data will have a code number.

We will keep all information about you safe and secure following UK data protection laws.

10. What are my choices about how my information is used?

- You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.

- If you agree to participate in this study, you may have the option to take part in future research using your data saved from this study.

11. What will happen to my information?

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor and data controller for this study. This means that we are responsible for looking after your information and using it properly.

All the information we collect from you will be securely stored at the Yorkshire Quality and Safety Research Group at Bradford Royal Infirmary for processing and analysis. It will remain confidential. However, if we have concerns that you or someone else is at risk of harm, we may break confidentiality and tell the relevant health services.

Bradford Teaching Hospitals NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished, and then the information will be securely destroyed.

In addition, the information collected may be used in an anonymous form to support other research publications in the future, and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. To enable this use, anonymised data will be added to an online Research Data Repository and accessible to the public after the study.

12. Where can I find out more about how my information is used?

- By asking one of the research team members
- You can contact us by emailing the Trust Data Protection Officer (DPO) at dataprotectionofficer@bthft.nhs.uk or the Information Governance team at Information.Governance@bthft.nhs.uk.
- By finding visiting: www.hra.nhs.uk/information-about-patients/ or from https://www.bradfordhospitals.nhs.uk/privacy-statement/

13. Confidentiality and ID numbers

We will keep your personal information (name and date of birth) separate from other information we collect. We will use an ID number to ensure any additional information we collect about you cannot be linked to your name. You will not be identified in any reports or academic papers we write.

We will store all information securely, enabling future researchers to continue to analyse the information we gather in this project. In the unlikely event that we discover serious issues of concern regarding your well-being, we will have to break patient confidentiality and inform the medical or social care authorities for your safety.

14. What will happen to the results of the research project?

We will present the results at meetings and write about them as academic papers. No individual will be identified in any publication or meeting.

15. How can I find out about the results of the study?

The researcher will be happy to email or post you a summary of the approved research findings and a full research report.

16. What will happen if I do not want to carry on with the project?

You can withdraw from the project at any time. This will not affect your care in any way. If you wish to do so, we will use the information collected up to the time of your withdrawal unless you tell us that you want all information to be destroyed.

17. How do I raise a concern?

- If you are concerned, wish to know more, or make a complaint about any aspect of this project, please contact Dr Justine Tomlinson at Tel: +44 (0) 1274 23238 or email j.e.c.tomlinson@bradford.ac.uk.
- If you feel you need to make a formal complaint, please contact our Patient Experience team on 01274 364810, and they will be able to advise and assist you. Formal complaints should (where possible) be made to us in writing. We would recommend that you use our downloadable complaint form (doc) (go to www.bradfordhospitals.nhs.uk/patients-and-visitors/compliments-concerns-complaints/ as it sets out all the information that we need to investigate your complaint. If you are unable to access the form or do not want to use it, you can write to us directly by letter or email. You will need to provide details of your complaint, the department involved, yours and the patient's contact details (if not you), including their date of birth. You can use the following details to send your complaint to us:
  Patient Experience – Formal Complaint
  Bradford Teaching Hospitals
  Duckworth Lane
  Bradford
  BD9 6RJ

  Email: patient.experience@bthft.nhs.uk

18. What do I do now?

Thank you for taking the time to consider the project and for reading this information. If you decide that you would like to take part, you will be given this information sheet to keep and asked to sign a consent form.

Once you consent to the study, the research nurse will assess your eligibility for participation.

19. Who do I contact for information or advice?

If you would like further information, please contact:

Dr Justine Tomlinson

Assistant Professor in Medical Education

University of Bradford

Richmond Rd

Bradford

BD7 1DP

Tel: +44 (0) 1274 232381

Email: j.e.c.tomlinson@bradford.ac.uk

Thank you for reading this information sheet.

Appendix 2: Participant Information Sheet-Hospital staff

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Information sheet for staff

1. Invitation to take part in the 'My Medicines Journey' research project

As part of the project on medicines management for people living with one or more long-term conditions, including frailty, we at Bradford Teaching Hospitals NHS Trust, would like to collect some information from professionals on their experiences of delivering the 'My Medicines Journey' and medicines management for older people living frailty and other long-term conditions. Before you decide on whether to take part in the project, we would like you to know why the research is being done and what would happen if you were to take part.

2. Who has reviewed and approved this project?

The project has been reviewed by an independent Research Ethics Committee, which safeguards the rights, safety, dignity and well-being of people participating in research.

3. What is the project about?

This project is funded by the National Institute for Health Research. The 'My Medicines Journey' project aims to test the feasibility of an intervention developed to improve medicines management for older people living with frailty and one or more long-term conditions. This toolkit called 'My Medicines Journey', is started by the hospital pharmacy team when the patient is admitted to the hospital and continues after the patient returns home with the community pharmacy-led Discharge Medicine Service (DMS). It includes a patient information resource and video, medicines support reviews, self-management planning and patient-held checklists.

4. Why have I been asked to participate in this research?

We are seeking to understand professionals' experiences of delivering the intervention to assess barriers and facilitators to implementation, the readability and face validity of the questionnaires, and collect data for health economic modelling.

5. What are the potential benefits of taking part?

Your involvement has the potential to enhance medicines management for people living with frailty and other long-term conditions.

6. What might be the risk of taking part?

We are not aware of any risks.

7. What would happen if I chose not to take part?

Participation in any aspect of the study is voluntary. You can choose not to take part at any stage of the project.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

8. What would happen if I agreed to take part?

- You would deliver the 'My Medicines Journey' intervention.
- We would ask you to complete questionnaires lasting approximately 20 minutes.
- We may observe you delivering the intervention.
- We will collect information about delivering the intervention for people living with frailty living in the community and their family carers in an interview lasting approximately 30-40 minutes.
- The interview with the research team will be audio-recorded.

9. Confidentiality, pseudonymity and anonymity

Personal data, such as your name and contact details, will be kept separate from the information we collect. Your pseudonymity will be maintained by being assigned an ID number, which will be used throughout the analysis. You will not be identified in any reports or academic papers from the work.

All information collected during the project will be made anonymous and kept strictly confidential to the research team and regulatory authorities. The interviews and their transcripts will be stored securely to enable researchers to continue the analysis of the project data. All information collected will be stored securely to enable researchers to continue analysis of the project data in future projects. Should you take part in an interview, your interview will be recorded via an audio device. The audio file will be transcribed by the research team, and a transcript of the interview created. Direct quotes from audio-recorded interviews for use in reports, presentations, and academic papers used with your consent will be anonymised. In addition, the information collected during the study may be used in an anonymous form to support other research publications in the future, and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. To enable this use, anonymised data will be added to an online Research Data Repository and accessible to the public after the study.

10. How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Initials
- Name
- Contact details
- Job role

People will use this information to do the research or to check records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

11. What are your choices about how your information is used?

- You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

12. Where can you find out more about how your information is used?

- You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or https://www.bradfordhospitals.nhs.uk/privacy-statement/.
- by asking one of the research team
- You can, if you so wish, contact by sending an email to the Trust Data Protection Officer (DPO) at dataprotectionofficer@bthft.nhs.uk or the Information Governance team at Information.Governance@bthft.nhs.uk.

13. What will happen to the results of the research project?

When the project has been completed (approximately 2 years), the results will be presented at meetings and published in health and social care journals. No individual will be identified in any publication or meeting.

14. How can I find out about the results of the study?

The researcher will be happy to provide you with a summary of the approved research findings and can also provide a full research report via email.

15. What will happen if I don't want to carry on with the project?

You can withdraw from the project at any time. If you wish to withdraw from the project, we will use the information collected up to the time of your withdrawal unless your express wish is for that information to be destroyed.

16. What if there is a problem?

If you are concerned or wish to know more or make a complaint about any aspect of this project, please contact Dr Justine Tomlinson on Tel: +44 (0) 1274 23238, email: j.e.c.tomlinson@bradford.ac.uk.

17. How to complain

We understand that people only make formal complaints when they feel there are no other options available to them. Therefore, if you are unsure whether you want to submit a formal complaint, please contact our Patient Experience team on 01274 364810, and they will be able to advise and assist you. Formal complaints should (where possible) be made to us in

writing. We would recommend that you use our downloadable complaint form (doc) (go to www.bradfordhospitals.nhs.uk/patients-and-visitors/compliments-concerns-complaints/ as it sets out all the information that we need to investigate your complaint. If you are unable to access the form or do not want to use it, you can write to us directly by letter or email. You will need to provide details of your complaint, the department involved, yours and the patient's contact details (if not you), including their date of birth. You can use the following details to send your complaint to us:

Patient Experience – Formal Complaint
Bradford Teaching Hospitals
Duckworth Lane
Bradford
BD9 6RJ

Email: patient.experience@bthft.nhs.uk

18. What do I do now?

Thank you for taking the time to consider the project and for reading this information. If you decide that you would like to take part, you will be given this information sheet to keep and asked to sign a consent form.

If you wish to know more about the project, please contact Dr Justine Tomlinson at Tel +44 (0) 1274 23238 or email j.e.c.tomlinson@bradford.ac.uk.

Thank you for reading this information sheet.

Appendix 3. Participant Information Sheet-Hospital staff [Staff Observations]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Information Sheet for Hospital Staff [Staff Observations]

1. Invitation to take part in the 'My Medicines Journey' research project

We invite you to take part in a research study. Before you decide whether or not you would like to participate, it is important that you understand why the research is being carried out and what will be involved if you decide to participate. The following information explains the purpose of the study and other relevant information. Please take time to read it carefully and discuss it with others if you wish. If there is anything unclear, please do not hesitate to ask.

2. Who is conducting the research?

The research is being conducted by Bradford Teaching Hospitals NHS Trust (BTHFT) and the University of Bradford.

3. Who has reviewed and approved this project?

The project has been reviewed by an NHS Research Ethics Committee (**REC Reference Number**), which safeguards the rights, safety, dignity and well-being of people participating in research.

4. What is the project about?

This project is funded by the National Institute for Health Research. The 'My Medicines Journey' project is testing the feasibility of an intervention to improve medicines management for older people living with frailty and one or more long-term conditions. This toolkit called 'My Medicines Journey', is started by the hospital pharmacy team when the patient is admitted to the hospital and continues after the patient returns home with the community pharmacy-led Discharge Medicine Service (DMS). It includes a patient information resource and video, medicines support reviews, self-management planning and patient-held checklists.

5. Why have I been asked to participate in this research?

We seek to understand professionals' experiences of delivering the intervention, assess barriers and facilitators to implementation, and assess the readability and face validity of the questionnaires. We will also collect data for health economic modelling. You have been invited to take part in this study as you carry out one or more aspects of medicine management as part of your everyday role, and you will deliver part of the intervention on the ward.

6. What will be involved if I take part?

If you consent to take part, you will be shadowed while you are conducting tasks relating to your interaction with patients and colleagues in managing medicines. This may include direct and indirect care, medication tasks using the 'My Medicines Journey toolkit', documentation, and professional communication. During the observation, the researcher will take notes. There are no audio or video recordings. The researcher will ensure that the shadowing does

not inappropriately affect patient care. Throughout the research, you may be observed in contact with patients. If this is the case, it is important that patients understand and are comfortable with the researcher's presence. You will be expected to explain to patients that you are being observed as part of a research study using the script provided below.

*"This is [**researcher name**]. He/she is a researcher observing me carrying out my practice. It is part of a research study to understand how medicines are managed. He/she is observing healthcare professionals and the processes and procedures they use, but he/she is not observing patients. You can choose for him/her not to be present, and this will not affect the care you receive. "Would you be willing to allow **[researcher name]** to observe me whilst I treat you? If at any point you would like him/her to leave please let me know."*

Any overheard/ observed confidential patient information will not be recorded or collected whilst the observations are taking place.

7. Do I have to take part?

No. You can decide whether or not to take part. If, however, you do decide to take part but then change your mind, you are free to withdraw at any time without giving a reason.

8. What happens to the information gathered during the study?

Your identity and any personal information that may be required to communicate with you will be completely confidential and known only to the research team. No record of actual names and locations will be kept. The information obtained will remain confidential and stored within a locked cabinet. The Data are held in accordance with the UK Data Protection Act, which means that it is stored safely and cannot be revealed to other people without your permission. You will also not be identified in any report or publication. In addition, the information collected during the observation may be used in an anonymous form to support other research publications in the future, and access to it in this form will not be restricted. It will not be possible for you to be identified from this data. To enable this use, anonymised data will be added to an online Research Data Repository and accessible to the public after the study.

9. How will we use information about you?

We will need to use information from you for this research project.

This information will include your

- Name
- Contact details
- Job role

People will use this information to do the research or to check records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

10. What are your choices about how your information is used?

- You can stop being part of the study at any time without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

11. Where can you find out more about how your information is used?

- You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or https://www.bradfordhospitals.nhs.uk/privacy-statement/.
- by asking one of the research team
- You can, if you so wish, contact by sending an email to the Trust Data Protection Officer (DPO) at dataprotectionofficer@bthft.nhs.uk or the Information Governance team at Information.Governance@bthft.nhs.uk.

12. What are the potential benefits of taking part?

Your involvement has the potential to improve medicines management for people living with frailty and other long-term conditions and ultimately improve patient safety.

13. What are the potential risks?

We are observing routine care, and the clinical risks are minimal. However, it is possible that we will observe inappropriate care, which might only be identified during later analysis. During this analysis, the data will already be anonymised. The data collected is not being shared with service or hospital managers. The observer is not a healthcare professional and will not interrupt your practice in any way. If the observer notices any safeguarding issues, then this will be brought to the attention of the ward manager.

14. What will happen to the results of the research project?

When the project has been completed (approximately 2 years), the results will be presented at meetings and published in health and social care journals. No individual will be identified in any publication or meeting.

15. How can I find out about the results of the study?

The research team will be happy to email you a summary of the approved research findings and a full research report.

16. What if there is a problem?

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

If you are concerned, wish to know more, or make a complaint about any aspect of this project, please contact **Dr Justine Tomlinson** at Tel: +44 (0) 1274 23238 or email: j.e.c.tomlinson@bradford.ac.uk.

Thank you for reading this information sheet.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Appendix 4: Consent Form: Older people [INTERVENTION SITES]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Consent Form: Older People

Participant Eligibility confirmed:……..

Study site:……
Participant Identifier:……...

Name of the Researcher:…….

If you agree, please initial box

1. I confirm that I have read the information sheet dated..... (Version.....) for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my involvement includes: ▪ being provided with the 'My Medicines Journey' intervention ▪ completing 2 questionnaires about my medicines management ▪ the research team collecting information from medical records and relevant professionals about my health ▪ potentially taking part in an interview ▪ Being audio-recorded during interviews	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. I understand that if I withdraw from the study, any data already collected about me will still be used for the study unless I specifically withdraw my consent for this.	
4. I understand that data collected during the project may be looked at by individuals from the research team, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access.	
5. I understand that information about me and my medical records relevant to the research will be used to undertake this study. I agree to the research team having access to routine data held about me.	
6. I understand that if the researcher hears or observes anything that causes serious concern about my health and safety or well-being, they have the duty to contact my GP.	
7. I understand that the information I give will be stored with an ID number and not my name.	
8. I understand that the information collected about me will be used to support future research publications, reports or presentations and may be shared anonymously with other researchers.	
9. I understand that my anonymised data may be included in a dataset to be archived in an online Research Data Repository.	
10. I agree to take part in the above project**.**	
11. I give my permission for the use of direct quotes.	

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Name of Participant	Date	Signature
……..……	……	……..
Name of Person taking consent	Date	Signature
……	……	……...

Once completed, one copy given to the participant and one copy to keep in the researcher file.

Consent Form: Older people [CONTROL SITE]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Participant Eligibility confirmed:……..

Study site:……
Participant Identifier:……...

Name of the Researcher:……

	If you agree, please initial box
1. I confirm that I have read the information sheet dated..... (Version.....) for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my involvement includes: ▪ completing 2 questionnaires about my medicines management ▪ the research team collecting information from medical records and relevant professionals about my health	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. I understand that if I withdraw from the study, any data already collected about me will still be used for the study unless I specifically withdraw my consent for this.	
4. I understand that data collected during the project may be looked at by individuals from the research team, regulatory authorities or the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access.	
5. I understand that information about me and my medical records relevant to the research will be used to undertake this study. I agree to the research team having access to routine data held about me.	
6. I understand that if the researcher hears or observes anything that causes serious concern about my health and safety or well-being, they have the duty to contact my GP.	
7. I understand that the information I give will be stored with an ID number and not my name.	
8. I understand that the information collected about me will be used to support future research publications, reports or presentations and may be shared anonymously with other researchers.	
9. I understand that my anonymised data may be included in a dataset to be archived in an online Research Data Repository.	

10. I agree to take part in the above project.	

Name of Participant Date Signature

……...…… ……. ……..

Name of Person taking consent Date Signature

…… ……. ……...

Once completed, one copy given to the participant and one copy to keep in the researcher file.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Baseline characteristics data collection form [ALL SITES]

About you Site ID: Participant ID:

Name:_____

Date of Birth: _____

NHS number: _____

Gender: ☐ Male ☐ Female

Ethnicity:

Your contact details:

Home address:

_____

_____

Postcode: _____

Contact email address (if you have one): _____

Home phone number: _____

Mobile number (if you have one): _____

GP name: _____

GP surgery: _____

Which community pharmacy do you usually use for you prescriptions?

_____

To be completed by research staff:

Additional support requirements e.g. visual/ hearing impairment, non-English speaker:

_____

_____

Date of discharge:

Number/ name of medicines at discharge documented on discharge paperwork:

Medical conditions as documented on discharge paperwork:

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Appendix 5: Consent form: Hospital staff [Interviews]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Consent Form: Hospital Staff [Interviews]

Participant Eligibility confirmed:……..
Study site:……
Participant Identifier:……...

Name of the Researcher:…….

If you agree, please initial box

1. I confirm that I have read the information sheet dated..... (Version.....) for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my involvement includes: ▪ Delivering the intervention ▪ Completing a questionnaire ▪ Taking part in an individual interview ▪ Being audio-recorded	
3. I understand that my participation is voluntary and that I can withdraw anytime without giving any reason or my legal rights being affected. I understand that if I withdraw from the study any data already collected about me will still be used for the study unless I specifically withdraw my consent for this.	
4. I understand that some of the project information collected may be looked at by authorised and responsible personnel from regulatory authorities or the NHS Trust to ensure that the project is being conducted properly.	
5. I agree that the information I give will be pseudonymised (given an ID number) and stored in a secure location.	
6. I understand that the information collected about me will be used to support future research publications, reports or presentations and may be shared anonymously with other researchers.	
7. I understand that my anonymised data may be included in a dataset to be archived in an online Research Data Repository.	
8. I agree to take part in the above project.	
9. I give my permission for the use of direct quotes.	

Name of Participant	Date	Signature
……..……	…….	……..
Name of Person taking consent	**Date**	**Signature**
……	…….	……..

Once completed, one copy given to the participant and one copy to keep in the researcher file.

Appendix 6: Consent form: Hospital staff [Observations]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Consent Form: Hospital Staff [Observations]

Participant Eligibility confirmed:……..

Study site:……
Participant Identifier:……...

Name of the Researcher:…….

If you agree, please initial box

1. I confirm that I have read the information sheet dated..... (Version.....) for the above project. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my involvement includes: ▪ Delivering the 'My Medicines Journey' intervention ▪ Administering 2 questionnaires about patient medicines management ▪ Being observed in contact with patients	
3. I understand that I must explain to patients and/or their relatives, where appropriate, that I am being observed as part of a research study. I will use the script provided and emphasise to the patient that they can choose not to be observed.	
4. I understand that my participation is voluntary and that I can withdraw anytime without giving any reason.	
5. I understand that the information collected from this study will be anonymised, confidential and kept securely.	
6. I understand that the data collected during the study may be looked at by relevant people from the regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access.	
7. I agree to take part in the above project.	

Name of Participant Date Signature

……..…… ……. ……..

Name of Person taking consent Date Signature

…… ……. ……...

Once completed, one copy given to the participant and one copy to keep in the researcher file.

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Appendix 7: Ward Manager Notification Letter

[Hospital headed paper]

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: A multi-methods evaluation (MY MEDICINES JOURNEY Study)

Dear Senior Sister/Senior Charge Nurse_____

Notification of ward-level observation for the MY MEDICINES JOURNEY Study

The research team for this study will conduct staff observations on your ward(s) as part of a feasibility study to assess the implementation of a toolkit to support medicines management after hospital discharge. An NHS Research Ethics Committee has approved this study, and it is being supported by your hospital.

The study will assess the feasibility of an intervention to enhance medicines management following hospital discharge for older people living with frailty and one or more long-term conditions. In the context of medicines management, the observations will include: direct and indirect care, medication tasks, documentation, supervision, administrative responsibilities, and social tasks.

Staff members may withdraw from the observation or notify the researcher if they do not wish to be observed. We will give each staff member an information sheet and a consent form (copies of which are attached). Staff can withdraw from the study at any time without providing a reason.

If you require further details about this study, please do not hesitate to contact **Dr Justine Tomlinson** at Tel: +44 (0) 1274 23238 or email j.e.c.tomlinson@bradford.ac.uk.

Yours sincerely

_____

My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Appendix 8: Outcome measure booklet One

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UNIVERSITY of BRADFORD

Participant Questionnaire

Follow-up Questionnaire 1

FOLLOW UP 1. FOR OFFICE USE ONLY

Study ID:

Date sent: __ __/__ __/__ __ __ __

This questionnaire has been sent to you as someone who had a recent hospital stay and who agreed to help with this research. Thank you for taking part.

By completing this questionnaire, you will help us improve the medicines management experiences of people aged 75 and over as they return home from hospital.

There are 4 sections to this questionnaire. Please answer all the questions as best you can. Although some of the questions may not seem relevant or appear similar, they all provide valuable information. All of your information is stored confidentially.

If you have any difficulty, ask a friend or relative to help, or contact us between 9am - 5pm (Mon to Fri). Tel: xxxxx Email: xxxxx

Thank you.

Dr Justine Tomlinson

Chief Investigator

Dr Adam Nyende

Research Fellow

Section 1: About your experience of your hospital stay

Instructions: These statements ask about the care you received, related to medicines, during your hospital stay and as you prepared to go home. Read each statement. Then, mark your level of agreement: strongly agree, agree, unsure, disagree or strongly disagree.

These statements are about the time you were in hospital

1. I received clear written and verbal information about my medicines. It included: why I am taking them, when to take them, side effects to watch for, and whether I need any follow-up tests.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
◯	◯	◯	◯	◯

2. I was able to talk about my medicines at appropriate times for me (e.g. outside of mealtimes, when I felt comfortable).

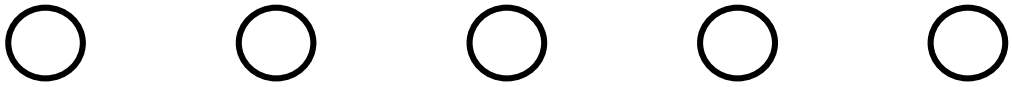
Strongly agree	Agree	Not sure	Disagree	Strongly disagree
◯	◯	◯	◯	◯

3. During my hospital stay I felt listened to and understood in conversations about my medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
◯	◯	◯	◯	◯

4. The people who matter to me were involved in discussions and decisions about my medicines if I wanted.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree



5. Hospital staff kept me up to date and involved me in decisions about changes to my medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

6. I am satisfied with the level of contact I had with my healthcare team (e.g. doctors, nurses and pharmacy team) about my medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

7. There were chances to discuss how I will take my medicines at home. I could also share any challenges and support I may need.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

8. I felt supported and reassured with my medicines and any concerns that I had.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

9. I could share my thoughts and concerns about my medicines with my healthcare team (e.g. doctors, nurses, and pharmacy staff).

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

10. I was able to stick to my medicine routine while in the hospital, and if I wasn't able to, the staff discussed it with me.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

These statements are about when you were preparing to leave the hospital

11. I was satisfied with the time it took to prepare my medicines to take home.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

12. I felt that my medicines needs were catered for when I was preparing to leave the hospital.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

13. I was given clear information on who to contact for help with my medicines after I left the hospital.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

14. I felt prepared to take responsibility for my medicines when I was leaving the hospital.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

15. I understood any changes to my medicines, including:

- new medicines,
- stopped medicines, and
- changes in strength or dose.

I also knew what they meant for me.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

16. When I left the hospital, I had all the medicines I needed.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

17. I was told who was responsible for arranging supplies of medicines after I returned home.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

18. The hospital has, to my knowledge, told the community healthcare team (e.g. chemist, GP) about my changed medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

Did you receive a 'My Medicines Journey' booklet?

- Yes ○
- No ○
- Can't remember ○

If 'yes' when did you use this?

- In hospital ○
- At home ○
- Not at all ○
- Can't remember ○

If you received the booklet, how useful did you find it?

Very useful ◯

Quite useful ◯

Not useful ◯

After reading the 'My Medicines Journey' booklet, did you contact any of your healthcare team for support or with questions about your medicines? If so, which ones?

Please tick all that apply:

GP ◯

Pharmacist ◯

Hospital ◯

Other (please write in) ◯ _____

Section 2: About your medicines

Instructions: These next statements ask about any issues with your medicines since you got home from the hospital. Read each statement. Mark if you have always, sometimes, or never experienced that problem in the last 2 weeks.

1. I have problems getting the medicines I need.

Never ◯ Sometimes ◯ Always ◯

2. I struggle to organise my medicines at home.

Never ○ Sometimes ○ Always ○

3. I am not sure how to store my medicines.

Never ○ Sometimes ○ Always ○

4. I am not sure how to get rid of unwanted medicines.

Never ○ Sometimes ○ Always ○

5. I struggle to physically take my medicines (e.g. swallowing or injecting them).

Never ○ Sometimes ○ Always ○

6. I forget to take my medicines.

Never ○ Sometimes ○ Always ○

7. I have problems planning when to take my medicines.

Never ○ Sometimes ○ Always ○

8. I do not know if my medicines are working.

Never Sometimes Always

9. I am not happy with how my medicines affect me.

Never Sometimes Always

10. I worry that taking medicines for a long time may cause future side effects.

Never Sometimes Always

11. I do not know if my medicines work well together.

Never Sometimes Always

12. Different healthcare professionals tell me different things about my medicines.

Never Sometimes Always

13. I do not understand the information I have been given about my medicines (e.g., discharge paperwork/packaging inserts).

Never Sometimes Always

14. I am confused about which medicines I should be taking.

Never ○ Sometimes ○ Always ○

15. I struggle to re-order my medicines.

Never ○ Sometimes ○ Always ○

16. Thinking about the last 2 weeks, how much time have **you** spent managing your medicines on an average day?

____ hours.

Section 3: About taking your medicines

- Many people find a way of using their medicines which suits them.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you use your medicines.

Here are some ways people have said they use their medicines.

Instructions: For each of the statements, please tick the box which best applies to you.

Your own way of using your medicines	Always	Often	Sometimes	Rarely	Never

I forget to take them					
I alter the dose					
I stop taking them for a while					
I decide to miss out a dose					
I take less than instructed					

MARS_5 2018 Medication Adherence Report Scale (MARS_5)

Instructions: These questions are about your confidence in taking your medicines. Read each statement. Then, mark your confidence in taking your medicines over the last two weeks. Choose: not confident, somewhat confident, or very confident.

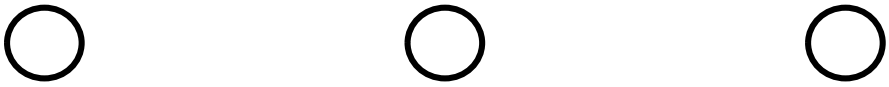
How confident are you that you can take your medicines correctly:

1. When you take several different medicines each day.

Not confident ○ Somewhat confident ○ Very confident ○

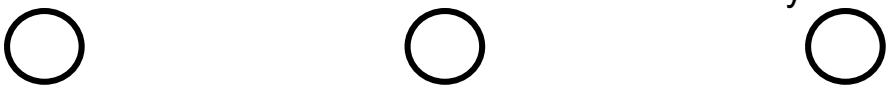
2. When you take medicines more than once a day.

Not confident Somewhat confident Very confident



3. When you are away from home.

Not confident Somewhat confident Very confident



4. When you have a busy day planned.

Not confident Somewhat confident Very confident

5. When they cause some side effects.

Not confident Somewhat confident Very confident

6. When no one reminds you to take the medicine.

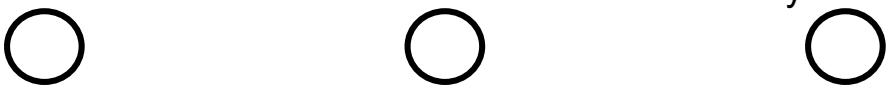
Not confident Somewhat confident Very confident

7. When the schedule to take the medicine is not convenient.

Not confident Somewhat confident Very confident

8. When your normal routine gets messed up.

Not confident Somewhat confident Very confident



9. When you are not sure how to take the medicine.

Not confident ○ Somewhat confident ○ Very confident ○

10. When you are not sure what time of day to take your medicine.

Not confident ○ Somewhat confident ○ Very confident ○

11. When you are feeling sick (you know, like having a cold or the flu).

Not confident ○ Somewhat confident ○ Very confident ○

12. When you get a repeat prescription of your medicines and some of the pills look different than usual.

Not confident ○ Somewhat confident ○ Very confident ○

13. When a doctor changes your medicines.

Not confident ○ Somewhat confident ○ Very confident ○

SEAMS scale © Jessica Risser

Section 4: About your health

Instructions: Please record whether you have used the following services in the last 2 weeks, and the number of times you have accessed the service.

In the community

Primary Care appointments	Tick if Yes	Tick if No	If yes, what is the total number of appointments
With General Practitioner (GP) in surgery			_____Appointments
With General Practitioner (GP) on phone or virtual			_____Appointments
With General Practitioner (GP), home visit			_____Appointments
With a pharmacist at your GP practice on phone or virtual			_____Appointments
With a pharmacist at your GP practice in surgery			_____Appointments
With Practice Nurse in surgery			_____Appointments
With Practice Nurse, home visit			_____Appointments
With Practice Nurse on phone or virtual			_____Appointments
With Community Pharmacist in pharmacy/ chemist			_____Appointments
With Community Pharmacist on phone or virtual			_____Appointments
With occupational therapist			_____Appointments

With physiotherapist			_____Appointments
With Social Prescriber			_____Appointments
With a community support group e.g. AgeUK			_____Appointments
Other, e.g., District nurse, Dietician, (please state who was seen and where)			_____Appointments

Hospital

Type of Service	Tick if Yes	Tick if No	If yes, what is the total number of days/attendances
Hospital Inpatient stay (more than 24 hours, or with an overnight stay)			_____Nights
If **YES** please state type of ward/speciality (e.g. respiratory, medical admissions unit, oncology)			
A&E attendances			_____Attendances
Hospital outpatient clinic appointments	**Tick if Yes**	**Tick if No**	**If yes, what is the total number of appointments**
With Hospital consultant/doctor			_____Appointments
With Specialist Nurse			_____Appointments
With Hospital Pharmacist			_____Appointments
With Occupational Therapist			_____Appointments
Other			_____Appointments

If other, please state who was seen (e.g. dietician)			

Support from family, friends or other informal carers

When answering this question please think **within the last 2 weeks**

Have you received help or support with your medicines from family or friends? If yes, how much time do they spend helping you with your medicines on an average day?	Yes ◯ No ◯ ___hours
Did they take any time off work to help or support you? If yes, how much time in total did they take off?	Yes ◯ No ◯ ___days ___hours

Instructions: 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)

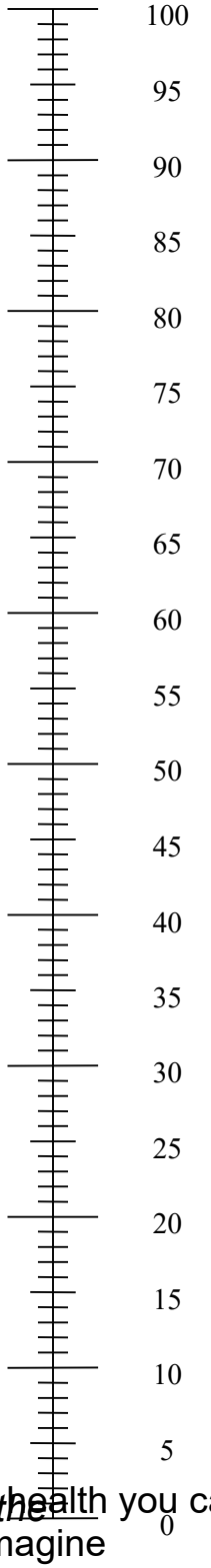
I have no problems doing my usual activities ❑
I have slight problems doing my usual activities ❑
I have moderate problems doing my usual activities ❑
I have severe problems doing my usual activities ❑
I am unable to do my usual activities ❑

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.

YOUR HEALTH TODAY = ☐

100 means the best health you can imagine.

0 means the worst health you can imagine.

Please mark an X on the scale to indicate how your health is TODAY.

Now, write the number you marked on the scale in the box below.

Date this questionnaire was completed: __ __ / __ __ /__ __ __ __

Did anyone help you complete this questionnaire?

Yes ☐

No ☐

If yes, how were you helped? (Please tick all that apply)

Someone read out the questions ☐

Someone translated the questions (if English is not your first language) ☐

Someone discussed the questions with you ☐

Someone marked the answers for you ☐

The whole questionnaire was completed on the patient's behalf without consulting them ☐

Other, please specify ……

On behalf of the research team: thank you!

You have now completed the questionnaire.

Please:

Check that you have answered all the questions

Return the completed questionnaire in the enclosed envelope

Thank you

FUNDED BY NIHR | National Institute for Health and Care Research

UNIVERSITY of BRADFORD

Participant Questionnaire

Follow-up Questionnaire 2

FOLLOW UP 2. FOR OFFICE USE ONLY

Study ID:

Date sent: __ __/__ __/__ __ __ __

This questionnaire has been sent to you as someone who had a recent hospital stay and who agreed to help with this research. Thank you for taking part.

By completing this questionnaire, you will help us improve the medicines management experiences of people aged 75 and over as they return home from hospital.

There are 4 sections to this questionnaire. Please answer all the questions as best you can. Although some of the questions may not seem relevant or appear similar, they all provide valuable information. All your information is stored confidentially.

If you have any difficulty, ask a friend or relative to help, or contact us between 9am - 5pm (Mon to Fri). Tel: xxxxx Email: xxxxx

Thank you.

Dr Justine Tomlinson

Chief Investigator

Dr Adam Nyende

Research Fellow

Section 1: About your medicines management experience at home

Instructions: These statements ask about the care you received, related to medicines, at home following your hospital stay. Read each statement. Then, mark your level of agreement: strongly agree, agree, unsure, disagree or strongly disagree.

1. I have received advice and support that has enabled me to continue to look after my medicines at home.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

2. To my knowledge, the hospital's changes to my medicines have been acted upon by my community healthcare team (e.g. GP, chemist).

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

3. Since returning home from the hospital, it has been easy for me to adjust to any medicines changes.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

4. I have been given consistent information about my medicines by all healthcare providers (e.g. hospital, GP, nurse, chemist).

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

5. I am kept up to date and involved in decisions relating to changes to my medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

6. The people who matter to me are involved in discussions and decisions about my medicines if I want them to be.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

7. My community healthcare team (e.g. GP, chemist, nurse) considers my needs and preferences with my medicines.

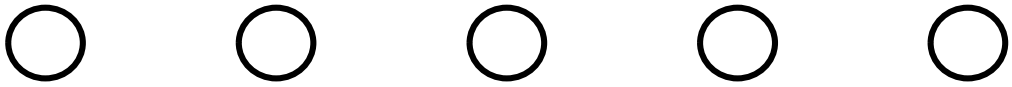
Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

8. I know who I can contact for information about my medicines, and I feel that I can approach them.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

9. I am satisfied with the level of contact I have with my community healthcare team (e.g. GP, chemist, nurse) about my medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree



10. In talks about my medicines with my community healthcare team (e.g. GP, chemist, nurse), I feel listened to and understood.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

11. Someone has dealt with my concerns and questions about my medicines.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

12. I know how my medicines affect me and am aware of any actions I need to take.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

13. I am able to order the medicines that I need and can access them from the pharmacy or the hospital.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

14. I feel supported by my family and friends or my social care team (e.g. carers) to manage my medicines at home if I want them to.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

15. I feel confident managing my medicines and need no further support.

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
○	○	○	○	○

Section 2: About your medicines

Instructions: These next statements ask about any issues with your medicines. Read each statement. Mark if you have always, sometimes, or never experienced that problem in the last 2 weeks.

2. I have problems getting the medicines I need.

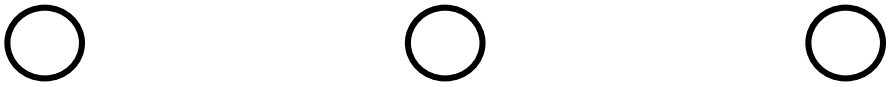
Never	Sometimes	Always
○	○	○

3. I struggle to organise my medicines at home.

Never	Sometimes	Always
○	○	○

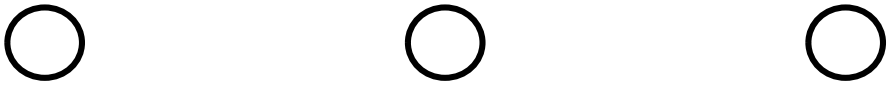
4. I am not sure how to store my medicines.

Never	Sometimes	Always



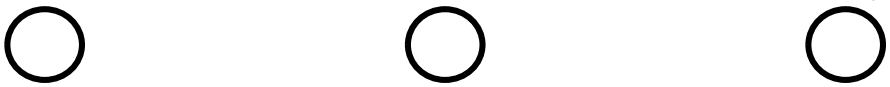
5. I am not sure how to get rid of unwanted medicines.

Never Sometimes Always



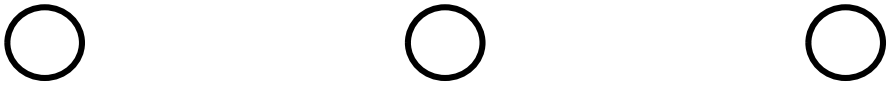
6. I struggle to physically take my medicines (e.g. swallowing or injecting them).

Never Sometimes Always



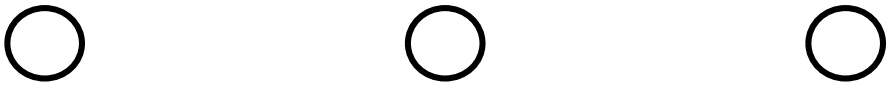
7. I forget to take my medicines.

Never Sometimes Always



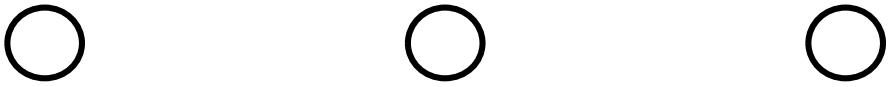
8. I have problems planning when to take my medicines.

Never Sometimes Always



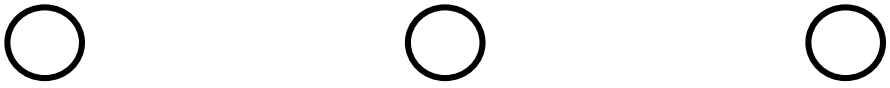
9. I do not know if my medicines are working.

Never Sometimes Always



10. I am not happy with how my medicines affect me.

Never Sometimes Always



11. I worry that taking medicines for a long time may cause future side effects.

Never ○ Sometimes ○ Always ○

12. I do not know if my medicines work well together.

Never ○ Sometimes ○ Always ○

13. Different healthcare professionals tell me different things about my medicines.

Never ○ Sometimes ○ Always ○

14. I do not understand the information I have been given about my medicines (e.g., discharge paperwork/packaging inserts).

Never ○ Sometimes ○ Always ○

15. I am confused about which medicines I should be taking.

Never ○ Sometimes ○ Always ○

17. I struggle to re-order my medicines.

Never ○ Sometimes ○ Always ○

18. Thinking about the last 2 weeks, how much time have **you** spent managing your medicines on an average day?

____ hours

Section 3: About taking your medicines

- Many people find a way of using their medicines which suits them.
- This may differ from the instructions on the label or from what their doctor has said.
- We would like to ask you a few questions about how you use your medicines.

Here are some ways people have said they use their medicines.

Instructions: For each of the statements, please tick the box which best applies to you.

Your own way of using your medicines	**Always**	**Often**	**Sometimes**	**Rarely**	**Never**
I forget to take them					
I alter the dose					
I stop taking them for a while					

I decide to miss out a dose					
I take less than instructed					

MARS_5 2018 Medication Adherence Report Scale (MARS_5)

Instructions: These questions are about your confidence in taking your medicines. Read each statement. Then, mark your confidence in taking your medicines over the last two weeks. Choose: not confident, somewhat confident, or very confident.

How confident are you that you can take your medicines correctly:

14. When you take several different medicines each day.

Not confident ○ Somewhat confident ○ Very confident ○

15. When you take medicines more than once a day.

Not confident ○ Somewhat confident ○ Very confident ○

16. When you are away from home.

Not confident ○ Somewhat confident ○ Very confident ○

17. When you have a busy day planned.

Not confident ○ Somewhat confident ○ Very confident ○

18. When they cause some side effects.

Not confident ○ Somewhat confident ○ Very confident ○

19. When no one reminds you to take the medicine.

Not confident ○ Somewhat confident ○ Very confident ○

20. When the schedule to take the medicine is not convenient.

Not confident ○ Somewhat confident ○ Very confident ○

21. When your normal routine gets messed up.

Not confident ○ Somewhat confident ○ Very confident ○

22. When you are not sure how to take the medicine.

Not confident ○ Somewhat confident ○ Very confident ○

23. When you are not sure what time of day to take your medicine.

Not confident ○ Somewhat confident ○ Very confident ○

24. When you are feeling sick (you know, like having a cold or the flu).

Not confident ○ Somewhat confident ○ Very confident ○

25. When you get a repeat prescription of your medicines and some of the pills look different than usual.

Not confident	Somewhat confident	Very confident
◯	◯	◯

26. When a doctor changes your medicines.

Not confident	Somewhat confident	Very confident
◯	◯	◯

SEAMS scale © Jessica Risser

Section 4: About your health

Instructions: Please record whether you have used the following services since the last questionnaire you completed on _ _/ _ _/ _ _. Also please note the number of times you have accessed the service.

In the community

Primary Care appointments	Tick if Yes	Tick if No	If yes, what is the total number of appointments
With General Practitioner (GP) in surgery			_____Appointments
With General Practitioner (GP) on phone or virtual			_____Appointments
With General Practitioner (GP), home visit			_____Appointments
With a pharmacist at your GP practice on phone or virtual			_____Appointments

With a pharmacist at your GP practice in surgery			_____Appointments
With Practice Nurse in surgery			_____Appointments
With Practice Nurse, home visit			_____Appointments
With Practice Nurse on phone or virtual			_____Appointments
With Community Pharmacist in pharmacy/ chemist			_____Appointments
With Community Pharmacist on phone or virtual			_____Appointments
With occupational therapist			_____Appointments
With physiotherapist			_____Appointments
With Social Prescriber			_____Appointments
With a community support group e.g. AgeUK			_____Appointments
Other, e.g., District nurse, Dietician, (please state who was seen and where)			_____Appointments

Hospital

Type of Service	Tick if Yes	Tick if No	If yes, what is the total number of days/attendances
Hospital Inpatient stay (more than 24 hours, or with an overnight stay)			_____Nights
If **YES** please state type of ward/speciality (e.g.			

respiratory, medical admissions unit, oncology)			
A&E attendances			_____Attendances
Hospital outpatient clinic appointments	Tick if Yes	Tick if No	If yes, what is the total number of appointments
With Hospital consultant/doctor			_____Appointments
With Specialist Nurse			_____Appointments
With Hospital Pharmacist			_____Appointments
With Occupational Therapist			_____Appointments
Other			_____Appointments
If other, please state who was seen (e.g. dietician)			

Support from family, friends or other informal carers

When answering this question please think **within the last 2 weeks**

Have you received help or support with your medicines from family or friends? If yes, how much time do they spend helping you with your medicines on an average day?	Yes ◯ No ◯ ___hours
Did they take any time off work to help or support you? If yes, how much time in total did they take off?	Yes ◯ No ◯ ___days ___hours

Instructions: 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

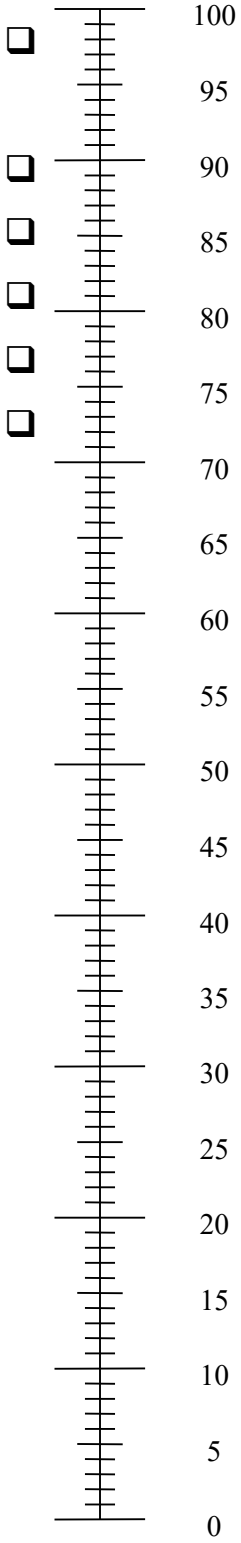
I am not anxious or depressed

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 best health you can imagine.

0 means the worst health you can imagine.

Please mark an X on the scale to indicate how your health is TODAY.

Now, write the number you marked on the scale in the box below.

Date this questionnaire was completed: __ __ / __ __ /__ __ __ __

Did anyone help you complete this questionnaire?

Yes ☐

No ☐

If **YOUR HEALTH TODAY =** y☐ were you helped? (Please tick all that apply)

Someone read out the questions ☐

Someone translated the questions (if English is not your first language) ☐

Someone discussed the questions with you ☐

Someone marked the answers for you ☐

The whole questionnaire was completed on the patient's behalf without consulting them ☐

Other, please specify …….

The worst health you can imagine

On behalf of the research team: thank you!

You have now completed the questionnaire.

Please:

 Check that you have answered all the questions

 Return the completed questionnaire in the enclosed envelope

Thank you.

Appendix 10: Interview topic guide-Older people

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Topic Guide: Older people

- Introduction, welcome and demographics (gender and age)

Orientation to medicine management

- What are some of the medicines that you are currently taking?
- How best do you manage these medicines?
- Do you have any current concerns about your medicines?
- What is the level of support you get from your formal and/or informal carers regarding medicine management? How does this make you feel?
- What are some of the challenges that you encounter when managing medicine after hospital stay? How does this make you feel?
- Do you think you are managing your medicines properly at home? If yes/no, why?
- What can be done to help you improve your medicine management at home?

Orientation to the Toolkit

- Have you ever heard of 'My Medicines Journey' Toolkit before? (Show us the toolkit to see how they are using it—what they've written/ticked boxes etc)
- Who gave you the toolkit and what did they tell you?
- Once at home how often did you use the toolkit?
  If they didn't use the toolkit- What was the main reason that you did not use the toolkit? Too difficult to understand? /Did not feel confident in completing it? /They did not know the answers? /Any other reason?
- Looking at the toolkit, are there any parts of the intervention you think older people may find difficult to understand?
- Would you have any questions/concerns about the toolkit?
- Are there any sections of the toolkit that you would prioritise when making decisions about your medicines management?
- What were your overall views of the toolkit? (easy to understand/ use or difficult) If so why?
- Is there anything in particular that you liked/disliked about the toolkit?
- Is there anything that is not in the toolkit that you would like to see added/ taken away?
- Did the toolkit contain information that you found useful? If so can you give examples?
- Did the toolkit contain any information that was not relevant to you? If so can you give examples?
- What do you think of the amount of information in the toolkit? Is it too long/short?
- How could the toolkit be improved? (Probe: design/ ease of use/ content)

Were you contacted by your community pharmacist after you left the hospital?

- Did the pharmacist offer to review your medicines? If so, did you find the review useful? In what way?
- Manage/ understand your medicines?
- Understand more about your medicines?

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Hoped for experience

- Thinking about your experience managing medicines, what would you hope the toolkit would do to help manage your medicines better?
- What would you be looking for as an indicator that a medicines management toolkit is helping you manage your medicines better?
- **Prompts:** What effect would the toolkit have to be useful for medicines management? Can you tell me more about that……?
- In an ideal world, what would a medicines management toolkit look and feel for you?

Ending

- Is there anything else you would like us to talk about today that we have not discussed?
- Thank you so much for your valuable time.

Appendix 11: Interview topic guide-Hospital Staff

Assessing the feasibility and implementation of the 'My Medicines Journey' intervention: a multi-methods evaluation

Topic Guide: Hospital Staff

Introduction, welcome and demographics (gender, age and role)

Orientation to service provision

- Discussion of the services provided to gain contextual information and focus
- **Prompts (**Can you tell me more about that?, What was it like for you?)
- From your experience, what is the process of managing medicines like for older people living with long-term conditions?
- How best do you support patients, especially older people, to manage their medicines?
- What is the healthcare system's level of support for older people to manage their medicines? How does this make you feel?
- What are the individual and system-wide challenges you encounter when supporting older people living with multiple conditions to manage their medicines? How does this make you feel?
- What can be done to support older people to manage their medicines better at home?

Orientation towards the tool kit

- Tell me how you used it. Which steps did you or didn't you engage with, and why?
- How did you fit it into your daily role? Was it manageable?
- From your experience delivering the intervention, are there any aspects useful to your work? Please tell me more…….
- Are there any aspects of the toolkit/intervention that you think need improving? If yes, what are these aspects?
- Are there any aspects or elements of current service provision that can benefit from or be enhanced by this intervention?
- Would you use it in the future?
- Would you have any concerns about the toolkit?
- Are there any sections of the toolkit that you would prioritise when making decisions about your work with patients?

Hoped for experience

- Thinking about your experience supporting older to manage their medication, what would you hope the toolkit would do to help older people do differently?
- Prompts: What effect would the toolkit have to be useful in your work?

Ending

- Is there anything else you want us to discuss today that we have not discussed?
- Thank you so much for your valuable time.

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Appendix 12: Hospital Staff Survey Questionnaire

My medicines Journey: Hospital staff survey

Background Information

What is your profession?

What is your job role?

How many years have you worked in your profession?

Section 1

We would like to understand how well the My Medicines Journey toolkit fits with the process (or flow) of medicine management that a typical patient will experience as they transition across care interfaces following discharge. We would like you to reflect on your experience using the toolkit to help a patient with a long-term condition further improve their medicines management.

Section 2

A. Thinking again about the toolkit, how many patients have you used it with?

B. Approximately how long did you spend working on the intervention with each participant?

C. Please indicate your level of agreement with each of the following statements:

	Strongly Disagree				Strongly Agree
1. I think the toolkit is easy to use	1	2	3	4	5
2. I find the various tasks within this toolkit well-integrated	1	2	3	4	5
3. Using this toolkit fits in well with my existing workload	1	2	3	4	5
4. I feel very confident using the toolkit	1	2	3	4	5
5. I found the toolkit to be unnecessarily complex	1	2	3	4	5
6. I think there is too much inconsistency in this toolkit	1	2	3	4	5
7. I find the toolkit very cumbersome to use	1	2	3	4	5
8. I think I would regularly need the support of colleagues to use this toolkit	1	2	3	4	5

9. I needed a lot of training and or support before I felt competent using the toolkit	1	2	3	4	5

Would you be willing to take part in an interview about your experiences? If yes, please contact **Dr Justine Tomlinson** at Tel: +44 (0) 1274 23238 or email j.e.c.tomlinson@bradford.ac.uk.

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Appendix 13: Hospital Staff Observation Checklist

My Medicines Journey: **Staff Observation Checklist**

Dimensions	Categories and Sub-categories	Task described
WHAT		
1.	**Direct care**	Tasks directly involved with patient care, e.g. direct communication with patient and/or family, support with taking medicines.
2.	**Indirect care**	All tasks indirectly related to patient care (e.g. reviewing medicines dosages, planning care)
3.	**Medication tasks**	• All medicine-related tasks including; preparation, administration, documentation, discussion and clarification. • **Find order** (Searching for medicine charts or medical records with drug order). • **Prescribe medicine** (Ordering a medicine (including discharge prescriptions and verbal orders) • **Electronic prescribing** (e.g. access to computers, looking at other electronic systems for information on medicines, transcribing from one system to another etc.) • **Transcribe order(s)** (Copying medicine orders from one medical chart to another) • **Prepare medicine** (All activity concerning medicine preparation and clean-up) • **Clarify** (Clarifying a drug order (with other people or other sources) • **Check medicine** (Checking and cosigning for a medicine given by another staff member) • **Administration** (Giving medicines to a patient) • **Chart** (Documenting medicine administration details) • **Discussion** (Talking about a medicine with a health professional, patient, or relative)

		• **Review** (Looking over medicine orders as part of planning care)
4.	**Documentation**	• Medicine documentation (paper and electronic). • Writing discharge summaries (using an electronic discharge summary system)
5.	**Professional communication**	All medicine-related communication with other health professionals, including ward and patient handovers.
7.	**In transit**	Time between tasks and between patients.
8.	**Supervision**	Supervising others, including students
9.	**Administrative**	Any administrative activity related to medicines management Documentation Talking to patients Eliciting support from other providers Transfer information to the community pharmacy
10.	**Social**	All non-work activity or communication, tea and meal breaks
11.	**Other:**	Any other task not included above
WHO/WITH WHOM		
	Patient Relative Nurse(s) Doctor(s) HCAs Pharmacist Trainee Other	
HOW/WITH WHAT	Computers Phone Permanent record Desk PC Paper Nothing	

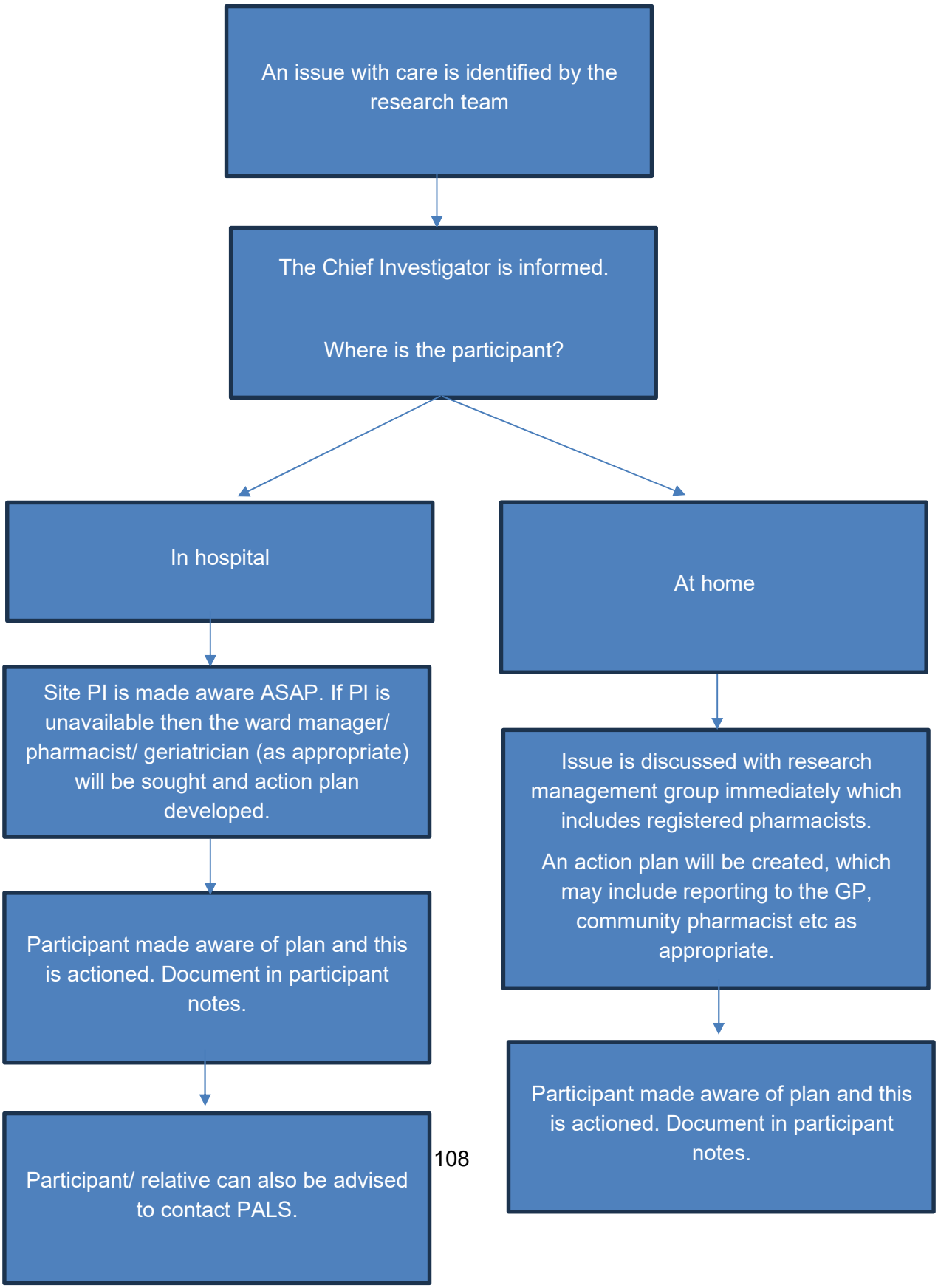
My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

MULTI-TASKING (Tasks conducted in parallel	Interviews	
INTERRUPTIONS	Interviews	
TASK DURATION		

Data collection form

Data collection form					Page
Record ID:	**Hospital/Site ID:**	**Ward:**	**Room:**	**Observer:**	**Date:**
Time start observation		Time finished observation			
Description of surroundings Single bed Multiple bed Other _____	**HCP observed** Profession_____ **Consent** Male Female		**Consultation type** Discharge Other_____ Samples/monitoring Patient called Medication dispensing		
Observer's notes Instructions: 1. Chronological observation of the content/tasks and the interaction between patient and HCP (sequence of events, quotes, non-verbal cues); description of the environment/situation. 2. Interpretation of the observation; perception of patient-HCP interaction; patient involvement; any potential impact of the observer on the interaction.					

Appendix 13: Reporting of concerns: Please follow the steps in the flowchart to escalate any care concerns.



My Medicines Journey: Assessing the feasibility and implementation of a Toolkit

Appendix 14: Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made