1. Full project title

An evaluation of a multifaceted intervention to reduce antimicrobial prescribing in care home residents [**RE**ducing **A**ntimicrobials in **C**are **H**omes (REACH)]: a non-randomised pilot study and process evaluation

Carmel M. Hughes[1*], Michael Tunney[1], Dermot O'Reilly[2], David Ellard[3], Martin Underwood[3], Mark Loeb[4], Bob Stafford[5], Evie Gardner[6], Ashley Agus[6].

School of Pharmacy, Queen's University Belfast, Medical Biology Centre, 97 Lisburn Road, Belfast, BT9 7BL

[2]Centre for Public Health, School of Medicine, Dentistry and Biomedical Sciences, Queen's University Belfast, Institute of Clinical Sciences Building, Royal Victoria Hospital, Grosvenor Road, Belfast, BT12 6BA

[3]Warwick Clinical Trials Unit, Division of Health Sciences, Warwick Medical School, The University of Warwick, Coventry, CV4 7AL

[4]McMaster University, Faculty of Health Sciences, Michael G. DeGroote Centre for Learning, Rm. 3208, 1200 Main Street West, Hamilton, Ontario L8N 3Z5

[5]Orchard Care Homes

[6]Northern Ireland Clinical Trials Unit, 1st Floor Elliot Dynes Building, The Royal Hospitals Grosvenor Road, Belfast, BT12 6BA

2. Summary of research

Concerns have been raised about the level of prescribing of antimicrobials in care homes,[1] with such facilities an important 'reservoir' of antimicrobial resistance.[2] In this non-randomised pilot study, we will test the feasibility of a multifaceted intervention in six care homes (at least one with and one without nursing care at each site) across Northern Ireland (NI) and England (West Midlands). We will adapt and refine an intervention previously shown to be effective in a Canadian study[3] for use in the United Kingdom (UK). We will present the proposed intervention (see below) to stakeholders (focus groups with care home staff and family members and semi-structured interviews with general practitioners, GPs) who will be asked to comment on and amend the content of the intervention. The proposed intervention consists of education and training of care home staff, and the principal general practices caring for pilot home residents, on appropriate management of common infections and antimicrobial stewardship. This will be achieved via visits to the care homes and practices, including training on the implementation of algorithms to guide recognition of signs and symptoms and treatment for infections by home staff and GPs. The intervention will be a complex whole home intervention targeting home staff and their linked general practices, focusing on use of antimicrobials in care homes with an implementation phase running for six months. A detailed process evaluation will run throughout the pilot study to assess whether care homes can be recruited to the study, the implementation and acceptability of the intervention, and how home staff and general practices interact. We will also test our approaches to data collection from care homes and community pharmacies, the assessment of appropriateness of prescribing, and determination of event rates for sample size calculations.

3. Background and rationale

3.1 Importance of the problem: Care homes (with or without nursing) provide care for older people who can no longer live independently. The most frequent acute health care intervention which care home residents receive is prescribing of medications.[1] There are serious concerns about the quality of prescribing generally, and antimicrobial prescribing in particular.[1] This has important implications for individual residents, and may have broader public health considerations due to the development of antimicrobial resistance (AMR). A number of prescribing decisions (not just antimicrobials) for care home residents may be made over the telephone,[4] and this can lead to medicines management problems, with erratic review of medicines and prescribing errors. A more 'whole-systems' approach, involving education, diagnosis, treatment and feedback, may help improve practice more broadly.

***3.2 Impetus for proposed research*:** We have previously shown that Northern Ireland (NI) nursing homes have the highest levels of and greatest variation in, antimicrobial prescribing, compared to facilities in 20 other European countries/jurisdictions.[5] England was ranked fourth in terms of overall prescribing.[5] Similar findings were reported for residential homes (those facilities which are not required to have qualified nursing staff).[6] Indeed, antimicrobial prescribing in care homes is seen as a global problem, contributing to increasing resistance.[1] The remit of the HS&DR AMR call, to which we are responding, highlights an interest in studies to evaluate interventions to modify prescribing behaviour. This follows on from the report entitled 'Infections and Antimicrobial Resistance' from the Chief Medical Officer (CMO) in England on AMR[7]. The ageing population and the requirements for high quality long-term care are important considerations for the National Health Service (NHS)[8] and have been recognised in the CMO's Report.[7] The latter highlighted 'the older adult', with recognition of this population's greater vulnerability to infection; this can be exacerbated by living with other older people with risk factors for infection in care homes. The Report stated that infections can be managed better than at present with the appropriate prescribing of antimicrobials being highlighted throughout the Report as an aspect of healthcare that needs to be tackled in the context of AMR. This theme was echoed in the UK Five Year AMR Strategy[9] and in the earlier NI Strategy for Tackling Antimicrobial Resistance 2012-17.[10] These reports emphasised the importance of better stewardship of antimicrobials which encompasses optimising therapy for individual patients, prevention of overuse, misuse and abuse, and the subsequent minimisation of resistance at both patient and community levels. Education of the healthcare workforce was seen as an essential element to draw attention to AMR and appropriate antimicrobial stewardship.[7,9,10] The proposed project will combine the priorities outlined in the CMO Report to develop and pilot test a cohesive intervention which will seek to address antimicrobial prescribing for highly prevalent infections in a vulnerable population.

***3.3 Evidence for the intervention*:** The CMO Report[7] indicated that *'there is a need to take an international view of this problem (*AMR*) and work with other nations'*, to tackle this problem. Therefore, we have established a collaboration with the Chief Investigator of a Canadian study which demonstrated the effectiveness of a multi-faceted intervention on antimicrobial prescribing for urinary tract infections (UTIs), the most common type of infection in care homes, in a sample of largely Canadian facilities.[3] In this study, 12 nursing homes in Ontario, Canada and Idaho, United States were randomised to receive a multifaceted intervention (based on education and the use of a structured approach to management of infections) and 12 homes were allocated to usual care. The intervention consisted of the application of diagnostic (signs and symptoms) and treatment algorithms for UTIs at nursing home level, supported by small group educational interactive sessions for staff, videotapes, written material, outreach visits and face-to-face sessions with physicians. Findings indicated that fewer courses of antimicrobials were prescribed for suspected urinary tract infections in the intervention homes than in the usual care homes. No significant differences were found between intervention and control sites in terms of total antimicrobials, admissions to hospitals and mortality. We have already carried out a short feasibility study in two nursing homes in NI, using some of the same intervention components,[11] such as interactive sessions, written material, out-reach visits to homes and educational sessions with GPs, along with the use of algorithms. The intervention was well-received by staff and GPs and provides confidence that we can extend this approach on a greater scale. In the proposed study, we will take the Canadian intervention and our feasibility findings, both of which focused solely on UTIs, and adapt for use in two UK geographic regions in a non-randomised pilot study, extending the focus to infections common in care homes (including respiratory and skin). **Our over-arching research question states 'Can a multifaceted intervention focussing on appropriate antimicrobial prescribing involving care home staff and associated GP practices be successfully implemented and evaluated?'** Our proposed study addresses many of the key points in the CMO report (infections in older people in care homes and associated prescribing) [7] and will address the points that have been raised by the Review Board.

3.4 Alignment with research, policy and practice priorities: The proposed research is aligned to one of the over-arching aims of the HS&DR programme which supports research to improve health services and the organisation and effectiveness of those services. It will address an issue of strategic importance to the NHS and our findings will allow us to assess the feasibility and acceptability of our approach in this proposed non-randomised pilot.

In the UK, 4% of those over 65 years live in care homes,[8] and this population has often been excluded from research that may have the potential to improve the quality of care (delivery and outcomes) they receive.[12] The detailed process evaluation, which will be an integral part of this pilot study, will enable us to assess how the intervention fits with the delivery of care in both care homes and general practice. We will also have the opportunity to assess what aspects of the intervention, its delivery and data collection processes require further modification before progression to a full randomised controlled trial.

4. Evidence explaining why this research is needed now

The proposed research is timely and relevant, particularly in light of the CMO's Report and the UK AMR Strategy.[7,9] Prescribing in care homes has been a perennial issue of concern. Several relevant systematic reviews have been published, addressing infection control, medication use in older people and those resident in care homes, and one review has focused on antibiotic prescribing in long-term care. CH and MT have recently updated their Cochrane review on infection-control strategies for preventing meticillin-resistant *Staphylococcus aureus* (MRSA) transmission in nursing homes for older people.[13] Only one study met the inclusion criteria, which failed to show that an education-based intervention affected the prevalence of MRSA in residents and staff in nursing homes randomised to receive this intervention; however, fidelity to the intervention was problematic. The review emphasised the importance of considering context in intervention development. An intervention that may work in one context is not necessarily transferable to another; for example, care homes are very different to an acute hospital setting. Other relevant systematic reviews e.g. polypharmacy in older people,[14] interventions to improve prescribing (including antimicrobials) in care homes,[15-17] indicated that multifaceted interventions involving education to improve prescribing skills and multidisciplinary working, were generally acceptable and had some effect on outcomes; however, the quality of evidence was low. At the time of submission, a search of trial registries has revealed no on-going studies on this or related topics and

further searches for systematic reviews have not identified any further publications. In view of the current state of evidence, and the recognised imperative to tackle antimicrobial prescribing, this proposed pilot study addresses an important topic in an under-researched environment and population.

5. Aims and objectives

Our aim is to evaluate the feasibility and acceptability of a multifaceted intervention on rational prescribing for infections in a non-randomised pilot study in care homes. The intervention will consist of an educational and management approach, supported by discussion on resident cases. The objectives of the study are as follows:

1. To recruit six care homes; three in NI and three in the West Midlands;
2. To adapt and develop an intervention originally developed and implemented in Canadian care homes;
3. To deliver training in respect of the intervention in the care homes and associated general practices;
4. To implement the intervention in the six pilot homes;
5. To undertake a detailed process evaluation of the non-randomised pilot phase and test data collection procedures.

The outcomes that we are interested in for this pilot study are primarily related to the process evaluation; these include: the acceptability of the intervention in terms of recruitment and delivery of training, feasibility of data collection from a variety of sources, the feasibility of measuring appropriateness of prescribing, and a comprehensive overview of the implementation of the intervention. The pilot study will also produce data to inform the design of the future definitive study. The study will be led by Hughes (CH) as Chief Investigator (CI) and a multidisciplinary team of investigators who have the necessary expertise and experience to undertake the work. Below, we describe our research plans and methods for the pilot study and process evaluation, followed by data collection.

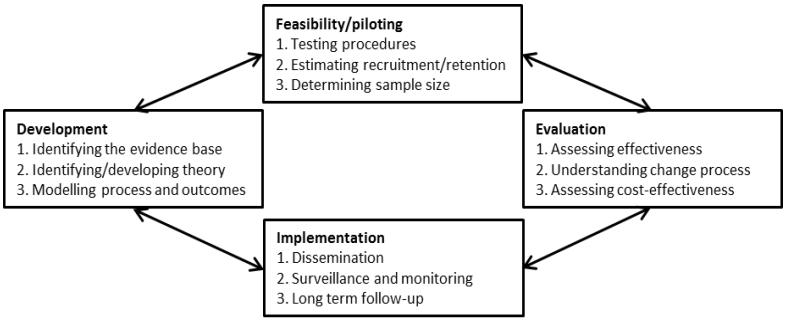

Figure 1. MRC framework for the development of a complex intervention

6. Research Plan/Methods

***6.1 Design*:** This will be a **non-randomised pilot study, with a parallel process evaluation**, in which the care home will be the focus for the intervention implementation. All aspects of the study will be conducted in three homes in NI and the West Midlands respectively (six homes in total). The day-to-day running of the two-year study will be undertaken by one research fellow based at QUB and an intervention developer to oversee the production of all intervention material, and a research fellow based at the University of Warwick leading on process evaluation.

***6.2 Theoretical/conceptual framework*:** This study is grounded within the Medical Research Council's (MRC) Framework [(18)] for the development of complex interventions (Figure 1). We have already completed some of the 'Development' and 'Feasibility' work, and in the proposed study, will proceed to a formal non-randomised pilot study. The underpinning theory for this research is Normalisation Process Theory (NPT).[(19)] This explains the social organisation of work, of making practices routine elements of everyday life (embedding) and of sustaining these embedded practices in context (integration). The elements of this theory are directly applicable to the approach that we will take with the intervention. In the context of this study, the social organisation of work refers to prescribing of antimicrobials. We will be cognisant of the way in which prescribing is organised within care homes and between these facilities and general practices (social organisation). Previous work by the CI has already mapped how this is organised in relation to the management of UTIs in care homes.[(4)] The intervention will seek to change prescribing practices for antimicrobials, so that a systematic approach to diagnosis and treatment becomes embedded. Finally, the duration of the intervention will allow some time for us to determine if there is potential for the intervention to be sustainable or not. The study will involve an

adaptation phase, a training phase and finally, an implementation phase in which the intervention will be piloted in six care homes; a process evaluation will run in parallel with all these phases.

6.3 Non-randomised pilot study

a. Recruitment of care homes: We have given careful consideration to the number of homes required for this pilot study. The sample size has been informed by the research team's previous experience in care home studies, in terms of what is considered acceptable for a pilot, what will provide the type and quality of data required, and allow us to understand the process and implementation challenges. At the time of this application, we have received expressions of interest from a number of homes interested in participating in this project. In previous qualitative work undertaken by the CI, data saturation has been achieved when recruiting staff for participation in focus groups and/or interviews from this number of homes (i.e. n=6). Furthermore, we have already indicated that we see the pilot study providing an opportunity to allow us to undertake a detailed process evaluation. The applicants from Warwick (DE and MU) undertook a thorough process evaluation in the OPERA trial that promoted physical activity in care homes.[20,21] They have demonstrated that this number of homes will be sufficient to produce a high-quality evaluation to help us understand the challenges and complexity of intervention development and implementation.

Therefore, we will recruit a purposive, maximum variation sample of **six care homes**, three in NI and three in the West Midlands. The inclusion criteria are: care homes (with/without nursing care), principally providing 24 hour care for older residents, with a minimum of 20 residents, associated with a small number of general practices (up to four per home providing care for a minimum of 80% of residents within a home) and an exclusive arrangement with one pharmacy for dispensing medications. There are no specific exclusion criteria for residents as the intervention will be delivered at the level of the home. We have selected a minimum of 20 residents as below this level, we would need to recruit more homes to achieve the required resident sample size which had been outlined in the original full proposal. We feel that it is important to maintain this approach for the pilot study. We will ensure that we have a mix of homes which demonstrate a range of characteristics e.g. with and without nursing care, number of beds, urban or rural location. These homes will also participate in all other aspects of the study including training in the intervention, the pilot phase in which the intervention is delivered and assistance with aspects of data collection. We will restrict the number of GP practices associated with each care home to a maximum of four per home to facilitate intervention implementation, with each practice looking after a minimum of five residents and the four practices looking after at least 80% of the residents at the time the home is recruited. Previous work has shown that there is considerable variation in the number of GP practices which may provide care to residents. One study led by the CI noted that up to 20 practices were associated with some care homes.[22] We have examined currently available data and in NI, over 50% of homes are associated with no more than four practices (O'Reilly, personal communication). From a sample of Orchard care homes in England, the mean number of practices associated with a home is 4.1 (Stafford, personal communication) as was reported in a previous care home study.[23] The situation with community pharmacies is more straight-forward in that standard practice is that a home usually engages with one community pharmacy for dispensing and delivery of all medication.[22,23]

Initial inquiries will be made prior to formal contact with the home to ascertain if they meet the criteria in terms of the number of beds, GP practices and community pharmacies. If a home meets the criteria, the manager (or appropriate contact person who can make decisions on participation) will be contacted by telephone by the research fellow in each of the geographical regions, and the study briefly explained. If the manager is interested, the research fellow will offer to visit the home and provide more detail about the study (written and oral). One week after this visit, a follow-up telephone call will be made to the manager asking them if they are willing to participate. If the manager (or appropriate contact person) agrees, the home will, following written, informed consent, be formally recruited to the study. This approach will continue until we have recruited a purposive sample of homes.

b. Adaptation phase: The previous Canadian study[3] has provided 'proof of concept' that antimicrobial prescribing can be influenced by an educational intervention. However, as a previous systematic review has shown,[13] context is important, in this case, the difference between the Canadian care home context and that of the UK. Transposing the intervention from Canada to the UK without any modification is unlikely to be

successful. Furthermore, the evidence on management of infections in older people will have developed since the Canadian study was undertaken (last follow-up was in 2003). Therefore, the intervention developed for the Canadian study will be updated and adapted for UK use through: (i) **production of rapid reviews and updating of minimum criteria for initiating antimicrobials** (ii) **development of intervention material and a training programme and** (iii) **adaptation of the intervention** via focus groups with care home staff, resident family members and semi-structured interviews with GPs. We will also seek National Institute for Health and Care Excellence (NICE) accreditation for the processes used to develop the intervention material and will refer to the 25 criteria to inform the development of all such intervention material.[24] Producing NICE accredited guidance on antimicrobial prescribing in care homes will be an important stand-alone deliverable from this pilot study. This approach has been used previously by the CI in which a medication review intervention developed in the United States (US) was adapted for use in NI nursing homes.[25]

(i) Production of rapid reviews and updating of minimum criteria for initiating antimicrobials: the research team will undertake a series of rapid reviews[26] with respect to antimicrobial prescribing for the most prevalent infections in care homes- urinary, skin and respiratory. The findings from these reviews will be used to update previously established minimum criteria for the initiation of antimicrobials developed by Loeb *et al*. prior to the Canadian study.[27] These criteria will be the basis for assessing prescribing appropriateness (see section 7.1 ii). This will be led by the research fellow and intervention developer based in QUB. The rapid reviews will examine systematic reviews, recent trials, guidelines and other sources of high quality evidence. For example, the Scottish Medicines Consortium has recently produced a decision aid for the diagnosis and management of UTIs in older people[28] while NICE is currently developing clinical guidance for the management of UTIs in adults (due May 2015) that will inform our models of best practice. Following synthesis of this material, the fellow will prepare a brief presentation on the background and aims of the study, followed by a description of the proposed intervention, its components and its mode of delivery (see 6.3b (ii), 6.3c, and 6.3d) to be used in the focus groups/interviews (see iii below). The fellow and intervention developer will also produce exemplars of the algorithms (produced from the rapid reviews; one example is shown below in Figure 2).

(ii) Development of intervention material and training programme: Intervention material will be prepared at Queen's University by the intervention developer, with input from co-applicants from Warwick and McMaster Universities. This will consist of the following: **case scenarios**, **summarised evidence on the management of infections (including leaflets and educational material on best prescribing practice)**, and copies of the **signs/symptoms (classification) and treatment algorithms**. We will also focus on **communication** between care home staff and GPs. In the Canadian study, the infection of interest was UTIs.[3] This study extends this approach to encompass other common infections, including respiratory (upper and lower) and skin, which are prevalent in care homes.[5,29]

Case scenarios: will consist of cases illustrating the most common infections encountered in older care homes residents and will be used as teaching aids to identify signs, symptoms and treatment decisions. These will be prepared from clinical examples encountered by relevant members of the team, and representing 'typical' care home cases. MU and ML are medically qualified, CH and MT are registered pharmacists and RS is a nurse, who has extensive experience of care homes, and all will contribute to this aspect. The cases will describe the resident, pertinent medical history, and their presenting symptoms and will be presented on a laminated card for use in training.

Summarised evidence: The case scenarios will be supported by a brief summary of up-to-date evidence for the management of common infections in older people which will have been drawn from the most recent literature and from clinical expertise within the research team. In addition to the publication of the Scottish Medicines Consortium guidance on the management of UTIs,[28] various other agencies have produced updated evidence/guidelines on the recognition of signs/symptoms and treatment of infections.[30,31] All such sources will be used to produce short, succinct and clinically useful information for each of the key infections on one A4 sheet (double-sided) which will also be laminated. Again, this material will be used in intervention training.

Signs/symptoms and treatment algorithms: these will assist in decision-making on antimicrobial prescribing. An example of a treatment algorithm for UTIs is shown below in Figure 2. This exemplar has been revised from that produced by ML for the Canadian study,[3] taking into account the most up-to-date evidence from a variety of sources.[28,32,33] All algorithms will be developed with reference to the most recent evidence and clinical expertise of those within the research team prior to use in the non-randomised pilot. The algorithms will guide care home staff and GPs on the recognition of signs and symptoms and decisions on treatment of common infections. They will be produced on a single A4 laminated sheet for easy use during training in intervention homes and for implementation in the trial.

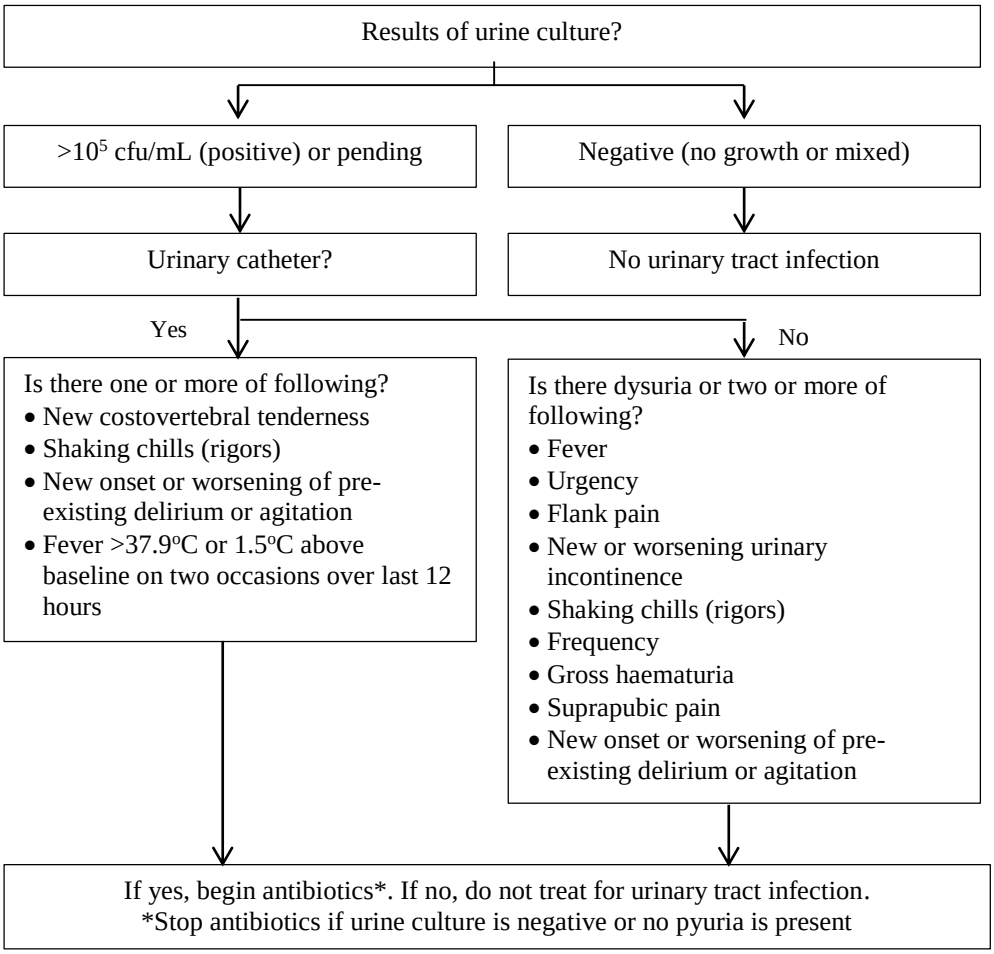

Figure 2 Exemplar updated algorithm for prescribing antimicrobials (antibiotics) for treatment of UTIs

Communication: the research fellows will train senior care home staff in using the SBAR tool (Situation-Background-Assessment-Recommendation) which consists of standardised prompt questions within four sections, and allows staff to share concise and focused information, and communicate assertively.[34] It will provide a structured framework by which care home staff can communicate information about residents to GPs in respect of infections. It has been recommended for use by the Royal College of Nursing in the context of paediatric nursing.[35]

The intervention developer, with input from all other members of the team, will produce a training programme, based on the various components outlined above. A blended learning approach will be taken, including conventional presentation material which will provide background to the study, problem-based learning using the case scenarios to demonstrate the use of evidence and algorithms, and role play to demonstrate the use of the SBAR tool. This programme will be implemented in the six participating homes (see section 7.3c/d).

(iii) Adaptation of intervention: We will convene six care home staff focus groups (~6-8 per group), three in NI and the West Midlands respectively, recruiting participants from each of the participating homes. We will also conduct semi-structured interviews with up to 10 GPs in NI and the West Midlands (five in each area); our experience is that arranging focus groups for GPs is impractical. These numbers are similar to those recruited in the previous medication review study[25] which achieved data saturation. Focus groups are an appropriate forum in which care home staff can share and discuss common experiences in relation to prescribing decisions; in the case of GPs, semi-structured interviews are the most appropriate (and pragmatic) approach to data collection and have been used before.[25] To recruit care home staff, the two research fellows will approach the manager in each of the participating homes to assist in this process. Written information about the focus group phase will be provided to the managers who will be asked to distribute it to all members of staff. If required, the research fellows will also make a brief presentation during staff meetings, outlining the nature of the study. This approach (using key informants) is an efficient way of generating high quality data from participants who will be able to make a meaningful contribution to the study. The research fellows in NI and the West Midlands will approach the practices (up to four) associated with the participating homes, and will seek to recruit up to five GPs in the two respective geographic areas (10 in total). Participation will be voluntary and written, informed consent will be obtained.

We will also ask the care home managers to assist in the recruitment of family members to participate in focus groups. Previous research has shown that family members can be influential in decision-making in relation to prescribing of antimicrobials;[4] therefore, we feel that it would be important to explore their views on the intervention and their perceptions of facilitators and barriers to implementation. We will seek to convene one family member focus group per home, each with between six-eight participants. Managers will be provided with written information to pass on to family members, and the research fellows will also be available by telephone to provide further explanation. Again, participation will be voluntary and written, informed consent will be obtained.

Focus groups and interviews will be held at a time and place suitable for the participants and will be facilitated by the research fellow from each research centre. In the focus groups for staff and interviews for GPs, the background to the study will be presented by the research fellow, followed by an overview of the intervention, including the minimum criteria for antimicrobial initiation, and the supporting materials which will be used. Each component of the intervention will be discussed and views sought. Particular attention will be paid to how the intervention can be implemented, embedded and sustained in the UK context. For the family member focus groups, a brief background to the study will be provided, along with an outline of the intervention. The family member topic guide will explore family members' views on antimicrobial prescribing, if they consider the intervention to be acceptable, and any other aspects that may be raised by participants. All discussions will be recorded and transcribed verbatim. Analysis will be undertaken using the 'Framework Method'[36] which we have used in previous studies.[21,25] The Framework Method is considered appropriate for this study as the objectives are set in advance i.e. adaptation of the intervention for use in the UK. All transcripts will be read and re-read to enhance familiarisation with the content. The main themes will be identified and coded according to the outline of the Canadian approach. Participant responses will be mapped on to the elements of the Canadian model, but with consideration given to the adaptations required for the UK setting as recognised and discussed by the participants. Findings will be presented to the research team for comment and feedback. We will consider views on the components of the intervention (what will be delivered and what is considered impractical) and the mode of delivery. We will pay close attention to how we can introduce best practice and evidence-based prescribing, while recognising the pressures of everyday practice in care homes and primary care. The intervention will then be refined by the research team, and focus group participants and interviewees will receive (via post) an overview of the refined intervention for final comment. The adapted intervention will then be tested in a non-randomised implementation phase (see section 6.3d).

c. Training phase: (i) Care homes: The research fellows will contact the three care homes in NI and the West Midlands respectively and arrange a visit with the manager in the first instance to discuss how best to organise the introduction of the intervention for all staff. As part of NPT (the underpinning theory),[19] we will seek to embed the intervention in everyday practice; therefore, this meeting will allow the manager and research fellow

to discuss how best to do this. The manager will be asked to arrange a time when as many care home staff can be free to attend the training session for the intervention. The manager will also attend the training session.

We have given consideration to whether it is also necessary to train care assistants who are not involved in clinical decisions about residents. Care assistants are most closely involved in the day-to-day care of residents and may be most attuned to changes in their status.[37,38] However, there may also be language difficulties for some care assistants for whom English is not their first language.[20] Therefore, the training provided to care assistants will be in a different session (albeit during the same visit to the home) to that for senior staff, and will be appropriate to their role within the home. The training will be offered on one occasion in each intervention home.

The research fellow will try to be as flexible as possible, and accommodate training sessions at times which work best for most staff (e.g. evening). We recognise that it will not be possible for all staff to attend the training session, as care-related activities will need to continue in the home. Furthermore, night staff may also be unable to attend the designated session. Therefore, we will produce a DVD recording of a training session for viewing by staff unable to attend. We are also aware that turnover of staff can be substantial in care homes (figures range from 19-42% annually),[39,40] thus we need to consider new staff who will require training at various times during the course of the implementation phase. Hence, the research fellow will ask the manager to identify up to two members of staff (to account for different shifts within the homes) who can act as 'intervention leads' and who will be responsible for delivering training to staff who are unable to attend the original session. These leads will receive the requisite training by the research fellow. This approach was used in an infection control study conducted in care homes led by the CI.[41] In the feasibility study conducted in NI, focusing on UTIs only, we monitored attendance at training across the two participating homes which was 63% in one home and 35% in the other.[11] In the OPERA study, 46% of care home staff were trained in depression awareness and activity training.[20] In both studies, no incentives were offered to encourage attendance. We recognise the importance of trying to embed this new approach to antimicrobial management in care homes, and the importance of engaging staff as fully as possible. Therefore, to further encourage attendance at the training sessions, we will offer a £10 voucher to each staff member, along with a certificate of attendance which will serve as evidence for continuing professional development (CPD) where required. Both the voucher and the certificate will only be provided on completion of the training.

At the training session for senior staff (an attendance record will be kept in order to follow up those who need to attend further sessions led by the intervention leads), the research fellows will deliver a brief overview of the study and the issue of antimicrobial prescribing in care homes. The attendees will receive copies of the **case studies** and the **summarised evidence** and these will be discussed during the session. The **signs/symptoms and treatment algorithms** will be provided to the senior staff and used to discuss decision–making, with reference to the case studies and the summarised evidence. This will provide the staff with an opportunity to practice this systematic approach to recognition of signs and symptoms, and transfer learning into practice. The research fellows will encourage discussion/questions to ensure that senior staff understand the nature of the intervention. Staff will also be trained in the use of the **SBAR tool** with examples provided on how it can be used to convey information to a GP and via role play. A session for care assistants will be delivered separately (again, an attendance record will be kept as per senior staff) and pitched at an appropriate level, emphasising the important signs and symptoms to be aware of in residents. Although these staff will not be using the algorithms, they will be made aware of their use by senior staff, so that they have a full appreciation of the nature of the intervention.

(ii) <u>GP practices:</u> the second target for intervention training will be the associated general practices. We will approach up to four practices which provide care for a minimum of 80% of residents in each pilot home.

We will offer training on one occasion to each of the four main practices for each pilot home. If the offer is accepted, this training will be delivered at a convenient time for staff, such as a lunchtime or staff meeting. We will fit into the usual routine of the practice as far as possible. All GPs and nurses within the practice will be invited to attend, and light refreshments will be provided. As with the care homes, the research fellows will provide brief details about the study and its background, the latest evidence for the management of common infections in care home residents, and the application of the algorithms, as illustrated with the use of the exemplar case scenarios. GPs will be asked to use the material (the summarised evidence and the

algorithms) when considering antimicrobial prescribing in care home residents. All those who attend the session will receive a certificate for CPD purposes (appropriately accredited). For practices which do not wish to avail of the training (and this will be noted), all material will be sent to them.

We will also facilitate an audit of antimicrobial prescribing within each practice visited. It is a usual requirement within general practice that audits are conducted on a range of activities in order to promote reflection on practice[42] and institute change if required. The research fellow will liaise with the appropriate person within the practice, and provide standard documentation to allow an audit of antimicrobial prescribing for care home residents to take place. The first cycle of the audit will cover the last 25 prescriptions for antimicrobials that were written for care homes residents. The research fellow and practice contact will discuss appropriateness, based on the criteria below (section 7.1 iv), and establish the baseline level of appropriateness for these 25 prescriptions. An increase in the level of appropriateness will be agreed between the fellow and practice contact, and 6 months later, a second set of 25 prescriptions will be examined to evaluate if appropriateness has increased. This will encourage reflection on prescribing, thereby embedding a focus on antimicrobials in care homes.

d. Implementation phase: Following the training programme, staff will apply the algorithms in all cases where residents present with signs and symptoms that may suggest an infection (see Figure 2 as an example). They will use the SBAR approach when contacting a GP to help structure communication. The intervention leads in each home will be asked to keep a record (data collection form to be developed for this purpose) within the home of the number of times the algorithms are used, details about each case which will have been extracted from care home records, and whether an antimicrobial was prescribed (see section 7.1 iii). This phase will last for six months.

Evidence from our previous work has demonstrated that the greatest effect is seen at the first delivery of an intervention.[22] However, it is important that the intervention is sustained over the course of the implementation phase. Therefore, the research fellows will return to the intervention homes approximately every two months to liaise with the manager and intervention leads to monitor progress. In advance of these visits, the research fellows will ask the leads and manager to select four cases from those which have been recorded and where the signs/symptoms and treatment algorithms were used. These will act as discussion points to assess how successfully the intervention is being implemented. This will also provide an opportunity for the research fellows to reinforce any aspect of the intervention which the intervention leads can cascade to other members of the home staff. The research fellows will also monitor how many new staff have joined intervention homes and have undergone training.

6.4 Process Evaluation

Successfully delivering complex interventions in care home settings is an emerging field. Only by carefully examining intervention processes can we understand reasons for success and failure of the intervention and develop plans for implementation. Our proposed process evaluation builds directly on our experience from the OPERA study, which, has in turn, informed the development of the planned intervention for this study.[21,43,44] The evaluation will be grounded in the framework proposed by Stecklar and Linnan[45] and mapped against this intervention's theoretical framework, NPT.[19]

The aims are:

- To comprehensively describe the implementation of this intervention, including the facilitators and barriers to implementation
- To develop a set of transferable principles regarding the intervention to inform its implementation on a wider scale.

The objectives are:

- To monitor all implementation processes (e.g. recruitment, development of the intervention, delivery of the intervention and acceptability/use of the intervention in practice); to undertake an ethnographic type observational study in the homes to understand current practice and to explore possible changes due to the intervention;
- To carry out in-depth interviews with a sample of care home staff, care managers and other stake holders e.g. GPs.

We will use a mixed methods approach, combining qualitative and quantitative data [46,47] to facilitate exploration of apparent discrepancies between findings.[48,49] The principal data collection method will be qualitative (e.g. interviews, focus groups, observational field notes), complemented and illuminated by the quantitative data (e.g. number of homes approached, recruitment to focus groups, training sessions provided, attendances at sessions), providing a depth and breadth of understanding. As this is a pilot study, all six homes will be included in the process evaluation. In the homes, the research fellow based at Warwick will observe homes' practice and intervention training sessions, day-to-day use of the algorithms and, where possible, interactions with study GP practices and care home staff.

7. Data collection

Data collection for this study will be overseen by the research fellows and will focus on the main outcomes for the **pilot study** as outlined above e.g. exploratory analysis of dispensing data. The **process evaluation** will run parallel to the pilot study. The data to be collected have been categorised according to these two aspects of this proposal:

7.1 Pilot study

(i) Collection of data from care homes (including hospitalisations and mortality data): The research fellows will collect data pertaining to characteristics of each of the six pilot homes: setting (rural, urban), ownership (private, statutory), part of a chain or single ownership, capacity (number of beds), number of nurses (if appropriate), number of care assistants.

Resident data will be collected from each care home. As we are not seeking individual resident consent, we have sought advice from the Privacy Advisory Committee in NI on how this should be done (see letter of support). The Chair of the Committee has advised that data such as gender, age, number and type of co-morbidities can be extracted from care home records by staff, and aggregated to the level of the home. Alternatively, individual data can be extracted, but must be anonymised before it can be passed to the research team. Therefore, specific proformas (self-carbonising so that the research team can receive anonymised copies) will be developed to allow the care home staff (a nominated member) to record data for residents (all assigned unique codes but which will prevent identification by the research team) at baseline. The data to be recorded are: age, gender, length of time in home, list of active medical conditions (based on a checklist), medications, cognitive assessment, and length of stay in the home.

We will also ask staff to maintain a running monthly log of GP contact (visit or telephone call), visits by community nurses, and other health care professionals over the course of the six-month implementation phase.

In the original application, we proposed accessing hospitalisation and mortality data from the Health and Social Care Information Centre in England, the Regional Warehouse in NI and the Registrar General's Office. For this pilot study, we will ask staff to record these events, including reason for admission and cause of death (where possible). Because of the time scale of this proposed project, data pertaining to the implementation phase of the pilot study will not be available due to the lag times (up to six months in some cases) associated with availability of relevant data. However, we will still test the processes of data extraction relating to these events from the large centralised databases. We will seek the relevant permissions to do this using residents' NHS numbers that can be provided in an encrypted form by the community pharmacist and sent directly to the data curators without breaching confidentiality and a pooled anonymous dataset returned. This is a challenging area for data retrieval. In the event permission is not forthcoming for our preferred approach, we will seek to obtain a pooled dataset on all hospital admissions and deaths based on the post codes of the pilot homes.

(ii) Measurement of appropriateness of prescribing / not prescribing: As requested by the Board, we have considered approaches to assessing appropriateness of prescribing. In other studies which have examined antimicrobial prescribing in care home residents, clinical information pertaining to the residents has been used as the basis for such an assessment, in conjunction with the use of minimum criteria for assessing appropriateness of the initiation of antimicrobials. As previously stated, such minimum criteria have been

developed by Loeb *et al*.[27] For example, the original minimum criteria for initiating treatment for an indication of a UTI in residents with an in-dwelling catheter included fever (>37.9ºC or 1.4ºC above baseline temperature), new costovertebral tenderness, rigors, with or without identified cause or new onset of delirium.[27] Following updating of these criteria in the adaptation phase from evidence synthesis (see section 7.3b i), we will use these criteria to measure appropriateness of prescribing. It is important to note that these criteria will not provide an assessment of the appropriateness of the antimicrobial selected for treatment. However, they will provide an assessment of **when** it is appropriate to initiate an antimicrobial. We do not feel that it would be helpful to attempt to assess **the appropriateness of the drug** per se, due to possible local variations in bacterial sensitivities. As stated in 7.1 i above, we will ask care home staff to extract information, based on these revised criteria, which will allow them to make a decision on whether an infection is present and an antimicrobial may be warranted. As described earlier, data on each case where the algorithms have been used will be collected by care home staff (anonymised), and the research team will apply the criteria to assess appropriateness.

The converse of inappropriate prescribing is failure to prescribe when it would be appropriate. This can occur either when the algorithm incorrectly suggests that no antibiotic is required, or when the algorithm was not triggered and an antibiotic was not prescribed. To explore whether antibiotics are being inappropriately withheld, we will ask care homes to identify all residents admitted to hospital (care homes are legally obliged to keep records of hospital admissions); we will ask them to identify any residents who might have been admitted due an infection and complete an anonymous proforma as to whether an opportunity to prescribe an antibiotic, that might have prevented the admission, had existed. Data to be collected will include: were symptoms identified, was the algorithm used, was the GP contacted and if so, did they attend the resident, and what diagnosis was made.

(iii) Antimicrobial prescribing data from community pharmacies: In the original application, our primary outcome had been based on a difference between intervention and control homes in the number of defined daily doses (DDDs) of antimicrobials dispensed per resident per year, collected from community pharmacies at baseline (pre-randomisation) and 12 months. The Board has requested that we consider the process of community pharmacy data collection for this pilot study.

It is usual practice that a care home will contract with one community pharmacy to provide all medications for that home.[22] These community pharmacies (all of which are computerised) will store information relating to the medications which have been dispensed for each resident in each home. Therefore, community pharmacy computer records will be the source from which we will obtain data on all antimicrobials dispensed for participating pilot homes. Members of the research team have already been in contact with the main pharmacy computer suppliers in NI and England-McLernon's, Cegedim and Rx Systems. These companies cover between 40-75% of all community pharmacies in these regions. Some preliminary work has already been conducted to test the feasibility and practicality of downloading and extracting data in a community pharmacy with the McLernon's system (most widely used system in NI), following the development of a bespoke program by the company. The pharmacist who undertook this download experienced no difficulties in conducting the exercise. Therefore, we are confident that this process will work for data download/extraction. In the pilot study, a baseline data download will be undertaken in each community pharmacy associated with each of the care homes prior to the intervention being introduced to the homes, following a standard operating procedure that will be developed from that used in our preliminary work. The research fellows will ensure that each community pharmacist is able to perform the download. In previous studies conducted by the CI, where appropriate ethical approval has been granted, community pharmacists have provided medication data (albeit not in this format) for research purposes.[50-52] We do not anticipate substantial difficulties in engaging with community pharmacists who will receive payment for undertaking the process. This download will relate to all antimicrobials dispensed in each participating home. We will use dispensing data from the year prior to study entry as our baseline level of antimicrobial use. Historical data may be available for up to six years. Subject to there being adequate data of a suitable quality, we will conduct an interrupted time series analysis which is a more robust approach than simply comparing one year before, and after joining the study. Antimicrobials are defined as those medicines which are listed in Chapter 5 (Infections) of the British National Formulary (BNF), the standard reference text which lists drugs and appliances available in the UK.[53] The antimicrobials of interest are listed in numbered sections of Chapter 5 and are as follows: antibacterial drugs (section 5.1),

antifungal drugs (section 5.2) and selected agents from antiviral drugs (section 5.3). The extracted data will include the name, strength, formulation and quantity of antimicrobial dispensed and cost. This will allow us to calculate the DDD exposure. The data will be produced in a comma delimited file which can then be directly transferred into Excel in the first instance. No individual resident will be identified in this download, but each will be assigned a unique identifier. The same exercise will be repeated at the end of the implementation phase. Collection of these data will allow us to refine the original sample size calculation that had been presented in the original application and should, depending on quality and quantity of the available data, allow us to produce some evidence of reduced antibiotic prescribing following our intervention.

7.2 Process evaluation

The process evaluation will gather data on:

a. The context of the homes across NI and the West Midlands, examining aspects of the larger social, political and economic environment that may influence implementation.

The research team will gain an understanding of the context of each of the homes from multiple sources including the Care Quality Commission (CQC)/Regulation and Quality Improvement Authority (RQIA) reports, observations within the homes, questions within focus groups or interviews and local government definitions of the area.

b. The proportion of the intended target audience (homes) that participates in the pilot phase (reach).

Data from CQC/RQIA public records will help us understand to what extent our pilot homes are representative of the homes in an area.

c. Recruitment rates:

We will monitor the number of homes approached to participate in the pilot study, the number meeting the inclusion criteria, and the numbers which decline. In the case of the latter, we will ascertain the reason for non-participation. We will also conduct a survey in a larger sample of homes to quantify the number of facilities interested in participating in a full trial (see section 7.5).

d. The number or amount of intended units of each intervention or each component delivered or provided (dose delivered). We will record and monitor this carefully.

As this is a pilot and thus a formative process for future work, we will monitor how the intervention was delivered to each home. We will monitor the establishment of the training sessions and examine how these sessions were integrated into the homes (or not) For example, were training sessions arranged, but then cancelled? When sessions were organised, did the appropriate people know they were due to attend and subsequently do so?

Similarly, we will monitor the convening of the focus groups for intervention development within the homes. What were the facilitators or barriers to their operation?

e. The extent to which staff/GPs actively engaged with and interact with the recommended resources (dose received).

We will record attendances and examine if we have provided training for all those who would need it in each home. We will use two approaches to seek assurance that the training is being implemented by those who have been trained. Firstly, this will be via the discussion of case studies as a measure of appropriateness of decision-making in prescribing. Secondly, either focus/discussion groups or interviews with these staff towards the end of the project will be used to explore the use of the intervention asking for evidence that it is being used (or not). In addition, a proforma will also be used to record the number of times the algorithms are used, details about each case which will have been extracted from care home records, and whether an antimicrobial was prescribed. These data will be used by the research team to assess appropriateness of prescribing (see above in 8.1 ii), as well as providing evidence that the intervention was being put into practice. The process evaluation will examine how many times these have been used and if not, why not.

f. We will also seek the views of wide range of different stakeholders in this study, including the care home staff, GPs and relatives.

In the Adaptation phase (see section 6.3b iii), focus groups will be taking place in each of the homes. It is possible during these sessions to gain an understanding of what participants think will be the facilitators or barriers to implementing the intervention. Several questions will be asked in each group exploring these points. The research fellows, during visits, will be getting to know the homes, the staff and their practices and will, with

careful observation, build up a picture of 'normal' operations within the home. Field notes will be made during each visit. Changes in practice will be noted over time as monitoring visits take place.

At the end of the implementation phase, interviews or focus groups (whichever is most appropriate and acceptable) with GPs, practice managers, care home staff and if appropriate, relative groups, will be conducted to determine opinions of the whole experience. These experiences, their attitudes to, and their suggestions for improving the intervention, will have a significant role in helping to interpret the outcomes and assessing the success of the pilot.

7.3 Data analysis: Analysis will be primarily descriptive, providing an overview of the characteristics of participating homes and residents. We will have data on antimicrobial prescribing extracted from community pharmacy computerised records at baseline, and at the end of the implementation phase. These latter data will allow us to estimate the effect size and intraclass correlation (ICC) from this non-randomised pilot study, thus informing the calculation for a full study. As stated under 7.1 iii, subject to the quality of data collected from community pharmacies, we will undertake an interrupted time series analysis to explore the trends in the prescription of antimicrobials before and after the intervention.

For the process evaluation in which most of the data are qualitative in nature, the Framework Method[36] defined in the Adaptation phase above (see section 6.3b iii) will be applied.

7.4 Economic evaluation: The cost of the intervention will be measured in this pilot study by recording the resource use associated with distinct costing stages:
Stage 0 - development of the intervention
Stage 1 - planning and preparation for delivery
Stage 2 – delivery stage
Costs will include those associated with labour, training, intervention materials, equipment and space and will be gathered prospectively where possible. These resource use data will be combined with appropriate unit costs to estimate a mean cost per patient and per nursing home to deliver the intervention. We will also pilot the proformas and log described in section 7.1i for collecting data on residents' use of health services (e.g. GP contacts and hospitalisations). Feedback from nursing home staff on the acceptability of maintaining these logs will be obtained during the qualitative interviews planned in the process evaluation. This will inform the design of a full cost-effectiveness analysis in a future RCT.

7.5 Outcomes and planning for a full study: Following completion of adaptation, training and implementation phases, we will have a detailed and in-depth understanding of all key aspects of this pilot study, which will help to inform the development of a full study. We will understand recruitment issues, how to best train participants in the intervention, how the intervention can be successfully implemented in routine practice, and issues pertaining to data collection and analysis. We also plan to explore the likelihood of recruitment to a full study by conducting a short postal survey with all care home managers in NI, the West Midland and West Yorkshire (the latter area having been part of the original full study and which will be included again if we proceed to a full trial). Contact details for all homes are publicly available. A cover letter will accompany each questionnaire, explaining the context. The content of the questionnaire will be informed by the outcomes from this pilot project; therefore, we cannot be definitive about exact questions and sections. However, we anticipate that questions will cover views on the duration of training, the content of training, intervention implementation and data collection. Respondents will also have the opportunity to provide free text responses. All returned questionnaires will be coded, entered into SPSS and analysed descriptively, such as the percentage of respondents willing to participate in a full trial, the percentage of respondents agreeing to participate in intervention training. The findings will provide us with an estimate of the number of homes willing to participate in a full study, and care home managers' views on the training programme and intervention.

8. Dissemination and projected outputs

A final report on the pilot project will be delivered to the funder. As required by the HS&DR programme, we will publish our findings in the NIHR HS&DR Journal. We will make our treatment algorithms freely available; QUB have agreed to host these on their website for five years after the end of the study. We will also publish findings in mainstream journals (all open-access; support has been requested to allow for such publication), particularly those within the Biomed Central group of publications which welcome pilot studies. We anticipate that one major paper will be published on this project, incorporating the adaptation and pilot phase, along with the process evaluation. We will also consider a separate publication from the focus groups conducted with family members. We will produce an abridged lay summary of the main findings, written in an accessible way for all health care professionals, carers and resident participants as appropriate, with a link to the full report. We will also present our work at relevant research conferences, through oral presentations and/or posters.

9. Plan of investigation and timetable

The main activities are outlined below in a Gantt chart. As detailed in section 11, we will need to seek ethical approval twice: once for the adaptation phase, and secondly for the pilot phase. The first approval for the adaptation study can be obtained relatively quickly through the QUB ethics review system, and endorsed by Warwick University (see section 11). The research team's contacts from previous studies will expedite recruitment and retention throughout the study.

Activity\Month	-5	2	4	6	8	10	12	14	16	18	20	22	24
Set-up and ethics submission for adaptation phase													
Recruitment of homes													
Pilot study-Adaptation phase: (i) identification of best practice													
Pilot study-Adaptation phase: (ii) Development of intervention material and training programme													
Pilot study-Adaptation phase: (iii) Adaptation of intervention including recruitment of staff, GPs and family members for focus groups and interviews													
Pilot study-Training phase in homes and practices													
Ethics submission for implementation phase													
Pilot study-Implementation phase including data collection													
Process evaluation													
Survey of care homes													
Analysis and write-up													

10. Project Management

Queen's University Belfast will act as Sponsor and a sub-contract will be drawn up with the University of Warwick.

All listed applicants will constitute the Pilot Study Management Group (PSMG) as core members. The PSMG will meet on a monthly basis, and all meetings will be chaired by the Chief Investigator (CH). There will

be two face-to-face meetings held during the course of the study, one in Belfast and one in Warwick, involving all applicants, and research fellows. All other meetings will be conducted via teleconference. An agenda will be drawn up in advance of each meeting, minutes will be taken and filed, and available for inspection by the funder. Close attention will be paid to progress as assessed against the study timetable (see above) and the achievement of key milestones and deliverables. As requested by the funding body, we will submit 6 monthly reports which will outline progress to date and provide other information/data as required. The key milestones for the project will be (following receipt of all necessary approvals): recruitment of homes for the pilot phase; completion of the adaptation of the Canadian intervention model; training in pilot homes and associated practices; completion of the implementation phase and process evaluation; analysis and write-up of study.

Although we are not running a trial per se, members of the research team considered that it would be good practice to have a Trial Steering Committee (TSC) which could have input into the pilot study. In the comments from NIHR, it was stated that it is a requirement to have an independent Study Steering Committee (SSC). Therefore, our proposed TSC will convert to a SSC. This will meet at the start and end of the pilot study, via teleconference. Prof. Catherine Sackley (Kings College London) has agreed, in principle, to act as the independent Chair. Prof. Sackley has experience of care home research and cluster trials. Two members of the research team (CH and MU) will also sit on this committee and we will also have two lay members, thereby enhancing the PPI elements. We will recruit an additional GP to the SSC, along with another clinician. We have given careful consideration to the need for a Data Monitoring and Ethics Committee (DMEC). The pilot study has been substantially scaled down from the original cluster trial. We view this pilot study to be low-risk, and will ask the SSC to discharge the functions of a DMEC.

11. Approval by ethics committees

We have considered the potential ethical issues for this study very carefully and have taken advice from a number of organisations. It is anticipated that we will need to seek ethical approval on two occasions: (i) to undertake the adaptation phase; (ii) to undertake the implementation phase. As noted in our response to the Board, we had previously been advised that the adaptation phase could be reviewed by a University Ethics committee, but since being informed about the status of this grant application, the CI consulted with Queen's University Research Governance office and the Office of Research Ethics Committees in Northern Ireland. We have now been advised that a NHS committee will be required to review the adaptation phase. We will ensure that the ethics documentation is prepared and submitted in a timely manner to ensure we are in receipt of approval prior to the start of the study. In the case of (ii) the pilot study, ethical approval will be sought from a NHS Research Ethics Committee (REC). We are advised that the data required for the proposed primary (drug dispensing data) can be obtained without requiring individual resident consent as the data will be available at home level from community pharmacies and will be anonymised. We will also need to collect data from care homes in respect of resident characteristics, limited clinical information, and hospitalisations and mortality. In this case, data will be extracted, anonymised and/or aggregated by the direct care team (care home staff). We have consulted with the Health Research Authority, the Office of Research Ethics Committees Northern Ireland (ORECNI) and the Privacy Advisory Committee (PAC) in NI who advise that our general approach is likely to be acceptable. The Chair of the PAC has provided a letter of support which states that '*I would not consider there to be any requirement for individual resident consent for the proposed clinical research use of aggregate anonymised data, including the anonymisation, extraction or aggregation of data by direct care staff*.' All previous care home studies conducted by members of the research team have received full ethical approval.

12. Patient and Public Involvement

In preparation for the original full application, we approached the IHCP in NI (a non-profit making organisation whose members provide nursing and residential care for older people), local authorities in West Yorkshire (who contract with independent sector care homes) and two corporate care home providers. A short survey was distributed to care homes via these organisations and to GPs, seeking views on: antimicrobial prescribing in care homes, the proposed study, education and training, and needs of family members and residents. Responses were received from 32 care homes and five GPs. Responses were positive and supportive of the study, particularly, the educational/training element, with recognition of over-prescribing of antimicrobials and resistance. They suggested using staff in homes to help with training in the study, and this aspect has been included in the pilot

phase (the intervention leads identified from care home staff). Family members and residents were also approached in two groups of care homes. They were supportive of the project and expressed concerns about antimicrobial side effects and prescribing by GPs without visiting residents. We also presented the proposed project to the Directors and Board of the IHCP who were enthusiastic, and particularly receptive to the training elements of the intervention. IHCP have provided a letter of support for the current proposal. For this pilot study, we will convene two Advisory Groups to provide PPI perspectives as well as contributing to the study design and development. One group will consist of residents (those with capacity) and/or next-of-kin of residents drawn from the pilot homes. This first Advisory Group will provide advice on implementation of the intervention. The second Advisory Group will consist of care home staff and GPs associated with our pilot homes. We will consult individually with members of the first group as residents in particular, may have difficulty in attending and contributing to meetings. The research fellows in each geographic region will visit residents and/or next-of-kin at the home in question. For the second group, there will be two meetings (face-to-face or via teleconference) over the course of the study. Both groups will advise on development of participant information sheets and consent forms to ensure clarity and lack of ambiguity. They will also be asked to comment on draft reports, and other forms of communication about the study that will be specifically aimed at key stakeholders such as IHCP, and the public. We will also ask IHCP and similar organisations to assist with dissemination of results and other forms of material, via their websites. As part of our research team, we have Mr. Robert (Bob) Stafford (RS) who is Head of Care and Compliance at Orchard Care Homes (letter of support provided for this revised pilot study). Mr. Stafford has responsibility for care compliance across the organisation which consists of over 100 care homes across the UK. As someone who has direct experience of managing and overseeing care homes, his perspective will be invaluable. He will participate in all PSMG meetings and will advise on implementation and trouble-shooting as and when required. We have also secured the agreement of Dr. Hilary Buchanan (former GP and volunteer with the Alzheimer's Society) who has a family member in a care home, to sit on the PSMG.

13. Expertise

The membership of the research team has been reviewed in light of the feedback from NIHR. We consider that the current applicants are essential to the successful conduct of this pilot study. The remaining applicants who were part of the original application agreed to withdraw from this proposal but have declared their commitment to a full study in the future. The research team assembled for this project have the necessary clinical and academic expertise to conduct this study. Research team members from Belfast have previously run trials in care homes, undertaken the observational research on antimicrobial prescribing and used large datasets in research (CH, MT); members from Warwick CTU (DE, MU) are highly experienced in trials' methodology, conducted the HTA-funded OPERA study and have particular expertise in process evaluation, which will be an essential part of the pilot study.[3] ML, as CI of the original Canadian study, will bring unique expertise and experience which will contribute to the successful running of this project. DOR has expertise in large administrative datasets and can advise on the testing of processed for data extraction. RS, Head of Care and Compliance at a major care home organisation will provide a practical perspective in terms of how the pilot phase may be successfully run in this study. The Northern Ireland Clinical Trials Unit (NICTU) staff (EG, AA) have the necessary trial management and data analysis skills which will be required for this study, and have retained some involvement in the present proposal. Research team members and NICTU staff are familiar with the amount of time required for each of the key tasks and the effort required to reach various milestones associated with all aspects of the research.

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