This protocol template is intended for use in clinical studies which **are not** Clinical Trials of Investigational Medicinal Products (CTIMPs) that are Sponsored or Co-Sponsored by the University of Dundee and/or NHS Tayside.

Section Headings in the protocol template should not be deleted.

MANDATORY fields/text MUST NOT be deleted.

Other sections may be adapted to suit a particular trial/study.

Other sections may be added as required by the specific trial/study.

All purple instruction text is hidden text and will not print. Follow these instructions as appropriate.

If you are unable to see the purple instruction text on your screen, the Formatting toolbar in Word has a button with the ¶ icon. If you hover your mouse over it, the ScreenTip says "Show/Hide ¶."

Trial/Study Protocol

Understanding and improving antimicrobial prescribing in care homes: a multidisciplinary approach

Work Package 4: Feasibility testing and optimisation

Trial/Study Acronym	Antibiotic Research in Care Homes Work Package 4: **ARCHeS**
Sponsor	University of Dundee
Sponsor ID	2.021.20
Funder	Economic and Social Research Council (ESRC)
Chief Investigator	Dr Charis Marwick
Principal Investigator	Dr Jane Dickson
REC Number	
Version Number and Date	V2 08/06/2021

PROTOCOL APPROVAL

Antibiotic Research in Care Homes (ARCH) Work Package 4: Intervention feasibility testing - "ARCHeS"

Signatures

The undersigned confirm that the following protocol has been agreed and approved by the Sponsor and that the Chief Investigator agrees to conduct the trial/study/study in compliance with this approved protocol and will adhere to the principles of GCP, the Sponsor SOPs, and any other applicable regulatory requirements as may be amended from time to time.

Dr Charis Marwick

Chief Investigator	Signature	Date
Individual Responsible for Statistical Review	Signature	Date

LIST OF ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CNORIS	Clinical Negligence and Other Risks Indemnity Scheme
CRF	Case Report Form
DMC	Data Monitoring Committee
GCP	Good Clinical Practice
ICF	Informed Consent Form
IF	Incidental Findings
ISF	Investigator Site File
PI	Principal Investigator
REC	Research Ethics Committee
SOP	Standard Operating Procedures
SMF	Study Master File
SAG	Study Advisory Group
WP	Work Package

SUMMARY/SYNOPSIS

Trial/Study Title	**Antibiotic Research in Care Homes (ARCH) Work Package 4: Intervention feasibility testing – "ARCHeS"**	
Trial/Study Design	Feasibility study: intervention implementation with process evaluation	
Trial/Study Population	Care Home staff	
Sample Size	Four care homes - 20 observations (if possible due to COVID-19 – detailed in protocol text) - 20 interviews - 8 Q&A sessions - 8 Antibiotic Champions	
Planned Study Period	01/06/2021 to 31/03/2022	
Clinical phase duration	NA	
Follow up phase duration	None	
Primary	Objectives: 1. To determine the feasibility of implementing the intervention. 2. To evaluate the intervention and its implementation through a parallel process evaluation to inform refinement for a future trial. 3. To determine the feasibility of measuring efficacy and safety outcomes and select the outcome measures for a future trial.	Outcome Measures: 1. Recruitment and retention of care homes. 2. Recruitment of individuals for observations and interviews and Antibiotic Champion role. 3. Measures of adoption, reach, acceptability, feasibility and fidelity. 4. Feasibility, timeliness and accuracy of measuring potential trial outcomes from routine data and bespoke data collection.
Secondary	Objectives NA	Outcome Measures NA
Inclusion Criteria	Care homes for older people registered in Tayside and Fife. Care home staff - managers, nurses, senior carers and carers	
Exclusion Criteria	None	

INTRODUCTION

Bacteria that cause infections are becoming increasingly resistant to currently available antibiotics. Antibiotics are essential in modern healthcare to treat infections, but bacteria develop ways of surviving their effects and develop resistance to them. Previous research has found that antibiotics are often used when they are not needed, which increases this effect. Antibiotic use among care home residents is high, as is antimicrobial resistance and other adverse effects of antibiotic use. Care home residents are vulnerable to infections so prescribing decisions are not straightforward and the amount of antibiotics used in different care homes varies significantly. There is general agreement that antibiotic use in care homes could and should be safely reduced but there is limited evidence about how this can be safely achieved in this complex, multi-stakeholder context, as most research on finding ways to reduce antibiotic use has been carried out in hospitals or GP surgeries rather than care homes.

This protocol is for feasibility testing of an intervention aimed at safely improving antibiotic use in care homes, within Work Package 4 (WP4) of ARCH (Antibiotic Research in Care Homes). The intervention and implementation strategy have been developed from the work undertaken in ARCH Work Packages 1-3, and a co-design workshop with 20 stakeholders from the care home sector, including a care home resident and a resident's relative.

In WPs 1-3 we conducted analysis of anonymised demographic and healthcare data on care home residents, linked to care home factors (WP1, R&D ref: 2016MC03, REC ref: 14/ES/0015); ethnographic observations and interviews with care home staff, prescribers and pharmacists, and care home residents and relatives (WP2, R&D ref: 2018MC03, REC approval no: 18/LO/164); behavioural psychology interviews and a questionnaire survey with care home staff and prescribers (WP3, R&D ref: 2018MC03, REC approval no: 18/LO/164).

In a co-design workshop conducted via Microsoft Teams (which did not require formal sponsor approval or ethics committee review, sponsor communication attached), stakeholders participated in facilitated discussion of potential intervention strategies and components arising from WP1-3 findings. They were invited to make any suggestions or comments and invited to complete a short anonymised post-workshop survey. Facilitated discussion and the survey were framed around the APEASE criteria (affordability, practicability, effectiveness, acceptability, safety, and equity) [1].

We have now developed an intervention package ready for feasibility testing with process evaluation and optimisation in a small number of care homes. The intervention will be aimed at care home staff.

COVID-19

At the time of writing this protocol, the care home sector has been severely affected by the COVID-19 pandemic. Vaccination has been offered to all care home residents and staff in Tayside and Fife with high levels of uptake and some easing of visitor restrictions. It remains unclear how the COVID-19 situation will evolve, with new variants emerging, and potential future epidemic waves and/or endemic infection. The intervention itself will be delivered remotely and there are remote options for all aspects of study organisation and process evaluation.

Recruitment of care homes and individual participants will be conducted with sensitivity in relation to timing and their capacity to participate, guided by stakeholders from the care home

sector in our Study Advisory Group and by the care home staff themselves. All the work outlined will be conducted in accordance with national guidance on social distancing and with local Sponsor and Infection Prevention and Control guidance in place at each specific time point. The introductory visit, which would ideally be done in-person, can be conducted virtually and remotely. Observations, which are part of the planned process evaluation, is the only element that absolutely requires a researcher (the PI) to be in situ in the care home. If this is not possible then extended interviews will capture additional data as detailed later. This is an evolving situation, and we will always adhere to national and local guidance and regulations, with safety taking priority over the research process.

Despite COVID-19 and its impact on care homes, representatives from the care home sector on the ARCH Study Advisory Group, and care home staff participants in WP2, WP3 and the WP4 co-design workshop are supportive of this work continuing and of the importance of improving antibiotic use among this vulnerable population (letter of support attached). Twenty key stakeholders, representing a variety of roles in the care home sector, voluntarily participated in a three-hour workshop in early February 2021, having registered for the workshop during December 2020 and January 2021 at the peak of wave 2 of the pandemic in the UK.

1 BACKGROUND & RATIONALE

Antibiotic resistance is a major problem for healthcare and society, with infections becoming increasingly difficult to treat. Antibiotic use contributes to the problem of resistance and there is evidence that antibiotic use can safely be reduced through avoiding unnecessary prescribing. The focus of ARCH (Antibiotic Research in Care Homes) is to understand and improve antibiotic prescribing in care homes for older people who can no longer live independently. These care homes vary in size, patterns of resident needs, ownership, proportion of trained nurses and carers, and how primary medical care is provided.

Antibiotic use in care homes varies widely with reports in the literature of up to 30% of residents receiving antibiotics at any one time [2, 3] and there are concerns over the quality of prescribing [4]. In Work Package 1 (WP 1) of ARCH we have found wide variation in antibiotic prescribing rates across care homes in Tayside and Fife, for total antibiotic prescribing (median 9.13 (range 1.64 to 24.08) antibiotic prescriptions per 1000 resident bed days) and for specific types of antibiotics (mean 6.67 (range 0.98 to 20.72) prescriptions for antibiotics active against coliform bacteria per 1000 resident bed days) and that rates of antibiotic use are associated with the risk of antibiotic resistance in urine cultures. [unpublished data, manuscripts in preparation]

Prescribing variation in care homes only partly reflects clinical need [5], and we know that the culture and composition of healthcare teams critically influences antimicrobial prescribing in hospital [6]. Prescribing culture in care homes has been difficult to quantify [7] but understanding how organisational and professional context influences prescribing is critical to designing effective interventions [8]. In WP 2 of ARCH we have found that prescribing is not a single act undertaken by a prescriber, but a process which begins much earlier than this. However, care home staff often do not recognise their influence on prescribing practices. Prescribing as a process, is highly influenced by the identification and escalation of potential infections within care homes as well as effective relationships with prescribers [unpublished data].

Antimicrobial stewardship aims to (i) ensure effective treatment for people with infection *and* (ii) reduce unnecessary use of antimicrobials and minimise associated harm. Achieving both in care homes is very challenging because residents are vulnerable to infection [9] but also vulnerable to adverse effects of antibiotics including antimicrobial resistance (AMR) [10-12] and *Clostridium difficile* infection [13]. Recent systematic reviews of antimicrobial stewardship interventions in hospital [14, 15], primary care [16] and care homes [17-19] reveal extremely variable, and at best modest, effectiveness. Understanding and addressing the behavioural barriers and facilitators involved in infection diagnosis and management in context is also critical to designing effective interventions [20]. In WP 3 of ARCH we have found a number of potential influences in the categories of capability (e.g., knowledge, skills), motivation (e.g., professional role and identity, beliefs about capability, beliefs about consequences) and opportunity (e.g., social influences, insufficient communication) that may contribute to unnecessary antibiotic use in the care homes. Some notable differences in these influences were found between care home staff, GPs, and advanced nurse practitioners [unpublished data].

We formally analysed and synthesised data from the first three work packages of ARCH, including identifying areas of good practice, and areas where processes could be improved. Using this empirical evidence, and the published literature, and guided by the Behaviour Change Wheel [1] we identified and developed potential antimicrobial stewardship intervention strategies to address identified barriers and enablers. We then held a co-design workshop with a follow-up survey, as part of ARCH Work Package 4, to guide the selection, prioritisation and development of these proposed strategies. The ARCH co-design workshop was held virtually (Microsoft Teams) and lasted three hours. It was attended by 20 participants and was facilitated by four members of the ARCH study team (the CI, a Co-Investigator, the PI and the UCL RF). The participants were comprised of care home staff (managers, nurses, senior carers and carers), general practitioners (GPs), Advanced Nurse Practitioners (ANPs) and pharmacists who provide care to residents of care homes, a care home residents and a resident's relative, and representatives from Scottish Care, Balhousie Care and the Care Inspectorate (an Improvement Advisor who is not involved in inspection/regulation). The workshop was audio-recorded, transcribed, and thematically analysed. These data were then reviewed by the research team, taking into account feasibility and reported acceptability by participants, to agree which intervention strategies to take forward for testing in the feasibility study.

The prioritised ARCHeS intervention package, summarised below (Table 2, section 4.1), has been specifically developed to be delivered remotely so it is resilient to changes in Infection Prevention and Control guidance. Another important consideration of intervention design and implementation in healthcare improvement is that the intervention should not constitute a significant additional workload. This intervention aims to replace and/or support previous elements of everyday practice and to be integrated into routine work. The training component is compatible with the existing training requirements for all care home staff registered with the SSSC (Scottish Social Services Council). Appropriate resources developed by NHS Education for Scotland and Healthcare Improvement Scotland (which includes the Scottish Antimicrobial Prescribing Group) have been incorporated into the intervention package. Findings from ARCH WP2 and WP3 indicate that existing resources are not currently disseminated or implemented universally.

The intervention package is now ready for feasibility testing in four care homes, with parallel process evaluation [21], and optimisation in preparation for a full trial in the future. This is in line with the MRC framework for design and evaluation of complex interventions [22], which

emphasises the importance of theory-based intervention development, then feasibility testing and optimising an intervention before proceeding to a full-scale trial. In line with this, we have conducted extensive empirical research to inform potential intervention strategies and components and developed these with key stakeholders in a co-design workshop into an intervention package. We are now ready to move onto the feasibility testing phase. As part of feasibility testing, we will also draw on the MRC guidance for conducting process evaluations [23] alongside implementation science frameworks (e.g., normalization process theory and the theoretical framework or acceptability) [24- 26] to evaluate implementation of the proposed intervention and identify areas for intervention refinement.

2 TRIAL/STUDY OBJECTIVES & OUTCOMES

The aim of this study is to feasibility-test and refine, with key care home stakeholders, an intervention package so that it is ready for evaluation in a future definitive trial. This involves implementing the intervention in four care homes with a process evaluation.

Measurable outcomes include: recruitment and retention of care homes; recruitment of individuals for observations and interviews; process measures including adoption, reach, acceptability, feasibility and fidelity of the intervention; the feasibility of using routine data and bespoke data collection for trial outcome measures, and selection of outcome measures,

Table 1: Primary Objectives and Outcome Measures

Primary Objectives:	**Outcome Measure:**	**Time point of outcome measured**
1. To determine the feasibility of implementing the intervention. 2. To evaluate the intervention and its implementation through a parallel process evaluation to inform refinement for a future trial. 3. To determine the feasibility of measuring efficacy and safety outcomes and select the outcome measures for a future trial.	1. Recruitment and retention of care homes. 2. Recruitment of individuals for observations and interviews and Antibiotic Champion role. 3. Measures of adoption, reach, acceptability, feasibility and fidelity. 4. Feasibility, timeliness and accuracy of measuring potential trial outcomes from routine data and bespoke data collection.	End of study 31/03/2022

4 TRIAL/STUDY DESIGN

4.1 INTERVENTION

The intervention is primarily aimed at healthcare workers (managers, nurses, senior carers and carers) in care homes. There are also materials which will be sent to prescribers - General Practitioners (GPs) and Advanced Nurse Practitioners (ANPs) - who have residents of study care homes as registered patients.

All resources will be provided to participating care homes in hard copy (paper for documents and USB stick for videos) and online electronic versions. A secure Microsoft OneDrive folder with all resources will be made available – hyperlinks between related documents will be included in OneDrive versions. Copies of all documents can also be provided by email and/or on a USB stick. Documents will be provided in paper copies with laminated versions for display purposes as appropriate.

Table 2. The intervention package:

INTERVENTION COMPONENT	CONTENT
1. Training in antimicrobial stewardship and the ARCHeS intervention. All staff are encouraged to attend/view videos at the study start and videos are available for new staff and for review throughout study period. Videos supplied on OneDrive and USB drive.	a. Training video (around 30 mins) recorded by the Project Lead for the Scottish Antimicrobial Prescribing Group. Focus on antibiotic stewardship and tailored to care home staff, addressing specific knowledge and skills gaps identified from ARCH WP2 and WP3.
	b. Training video (around 20 mins) featuring healthcare professionals (e.g. a senior carer, a carer, a nurse) using the ARCHeS intervention tools (2a-d below) in a simulated clinical scenario. Demonstrating practical use of the tools and including discussion points that illustrate how using the tools promotes good use of antibiotics.
	c. Two live online (MS Teams) Q&A sessions (up to one hour) with a topic/sector expert (Advanced Nurse Practitioner in Antimicrobial Stewardship) and a member of the ARCHeS study team to answer any questions or concerns about antibiotic use, stewardship and the ARCHeS intervention/tools. One session (per care home) to be delivered in the first month after all/most staff have had the opportunity to view the two training videos (1a and 1b), and one session (per care home) to be delivered at the start of month four. Within the feasibility study, these sessions will be recorded as part of the process evaluation.
2. Tools to support resident assessment and monitoring, and to support	a. Algorithm to be used in the initial assessment and management of a resident with suspected infection, aligns with the Scottish Antimicrobial Prescribing Group's (part of Healthcare Improvement Scotland) Good practice recommendations for antimicrobial use in frail elderly people [27], and is adapted from

communication about infections and antibiotics. Provided in electronic (OneDrive and via USB drive) and paper copies (plus laminated versions) for use throughout the feasibility study.	Scottish Antimicrobial Prescribing Group's algorithm for suspected urinary tract infections [28, 29] and the REACH algorithm for suspected urinary tract, respiratory, skin infections in care home residents [30]. Key features of the algorithm include: advice against the use of urine dip tests in suspected UTI; cues to consider other causes of altered status; safety-netting advice to escalate at any time for assessment if there are concerns about a resident's condition. Outcomes from using the algorithm would include: – Continue to monitor resident for suspected infection, using Monitoring Tool (2b below), and continue supportive care (e.g. encourage oral fluids) – Escalate to prescriber straight away, using SBAR tool (2c below) – Alternative cause is decided to be more likely by care staff (and appropriate management instituted)
	b. Monitoring Tool to be used in active watching and waiting of resident with suspected infection but who does not need urgent review. Includes specification of parameters (including temperature) and frequency (e.g. two hourly) of recording and triggers for review to be requested. Staff have the option to record the same information within existing documents to avoid duplication but must be clearly labelled.
	c. SBAR (Situation, Background, Assessment, Recommendation) structured communication form to use when requesting input (advice or review) from a GP or ANP. SBAR tools are widely used internationally including in the NHS, and some social care settings, in the UK (example available [31]).
	d. Stickers (two different paper visual prompts) to highlight current antibiotic prescriptions and trigger discussion amongst care home staff, including during handovers: i) Individual resident sticker noting a current antibiotic prescription to be inserted in their care plan (bright colour, approximately A6 size). Staff member writes on the sticker: antibiotic name; indication (i.e. what infection prescribed for); when started; how long a course (e.g. day 3 of 5-day course); any problems with administration/side effects. To be used at each shift handover (once per day minimum). ii) Sticker summarising current antibiotic use across the whole care home (or across a unit/wing if large home with separate team/handover) to be inserted in handover documents (bright colour, A6 size). Lists all residents currently on antibiotics and any related issues or concerns.

3. Identification of staff **Antibiotic Champions**	Two members of each care home staff (one nurse/senior carer and one carer per care home) to assume Antibiotic Champion role to promote and support the ARCHeS intervention (and process evaluation) in their care home. Specific tasks include: – encourage engagement with ARCHeS training and take staff training log – ensure all staff are aware of the ARCHeS communication tools and ensure these are placed appropriately and readily available – encourage and model use of the tools in practice – assist study team with process evaluation data collection (section below on process evaluation). Specific training (one-hour MS Teams session) for Antibiotic Champions clarifying the role, responsibilities and practicalities (e.g. data collection methods) will be provided by the study team and support will be available (via the PI) throughout the feasibility study.
4. Information for prescribers (GP and ANP) associated with study care homes and to study care home managers	The information will be sent to relevant practices to inform them about the study and enable them to support the care home's participation. The same information will also be available as additional information within the OneDrive resource centre plus hard copies will be provided to the study care home managers and Antibiotic Champions, to be shared with any interested staff. This information includes: – Single page of Key Points for prescribers, including dissuasion from requesting urine dip tests, and advising that care homes will be using SBAR tools for referrals. – Rates of antibiotic prescribing and resistant urine isolates in any study care home associated with the practice, and across care homes in the region for comparison, plus concise explanatory text (1-2 pages). – Additional information about the intervention development and evidence supporting the approaches taken (approximately 8 pages).

4.2 TRIAL/STUDY DESCRIPTION

Four care homes across Tayside and Fife will be recruited to receive and test the intervention. The intervention will be implemented as in a full trial. The aim is that it is compatible with existing training requirements, and that it informs, facilitates or replaces activities conducted during routine work, keeping any additional participant burden low. It is designed to assist staff in the assessment, monitoring and management of residents with suspected infection and to encourage and support discussion around infections and antibiotics within the care homes and with external healthcare staff (prescribers) with the ultimate aim of safely improving antibiotic use.

Feasibility testing involves the care homes engaging with the intervention and process evaluation over a six-month period. The components are detailed in Table 2 above - the intervention is directed at healthcare staff in the care homes, with information also sent to prescribers (GPs and ANPs) providing care to their residents.

Remote delivery is a key feature of the intervention, making it deliverable regardless of the Infection Prevention and Control guidance and will facilitate upscaling of the intervention should it prove feasible (and effective in the future definitive trial). Implementation will be led and coordinated by the PI with direction and support from the rest of the Study Team, including the behavioural psychology team at University College London. Antibiotic Champions, two to be identified within each study care home, will provide a key link between care home staff and the Study Team. Their role includes promotion and support of the intervention implementation and providing feedback on any issues encountered during day to day use of the intervention tools (detailed in section 2 in Table 2).

An introductory meeting (in-person if possible, remote if not) will involve the CI, PI +/- another study team member, the care home manager and the identified Antibiotic Champions. This will last approximately one hour and will clarify the study plan, timetable and roles and responsibilities.

Hard-copy intervention materials will be hand-delivered at the introductory meeting or posted to the care home if an in-person meeting is not feasible. All resources will also be provided as secure electronic copies and online in a secure study-specific resource centre on Microsoft Office OneDrive (see Table 2 in section 4.1 above).

In the first month, all staff should view the ARCHeS training videos (1a and 1b in Table 2) and as many as possible should attend the initial training Q&A session (1c). The main activity after this is to use the tools (2a-2d in Table 2) to support the management of any residents with suspected infection and encourage discussion around infections and antibiotic use within the care home, with Antibiotic Champions (section 3 in Table 2) providing role models, encouragement and support. The information sent to prescribers (section 4 in table 2) means that they should be aware of the care homes' approach to resident assessment, and it aims to improve communication between prescribers and care home staff, and facilitate their discussion around infections and antibiotics.

The intervention package described above will be implemented as it would be in a full trial with the exception that it can be refined during the feasibility study if needed, and between the feasibility study and definitive trial if the process evaluation findings would recommend adaptation. Components may be adapted or removed if it becomes clear that they are not practical to implement and/or healthcare staff do not engage with them. Additional supportive resources (e.g. additional documents or instructions) may be added if specifically requested and/or there are difficulties interpreting or using particular intervention components. Such adaptation is in line with Medical Research Council Guidance on design and testing of complex interventions [23, 26]. Decisions about any adaptation will be guided by data collected as part of the process evaluation and informal feedback provided via the Antibiotic Champions or at the live question and answer sessions delivered as part of ARCHeS training.

Process Evaluation

This will be a mixed-methods process evaluation and will begin approximately one month after the study start to allow time for the intervention to be delivered and embedded in practice. We will use quantitative and qualitative approaches, in accordance with MRC

guidance on process evaluation [22, 23] and informed by implementation science theories and frameworks [24]. The process evaluation will contribute to assessing different aspects of the feasibility and acceptability of care homes implementing the intervention and participating in a trial. Table 3 describes the key implementation outcomes [32] we plan to assess, and the proposed corresponding methods.

Many of the process outcomes will be evaluated qualitatively using semi-structured interviews and observations. Data from the recorded training Q&A sessions will also contribute to these measures. The interview topic guides, and the focus of the observations, will be structured using the frameworks mentioned above to cover all outcomes of interest. Qualitative data from the interviews, observations and Q&A sessions will be supplemented by quantitative data (e.g. numbers of participants), where feasible and relevant (Table 3) and by qualitative document analysis and unstructured feedback from care home staff. Data collection for the quantitative measures, document analysis and unstructured feedback will be supported by the Antibiotic Champions.

Table 3. Summary of Process Evaluation Outcomes, Measures and Methods

Implementation Outcomes (definitions from Proctor *et al* [32])	**Proposed Measures and Methods**
Fidelity (i.e. the extent to which an intervention is delivered as intended) **Any adaptation** (i.e. the extent and type of changes made to the tools, materials, or processes)	Measures of the extent to which the intervention is delivered as intended Quantitative: Fidelity of intervention delivery will be assessed quantitatively in terms of the number of training and Q&A sessions delivered to care homes, including checklists to be completed by intervention providers to ensure core components of the intervention have been introduced and explained. Checklists of key activities appointed Champions are expected to perform, to be completed on weekly intervals. We will calculate the % of activities done as intended (in full), partially done, or not done- with any reasons for omissions. Qualitative: Ethnographic observations of intervention delivery (e.g. delivery of Q&A sessions). Observations will explore the proportion of intervention components delivered as intended according to the intervention manuals/protocols (e.g. whether the training sessions encouraged and instructed on the use of the algorithms). To assess adaptation, Antibiotic Champions will complete a weekly log to record any adaptations or departures from the intended protocols, and will also collect a sub-sample of tools at certain time points (e.g. once a month) for a document analysis to check whether staff made any changes to the content and/or structure of the ARCHeS tools, e.g. to make them more acceptable or usable.

Adoption (i.e. Intention, initial decision, or action to try or employ an innovation or evidence-based practice; sometimes referred to as uptake)	Measures of the extent to which care home staff use the intervention components in routine practice. Quantitative measures collected by the Antibiotic Champions, such as: document analysis, including the number of times specific ARCHeS tools and documents are used or completed (out of the number of opportunities) for example the number of handovers where an ARCHeS sticker has been placed on notes and completed (proportion of all handovers when there are current antibiotic prescriptions in the care home), or number of SBARs that have been completed when care home staff contact a GP or ANP. Qualitative measures: self-reported use (actual + intended) of the ARCHeS intervention tools in day-to-day practice, assessed during semi-structured qualitative interviews with care home staff of different roles. This will be supplemented with ethnographic observations (if possible due to COVID-19 restrictions see later sections) of actual current practice among care home staff to assess extent to which care home staff use the algorithm, and monitoring and communication tools, when managing residents with suspected or confirmed infections that may require antibiotics. We will also observe the extent to which Antibiotic Champions encourage and reinforce the use of the tools.
Reach / Penetration (i.e. the integration of a practice within a service setting and its subsystems)	Measures of the how well the intervention has reached the target population Quantitative: Proportion of staff viewing the training videos and attending Q&A sessions. Logs collected by care home managers or Antibiotic Champions. Qualitative: Interview questions and observations assessing awareness of all intervention tools and where to find them in their care home/online. Interviews with care home staff will also ask whether they received and were exposed to the intervention components (i.e. did they receive the algorithms, monitoring tools, were they offered training etc).
Acceptability (i.e. perception among implementation stakeholders that a given treatment, service, practice, or innovation is agreeable, palatable, or satisfactory)	Measures of how much the staff like the intervention and find it suitable for use. Qualitative: Interviews with care home staff to explore their perceptions of the intervention (i.e. Did they like it? Did it make sense to them? Was it useful? Was it burdensome? Did it change practice? Were there any downsides or tradeoffs to using the intervention?). Sections of the interview topic guide are structured around the theoretical framework of acceptability (TFA) [33]
Feasibility	Measures of actual fit or utility; suitability for everyday use; practicability, including exploration of barriers and enablers

(i.e. the extent to which a new treatment, or an innovation, can be successfully used or carried out within a given agency or setting)	that impact extent to which the intervention can be feasibly used in practice. Qualitative: Assessed via ethnographic observations and semi-structured interviews. The interviews will include questions on barriers and enablers to intervention use and draw on domains of implementation theories and frameworks (e.g. normalization process theory [24] and Theoretical Domains Framework [34, 35].

Qualitative evaluation: To qualitatively explore the implementation outcomes listed in the table above, we plan to conduct 20 interviews and 20 periods of observation, over four care homes with care home staff. We do not plan to interview prescribers (i.e., GPs and ANPs), as the focus is on the care home, but will aim to do so if this is identified as necessary during feasibility-testing.

The interview topic guide is informed by implementation science frameworks often used in process evaluations [22, 23, 24]. Normalisation Process Theory [24] is particularly concerned with how the intervention may become embedded in practice, with the main components being: coherence (or sense-making); cognitive participation (or engagement); collective action (work done to enable the intervention to happen); reflexive monitoring (formal and informal appraisal of the benefits and costs of the intervention) [24]. Theoretical Domains Framework [35] offers a framework to assess individual, socio-cultural and environmental barriers and enablers to implementing change in clinical practice across 14 domains (e.g. knowledge, skills, beliefs, social influences, resources). Finally, the Theoretical Framework of Acceptability [33] provides a framework to assess different aspects of intervention acceptability (e.g. burden, self-efficacy).

Ideally, we aim to conduct 20 ethnographic observations, across the four study care homes, with care home staff. In-situ observation would contribute unique insights into how things are really working (or not) and will supplement self-report in the interviews. If the current situation with the COVID-19 pandemic means that it is not possible to conduct observations, additional interview data will be collected, while accepting that some insights can only be gained through direct observation. The additional interview data will be collected either by extension of 12 (three per care home) of the above interviews, or by having a separate shorter interview if any of the 12 participants prefer that option. The observations or additional interview data will focus on step by step use of the tools in practice, informed by NPT [24].

The observations and interviews over the four care homes will be conducted at time points to best observe the intervention in use - with approximately half of each conducted in months two and three (to look at initial delivery and uptake of the intervention), and half in months four to six (to look at sustained uptake of the intervention). Some of the later interviews and observations may be specifically directed towards scenarios where the intervention appears to be more/less well accepted or adopted. This would be guided by any specific feedback received via the staff Antibiotic Champions or in interviews and/or observations.

The 20 interview participants will be selected across roles to represent the range of target intervention users. The interviews will be conducted in person (if possible) or remotely via telephone or MS Teams by the PI or UCL RF, who are experienced interviewers (including in ARCH WP 2 and WP3) and have been involved in development of the topic guide. The interviews will be audio-recorded, transcribed intelligent verbatim, and anonymised (all names

of persons, places, healthcare boards and identifying features removed) for further qualitative analysis The interviews will be analysed using framework analysis combining deductive coding (informed by the frameworks and constructs listed above) and supplemented by inductive coding enabling new themes to emerge as driven by the data.

The observations (if possible) will also focus on a range of target users and scenarios but we know, from previous experience in WP 2, that there is significant variation in the number of staff on shift during any observation period, so the number of participants is uncertain (estimated in relevant sections below). The observations, if possible, will be conducted in person by the PI who an experienced ethnographer (including observations in care homes in ARCH WP2). Periods of observation will last up to three hours with the PI making fieldnotes at the time, to be typed up later. These will be coded in NVivo, with the coding framework initially designed around implementation theories (as above) but further developed as new themes emerge from the data.

Quantitative evaluation: The aim is to collect enough data to be informative, but we will be mostly reliant on data collected and reported by the Antibiotic Champions, and care home managers to a lesser extent, for this remotely delivered intervention. Therefore, we will focus on what is most relevant and feasible to collect. The burden of data collection will be minimised to enhance feasibility and acceptability, as per suggestions in a previous intervention study in care home settings [30]. The measures and methods are detailed in Table 3 above but include simple logs of counts and proportions, e.g. of staff completing training, the use of ARCHeS tools (as a proportion of opportunities for use) and completion of Antibiotic Champion reporting. Also included are measures of how well delivery matches intended delivery measured e.g. through checklists of whether Q&A sessions covered all intended material and logs of any adaptations to how the ARCHeS tools are being used. We will ask the Antibiotic Champions to carry out document analysis by reviewing a sample of tools that have been used to record and report the completeness of data entered and any sections/fields that are proving difficult to complete. We will also ask them to share anonymised (i.e. names removed by the Antibiotic Champion so that individuals cannot be identified) versions of a sample of completed tools so the Study Team can also conduct some document analysis. Part of the Antibiotic Champion training will include instruction on anonymising the tools to ensure that the Study Team do not see any identifiable resident data.

Intervention adaptation/refinement by the Study Team

One purpose of the process evaluation is to guide refinement of the intervention package before it is tested in a future full trial, as well as testing the feasibility of delivery of the intervention package. The process evaluation data will be analysed throughout the six-month feasibility study so, by the end of the study, we will able to finalise the intervention for definitive evaluation.

If any specific problems, difficulties or concerns with the intervention (content or implementation) are raised during the feasibility study, we will respond to these and consider (as a study team) making small, specific adaptations to increase the value of data collected over of the remainder of the feasibility study. Issues could be raised either through formally collected process evaluation data (above) or through informal feedback from Antibiotic Champions, managers or other care home staff. A clear record and audit trail of any adaptations made during testing will be kept.

Outcome Measures

Outcome measures for this feasibility study are:

1. Recruitment and retention of care homes.

2. Recruitment of individuals for observations and interviews.

3. Implementation outcomes (detailed in process evaluation section above)

4. Feasibility of measuring potential future trial outcomes using routine data and bespoke data collection.

5. Selection of outcome measures for future trial.

We will consider recruitment of care homes to be successful if 25% of owners/managers invited agree to participate, particularly given the current challenges in the health and social care sector, and if all care homes are able to identify at least one Antibiotic Champion staff member. Care home managers will be asked (in their process evaluation interviews) about whether they would be willing to participate in a full scale trial of an intervention like this, with the chance that they would be randomised to a comparator group, or a delayed intervention group in the case of a step-wedge trial design. Successful retention will formally be recorded if no more than one care home withdraws from the study, but meaningful retention requires continued engagement. This will be indicated by continued participation in the process evaluation, along with the process evaluation data collected (e.g., numbers/proportions of staff viewing training videos and participating in Q&A sessions).

Recruitment of individuals for observations and interviews will be considered successful if 50% of those invited agree to participate. This is realistic, based on our experience in ARCH WP 2 and WP 3, where very few potential participants declined the invitation.

Outcomes for the future trial: The feasibility of measuring any potential trial outcomes is critical and will guide the selection of the definitive trial outcome set. This feasibility study is not powered to detect changes in any of these outcomes. Proposed measures include effectiveness and safety measures. Safety measures are necessary because the intervention package may reduce use of routine pathways of care and/or antibiotic prescribing within normal working hours, with the potential to increase healthcare contact out of hours with possible associated delay in antibiotic therapy.

Proposed effectiveness outcome measures: Total antibiotic prescriptions for care home residents (rate per 1000 resident bed days (RBD)); prescription of broad spectrum antibiotics for care home residents (rate per 1000 RBD); proportion of antibiotic prescriptions for care home residents that are for first line recommended antibiotics; rate of submission of care home residents' urine samples to microbiology (per 1000 RBD); rate of antibiotic resistance among E.coli isolated from residents' urine samples.

Proposed safety outcome measures: Rates of unscheduled care use by care home residents by individual service and in total; all-cause mortality. Unscheduled care services include GP out of hours, Scottish Ambulance Service, NHS24, A&E attendance, and emergency admissions to hospital.

We will evaluate the ability to measure potential trial outcomes from routine NHS data held in the Health Informatics Centre (HIC), University of Dundee, accurately and in a timely manner. The ability to detect signals in the safety measures in a timely manner, which could be used

to inform a Data Monitoring and Safety Committee in a full trial, will be assessed. Exploration of how equivalent data could be accessible on a national basis will be important in guiding whether proposed outcome measures would lead to geographical restrictions to the definitive trial population. This would not necessarily restrict the population for wider implementation if the intervention proved safe and effective in the definitive trial.

At the introductory visit, we will ask care home managers to report how many beds they have and how many residents they have at that time and will request updated figures each month. We will ask the Antibiotic Champions to report the number of new antibiotic prescriptions in the care home each week. We will only collect numerical data and no identifiable data about residents will be requested or recorded. We will compare prescribing rates calculated using the HIC routine data and rates calculated using reports from staff in the care homes. Information on the ease of data collation and burden of reporting for the study will be collected.

Care home managers will be asked (during their process evaluation interviews) whether there are additional trial outcomes that would be important to them and their staff. Any such measures which would require manual data collection by staff in the care homes could be feasibility-tested in the second three months of the feasibility study.

Selection of outcome measures for the definitive trial will be selected by the Study Team, guided by assessments of feasibility, accuracy and timeliness, and in discussion with stakeholders in the ARCH Study Advisory Group.

Progression to a Full Trial Proposal

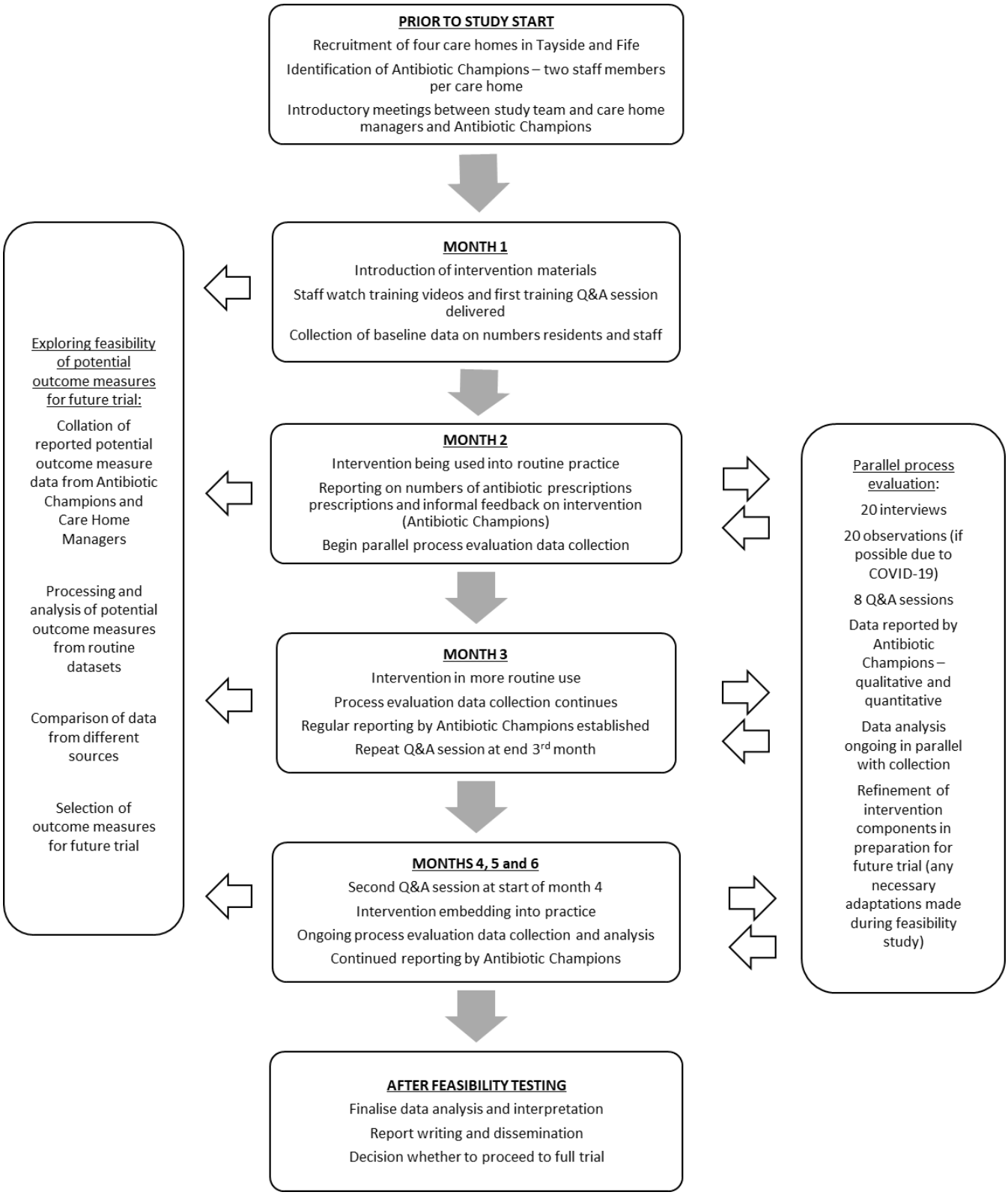
There are three possible broad scenarios following the feasibility study:

1. The intervention is feasible and acceptable (or will be so after refinement clearly indicated by the process evaluation) and merits testing in a full trial - cluster randomised controlled trial (RCT) or other design e.g., step-wedge randomised trial. Any such trial would have an internal pilot designed in to increase efficiency.

2. The intervention is not acceptable and/or feasible and a definitive trial is not justified.

3. The policy context is such that a national stewardship programme for care homes is being actively rolled out, limiting the likelihood that a trial would be able to demonstrate any additional benefit of this intervention. In this case, ARCHeS components that have been well received would be offered for inclusion in a national programme (via the Scottish Antimicrobial Prescribing Group).

4.3 STUDY FLOWCHART



4.5 TRIAL/STUDY SAFETY ASSESSMENTS

At all times the welfare of study participants and care home residents will be prioritised over the research process. The research will be conducted in accordance with the Adult Support and Protection (Scotland) Act 2007.

The COVID-19 situation, and corresponding regulations, has implications for the safety and therefore feasibility of conducting the introductory visit in person and the parallel process evaluation observations in situ. The intervention itself has been specifically designed for remote delivery to negate any infection-related safety issues.

The COVID-19 situation and regulations may impact on the capacity for care homes to participate in the study and for individuals to participate in the parallel process evaluation. Recruitment at both levels will be conducted with sensitivity in relation to timing and capacity to participate, guided by stakeholders from the care home sector in our Study Advisory Group and by the care home staff themselves. Any permitted fieldwork will be conducted in accordance with specific local Sponsor and Infection Prevention and Control guidance in addition to national guidance on social distancing.

If COVID-19 restrictions on visitors in care homes are still in force at the time when the observations and interviews are to be carried out, the interviews will be conducted by telephone or online (MS Teams) by agreement and the observations will be replaced by the collection of additional interview data.

There are no other risks to safety expected from involvement in the study. The interviews may include discussion around sensitive topics, but participants do not have to talk about anything they prefer not to. This is made clear in the PIS and the researchers; the PI and the Research Fellow at University College London (RF UCL) have experience in conducting interviews with a broad range of participants and will be sensitive to participants' feelings and comfort.

If a participant becomes upset or distressed during an interview, then the researchers (PI or RF UCL) will immediately stop conducting the interview. Support from the researcher, as appropriate, will be offered and another member of care home staff will be sought to provide any ongoing comfort and support required. Any further involvement of an affected participant in the study will be entirely at their discretion.

Participants in the observations may feel that it is inconvenient, or feel uncomfortable, having someone watch them work and make notes about it. The PI has experience in conducting healthcare worker observations and will make them as unobtrusive and sensitive as possible. If a participant, or someone else present during observations, becomes upset or distressed by the research being conducted then the PI will immediately stop conducting the observation. Support from the PI, as appropriate, will be offered and a member of care home staff will be sought to provide any ongoing comfort and support required. Any further involvement of an affected participant in the study will be entirely at their discretion. If anyone becomes unwell then staff help will be sought immediately.

4.8 INCIDENTAL FINDINGS

There is the potential for sensitive information to be disclosed during an observation or interview. Participants do not have to disclose anything they prefer not to, and all information will be kept confidential unless there is a legal requirement to breach confidentiality. This is stated clearly in the PIS documents.

There is the unlikely possibility that criminal activity and/or professional malpractice is observed or disclosed, including about a third party. In these circumstances, the right to confidentiality does not apply. Any criminal activity will be reported to the police and/or care home management. Any professional malpractice (breaching professional Codes of Conduct, for example someone who is not a registered prescriber writing a prescription) will be reported to the appropriate authorities, which may include any, or all, of: the care home management, the Local Authority, the Care Inspectorate, the Scottish Social Services Council (SSSC), the Nursing and Midwifery Council (NMC), the General Medical Council (GMC), the General Pharmaceutical Council (GPhC). This is stated in the PIS'. Before starting work in care homes in earlier work packages, the PI received advice and training as to what constitutes malpractice so that she can recognise the seriousness of any allegation or incident that is disclosed or observed. She will seek further advice from the research team, which includes a GP, a consultant and two pharmacists, about any allegations or incidents that cause concern but do not constitute criminal activity or medical malpractice.

4.9 TRIAL/STUDY POPULATION

Care home staff

4.10 NUMBER OF PARTICIPANTS

Four care homes.

The individual participant numbers to be recruited are estimated as follows:

Antibiotic Champions: 8 (2 per care home)

Training Q&A sessions: approximately 80 participants (8 sessions in total, all care home staff invited)

Observations: approximately 35-60 participants (20 periods of observation)

Interviews: 20 participants

Participant total (estimated maximum): 168

Some staff members will participate in more than one activity and observations may not occur due to regulations, so the total number is a broad estimate of the maximum realistic number.

4.11 INCLUSION CRITERIA

Care homes: Location in Tayside or Fife, primarily for older people, at least 10 residents.

Individuals: – staff working in study care homes (managers, nurses, senior carers and carers) are eligible for all intervention and process evaluation activities.

4.12 EXCLUSION CRITERIA

None (if inclusion criteria are met).

5 PARTICIPANT SELECTION AND ENROLMENT

It is understood by the study team, that process evaluation observations and in-person interviews may not be possible under COVID-19 restrictions. If this is the case, then interviews will be conducted remotely (telephone or MS Teams) and additional interview data will be collected to substitute some observation data.

Recruitment period: Based on experience in earlier ARCH work packages we anticipate a one-month recruitment period to recruit four care homes for feasibility testing. Recruiting individual participants within these care homes for the process evaluation observations and interviews will be done during the six-month implementation.

Care Home Selection and Invitation

The four care homes will be recruited from the NHS Tayside and Fife regions. Initially, purposive sampling, as was successful in ARCH WP2 and WP3, will be used to select care homes for invitation to participate. This sampling is based on the statistical analysis in WP1 and involves the Health Informatics Centre (HIC), University of Dundee, identifying care homes selected to represent variation in size, type of care (residential and nursing), and rates of antibiotic prescriptions. Managers/owners of the selected care homes will be contacted using publicly available information on the Care Inspectorate register and/or the care homes' own websites. If this recruitment strategy is unsuccessful then opportunistic recruitment via care home organisations represented on the ARCH Study Advisory Group and/or approaching care homes that have participated in ARCH WP2 and WP3, still ensuring some variation in size and including at least one residential home if possible.

The care home owner and/or manager will be responsible for allowing and facilitating implementation of the intervention within their care home and they will be required to provide a Letter of Access. Recruiting the care home does not require informed consent from all individuals working in the care home, although all staff will be encouraged to undertake the training and use the intervention materials and we expect managers to disseminate information about the study to all staff, including to assist in the identification of two staff Antibiotic Champions in each care home.

The manger will be asked to send information which we will provide, about the study, to GP and ANP practices who provide care to any residents of the care home.

Individual participant activities

Individuals to take on the Antibiotic Champion role, and to participate in training Q&A sessions, and process evaluation observations and interviews will be recruited from those working in the four study care homes.

We anticipate that all care staff and nurses working in the homes will be eligible and the manager will be asked to circulate the ARCH invitations to participate to all staff. It will be made clear that participation will be voluntary for all activities. Depending on the COVID-19 situation, and whether the PI can be present in the care home, recruitment will either be done in person by the PI or via email/phone response to the invitations circulated by the manager. It will be made clear that the choice to participate or not participate is entirely individual. If someone who is present during a period of observation does not wish to consent, then the PI will not make any field notes about that person. Non-participation or participation will not be disclosed or reported to line managers and will not adversely affect their employment or their relationship with the Health Board.

GPs, ANPs and practice nurses who visit the participating care homes in their professional capacity may be eligible to participate in process evaluation observations. Information about the observations (if it is feasible to conduct these in situ given COVID-19 restrictions) will be included with the intervention information sent to practices. Visiting professionals will be recruited, with informed consent, at the time of any visit. It would be made clear that the participant can withdraw at any time, including later, if they so wish.

5.1 CONSENTING PARTICIPANTS

The informed consent process will be conducted in compliance with TASC regulations for obtaining informed consent from potential participants in clinical research.

Where a participant requests to speak with a member of the study team the consent process will not be completed until the participant has spoken to the member (CI or PI) and has had all their questions answered to their satisfaction.

Care Homes

Initial contact with care homes will be by email, sent from the Study Administrator on behalf of the CI, using the named contact on the publicly available contact information from the care home's own, or the Care Inspectorate's, website. The email will include the Care Home Invitation Letter and Information Sheet.

A positive reply to the initial contact will be followed up by a telephone call from the CI or PI to discuss the study and to arrange a face-to-face / online meeting with the care home Manger. The meeting will be attended by the PI and a co-investigator, (using the Current COVID-19 guidelines) and at the discretion of the manager and with no obligation to participate attached. It will be made explicit to the care home owner / manager that they can withdraw their agreement to participate at any time without having to provide an explanation.

The owner / manager of each care home will be given a minimum of one week, or more if they wish, to consider their decision. This will allow time to review the information and discuss with other relevant people before deciding whether to participate. A signed Letter of Access from the care home owner or manager will be obtained before the study can begin in that care home. A Letter of Access template will be provided to ensure the owner/manager understands their role in the implementation and evaluation process.

Prior to the study activities commencing in each care home, an introductory meeting (in-person visit or online via MS Teams) between the CI, PI, care home manager and Antibiotic Champion will be held to clarify plans, timetables, roles and responsibilities. Posters and flyers providing information about the purpose and nature of the study and contact details of the research team will be placed in prominent areas in the care home. If the COVID-19 restrictions indicate, and the PI will not visit the care home, the care home owner/manager will still be asked to use these materials to highlight the study to staff, residents and visitors.

Attending training and using the intervention materials does not need individual informed consent, and engagement with the intervention is at an individual's discretion. However, assuming the Antibiotic Champion role, and participation in recorded Q&A sessions and the process evaluation observations and interviews will require individual consent. This means that, although individuals attending a training session would not necessarily need to give informed consent, when a session is being observed (with recording and/or note-taking) and/or an individual was to give an interview about the training session, the observation

and/or interview collecting research data would require individual informed consent from participants (as below).

Individual Participants

We will ask the manager to email all the care home staff to make them aware of the study observations and interviews, as well as informing them in person. Staff will receive letters of invitation and PIS at least 24 hours in advance of each activity to ensure they can ask for any further information and carefully consider participation. Care home managers will not be asked to recruit or consent individuals.

Antibiotic Champions

It will be made clear to all staff in the PIS that assuming the role of Antibiotic Champion is voluntary. This is designed to prevent the possibility of perceived coercion from the care home manager or owner. The ability to withdraw or change their mind at any point will be made clear. The identity of those who assume the role of Antibiotic Champion will be known to the manager, other staff in that care home and the Study Team but will not be revealed to anyone external to the care home. The identity of anyone invited to assume the role but declines will not be revealed to their line manager or anyone else. It will be made clear that non-participation will not affect their work in any way.

Signed, informed consent, using a standard form will be in place before any activities associated with the Antibiotic Champion role commence. A one-hour training session (in-person or online via MS Teams) will be provided to all Antibiotic Champions before the feasibility study starts. Further advice will be available from the PI and Study Team for the six-month feasibility study duration.

Antibiotic Champions will be offered £200 (£100 at start of feasibility testing and £100 at end) as a thank you for their time and effort in collecting and reporting data for the Study Team. The split payment will allow part-payment to be offered to a new Antibiotic Champion should the original member of staff be unable to complete six months in the role, for any reason.

Observations

As mentioned above, non-participant observations will be carried out only if appropriate at the time, given COVID-19 restrictions, and in consultation with the care home manager.

It will be made clear to all staff in the PIS that participation is voluntary. This is designed to prevent the possibility of perceived coercion from the care home manager or owner. The ability to withdraw or change their mind at any point will be made clear. The identity of those who do not consent will not be revealed to any other team members or line managers. It will be made clear that non-participation will not affect their work in any way.

Healthcare workers (GPs and ANPs) visiting a care home during an observation period will be consented, where appropriate, for participation in the observation. A visit during an observation period is unpredictable, so all relevant services who provide care for any residents will have been sent study information (letters and PIS) more than 24hrs before the observations commence in that care home. The PI will obtain consent at the time of the visit. The ability to withdraw or change their mind at any point, even afterwards, without this having an adverse effect on their role, will be made clear.

Signed, informed consent, using a standard form will be in place before any observations commence. Only healthcare workers who have consented to non-participant observations will have field notes made about their work. No payment will be offered for observations.

The focus of the evaluation is on professionals in the care home. While non-participant observation of professionals may include interactions between staff and residents and/or their relatives, the researcher will not record any information about them, so formal consent from them for this aspect of the study is not required and will not be sought.

Interviews (and Q&A sessions)

Individual informed consent for participation in each activity will be taken by the PI or UCL RF in person or online on the day the activity takes place. Whether interviews are conducted in person or remotely, by telephone or online (MS Teams), depends on the COVID-19 restrictions at the time. The Q&A sessions are part of the ARCHeS training and would not require formal recruitment and consent in themselves, but they will be recorded and the transcripts analysed as part of the process evaluation and informed consent is required for this aspect.

All potential participants will be given invitation letters and PIS at least 24 hours before the activity, with sufficient time to consider participation fully and to contact the team with any questions they may have. They will be able to speak to the CI or PI by email, telephone, or online (e.g. Teams, Zoom, texting service), whichever they prefer. The participants may withdraw at any time without having to explain and this will not adversely affect their employment or care.

Interviews are each expected to last 30-60 minutes (up to 90 minutes if extended to accommodate additional questions to substitute for observations) and it will be made clear that participants can stop for a break at any time if they need and take as long a break as they need, even if it means resuming the interview another day. The Q&A sessions are expected to last one hour. If any participant becomes distressed or uncomfortable during any activity, the activity will cease, and help will be sought if anyone becomes unwell.

Consent will also be sought for recording and audio-transcription of interviews and Q&A sessions, with assurance of confidentiality of the interview or Q&A session and anonymity of documentation following transcription.

Interview participants will be offered £50 as a thank you for their time and effort in interview participation.

All thank you payments will be paid in cash or through BACs by arrangement with the Study Administrator.

Participants may withdraw at any time from any activity without having to explain and this will not adversely affect their employment or care.

5.2 SCREENING FOR ELIGIBILITY

All care homes (except very small care homes with less than 10 occupied beds) for older people in Tayside and Fife will be eligible to participate but only four care homes can participate. We will select care homes for invitation to include care homes of different sizes, at

least one residential home and homes with variation in rates of antibiotic use, for invitation to participate. The aim will also be that at least two of the care homes will not have participated in ARCH WP2 and WP3.

All care home staff in the four study care homes, and potentially prescribers who provide care to their residents, will be eligible to participate in the process evaluation. The PI will purposefully sample roles for participation in observations and interviews, prioritising roles which have direct involvement with the intervention components.

5.3 INELIGIBLE AND NON-RECRUITED PARTICIPANTS

Ineligible and non-recruited potential participants will not be affected by this study. No notes will be made during observations about any staff who have not given informed consent and no notes will be made about residents or their relatives.

5.3.1 Withdrawal procedures

Ongoing, informed consent will be sought from all participants being observed and interviewed. Participants will be free to withdraw their consent at any stage without needing to give a reason. If someone withdraws, any notes, recordings or transcripts of them will be destroyed if they request this. This will not affect their relationship with the University of Dundee, their care home employer or, if a resident, their ongoing care.

If a participant, or anyone else present, becomes upset, distressed or unwell during any activity it will be discontinued immediately. Help and support will be provided if needed. The activity can be resumed or rescheduled if the participant wishes. If a participant wishes to withdraw from the study altogether, their data will be deleted unless they request it is retained.

6 DATA COLLECTION & MANAGEMENT

6.1 DATA COLLECTION

Quantitative Data

This will include, for example (see Table 3 for details) the numbers and grades of staff attending training sessions, the number of times ARCHeS support system tools are used, and the number of residents and antibiotic prescriptions over time in the care home. These data will largely involve summary and/or aggregate numbers from each of the four care homes.

Many of the data items will be recorded by the Antibiotic Champions via a weekly report to the PI (Study Team) by email or phone. Some anonymised, completed tools will be scanned and sent to the PI for document analysis.

Data will be managed by the PI and stored in reports within the secure shared OneDrive ARCH folder on the University of Dundee network.

Qualitative Process Evaluation Data

All data collection for process evaluation, including Q&A session recordings, observations and interviews will be conducted by the PI or UCL RF and managed by the PI.

Observations

If observations are feasible, given COVID-19 restrictions at the time, they will include observing care home staff, and potentially GPs or ANPs, during the implementation and

embedding process of the intervention components. The data gathered are targeted to a series of criteria set to evaluate the components of the intervention. Generally, observations will explore how individuals embed the intervention in their daily practice (i.e. adoption), how easy it is to do so (e.g. feasibility) and any barriers and enablers encountered. It will also include any impact these elements might have on infection diagnosis and antibiotic decision-making in each care home setting, through in-depth observations of key formal and informal activities. Notes will be made of staff working patterns and interactions with the intervention components, but no observations and notes will be made of the residents or their visitors. Observations will be carried out by the PI.

Observations will initially be recorded in hand-written field-notes by the PI and later transcribed (typed up), also by the PI, for analysis. Field-notes will only be made about staff and visiting healthcare workers who have consented to participate. Observations will be conducted in communal areas, staffrooms and offices, meaning that people other than the staff participants (for example residents, other staff members and visitors) may be present during observations. These other people will not be the focus of the PI's attention and no field notes will be made, or any other form of data collected, about anyone except consented staff members or visiting professionals.

We are sensitive to the potential disruption of having a stranger present in the residents' home environment and we will always prioritise their right to privacy and dignity over the research process. We are also sensitive to the confidentiality of staff members consent (or not) to participate in the observations. It may inevitably become apparent to others present that a staff member is being observed and information advising this is included in the PIS. Preserving confidentiality around staff members not consenting, particularly from line managers and colleagues, means that observations should (and will) take place while non-participant staff members are present, but no notes will be made about them. This information is included in the PIS staff will be given to read before deciding whether to participate.

While the observations will not include the details of any interactions with residents or non-participant staff members, the observation and corresponding field notes may note the fact that, for example, a consented participant had a conversation with 'a resident' or 'another member of staff' in order to document the participant's activity. However, the interaction itself would not be observed and the field notes would not record details of the conversation or of who the conversation was with.

Ensuring that residents are not adversely affected by the research is of the utmost importance. Observations will be conducted as unobtrusively and sensitively as possible and will not take place in residents' private rooms or other sensitive areas such as in or around bathrooms or toilets. The PI will verbally check at the start of each observation whether anyone objects to her presence in communal areas. If anyone in the area becomes distressed or if anyone is unhappy about her presence at any time, she will immediately withdraw from that area. Her focus is on consented staff members, but clearly she would respond if a resident (or anyone else) initiates conversation, including explaining what she is doing if asked, but such conversations are not part of the research and will not be recorded in field-notes.

Consenting staff members will have a unique study identifier and their professional role recorded in field notes, but no other personal information will be recorded. No payment will be made for observations.

The PI will take no participation in any of the work of the care home. She has experience in non-participant observation work in care homes and will conduct her observations in a respectful way that is sensitive to maintaining the dignity, privacy and safety of research participants and other people present.

Interviews (and Training Q&A sessions)

Interviews (n=20) will be arranged at a time and place convenient for the interviewee and agreed between interviewer and interviewee. Staff interviews will take place during normal working hours if possible, and either in a private office in the care home/practice, or at a private location of the interviewee's choosing, or online / telephone. Each semi-structured interview will last between 30-60 minutes and will be conducted by the PI or the RF. If the interviewee wishes, they can take a break at any time and the interview can be resumed later, even on another day.

The semi-structured interview topic guide is structured around relevant theoretical frameworks [21-25] guiding the process evaluation. Interviews will be arranged and carried out by the PI and the RF. Both researchers are experienced in interviewing care home staff as part of ARCH WP2 & 3. Online interviews will be conducted over MS Teams. Interviews conducted by PI will be recorded on an Olympus Linear PCM Recorder LS-P4 owned by the ARCHeS Study. Interviews conducted by RF will be recorded on an Olympus Digital Voice Recorder WS-331M and, as back-up or potentially better quality, on her laptop using software 'Voice Recorder' available on Windows 10.

No personal identification will be stored on these devices. Recordings will be uploaded to the researcher's computer as soon as possible after the interview and the recording on the voice recorder deleted thereafter. No personal identification will be used on these devices.

The Q&A sessions (n=8, two per care home) are part of the ARCHeS training in the intervention package but analysis of recordings of the sessions will form part of the process evaluation.

Consent will also be sought for audio-recording, transcription and potential re-contact with participants, with assurance of confidentiality of the interview and Q&A sessions themselves and anonymity of the documentation following transcription. Audio-recordings will be transcribed verbatim by the company 'TP Transcription'. Interviews and Q&A sessions will be anonymised so that no individual or organisation may be identified from the data.

No identifiable information about residents or their medical conditions will be collected from care home records. The research team will not have access to care home residents' medical or other care records, or to any staff files. Data will be collected for ARCHeS by the staff Antibiotic Champions from care home records but will consist of non-identifiable summary data, for example the number of residents with a new antibiotic prescription in the last week and the number of these who had an ARCHeS antibiotic sticker used in their care plan.

6.2 DATA MANAGEMENT SYSTEM

Data management will be conducted in compliance with TASC regulations for Data Management. Information from this research study will be kept in accordance with General Data Protection Regulation (GDPR) instructions. The University of Dundee will keep identifiable information about participants from this study only until the end of the study. Identifiable information includes any telephone or email details participants have shared with the PI, CI or SA.

UCL Data Protection and GDPR teams have been consulted to align data collection and management at UCL with their recommendations – data management will follow data protection and GDPR rules (including registering data collection with the UCL data protection office). Only the immediate ARCH study team will have access to any potentially identifiable information. UCL will anonymise all study data as soon as possible and will transfer any potentially identifiable information that requires filing to University of Dundee for processing as outlined below.

The database is managed in line with all applicable principles of medical confidentiality and data protection laws. The Data Controller will be the University of Dundee and the Data Custodian will be the PI.

The DMS will be based on the protocol and the individual requirements of the investigators. The PI will collect only information that is required to meet the aims of the study and to ensure the eligibility and safety of the participant. Electronically held data will be stored on password protected computers and laptop computers at the University of Dundee and partner universities. These will only be accessible by members of the research team. The data management systems (DMS) will be Excel, Word, SSPS, MS Teams and NVivo as approved by the Sponsor.

A password-protected shared drive, OneDrive based on the University of Dundee's network drive, is established so that primary data can be securely shared between team members. Anti-virus and firewall protection, and versions of all software and media storage devices on researchers' PCs will be updated regularly to ensure data integrity. All data files will be identified by version number and design date. Version information will be updated by the PI and will be stored on a spreadsheet and on the network drive.

In accordance with University of Dundee policy, the ownership of intellectual property for the project will rest with the University of Dundee, while ownership of copyright will rest with the CI and Co-Is. The Data Protection laws stipulate that data shall not be kept for longer than necessary for the specified purposes of research. In compliance with this, the data generated by the project will be managed as follows: for research governance purposes, all data will be retained until publication of all expected outputs of the research (expected to be within three years of the project's end date and completed by five years after the end date). At this stage, hard copies and audio files will be safely disposed of (i.e., shredded, overwritten). De-identified copies of interview transcripts and questionnaire data will be converted to standard data formats for future use by the research team and other researchers.

TP Transcriptions use an encrypted UK Based SSL Secure ISO 27001 upload Service. When uploaded to their system they are stored on secure, private, dedicated, servers with transfers using 256bit SSL encryption. Files are stored using AES 256bit encryption. A contract is in place with TP Transcription and their selection has been approved by University of Dundee Procurement.

Field notes, interview transcripts (MS Word/rich text files) and audio data (MP-4) will be stored in electronic format on password-protected computers at the University of Dundee. No recordings will be stored on the voice recorders, they will be deleted after upload. After the study is completed, the study-owned recorders will be returned to the CI. The full dataset will only be shared by the research team, on OneDrive, with a filing system developed to ensure the consistent organisation and easy retrieval of data.

In line with the ESRC's Research Data Policy, anonymised project data will be made available to future researchers for secondary analysis. Interview and observation data

generated will be deposited at the UK Data Archive. Permission for the archiving of data will form part of the consent process, and all data will be anonymised by the PI prior to archiving. Restrictions to the amount and type of data archived will ensure confidentiality and anonymity. Data will be converted to standard formats that most software are capable of interpreting, as per UK Data Archive guidelines (e.g. Rich Text Format for all textual data). Other metadata developed (e.g. interview guides, consent form templates) will also be revised into suitable formats and deposited to aid analysis.

7 STATISTICS AND DATA ANALYSIS

7.1 SAMPLE SIZE CALCULATION

As appropriate for a feasibility study, particularly given the large proportion of qualitative data, a formal sample size calculation is not appropriate.

The number of observations (20), if they occur, will be enough to observe the elements of the intervention in situ and being used. The number of participants in each observation will vary, with maximum total number of participants estimated at 60. The number of interviews planned (20) was influenced by the number of different types of participants it is important to include. Based on the experience of the research team, and sample size recommendations for qualitative research [36] this number of interviews will provide enough data, spread over four care homes to be able to evaluate the context of intervention selection and adoption.

We expect to recruit a maximum of 168 participants (8 Antibiotic Champions, observations including up to 60 participants, 20 interviews and up to 80 attendees at recorded Q&A sessions). The actual number is likely to be lower than this as some observations will involve a single participant and some individuals will participate in more than one activity.

7.2 PROPOSED ANALYSES

Quantitative data

The quantitative data include measures such as: the numbers and grades of staff attending training sessions, as counts and as proportions of total numbers; the numbers of ARCHeS tools used, as counts and proportions of opportunities for use, and; the coverage of planned topics at the Q&A sessions. The analysis will all be descriptive as the number of data points (maximum five months with data collected) and care homes (four) will be too small for formal statistical analysis of any one measure. The breadth and depth of data collected (once combined with the qualitative data) should be sufficient to assess the intervention's suitability for testing in a future trial, assessed against the implementation outcomes (Table 3 above), and to inform on any refinement required before such testing.

The data on outcome measurement will include descriptive comparison between the use of manually reported *versus* routinely collated administrative data, and examination of the variation in measures over time, to inform the feasibility and selection of outcome measures for the future trial. The study is not powered to detect any changes in these outcome measures.

Interviews, Observations and Q&A sessions

Data will consist of observations (where possible) of the intervention in situ, qualitative interviews to discuss aspects of how the intervention is working for care home staff, and qualitative discussion data from the Q&A sessions.

Following a combined inductive thematic and deductive framework analysis approach [37], researchers will first read through the transcripts several times to familiarise themselves with the data and develop an initial set of codes (e.g. by highlighting sections of the text and generating short-hand codes to summarise and describe the participant response). Next, the generated codes will be examined within and across transcripts to identify patterns and generate higher-order summary themes. The generated themes will then be deductively mapped to the domains of the theoretical frameworks that guided the design of the interview guide (i.e. domains of NPT, Theoretical Domains Framework, and Theoretical Framework of Acceptability), as well as the different implementation outcomes assessed in the interviews (acceptability, adoption, feasibility). The aim of the themes is to summarise how care home staff felt about the intervention, how it was embedded and used in daily practice, and areas for intervention optimisation and refinement to improve acceptability, feasibility, and adoption ahead of a future evaluation trial.

All data (fieldnotes, interview transcripts) will be content analysed and coded using NVivo. Emergent codes will be analysed with reference to the overall analytical framework to develop a detailed understanding of how and why the intervention might (or might not) improve the management of infections in care homes and antibiotic prescribing practices.

Findings will provide a descriptive and explanatory understanding of how the co-designed intervention elements are being integrated to influence infection management and antimicrobial decision-making. This will be developed from the combined perspectives of healthcare professionals across this complex organisational context. The findings will also guide any refinement of the intervention package required prior to testing in a definitive trial.

7.3 TRANSFER OF DATA Some sound files may be transferred from co-investigators to the PI and this will be accomplished securely via the ARCH OneDrive held at University of Dundee. Sound files will be transferred to TP Transcriptions for transcription. TP Transcriptions use an encrypted UK Based SSL Secure ISO 27001 upload Service. When uploaded to their system, files are stored on secure, private, dedicated servers with transfers using 256bit SSL encryption. Files are stored using AES 256bit encryption. A contract is in place with TP Transcription and their selection has been approved by University of Dundee Procurement. MS Word files are transferred to the PI who checks for anonymisation, password protects each word file and transfers these to the ARCH secure OneDrive folder.

Anonymised and password protected research data may be transferred between the University of Dundee and the partner universities: University College London; Queens University Belfast and University of Edinburgh. A legal Collaboration Agreement between the University of Dundee and the partner institutions is in place (RIS reference: 10247).

The full dataset will only be shared by the research team, with a detailed review, sharing and anonymization process agreed to ensure quality and consistency.

Except for any potentially identifiable information collected at UCL that is transferred only to the University of Dundee for filing as per regulations, only anonymised interview and observational data will be transferred between the University of Dundee and the partner universities for further analysis. All researchers are very experienced in receiving, storing and analysing data of this kind.

8 STUDY MANAGEMENT AND OVERSIGHT ARRANGEMENTS

8.1 STUDY MANAGEMENT GROUP

The study will be co-ordinated by a Study Management Group (SMG), consisting of the grant holder and Chief Investigator (CI), Principal Investigator (PI), Co-investigators and Study Administrator.

8.2 STUDY STEERING COMMITTEE

The ARCH Study Advisory Group (SAG) has successfully worked to oversee the conduct and progress of WP1-3 and will continue to oversee WP4.

The SAG includes representation from NHS Improvement England (Elizabeth Beech), NHS Fife (Julia Cook, Infection Control Manager), Scottish Care (https://scottishcare.org/ Becca Gatherum, Policy & Research Manager), Balhousie Care Group (https://balhousiecare.co.uk/ Pablo Vilar, Operations Manager and Lindsay Dingwall (Clinical Care Quality Manager), a care home resident representative (Mairi Hall) invited via the Care Inspectorate, and a care home manager (Celia Findlay).

8.3 INSPECTION OF RECORDS

The CI, PI and all institutions involved in the study will permit study related monitoring, audits, and REC review. The CI agrees to allow the Sponsor or, representatives of the Sponsor, direct access to all study records and source documentation.

9 GOOD CLINICAL PRACTICE

9.1 ETHICAL CONDUCT OF THE STUDY

The study will be conducted in accordance with the principles of good clinical practice (GCP).

In addition to Sponsorship approval, a favorable ethical opinion will be obtained from the appropriate REC and appropriate NHS R&D approval(s) will be obtained prior to commencement of the study.

9.2 CONFIDENTIALITY AND DATA PROTECTION

The CI and study staff will comply with all applicable medical confidentiality and data protection principles and laws with regard to the collection, storage, processing and disclosure of personal data.

The CI and study staff will also adhere to the NHS Scotland Code of Practice on Protecting Participant Confidentiality.

All study records and personal data will be managed in a manner designed to maintain participant confidentiality. All records, electronic or paper, will be kept in a secure storage area with access limited to appropriate study staff only. Computers used to collate personal data will have limited access measures via usernames and passwords.

The CI and study staff will not disclose or use for any purpose other than performance of the study, any personal data, record, or other unpublished, confidential information disclosed by those individuals for the purpose of the study. Prior written agreement from the Sponsor will be required for the disclosure of any said confidential information to other parties.

Access to collated personal data relating to participants will be restricted to the CI and appropriate delegated study staff.

Where personal data requires to be transferred, an appropriate Data Transfer Agreement will be put in place.

Published results will not contain any personal data that could allow identification of individual participants.

If a complaint is made against the care home or any member of staff during an interview, the PI will discuss the ways in which this could be taken forward. If the person making the allegation agrees, she may also discuss this with the more senior of the research team to find the best way to handle the situation.

If anyone discloses any criminal activity or professional malpractice, or the PI witnesses any criminal activity or malpractice, then s/he will be required to break confidentiality and report this to the research team, the management of the care home and, if criminal, the police. In the case of professional malpractice (breaching professional codes of conduct, for example someone who is not a qualified prescriber writing a prescription), the appropriate regulatory authorities will be informed, which could be one or all of: the care home management, the Care Inspectorate, the Local Authority, the Scottish Social Services Council (SSSC), the Nursing and Midwifery Council (NMC), the General Medical Council (GMC), the General Pharmaceutical Council (GPhC). This information is included in the relevant PISs.

9.3 INSURANCE AND INDEMNITY

The University of Dundee are sponsoring the study.

Insurance - The University of Dundee will obtain and hold a policy of Public Liability Insurance for legal liabilities arising from the study.

Indemnity - The sponsors do not provide study participants with indemnity in relation to participation in the Study but have insurance for legal liability as described above.

10 ANNUAL REPORTING REQUIREMENTS

Annual reporting will be conducted in compliance with TASC regulations for preparing and submitting progress and safety reports in CTIMPs and Non-CTIMPs, as a condition of sponsorship and as a condition of a favourable opinion from a REC. An HRA Annual Progress Report for NCTIMPs will be prepared and submitted by the CI to REC, and copied to the Sponsor, on the anniversary date of the REC favourable opinion.

Any safety reports for example, reports of a DMC, will be sent by the CI to REC, with a Safety Report Form, and to the Sponsor.

11 STUDY CONDUCT RESPONSIBILITIES

11.1 PROTOCOL AMENDMENTS, DEVIATIONS AND BREACHES

Amendments to the protocol or other study documents will not be implemented without appropriate approvals.

All breaches will be notified to the Sponsor when identified.

11.2 STUDY RECORD RETENTION

Archiving of study documents will be for five years after the end of study. Anonymised data will be deposited at the UK Data Archive for use in future research as required by the research funder (ESRC). Consent for this will be included in all consent forms.

11.3 END OF STUDY

The end of study is defined as the end of the six-month process evaluation period or the last observation or interview conducted (whichever comes last). The Sponsor, CI and/or the SC have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the Sponsor and REC within 90 days, or 15 days if the study is terminated prematurely. The CI will ensure that any appropriate follow up is arranged for all participants.

A summary report of the study will be provided to the Sponsor and REC within 1 year of the end of the study.

12 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

12.1 AUTHORSHIP POLICY

Ownership of the data arising from this study resides with the study team and their respective employers. On completion of the study, the study data will be analysed and tabulated, and a clinical study report will be prepared.

12.2 PUBLICATION

The study report will be used for publication and presentation at conferences and meetings. Investigators have the right to publish orally or in writing the results of the study.

Summaries of results will also be made available to Investigators for dissemination within their clinical and specialty areas (where appropriate and according to their discretion).

12.3 PEER REVIEW

This study proposal was peer-reviewed by a panel convened by the Economic and Social Research Council (ESRC) and their nominated independent reviewers prior to funding being awarded. The proposal has also been reviewed by the Study Team and representatives of stakeholder organisations (including Balhousie Care Group and Scottish Care) who agreed to support the study.

13 REFERENCES

1. Michie S, Atkins L, West R. *The behaviour change wheel. A guide to designing interventions.* Great Britain: Silverback Publishing. **2014**; 1003-10.
2. McClean P, Hughes C, Tunney M, Goossens H, Jans B, on behalf of the European Surveillance of Antimicrobial Consumption Nursing Home Project G. Antimicrobial prescribing in European nursing homes. *Journal of Antimicrobial Chemotherapy* **2011**; 66(7): 1609-16.
3. McClean P, Tunney M, Gilpin D, Parsons C, Hughes C. Antimicrobial prescribing in Nursing Homes in Northern Ireland: Results of two point-prevalence surveys. *Drugs and Aging* **2011**; 28(10): 819-29.
4. Hughes CM, Tunney MM. Improving prescribing of antibiotics in long-term care: Resistant to change? *JAMA Internal Medicine* **2013**; 173(8): 682-3.
5. Chen Y, Briesacher BA, Field TS, Tjia J, Lau DT, Gurwitz JH. Unexplained variation across US nursing homes in antipsychotic prescribing rates. *Archives of Internal Medicine* **2010**; 170(1): 89-95.
6. Charani E, Castro-Sanchez E, Sevdalis N, et al. Understanding the determinants of antimicrobial prescribing within hospitals: the role of "prescribing etiquette". *Clinical Infectious Diseases* **2013**; 57(2): 188-96.
7. Hughes CM, Donnelly A, Moyes SA, et al. "The Way We Do Things Around Here": An International Comparison of Treatment Culture in Nursing Homes. *Journal of the American Medical Directors Association* **2012**; 13(4): 360-7.
8. Campbell NC, Murray E, Darbyshire J, et al. Designing and evaluating complex interventions to improve health care. *BMJ* **2007**; 334(7591): 455-9.
9. Petersen I, Johnson AM, Islam A, Duckworth G, Livermore DM, Hayward AC. Protective effect of antibiotics against serious complications of common respiratory tract infections: retrospective cohort study with the UK General Practice Research Database. *BMJ* **2007**; 335(7627): 982.
10. Marwick C, Santiago VH, McCowan C, Broomhall J, Davey P. Community acquired infections in older patients admitted to hospital from care homes versus the community: cohort study of microbiology and outcomes. *BMC Geriatrics* **2013**; 13(1): 1-6.
11. O'Fallon E, Pop-Vicas A, D'Agata E. The Emerging Threat of Multidrug-Resistant Gram-Negative Organisms in Long-Term Care Facilities. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences* **2009**; 64A(1): 138-41.
12. Xie C, Taylor DM, Howden BP, Charles PGP. Comparison of the bacterial isolates and antibiotic resistance patterns of elderly nursing home and general community patients. *Internal Medicine Journal* **2012**; 42(7): 157-64.
13. Marwick CA, Yu N, Lockhart MC, et al. Community-associated Clostridium difficile infection among older people in Tayside, Scotland, is associated with antibiotic exposure and care home residence: cohort study with nested case–control. *Journal of Antimicrobial Chemotherapy* **2013**; 68(12): 2927-33.
14. Davey P, Brown E, Charani E, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients. *Cochrane Database of Systematic Reviews* **2013**; (4).
15. Davey P, Peden C, Brown E, et al. Interventions to improve antibiotic prescribing practices for hospital inpatients (updated protocol). *Cochrane Database of Systematic Reviews* **2014**; (8).
16. Hernandez Santiago V, Marwick C, Guthrie B, Davey P, Brown E. Interventions for improving antimicrobial prescribing in the community: a systematic review (PROSPERO registration). **2014**.
17. Nguyen H, Tunney M, Hughes, C. Interventions to Improve Antimicrobial Stewardship for Older People in Care Homes: A Systematic Review. *Drugs & Aging* **2019;** 36(4): 355-369. doi.org/10.1007/s40266-019-00637-0.
18. Craytom E, Richardson M, Fuller C. et al. Interventions to improve appropriate antibiotic prescribing in long-term care facilities: a systematic review. *BMC Geriatr* **2020;** 20(237). doi.org/10.1186/s12877-020-01564-1

19. Smith C, Williams H, Jhass A, Crayton E, Lorencatto F, Miche S, Hayward A, Shallcross L. Antibiotic prescribing in UK care homes 2016-2017: retrospective cohort study of linked data. *BMC Health Services Research* **2020**; 20(1): 1-2.
20. Lorencatto F, Charani E, Sevdalis N, Tarrant C, Davey P. Driving sustainable change in antimicrobial prescribing practice: how can social and behavioural sciences help? *Journal of Antimicrobial Chemotherapy* **2018**; 73(10): 2613-24.
21. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, Griffey R, Hensley M. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* **2011**; 38(2): 65-76.
22. Medical Research Council. *Developing and Evaluating Complex Interventions: New Guidance*. London: Medical Research Council; **2020**.
23. Medical Research Council. Process Evaluation of Complex Interventions. London: *Medical Research Council*; **2020**.
24. Murray E, Treweek S, Pope C, May C. *et al.* Normalisation process theory: a framework for developing, evaluating and implementing complex interventions. *BMC Med* **2010;** 8**(**63). doi.org/10.1186/1741-7015-8-63.
25. Atkins L, Francis J, Islam R, O'Connor D, Patey A, Ivers N, Foy R, Duncan EM, Colquhoun H, Grimshaw JM, Lawton R. A guide to using the Theoretical Domains Framework of behaviour change to investigate implementation problems. *Implementation Science* **2017**; 12(1): 77.
26. Lorencatto F, Charani E, Sevdalis N, Tarrant C, Davey P. Driving sustainable change in antimicrobial prescribing practice: how can social and behavioural sciences help? *Journal of Antimicrobial Chemotherapy* **2018**; 73(10): 2613-24.
27. Health Improvement Scotland (HIS) & SAPG. *Antibiotics - an information leaflet for staff in care homes and community hospitals*. **2018**.
Online: https://www.sapg.scot/media/3678/antibiotics-in-frail-elderly-for-staff-for-upload-to-website.pdf.
28. Health Improvement Scotland (HIS) & SAPG. *Decision Aid for Diagnosis and Management of Suspected Urinary Tract Infection (UTI) in People aged 65 and Over.* **2021**. Online: https://www.sapg.scot/media/5844/decision-aid-for-diagnosis-and-management-of-suspected-uti-in-people-over-65-years.pdf
29. Health Improvement Scotland (HIS) & SAPG. *Improvement in the diagnosis and management of urinary tract infections in adults living in care homes with nursing*. **2021**. Online: https://www.sapg.scot/media/5837/care-home-uti-assessment-tool.pdf
30. Hughes, C., Ellard, D. R., Campbell, A., Potter, R., Shaw, C., Gardner, E., ... & Tunney, M. Developing evidence-based guidance for assessment of suspected infections in care home residents. *BMC geriatrics* **2020**. 20(1): 1-11.
31. Institute for Healthcare Improvement. *SBAR Tool: Situation-Background-Assessment-Recommendation*. **2021**.
Online: http://www.ihi.org/resources/Pages/Tools/SBARToolkit.aspx
32. Proctor E, Silmere H, Raghavan R, Hovmand P, Aarons G, Bunger A, Griffey R, Hensley M. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* **2011.** Mar 1;38(2): 65-76.
33. Sekhon M, Cartwright M, Francis J. Acceptability of healthcare interventions: an overview of reviews and development of a theoretical framework. *BMC Health Services Research* **2017**: (1): 1-3.
34. Nilsen P. Making sense of implementation theories, models and frameworks. *Implementation science* **2015**. Dec;10 (1):53.
35. Cane J, O'Connor D, Michie, M. Validation of the Theoretical Domains Framework for use in Behaviour Change and implementation Research. *Implementation Science* **2012**: 7(37).
36. Francis J, Johnston M, Robertson C, Glidewell L, Entwistle V, Eccles M, Grimshaw J. What is an adequate sample size? Operationalising data saturation for theory-based interview studies. *Psychology and Health* **2010**: 25(10): 1229-45.
37. Clarke V, Braun V, Hayfield N. Thematic analysis. In J. Smith (Ed.), *Qualitative*

psychology: A practical guide to research methods. Sage Publications Ltd. **2015;** 222-248.