Title

Interventions to improve antimicrobial prescribing of doctors in training: A realist review

Summary of Research

"Antimicrobial resistance is a very real threat. If we have no suitable antibiotics to treat infection, minor surgery and routine operations could become high risk procedures."
Professor Dame Sally Davies, Chief Medical Officer

Prescribing is a high risk area of medical practice, with most errors in hospital settings being associated with antimicrobial drugs. In addition, the development of antimicrobial resistance has been described as a global crisis, for which better prescribing is part of the solution. Behaviour change interventions, often using an education component, are urgently required to reverse this situation and improve patient outcomes. The literature includes different types and combinations of prescribing behaviour change interventions but systematic reviews conclude that their impact is highly variable. Therefore researchers and policy makers have been unable to draw firm conclusions or make recommendations about 'what works' and 'what works best' for their local context. Doctors in training are an important group to study, being numerically the largest group of prescribers in UK hospitals. Unfortunately very few interventions have specifically targeted this group. This raises important research questions such as: why are some antimicrobial prescribing behaviour change interventions successful in some contexts, and some clinician groups, but not in others? Recent research has identified the need for studies targeting doctors in training and greater use of review methods (such as realist review) that are able to take account of local context. In this project our realist review will synthesise the literature taking into account context and make clear recommendations about effective prescribing behaviour change interventions for doctors in training.

Background and rationale

"*A post-antibiotic era—in which common infections and minor injuries can kill—far from being an apocalyptic fantasy, is instead a very real possibility for the 21st century*", said Dr Keiji Fukuda, World Health Organisation (WHO) Assistant Director-General in a recent global report on antimicrobial resistance (AMR) surveillance (1).

AMR is the ability of microorganisms that cause disease to withstand attack by antimicrobial medicines (WHO). Infections with bacteria such as *Klebsiella pneumoniae*, *Staphylococcus aureus* and *Neisseria gonorrhoeae*, which were once routine to treat, can now be untreatable. AMR is also costly, estimated at US$21-34 billion dollars per annum in the US (1). The consequences extend beyond patients who present with infections. Many surgical procedures (where antibiotics are given prophylatically in the hope of preventing infections) may be harder to justify as the risk and consequences of infection become more likely and serious.

There are two important strands of activity to address this global crisis. The first is to develop new antimicrobials but, unfortunately, there have been no new classes of antibiotics for more than two decades because pharmaceutical firms lack incentives to develop new antibiotics. The second is to urge all countries to be more sparing in their use of antimicrobials - this is the focus of our proposed research. Antimicrobial stewardship aims to promote optimal care for patients with infections, whilst minimising the public health threat of drug resistance. However, changing prescribing behaviour is difficult and significant change is required given that up to 50% of antibiotic usage in hospitals is inappropriate (2).

Organisations globally and nationally have responded to the crisis (3), e.g. WHO Global Strategy for Containment of Antimicrobial Resistance, 2001; World Health Day 6-point AMR policy, 2011; Department of Health (DH) UK Antimicrobial Resistance Strategy and Action Plan (2000); DH/British Society of Antimicrobial Chemotherapy's "Start Smart, Then Focus" campaign (4;5) and; the TARGET Antibiotics toolkit in general practice (6).

However these strategies alone are proving incapable of addressing the global crisis at hand. Focussed strategic and integrated action, informed by high quality research targeted at prescribing behaviour, is now required.

Doctors in training and antimicrobial prescribing

Given the lack of new antimicrobials in the pipeline, a focus on strategies to curtail the emergence and spread of AMR is vital. If this does not occur, there will be very significant human cost in terms of morbidity and mortality from previously treatable infections, and substantial financial cost resulting from increased use of expensive second and third line drugs, extended healthcare stays, and the inevitable complications of failed treatments.

One key element of curtailing the emergence and spread of AMR has been to focus on the prescribing behaviours of health care professionals to ensure they are only using antimicrobials when indicated, and that they are using the right drug, at the right time, at the right dose, for the right duration. The importance of education for prescribing behaviour change has been described as self-evident (7) and doctors in training are an important target group both as numerically the largest prescribers in the hospital setting (8) and as a key part of a future generation of antimicrobial prescribers. However the effectiveness of educational interventions has proved variable (9) due to the complex environments in which these interventions are embedded (10), with powerful forces including hierarchy and role modelling dampening the potential effects.

After graduating from medical school, new doctors enter the two year Foundation Programme, which mostly occurs in hospital settings, before undertaking a further 5 years as a Core / Specialty Trainee in hospitals or 3 years in general practice. Trainees across all stages are classed as independent prescribers and will prescribe for patients, typically on a daily basis. For many trainees, decisions around antimicrobial prescribing make up a significant part of their daily practice (e.g. GP, Paediatrics or Emergency Medicine training). Optimal prescribing is imperative in order to promote optimal care for patients with infections and minimise the public health threat of AMR

Many initiatives (particularly educational ones) exist to improve prescribing knowledge and technical skills in doctors, both those in training and beyond - e.g. Hospital Pharmacy Initiative (11); Medical Schools Councils Safe Prescribing Working Group (12). Many types of behaviour change interventions have been developed to improve doctors' antimicrobial prescribing practice – ranging from' distribution of educational materials (13-15), lectures and seminars (16;17), audit and feedback on performance (15;18), to manual and automated reminders (19;20). However, very few have been specifically tailored to the needs of doctors in training.

Evidence indicates that it is unclear if current educational prescribing behaviour change interventions have any consistent effect (21). For example, a systematic review of prescribing behaviour change educational interventions of hospital prescribing in new prescribers found that the impact of particular types or combinations of interventions was highly variable (9). A systematic review focussing on behaviour change interventions in all prescriber types, reported similar findings (22). This raises the question as to why some prescribing behaviour change interventions are successful in some contexts but not in others? Answering this question is important if we are to design interventions that are more effective (7).

Thus, it is clear from the literature that uncertainty exists about which intervention types to implement and if refinements are needed for local circumstances. As such it is unclear if and how existing interventions are instructing doctors in training to prescribe appropriately.

This knowledge gap has partly come about because much of the current literature has not taken sufficient account of the wider context in which doctors in training prescribe antimicrobials. Prescribing is a complex mix of knowledge, skills and behaviours and there is no simple relationship between them (23;24). Prescribing the right antibiotic at the right time is not just about having the correct knowledge about (for example) local formularies, resistance patterns and dosages, but also understanding a patient's expectations, concerns, co-morbidities, and social context.

Education is an important element that influences prescribing practice, but it is not the only one. Qualitative work by one of the applicants (KM) that sought to understand the antimicrobial prescribing experiences of Foundation Year (FY) doctors in training found that the hospital context and processes played important roles (25). The antimicrobial prescribing challenges faced by the FY doctors ranged from knowledge deficits (not knowing what to do in certain situations), to the mundane of not knowing that local prescribing protocols even existed on a ward, through to having to 'take sides' when more senior health care professionals disagreed on prescribing decisions. This work adds to a growing literature that acknowledges the importance of the wider context. For example, Ross et al. point out that doctors in training work within a strict medical hierarchy in complex organisations and their prescriptions are often influenced by other doctors (10). McLellan et al. that a technical focus on isolated prescribing competencies is unlikely

to support doctors in training to become safe prescribers (26). The implication is that any review that seeks to understand antimicrobial prescribing behaviour change interventions in this group needs to look beyond just educational interventions and seek to make sense of the role of wider contexts. This need to account for context provides the rationale for our use of the realist review methods in this application (see Research plans below for more details on realist reviews).

To summarise, antimicrobial prescribing continues to come under the spotlight because of the significant harm that sub-optimal prescribing causes, both at the patient and public level. Its importance has been recognised by the WHO internationally. In the UK it has resulted in a themed call by the NIHR directed at "Preventing the Development and Spread of Antimicrobial Resistance". This proposal aims to address the development and spread of antimicrobial resistance by seeking to understand how interventions to change antimicrobial prescribing behaviours in doctors in training produce their effects. Such an understanding will enable us to develop recommendations that will enable the optimal tailoring, design and implementation of these interventions.

Evidence explaining why this research is needed now

Antimicrobial resistance is a major challenge facing modern day health care now. Globally, its emergence has resulted in an urgent call for action by the World Health Organzation (1). In the UK, the Chief Medical Officer has recognised the importance of this issue resulting in increased national action and a NIHR themed call. Two broad courses of action have been suggested; the development of new antimicrobials and; more sparing use of antimicrobials – antimicrobial stewardship. The latter is the focus of our proposed research. Antimicrobial stewardship aims to promote optimal care for patients with infections, whilst minimising the public health threat of drug resistance.

This proposal seeks to address the issue of antimicrobial stewardship from the perspective of understanding how interventions to change antimicrobial prescribing behaviours in doctors in training produce their effects. We have focussed on doctors in training as they are numerically the largest group of prescribers in hospitals (8). Evidence indicates that their prescribing is frequently sup-optimal (27). In addition (as detailed above) it is at present unclear how prescribing behaviour might be changed. If no action is taken now, our knowledge gaps in this area will remain – with impacts not only on patients as antimicrobial resistance develops further but also NHS finances as ineffective behavioural change interventions continue to be implemented.

Aims and objectives

Aim:

To understand how interventions to change antimicrobial prescribing behaviours of doctors in training produce their effects.

Objectives:

1. To conduct a realist review to understand how interventions to change antimicrobial prescribing behaviours of doctors in training produce their effects.
2. To provide recommendations on tailoring, implementation and design strategies to improve antimicrobial prescribing behaviour change interventions for doctors in training.

Review Questions:

1. What are the mechanisms by which antimicrobial prescribing behaviour change interventions are believed to result in their intended outcomes?
2. What are the important contexts which determine whether the different mechanisms produce intended outcomes?
3. In what circumstances are such interventions likely to be effective?

Research plans

Objective 1: To conduct a realist review

The plan of investigation will follow a detailed realist review protocol which will be written by the project team and will be informed by Pawson‘s five iterative stages in realist reviews (28). We have chosen to use a realist review approach as outlined above in the ‘Background and rationale’ section To recap, we have argued that any evidence synthesis that seeks to make sense of how interventions to change antimicrobial prescribing behaviours in doctors in training produce their effects must take into account the context in which the prescribing decisions take place.

The realist review is an interpretive, theory-driven approach to synthesizing evidence from qualitative, quantitative and mixed-methods research. Its main strength comes from providing findings that coherently and transferably explain how and why context can influence outcomes.

This process of explanation building starts with the development and refinement of a realist programme theory of interventions to change antimicrobial prescribing behaviours of doctors in training. To do this, we will ‘map’ the sequence of steps needed to achieve the final desired outcome from such an intervention. For each step, a realist logic of analysis will be applied, so as to explain how the (intermediate) outcome for each step might be achieved in realist terms – i.e. what interaction between context and mechanism(s) might lead to that outcome. For each step in the sequence, we will seek to identify what mechanism(s) will generate the outcome and in what contexts this mechanism might be triggered.

Our realist review protocol will be written by the project team, who have extensive experience in conducting such reviews and it will be registered with PROSPERO (29).

Step 1: Locate existing theories

The goal of this step is to identify theories that explain how antimicrobial prescribing behaviour change interventions are supposed to work (and for whom), when they do work, when they do not achieve the desired change in clinical practice, why they are not effective, and why they are not being used (30). The rationale for this step is that interventions are “theories incarnate” – that is underpinning the design of such interventions are theories of why certain components are required. In other words, the designers of interventions have put them together in a certain way based on their theories about what needs to be done to get one or more desired outcomes (31). For example the literature indicates that 28% of interventions designed to change antimicrobial prescribing behaviour in new prescribers distribute educational materials (9). The theory underlying such a practice is that poor prescribing behaviour is partly due to knowledge deficits and the way to address this problem is through educational means.

To locate these theories, we will iteratively; a) consult with key content experts in our stakeholder group (see below) and; b) informally search the literature to identify existing theories. This informal searching differs from the more formal searching process in Step 2 in that it is more exploratory and aimed at quickly identifying the range of possible explanatory theories that may be relevant. More exploratory and informal search methods, such as citation tracking and snow-balling (32), along with more structured searching for theories (33) will be used. From these we will build an initial programme theory to test in the review. Building the programme theory will require iterative discussions within the project team to make sense of and synthesise the different theories into an initial coherent programme theory. We have recruited a stakeholder group to provide content expertise for programme theory refinement (see Box 1) and will extend the membership, as needed. Once the programme theory has been developed by the project team it will be presented to the stakeholder group to obtain their feedback. We will refine the initial programme theory based on their feedback. The group will meet six times during the study and communicate via e-mail as necessary.

Box 1: Confirmed stakeholder group members:

Dr Alice Miller, Consultant in Acute Medicine, Torbay.
Dr Katy Marden, Consultant Microbiologist, Exeter
Ms Hazel Parker, Antimicrobial Pharmacist, Exeter
Ms Esmita Charani, Senior Lead Pharmacist, Imperial College
Dr James Read, Academic Clinical Fellow, Plymouth
Mr John Poole, third year medical student, Peninsula College of Medicine & Dentistry
Dr Russell O'Brien, Clinical Pharmacologist, Exeter
Professor Laura Piddock, Professor of Microbiology, Birmingham
Ms Shirley Stevens - PPI stakeholder
We have secured involvement from PenPIG and agreed that if this project is funded they have suggested we recruit (if possible) up to 3 additional PPI stakeholders.

Step 2: Search for evidence

Formal search

The purpose of this Step is to find a relevant 'body of literature' with which to further develop and refine the programme theory from Step 1. Searching will be designed, piloted and conducted by an information specialist with extensive experience of conducting searches for complex systematic reviews, particularly realist reviews. Searching will initially be guided on the strategy from a previous closely related systematic review by Brennan and Mattick on educational interventions to change the behaviour of prescribers in the hospital setting with a particular emphasis on new prescribers (9). However we will need to make modifications to the search strategy used in Brennan and Mattick as this review focussed on all prescribers within 2 years of qualification. We will modify the search to focus only on doctors in training. Another modification that will be needed is to increase the scope of the context of the prescribing, as we wish to also include doctors in training who are working in the hospital *and* primary care. Our preliminary exploratory searching using these modifications indicates that we can expect almost 200 papers that may well be relevant. We anticipate that we may need to search the following databases; Embase; Medline; OpenGrey, Cinahl, PsychINFO, ERIC, DARE, ASSIA but will be guided by the Information Specialist . We will also search any other relevant database identified by the Information Specialist. We will also undertake 'cited by' article searches and search the citations contained in the reference lists of relevant documents. We will search the databases with the following free text keywords in a variety of combinations 'prescribing or drug administration or drug prescription or drug utilization' and 'medical education or continuing medical education depending on the database. Subject headings relevant to each database will also be used (for example) MeSH and Emtree.

Brennan and Mattick's review identified 64 relevant documents, 13 of which specifically focused on doctors in training. The other 51 documents had large numbers of participants (including doctors) from all stages of training and so will likely contain some data that are relevant. By increasing the scope to include both hospital *and* primary care for our realist review, we are confident there are sufficient documents to form a 'body of literature' with which to refine any initial programme theory we develop.

Screening

For the initial search above, our inclusion and exclusion criteria are broad as we seek to find quantitative, qualitative and mixed-methods documents. For the purposes of this review, prescribing will be defined as the act of determining what medication a patient should have and the correct dosage and duration of treatment. The following criteria will be applied:

Inclusion:

- Aspect of prescribing – all studies that focused on developing one or more aspects of prescribing as defined above.
- Study design – all study designs.
- Types of settings – all studies that were conducted in hospital or primary care settings.
- Types of participants – all studies that included doctors in training (any specialty and at any level). If the study participants involved all prescribers in a hospital setting (which would include doctors in training) then it will be included.
- Types of intervention – interventions or resources that focus on changing or developing antimicrobial prescribing behaviour.

- Outcome measures – all prescribing related outcome measures.

Exclusion

- Studies focusing only on drug administration

Screening will be undertaken by the Research Fellow (SRF) we will recruit. A 10% random sub-sample of the citations retrieved from searching will be reviewed independently for quality control by GW. Any disagreements will be resolved by discussion between SRF and GW. If disagreements still remain then the matter will be presented to the whole project team for discussion and resolved by majority vote.

Additional searching

An important process in realist reviews is searching for additional data to inform programme theory development. In other words, more searches will be undertaken if we find that we require more data to develop and test certain sub-sections of the programme theory. As we have outlined above (in Step 1: Locate existing theories) we anticipate that we will need to develop a programme theory that takes into account the influence of the wider context in hospitals and primary care that influence the prescribing behaviour of doctors in training. Areas that we believe at this stage that we will need to search for literature on include systems for providing support to doctors in training, conflict resolution, time pressures, dealing with uncertainty and the 'informal' and 'hidden' medical curricula. The informal curriculum is ward-based teaching which tends to be unscripted, predominantly ad hoc, and highly interpersonal. The hidden curriculum refers to the healthcare culture (a set of influences that function at the level of organizational structure and culture) that influences what is learnt (25).

These additional areas that we will need to search will greatly increase the amount of relevant data available to us for the realist review. The review by Brennan and Mattick did not search for such literature. We will therefore have to develop, pilot and refine additional searches with the help of an Information Specialist. These searches will be of a different nature to that mentioned above as they are much more exploratory and purposive and less well categorised and from a range of different disciplines. Where applicable, we will follow the search strategies developed by Booth et al. developed for just such data (33).

For each additional search the project team will meet to discuss and set inclusion and exclusion criteria. The screening processes will be as described above for the initial search.

Step 3: Article selection

Documents will be selected based on relevance (whether data can contribute to theory building and/or testing) and rigour (whether the methods used to generate the relevant data are credible and trustworthy) (31). Even when a document found from the initial search has been screened and has met inclusion criteria, it may still not contain any data that is relevant for programme theory development and refinement.

The SRF will read all the included papers and finally include documents or studies that contain data that is relevant to the realist analysis – i.e. could inform some aspect of the programme theory. At the point of inclusion based on relevance, an assessment will also be made of rigour (how trustworthy were the data being used) (31). To illustrate how we will operationalise rigour, if data have been generated using a questionnaire, then the trustworthiness of the data would be considered to be greater if the questionnaire had been previously tested and shown to be reliable and valid and had not been altered (or if alterations had been made subsequent testing had been undertaken). A random sample of 10% of documents will be selected, assessed and discussed by the SRF and GW to ensure that decisions to finally include have been made consistently. The remaining 90% of decisions will be made by the SRF (though a number of these may require further discussion/joint reading between the SRF, GW and/or the wider project team as there may be uncertainty over issues of relevance and/or rigour). We will employ the same decision making process as outlined above in Step 2.

Step 4: Extracting and organising data

Data extraction and organising of data will be undertaken by the SRF. A random sample of 10% of finally included documents will be independently checked by GW for quality control. Any disagreements will be resolved by discussion

between SRF and GW. If disagreements still remain then a third member of the project team will be asked for their opinion and resolution will be by majority vote.

The full texts of the included papers were will be uploaded into NVivo (a qualitative data analysis software tool). The exact software used may change depending on the experience and expertise of the SRF. If necessary GW will provide training to the SRF on the use of NVivo. Relevant sections of texts relating to contexts, mechanisms and their relationships to outcomes will be coded in NVivo. This coding will be both inductive (codes created to categorise data reported in included studies) and deductive (codes created in advance of data extraction and analysis as informed by the initial programme theory). The characteristics of the documents will be extracted separately into an EXCEL spreadsheet. Each new element of data will be used to refine the theory if appropriate, and as the theory is refined, included studies will be re-scrutinised to search for data relevant to the revised theory that may have been missed initially.

Step 5: Synthesising the evidence and drawing conclusions

Data analysis will use a realist logic of analysis to make sense of the initial programme theory. We will use interpretive cross-case comparison to understand and explain how and why observed outcomes have occurred, for example, by comparing interventions where prescribing behavioural change has been 'successful' against those which have not, to understand how context has influenced reported findings. The process of evidence synthesis in realist review is achieved by (34):

a) Juxtaposition of sources of evidence – for example, where evidence about behaviour change in one source enables insights into evidence about outcomes in another source

b) Reconciling of sources of evidence – where results differ in apparently similar circumstances, further investigation is appropriate in order to find explanations for why these different results occurred

c) Adjudication of sources of evidence – on the basis of methodological strengths or weaknesses

d) Consolidation of sources of evidence – where outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently

During the review, we move iteratively between the analysis of particular examples, refinement of programme theory, and further iterative searching for data to test particular subsections of the programme theory. The realist review will follow current quality and publication standards (35).

Objective 2: To provide recommendations

Our programme theory will be used to develop recommendations for improving prescribing behaviour change interventions and their implementation. Further details are provided in the Dissemination and project outputs section below.

Dissemination and project outputs

Dissemination

Our dissemination strategy will build on the participatory approach (involving stakeholders) that we used in the development of this research proposal. Our approach will be integrative, valuing the different forms of knowledge needed to produce findings capable of informing complex decision making (36). A range of stakeholders will be interested in the findings and recommendations from our review. Different strategies are likely to be needed. We will draw on the advice and expertise of our stakeholder group to help; a) clarify who the main players are for dissemination for each audience and; b) to develop materials which are tailored and relevant to each audience. For each audience, once we have clarified the main players we will contact the organisation directly to seek advice on their preferred channels and format for optimal dissemination to their members. We are aware that there is likely to be overlap in the optimal dissemination strategies for each audience, and our approach will be informed by the 'Knowledge to Action cycle' – see the Project Outputs section below for more details.

Audience 1: Doctors in training

Doctors in training are an important group to disseminate to as they are the 'targets' of any behavioural change intervention. We want to ensure that this audience is provided with the most up to date evidence on the different pressures that may influence their antimicrobial prescribing behaviour and how educational interventions and other

more system-wide changes may help to mitigate these pressures. This is important as students and trainees are increasingly involved in shaping their educational experiences and their satisfaction is often a key outcome measure in assessing the quality of their education and training.

The more traditional forms of dissemination are probably unlikely to be effective. We are aware that organisations exist for doctors in training who are interested in medical education (e.g. JASME, and TASME). We will specifically approach these organisations to seek their advice. It is likely that social media (e.g. Twitter and Facebook) will prove to be more effective dissemination channels for this (and potentially other) audiences and we will ensure these are developed accordingly.

Audience 2: Clinical supervisors/trainers and medical educators

This audience is responsible for designing, tailoring and/or delivering the training interventions and educational environment to change antimicrobial prescribing behaviour in doctors in training. We anticipate using the following strategies for this audience:

- One or more publications in relevant high impact journals
- A 'How to' publication that outlines practical advice to optimise existing training opportunities
- Presentation at conferences
- Brief summaries of the main recommendations

Audience 3: Policy, decision makers, regulators and Royal Societies

Doctors in training work in settings that are managed, influenced and/or regulated by a range of organisations (e.g. the GMC nationally, Monitor, the CQC and HEE in England, the Royal Colleges and the UK Foundation Programme Office). Many (e.g. such as BSAC and the RCGP) have specific initiatives aimed at improving antimicrobial prescribing practice. We will work with our stakeholder group to identify the key organisations to target.

This audience represents an important group, as we anticipate that not all the changes needed to optimise antimicrobial prescribing in doctors in training will necessarily just be related to educational interventions alone. We anticipate that the educational and working environment of the doctors in training will turn out to be important contextual influences on antimicrobial prescribing behaviour. We will seek the help and advice of national and professional bodies (via for example their communications teams) on how such findings might be effectively disseminated to the appropriate actors for greatest impact.

Project Outputs

We want to ensure that the outputs of this project will be useful and freely available to the NHS. To do this we will use the Knowledge-To-Action Cycle framework provided by the KT Clearinghouse (http://ktclearinghouse.ca/knowledgebase/knowledgetoaction). This is a website that provides knowledge translation resources that is funded by the Canadian Institute of Health Research. The Knowledge-to-Action Cycle graphically sets out the steps necessary in bridging the knowledge-to-action gap. Specifically within this framework, with input from the from our stakeholder group, this realist review will generate knowledge that will inform the following phases of the Knowledge-To-Action Cycle framework:

- producing stakeholder relevant knowledge (as described in the 'knowledge funnel in this framework)
- adapting knowledge to local context and;
- assessing barriers to knowledge use.

This project will produce three major types of outputs:

1) The findings from the review will be submitted for publication to a high-impact peer-reviewed journal

We anticipate that such a publication is most likely to impact at an academic level - informing the understanding and theoretical basis of antimicrobial prescribing behaviour change interventions.

2) A 'How to' publication that outlines practical advice to optimise, tailor and implement existing interventions designed to change prescribing behaviour in doctors in training

With this publication we aim to impact the day to day antimicrobial prescribing practice of doctors in training. This document is mainly targeted at Audience 2: Clinical supervisors/trainers and medical educators. This audience is predominantly responsible for making the necessary changes at the 'coal face' to bring about antimicrobial prescribing

behavioural change. To gain impact we will make the contents of our 'How to' publication as relevant and feasible as possible - our goal being to avoid bland sweeping statements that are difficult to operationalise in the NHS.

To do so we will be drawing on expertise within the project team (e.g. KM and GW) and also the experience and expertise of our stakeholder group members. Later on in the project when we will be developing our outputs and recommendations, we intend broaden the membership of the stakeholder group meetings. This is so as to ensure that we have a wider representation of relevant stakeholders. We will augment the stakeholder group to include additional PPI members, ‘coal-face’ doctors in training, educators, pharmacists and policy and decision makers. Feedback from PenPIG (our PPI partners) suggested that PPI input would be most valuable at this stage in the project.

In month 14 of the project we will start to develop our outputs and recommendations (as indicated in our project timetable). At this point we will schedule our first ‘augmented’ stakeholder group meeting. By this stage we will have completed the bulk of the data analyses, synthesis and programme theory refinement. We will use our preliminary data as a starting point in our discussions with the stakeholder group. We will present our data and then ask the group what actions (if any) are needed. Suggestions made will be noted and discussed in detail to ensure that implementation is acceptable and feasible within different settings in the NHS - i.e. what are the challenges to making this happen and how might they be overcome (if possible). We will ensure that any suggestions made are backed up by evidence from our review. Where there is a discrepancy we will initiate further discussions about the validity of a suggestion. We will use this iterative dialogue with our augmented stakeholder group to work through our review's findings. We will use the stakeholder group meeting planned for month 17 for a similar purpose, but use email and teleconferencing (as needed) with the group between meetings to continue to work on the 'How to' publication output. We have successfully employed this strategy in a previous study to produce relevant and feasible recommendations (25).

As an example to illustrate the processes, we might find (as reported in a qualitative study (25)) that doctors in training, because they are often abruptly rotated between wards in their training are unsure about where to find relevant prescribing guidelines. Such a finding would be presented to the stakeholder group and suggestions ask for what might need to be done about this finding. A suggestion might be that this problem could be addressed by providing guidelines at the point of prescribing on the e-prescribing systems that are currently being installed across many hospitals in the NHS. This suggestion for change runs the risk of being a bland sweeping statement. We would thus initiate further discussion on this topic, driven by our findings. Questions we might raise would include “Does the provision of guidelines and alerts at the point of prescribing change behaviour?” “If so, under what contexts and for whom?” We would then elicit responses from stakeholders on whether the suggested solution is viable. To inform such a discussion (where possible) we would bring up data we had found in the course of the review. If such data indicate that guidelines and alerts at the point of prescribing alone have little effect, then our suggestion might be that this suggestion needs further work before it is turned into one of the review’s recommendations. This may involve us searching for more data to provide to our stakeholder group for their feedback. Through similar iterative cycles we will develop practical advice that is relevant and feasible.

3) User-friendly summaries of the review’ findings that are tailored to the needs of the following audiences:

- Doctors in training
- Clinical supervisors/trainers and medical educators
- Policy, decision makers, regulators and Royal Societies

The intended impact of this series of documents is focussed more on making relevant stakeholders aware of the 'headline' findings of the realist review. These outputs are thus closely linked to our dissemination strategy. We will again draw on the expertise within the review team and stakeholder group to produce summaries that are user-friendly and relevant to the audiences we have identified. We aim to inform the relevant audiences that a review has been done in this topic area and that relevant and feasible advice is available for those interested in moving forward this topic area.

Plan of investigation and timetable

The key tasks and their timings are outlined in the Gantt chart. Briefly:

MONTHS 0-3

- Brief, recruit and train (where requested) Steering Group
- Run 1st Steering Group meeting

- Brief, recruit and train (where requested) Stakeholder Group
- Run 1st Stakeholder Group meeting
- Start Step 1 of realist review – locate existing theories and build programme theory (with input from first Stakeholder Group meeting)
- Start Step 2 of realist review – searching for evidence and screen search results

MONTHS 4-6

- Complete Step 1 of realist review
- Complete Step 2 of realist review
- Start Step 3 of realist review – article selection
- Start Step 4 of realist review – extracting and organising data
- Start Step 5 of realist review – synthesising the evidence part only
- Iteratively refine initial programme theory – based on data from initial search and undertake any additional searching as needed and informed by the programme theory
- Run 2nd Stakeholder Group meeting – feeding in findings as appropriate
- Run 2nd Steering Group meeting – with updates on progress, findings and expenditure

MONTHS 7-9

- Complete Step 3 of realist review
- Continue with Steps 4 and 5 of realist review
- Iteratively refine initial programme theory
- Run 3rd Stakeholder Group meeting – feeding in findings as appropriate and start discussions on dissemination strategy

MONTHS 10-12

- Continue with Steps 4 and 5 of realist review
- Iteratively refine initial programme theory
- Run 4th Stakeholder Group meeting – feeding in findings as appropriate
- Run 3rd Steering Group meeting – with updates on progress, findings and expenditure

MONTHS 13-15

- Complete Step 4 of realist review
- Continue with Steps 4 and 5 of realist review
- Iteratively refine initial programme theory
- Run 5th ‘augmented’ Stakeholder Group meeting – feeding in findings as appropriate, discussion on dissemination strategy and project outputs
- Draft project outputs and academic papers and circulate for feedback from Stakeholder group

MONTHS 16-18

- Complete Step 5 of realist review
- Finalise programme theory
- Run 4th and final Steering Group meeting
- Run 6th and final ‘augmented’ Stakeholder Group meeting – discussion and refinement of dissemination strategy and project outputs
- Finalise and disseminate project outputs
- Finalise and publish academic papers
- Write final report

Project timetable

		2015							2016											
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
		Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov
Key review processes	Steering group meetings																		
	Establish stakeholder group																		
	Stakeholder group meetings														A			A	
	Step 1 – locate existing theories (includes building initial programme theory)																		
	Step 2 – searching for evidence																		
	Step 3 – article selection																		
	Step 4 – Extracting and organising data																		
	Step 5 – Synthesising the evidence and drawing conclusions																		
	Refine initial programme theory and additional searching as needed																		
	Preparation of outputs, academic papers, report and dissemination																		

A = augmented stakeholder group

Project management

The core project team will meet monthly and in between these meetings will be in regular contact as needed (e.g. via email, using the NIHR hub, Skype and/or telephone). We will run six monthly face to face steering group meetings and separate 3 monthly stakeholder group meetings (as set out in the Plan of investigation and timetable section above).

This infrastructure will support (but not replace) regular meetings between different members of the project team, as needed, to execute the study, screen search results, select and appraise documents, extract data, conduct analyses, discuss emerging findings and prepare outputs.

The core project team, chaired by GW, will include KM, MP, NB and the SRF (we will employ). We will use online software (e.g. the NIHR Hub - http://start.nihr.ac.uk/) as needed to enable us to conduct high-quality remote interaction and file sharing. This team will plan and monitor day to day progress, ensure ongoing communication among team members, review quality and timeliness of outputs, and manage day to day risks and issues. The core project team will be responsible for undertaking the realist review, producing the project outputs and dissemination.

The steering group will have cross-sector representation (including experts in realist review, research users, NHS professionals and/or at least two representatives from the patient advisory group). It will monitor progress against milestones and spend against budget, provide advice, promote the project, communicate with stakeholders and also help maximise dissemination and impact of findings.

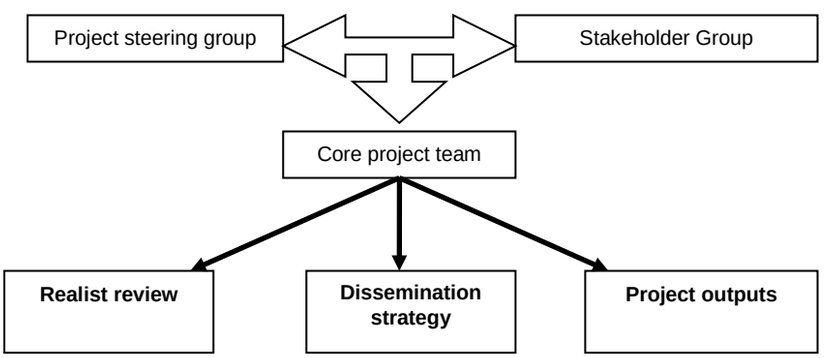
The stakeholder group membership and its roles have been outlined in the Research plan and Dissemination and outputs Sections above. In brief summary this group (which will be augmented later on in the project), consisting of content experts in education, pharmacy, microbiology, medicine and importantly with representation including doctors in training and lay people, will help us to:

a) Develop and refine the programme theory on interventions to change antimicrobial prescribing behaviours of doctors in training and;
b) Optimise our dissemination plans
c) Produce feasible and practical recommendations for relevant stakeholder groups on how interventions to change antimicrobial prescribing behaviours of doctors in training might be tailored for best effect.

The Principal Investigator for this project, GW, has extensive experience in conducting realist reviews, having personally undertaken four funded reviews and provided methodological support to six others. With oversight from GW, the SRF and the project team will clarify the project brief, roles and responsibilities, terms of reference, communication plans and so on and monitor project progress. Figure 1 below provides an outline of the project's organisational structure.

Research governance and financial management will be formally overseen by the Joint Research and Management Office (JRMO) at Queen Mary University of London (QMUL). All data will be handled in accordance with the Data Protection Policies of our respective institutions.

Figure 1: Project's organisational structure



Approval by ethics committees

We will seek exemption from NHS research ethics approval before the start of the study on the grounds that this is secondary research.

Patient and public involvement

This project has involved patients and the public from the start. At the outline bid stage, in consultation with the Peninsula Patient and Public Involvement Group (PenPIG) at the NIHR CLAHRC for the south-west Peninsula, we produced a Plain English summary of the proposed research - changing prescribing practice- and circulated this to PenPIG. Members of the project team had worked with this group in the past. We requested feedback on a) the importance of the project aims and objectives to them and b) how we might improve our project to better meet what they thought were important for such a project. In brief summary the feedback we received from three PenPIG members was that this was an important topic area to better understand and in need of more research. A number of suggestions for improving clarity were incorporated into the Plain English summary. The feedback we received also endorsed our strategy of recruiting a stakeholder group.

For this full bid, we again sought feedback from PenPIG. They provided us with feedback on; our dissemination strategy; issues that may arise with the audiences for the project outputs; how and where PPI stakeholders might be able to contribute the most and the number of PPI members needed for the stakeholder group. Their input has been incorporated into the project. For example, they suggested that not all PPI stakeholder group members would necessarily turn up to all meetings and so we need to increase the numbers we ask to participate to allow a degree of leeway. Also they pointed out that the PPI input is probably most likely to be most valuable at the stage when we produce our project outputs (specifically the 'How to' document of recommendations). We therefore decided to augment the stakeholder group from month 14 of the project to include additional PPI members as well as 'coal face' clinicians and policy and decision makers. We believe we have strong PPI support for this full bid and have laid the foundations for their continuing involvement.

This project seeks to understand interventions designed to change the antimicrobial practice of doctors in training. Patients and the public expect doctors in training to prescribe appropriately and rationally when treated by them. Doctors in training expect to be well supported and prepared for prescribing.

In this project, we will take a wide perspective of these interventions to understand the role and impact of patients and the public as contextual influences on prescribing practice. We thus want to involve patients and the public throughout this project. Whilst not strictly members of the public or patients, doctors in training are key stakeholders in our research and will be included in our stakeholder group.

We will recruit up to four members of the public/patients to the project's stakeholder group (see Research plans section) from the Peninsula Patient Involvement Group (PenPIG) at PenCLAHRC (University of Exeter Medical School). We will provide training and information and participation will be entirely voluntary. MP will act as key liaison and provide support. We have extensive experience in working successfully with and facilitating patient/public groups. When we come to the stage in the project when we will develop the project outputs, we will be augmenting the size of the stakeholder group with additional PPI members. We will seek the help and advice of PenPIG to identify suitable individuals.

Expertise and justification of support required

Project team expertise and roles:

Principal investigator: Geoff Wong (GW)
-experienced educationalist and Fellow of the Higher Education Academy.
-NHS GP and practice's commissioning lead
-extensive experience in realist review methodology and supporting reviews. Lead researcher on RAMESES project (www.ramesesproject.org) that developed realist review quality and publication standards and training materials.

Co-applicant: Karen Mattick (KM)
-Clinical Scientist in microbiology background (6 years service in NHS)
-experienced educationalist (Principal Fellow of the Higher Education Academy, National Teaching Fellow, Co-Director of an undergraduate medical programme)
-experienced education researcher (including systematic review of educational antimicrobial prescribing behaviour change interventions and junior doctors' antimicrobial prescribing).
-experience of working with stakeholders and patient groups

Co-applicant: Mark Pearson (MP)
-experienced social scientist and evidence synthesis researcher
-professional background as Registered Nurse (10 years service in NHS)
-experienced realist review methodologist and in supporting reviews
-lead or co-authored eight systematic reviews in public health for NICE.
-experience of working with patient groups on two realist reviews

Co-applicant: Nicola Brennan (NB)
-social scientist background
-experienced medical education researcher (evidence synthesis methods).
-postgraduate teaching and Masters module lead on evidence synthesis in clinical education.
-completed 4 systematic reviews including of educational interventions

Roles:
The project team all have overlapping areas of expertise and this provides a degree of resilience against unexpected events.
Overall responsibility - GW
Develop protocol - all
Supervise and manage research fellow (SRF) – GW
Stakeholder group involvement - KM
PPI support and involvement – MP
Realist review methodological support – GW, MP
Content expertise - KM, GW, NB
Educational input – KM, NB, GW
Assist SRF with review – GW, MP, NB
Prepare reports and publications – all, lead GW
Execute dissemination plans – all, lead GW

We will employ a full time SRF to:
-undertake review
-run project from day to day.
Due to the complexity and extent of the topic area an experienced researcher (ideally with realist review expertise) will be needed.

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Flow diagram / Project plan