National Institute for Health Research

HS&DR Project: 16/53/12 - Care Under Pressure: a realist review of interventions to tackle doctors' mental ill-health and its impacts on the clinical workforce and patient care

PROTOCOL: Version 1.1.

Version control

Version	Date	Author(s)	Rationale
0.1	Sep 2016	Applicant team	Protocol embedded within the Detailed Project Description that was submitted with the funding application.
0.2	Mar 2017	Applicant team	Detailed Project Description updated in response to the Board's feedback.
0.3	May 2017	Applicant team	Detailed Project Description updated in response to the Board's feedback.
1.1	Jun 2017	Investigator team	Protocol information extracted from the Detailed Project Description document (V0.3) for sharing via the HS&DR website.

Background

The National Health Service (NHS) needs healthy, motivated staff to provide high quality patient care but being a doctor is a challenging job. In recent years, increasing workload due to societal demand for healthcare services, combined with increasing external scrutiny of their work, has been associated with a high prevalence of mental ill-health amongst doctors. In November 2015, the Head of Thought Leadership at the King's Fund said stress levels among NHS staff are "astonishingly high". Our focus on doctors working in the NHS reflects the pressing recruitment and retention issues in this profession (e.g. doctors-in-training, general practice, emergency medicine), the significant potential for sick doctors to cause harm to patients and the financial implications of doctors' mental ill-health. Changing the work environment to prevent the development of mental ill-health would be preferable to a focus on alleviating the 'symptoms' of mental ill-health, such as presenteeism, absenteeism and challenges with workforce retention. However, prevention strategies may be challenging and take time to implement. A multi-pronged approach of prevention, support and treatment, tailored to suit the needs of different groups of doctors in different contexts, is likely to be needed for the foreseeable future.

Aims and Objectives:

Aim:

This research aims to improve understanding of how, why and in what contexts mental health services and support interventions can be designed in order to minimise the negative impacts of providing care on doctors' mental ill-health.

Objectives:

1. To conduct a synthesis of the literature (realist review) on interventions to tackle doctors' mental ill-health and its impacts on the clinical workforce and patient care, drawing on diverse literature sources and engaging iteratively with diverse stakeholder perspectives to produce actionable theory.

2. To produce recommendations that support the tailoring, implementation, monitoring and evaluation of contextually-sensitive strategies to tackle mental ill-health and its impacts.

Research Questions:

1. What are the processes by which mental ill-health in doctors develops and leads to its negative impacts, and where are the gaps that interventions do not address currently?
2. What are the mechanisms, acting at individual, group, profession, and organisational levels, by which interventions to reduce doctors' mental ill-health at the different stages are believed to result in their intended outcomes?
3. What are the important contexts which determine whether the different mechanisms produce the intended outcomes?
4. What changes are needed to existing and/or future interventions to make them more effective?

Research plan

<u>Objective 1. To conduct a synthesis of the literature using a realist review approach</u>

The plan of investigation will follow a detailed realist review protocol informed by Pawson's five iterative stages in realist reviews and the RAMESES quality and publication standards for realist reviews. The realist review protocol has been written by the project team, who have extensive experience in conducting such reviews and it has been registered with PROSPERO. The review process also incorporates iterative cycles of engagement with the literature and with our Stakeholder Group (comprising clinicians, service users, senior managers, therapists from the PHP, policy makers and charities), who will provide their own perspectives on the positive and negative interactions between healthcare contexts, the development of mental ill-health in doctors, and the subsequent impacts such as presenteeism, absenteeism and workforce retention. These cycles of engagement will enable the production of action-oriented middle-range theory which can inform change at individual, group, profession, and organisational levels.

We have recruited a Stakeholder Group (that includes patient and public representation, and doctors who have experienced mental ill-health) to provide content expertise for programme theory refinement and will extend the membership, as needed. This group will meet regularly to discuss the process, findings, outputs and dissemination activities; and may be contacted by email between meetings. The diverse members will include individuals representing different perspectives, doctors from shortage specialties, doctors who have experienced mental ill-health, other healthcare professionals, NHS managers, patients and the public, charities with an interest in mental ill-health, and doctor support organisations such as the Practitioner Health Programme. Given the potential tensions and

inhibitions that may exist for some group members within the larger meeting format, we will also provide opportunities to discuss the topic further with the research team between meetings. We recognise that not every member will be able to attend every meeting and will encourage non-attenders to send a nominee and/or to contribute their insights by another means e.g. email and/or telephone conversation. The Stakeholder Group will be consulted for content expertise on the following tasks: Ongoing development and refinement of programme theory; Guidance for additional literature that may be relevant to the review; Implementation of review findings in practice and measurement for improvement; Development of feasible and practical recommendations; Development and optimisation of engagement materials; and Dissemination of academic articles and other outputs to different audiences.

Step 1: Locate existing theories

The goal of this step is to identify theories that explain how interventions aiming to support doctors challenged by mental ill-health are supposed to work (and for whom), when they do work, when they do not achieve the desired change in practice, why they are not effective, and why they are not being used. The rationale for this step is that interventions are "theories incarnate" – that is, underpinning the design of such interventions are assumptions about 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.

To locate these theories, in the first instance we will iteratively; a) draw on the preliminary qualitative interviews with the PHP core clinical team of therapists conducted prior to the current study, which have highlighted the importance of workload management and flexibility, physical work environment, and organisational and regulatory culture; b) consult with key content experts representing multidisciplinary perspectives in our Stakeholder Group; and; c) draw on literature we are already familiar with, along with additional informal searching 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, along with more structured searching for theories will be used.

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. 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.

Step 2: Search for evidence

Formal search

The purpose of this Step is to find a relevant 'body of literature' that might contain data with which to further develop and refine the programme theory from Step 1. Searching will be designed, piloted and conducted by an information specialist (SB) with extensive experience of conducting searches for complex systematic reviews, particularly realist reviews.

We anticipate that we may need to search the following databases: MEDLINE, MEDLINE-in-Process, PsycINFO, Web of Science, the Cochrane Library and ASSIA, and any other relevant databases identified by the Information Specialist. We will also undertake forward citation searches and search the citations contained in the reference lists of relevant documents. We anticipate that we will search the databases using free text terms for "doctors", "mental health", "absenteeism", "presenteeism" and "workforce retention", although the exact search terms, syntax and search structure will be

determined by the results of Step 1. Subject headings relevant to each database will also be used, for example, MeSH for MEDLINE.

Screening

We will include literature relating to all doctors from the outset. We believe greater explanatory insight might be attained by looking across stages of training and across specialties, particularly since our preliminary work suggests common mechanisms may be at play in different settings (e.g. inflexible working patterns, wider NHS culture).

The following initial inclusion criteria will be applied:

- Mental ill-health and its impacts (e.g. presenteeism, absenteeism, workforce retention) – all studies that focused on one or more of these aspects. Note, generic occupational health services targeting whole populations of doctors, rather than doctors suffering mental ill-health, would not be included.
- Study design – all study designs.
- Types of settings – all healthcare settings.
- Types of participants – all studies that included medical doctors.
- Types of intervention – interventions or resources that focus on improving mental ill-health and minimizing its impacts.
- Outcome measures – all mental health outcomes and measures relevant to its impacts (e.g. absenteeism, presenteeism, retention).

Screening will be undertaken by the Research Fellow (RF) we will recruit. A 10% random sub-sample of the citations retrieved from searching will be reviewed independently for quality control. Any disagreements will be resolved by discussion between the RF and the second reviewer. 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 finding additional data needed to confirm, refine or refute aspects of developing programme theory. In other words, more searches will be undertaken if we find that we require more data to develop and confirm, refute or refine certain sub-sections of the programme theory. To learn more about the influence of wider contexts on mental ill-health and its impacts, we may also look at literature about doctors working in other countries, other groups of healthcare professionals working in the UK and professions outside healthcare who experience the same broader societal changes but in a different industry. Searches may also seek to identify 'good practice' examples in healthcare, where mental ill-health of some institutions is particularly low. For each additional search the project team will meet to discuss and set inclusion and exclusion criteria. Different search terms and databases are likely to be needed for these purposive searches which will be developed, piloted and conducted in conjunction with our information specialist. These searches will greatly increase the amount of relevant data available to us for the realist review. The screening processes will be as described above.

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). 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.

Included papers would be divided into those which can make 'major' or 'minor' contributions to our research question. For example, we may classify as 'major' those studies conducted in countries where doctors predominantly work in universal, publicly-funded health care systems with similarities to the NHS; or those where the mechanisms (which cause doctors' mental ill-health to develop) are similar, even if they are operating in different contexts. This will enable us to focus effort on the studies which make a major contribution, whilst ensuring that we do not miss any important relevant data from the wider literature. In this way we will inevitably prioritise studies from the UK but also include studies from other countries that provide useful insights for the UK. This strategy will enable us to be rigorous while keeping the project manageable. Our provisional criteria for classifying studies as 'major' or 'minor' are:

Major:

- Studies which contribute to the research questions and are conducted in an NHS context; or,
- Studies which contribute to the research questions and are conducted in contexts (e.g. universal, publicly-funded health-care systems) with similarities to the NHS; or,
- Studies which contribute to the research questions and can clearly help to identify mechanisms which could plausibly operate in the context of the NHS.

Minor:

- Studies conducted in health-care systems that are markedly different to the NHS (e.g. fee-for-service, private insurance scheme systems) but where the mechanisms could plausibly operate in the context of doctors working in the NHS.

Classification decisions will be checked between two reviewers and discussed with the rest of the team.

The RF will read all included papers and finalise article selection by including documents or studies that contain data 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 of rigour will also be made (how trustworthy were the data being used). To illustrate how we will operationalise rigour, if relevant 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 in that population. A random sample of 10% of documents will be selected, assessed and discussed between the RF and second reviewer to ensure that decisions for final inclusion have been made consistently. The remaining 90% of decisions will be made by the RF (though a number of these may require further discussion/joint reading between the RF, second reviewer 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. Article selection for any additional searches will follow the process described above.

Step 4: Extracting and organising data

The full texts of the included papers will be uploaded in a qualitative data analysis software tool. Relevant sections of texts that have been interpreted as related to contexts, mechanisms and/or 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). Each new element of relevant data will be used to refine aspects of the programme theory, and as it is refined, included studies and documents will be re-scrutinised to search for data relevant to the revised programme theory that may have been missed initially. The characteristics of the studies and interventions will be extracted separately into an Excel spreadsheet to provide a descriptive overview. Information about how much

the various interventions cost will be extracted from the literature identified through the review process (where this information is provided).

We will start the coding and analysis process by using the literature that has been deemed to make a 'major' contribution to the research questions to start building and refining our programme theory, while progressively focusing the review. Articles categorised as providing 'minor' contributions will be analysed to address particular aspects of the programme theory where necessary. The aim of the review will be to reach theoretical saturation in understanding the problem of mental ill-health, rather than to aggregate every single study that exists in the area. Decisions about whether a study can have a 'major' or 'minor' contribution may change over the course of the project, as the analysis progresses. All changes will be documented and recorded as part of an audit trail to increase transparency and ensure consistency.

In our realist review we are not undertaking a formal health economic assessment. However we will extract (from included documents) all data on the cost of various interventions to tackle doctors' mental ill-health. Our goal here is to identify what data exist on costs and also if any of these are useful in helping us to suggest any implications for policy and practice. During the review process, we will extract the following types of economic data or information (where available):

- Direct costs of interventions;
- Indirect costs relating to the intended beneficial effects of interventions (accessing mental health services, Occupational Health consultations, and so on);
- Unit costs and total costs;
- Currency;
- Time period to which economic data relates.

A random sample of 10% of coded documents will be independently checked by the second reviewer for quality control. Any disagreements will be resolved by discussion between the RF and second reviewer. 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.

Step 5: Synthesising the evidence and drawing conclusions

Data analysis will use a realist logic to make sense of the initial programme theory. A realist logic of analysis builds context-mechanism-outcome configurations (CMOCs) for the programme theory. To achieve this, the data will be interpreted to ascertain if it pertains to context (C), mechanism (M), outcome (O), the relationships between C, M, and O and/or the relationships between CMOCs. In addition, during analysis we will use interpretive cross-case comparison to understand and explain how and why observed outcomes have occurred, for example, by comparing interventions where reducing mental ill-health has been 'successful' against those which have not, to understand how context has influenced reported findings. This type of analysis will enable us to understand the behaviour of the most relevant and important mechanisms under different contexts, thus allowing us to build more transferable CMOCs.

During the review, we move iteratively between the analysis of particular examples from the literature, 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. Finally, when making sense of our data during analysis we will use the following analytic concepts:

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.

This process will allow us to explore why some interventions might work well for some doctors and in some contexts but not others.

The way that economic evaluations are conducted and reported makes it unlikely to be possible to link the data in any included economic evaluations directly to the context-mechanism-outcome configurations identified in the realist review. We therefore anticipate presenting the cost information, where it is available, separately from the CMO configurations, which will make it easily accessible to readers interested in this particular area.

Objective 2: To use the Evidence Integration Triangle to design contextually-sensitive strategies to tackle mental ill-health and its impacts on doctors, their colleagues and their patients.

We will use our existing strong relationships with stakeholders as a foundation for building the networks and understanding that will enable the findings from this research to be widely disseminated and acted upon. We will use the 'Evidence Integration Triangle' (EIT) as a framework for bringing together stakeholders around evidence in a collaborative, action-oriented way. Using the EIT will enable us to create a facilitative context in which research can inform practical decision-making, and for experiential knowledge from lived experiences and from professional practice to inform interpretation of that research.

We will use the three components of the EIT (1. practical evidence-based interventions; 2. pragmatic, longitudinal measures of progress; and 3. participatory implementation processes) to structure and inform the facilitation of the Stakeholder Group meetings. The timing of these meetings has been selected to maximise input to the realist review process and enable local, regional and national dissemination at the most appropriate stages of the project. The three components of the EIT, with examples to demonstrate, how these might inform the meeting discussions, are given below:

1. Practical evidence-based interventions. The emerging contextualised findings of the review will be presented to the Stakeholder Group at each meeting. Critical discussion of these findings in the light of stakeholders' personal and professional experiences will be facilitated, and the insights incorporated into the review. For example, if the review suggested that coaching was effective in retaining GPs, the Stakeholder Group might draw on their own experiences of coaching in NHS settings to provide us with additional data on the contexts of when coaching happens and does not happen successfully in the NHS setting and in what format. Such data will enable us to have an even better understanding of how coaching would need to be tailored if it were to be used in the NHS. Where needed, we will seek input from stakeholders on specific issues between meetings.
2. Pragmatic, longitudinal measures of progress. The implementation of research findings can be facilitated by workplace measures against which improvement can be assessed. Without this translation, practitioners/managers/leaders are held back from monitoring and evaluating changes they make in their local contexts. To address this, the Stakeholder Group will start to discuss what is useful and meaningful in the workplace to monitor wellbeing and impacts of mental ill-health on professional life from the outset of the project and continue these discussions as the project evolves. This will inform our understanding of how project findings can inform the design of locally-relevant, meaningful and usable measures or indicators within local/regional/national systems. For example, if the review suggested that junior doctors were preferentially selecting medical specialities that they anticipated would be less stressful for their future careers, it might be useful to monitor measures of specialty choice at various stages of education.

3. Participatory implementation processes. We expect local understandings of implementation issues to be particularly important for the review but this may work 'both ways'. Therefore, we will challenge our stakeholders to consider what *might* be possible in terms of implementation in their workplaces, or what changes would enable something to *become* possible. For example, if the review suggested that taking a lunchbreak was critically important for doctors but our Stakeholder Group said this was not feasible, we might challenge them to explore what would need to change in order for this to become possible. We will also ask our stakeholders to consider not just what is possible but what is likely to be sustainable.

The three components of the EIT are complementary and each will be considered as part of the dissemination process. We will treat 'evidence integration' not as an end in itself, but as an inherent part of disseminating usable research findings which build on the engagement with stakeholders throughout the life of the project.

Many stakeholders will benefit from the findings and recommendations but the key messages and communication strategies will need to be tailored by group. The Stakeholder Group will be well placed to advise on the key audiences and how we should target messages to that audience. We will also draw on existing networks and communication strategies, for example healthcare services and professional bodies, wherever possible to reach the widest possible number of beneficiaries. Our starting point in thinking about the different audiences and dissemination strategies is as follows:

- Group 1: Policy makers who can influence change that will affect doctors at a national level.
- Group 2: Employers and healthcare leaders who can shape the structure of organisations in which doctors work.
- Group 3: Team leaders who can shape the immediate working environment for individual doctors.
- Group 4: National, regional and local groups and organisations that provide support to doctors experiencing mental ill-health.
- Group 5: Doctors who are experiencing mental ill-health, and their families and colleagues.

Dissemination and projected outputs

The project will produce five major types of output. We will consult with our Stakeholder Group and use their knowledge and experience to refine the development, presentation and dissemination of these outputs:

1. Conventional academic forms. A report for publication in the NIHR HS&DR Journal; a report for publication in a high-impact peer-reviewed journal (e.g. BMJ, JAMA, or Journal of Health Services Research & Policy); conference presentations (e.g. Health Systems Global, Health Services Research UK). This will achieve impact over the longer-term (3-5 years) through informing the agenda for debate and action in health services and in public policy more widely. (Groups 1 to 5)
2. More innovative forms. We have had positive experiences of involving graphic artists to help with the communication of the outcomes of our recent symposium (see Supporting Documents). Therefore, depending on the results of the realist review, we propose to translate some of our outputs into comics, animations and/or information graphics that might be distributed more widely (e.g. for notice boards on wards, inductions, teaching sessions) to raise awareness and normalise mental health issues. Comics can provide an appropriate format for tackling delicate issues such as mental ill-health. (Group 5)
3. Measures/indicators. This builds on our use of the Evidence Integration Triangle to inform our interpretation/dissemination strategy and would be offered for use in existing systems to monitor and evaluate the impact of changes made based on our research findings. This will

achieve impact over the longer-term (3-5 years) through enabling frontline staff and managers to implement and monitor the impact of research-informed changes in practice. (Groups 1 to 4)

4. Plain English summaries. The research findings would be tailored to different audiences (e.g. doctors, patients, health service managers, medical educators, policy makers). This will achieve impact in the short- to medium-term (1 month-2 years) by providing a meaningful summary of findings which increase stakeholders' recognition and understanding of the issue and how evidence can inform actions they can take. (Groups 1 to 5)
5. Media engagement strategy. We anticipate that more traditional forms of dissemination (e.g. peer-reviewed publication) will be ineffective in reaching some groups but other routes (e.g. Royal Colleges, UK Foundation Programme Office, Health Services Journal, Pulse, Politics Today, The Conversation, Twitter) may work better for these. This will achieve impact in both the short- and long-term by *raising awareness,* informing public and professional understanding and stimulating debate on a large-scale, changing how the issue is understood at a policy level, mobilising public opinion and professional action to take action informed by the findings. We will also create a project webpage to maximise engagement with the project and its findings, and to encourage further debate. We will consult experienced communications officers at the University of Exeter, PenCLAHRC and the University of Oxford for support in these areas and they will be invited to the Stakeholder Group meetings in the second half of the project. (Groups 1 to 5)

The expertise of the project team and the Stakeholder Group will be key to the creation of appropriate outputs. The Stakeholder Group, including PPI representatives, will be encouraged to think about alternative or additional approaches to dissemination, which will inevitably include approaches or networks that we might not have thought of. PPI representatives will be actively involved in the production of the comics, animations and/or information graphics; the Plain English summaries; and written articles beyond the formal academic literature.

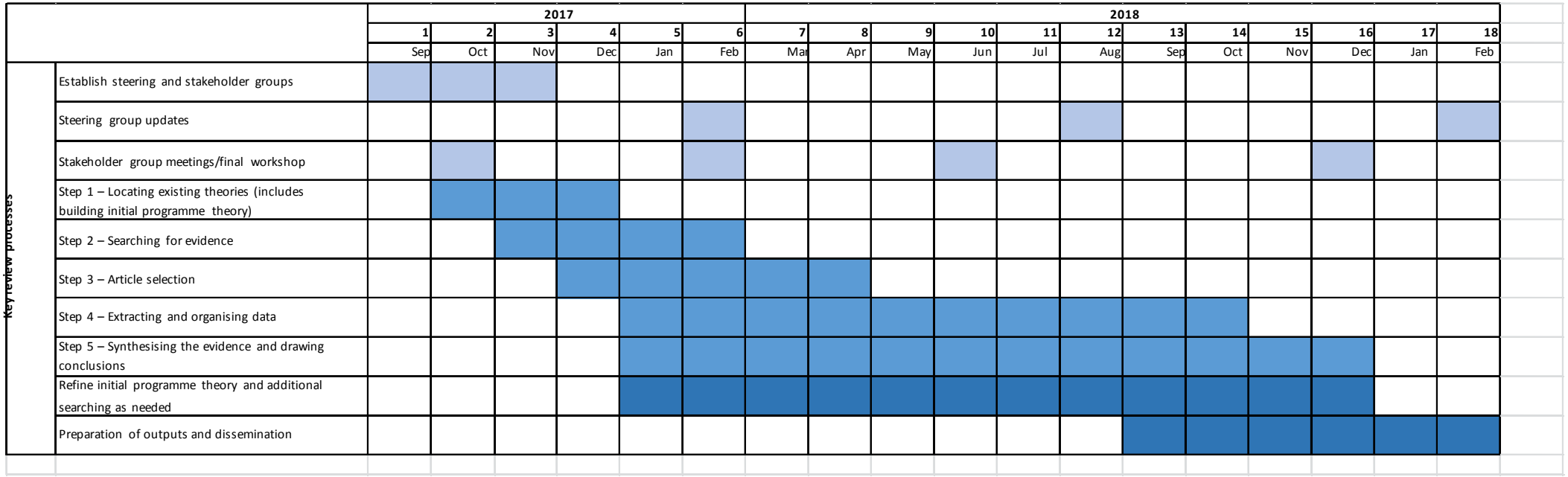
Plan of investigation and timetable

The key tasks and their timings are outlined briefly below and shown in the Project Timeline:

- In Months 1-3, we would recruit, brief, and train (where requested) the Steering Group members; recruit, brief, and train (where requested) the Stakeholder Group members and schedule and run the first Stakeholder Group meeting; start Step 1 of the realist review (locate existing theories and build programme theory) with input from the first Stakeholder Group meeting; and start Step 2 of the realist review (search for evidence and screen results).
- In Months 4-6, we would complete Steps 1 and 2 of the realist review, and start Step 3 (select articles), Step 4 (extract and organize data) and Step 5 (synthesise the evidence). We would iteratively refine the initial programme theory based on initial search data and run additional searches as indicated by the emerging programme theory. We would run the second Stakeholder Group meeting and provide the Steering Group with an update on progress, findings and expenditure.
- In Months 7-9, we would complete Step 3 of the realist review and continue with Steps 4 and 5, refining the programme theory.
- In Months 10-12, we would continue with Steps 4 and 5 of the realist review, continuing to refine the programme theory. We would run the third Stakeholder Group meeting, which would start to focus more on the dissemination strategy. We would provide the Steering Group with an update on progress, findings and expenditure. We would also start drafting the final project report and journal articles, along with materials for different audiences, i.e. with plain English summaries, success indicators to measure impacts of change in practice, further engagement with the media and professional publications.

- In Months 13-15, we would complete Step 4 of the realist review and continue with Step 5, refining the programme theory. We would continue to draft the final project report and journal articles, along with materials for different audiences, i.e. with plain English summaries, success indicators to measure impacts of change in practice, further engagement with the media and professional publications.
  In Months 16-18, we would complete Step 5 of the realist review, resulting in a final programme theory. We would run the final Stakeholder Group meeting, with draft documents shared for feedback and advice. We would also run the policy workshop (to which a PPI representative would be invited) and provide the Steering Group with an update on progress, findings and expenditure. We would also finalise and disseminate project outputs, including writing and submitting the final report.

Project timeline



Project management

The project team will be led by KM and MP and will consist of the co-applicants and the recruited Research Fellow. KM and MP have substantial project management experience, as well as topic and methodological expertise (see Expertise section below), for example in overseeing programmes of research of equivalent complexity with researchers and in their other academic responsibilities as module leads and programme directors. They are supported by the wider Institute of Health Research and Peninsula Collaboration for Leadership in Applied Health Research & Care (PenCLAHRC) at the University of Exeter Medical School. KM and MP, with the help of the Research Fellow, will take overall responsibility for the project and outputs, including:

1. Project management, including budget management (with support of institutional administrative and research support systems) and day-to-day risks and issues.
2. Project outcomes quality and timely delivery.
3. Relationships between researchers, Stakeholder Group, and partners.
4. Data management. The core team will plan and share all elements using appropriate software. Any data held will conform to local and national data protection policies.
5. Guidance and career development support for the recruited Research Fellow.
6. Production of outputs and their dissemination.
7. NIHR reporting requirements.

The project team will meet every other month, ideally face-to-face to coincide with Stakeholder Group meetings, but with individuals joining meetings remotely where necessary (e.g. phone, Skype). Meeting minutes and action points will be circulated to all co-applicants. A subset of the project team (KM, MP, DC, and the Research Fellow, who are based in Exeter) will meet fortnightly. Additional meetings and email contact between team members will take place as and when needed, and will complement the project meetings. Secure file-sharing will take place using the University of Exeter's licensed Microsoft Office 365, which also allows non-Exeter users to access authorised folders. Overall research governance and financial/project management oversight will be provided by University of Exeter Medical School; and all data handling will comply with the Data Protection Policies of our respective institutions.

The steering group will monitor progress against milestones and spend against budget, provide advice where necessary (for example around dissemination and impact), promote the project, and facilitate communication between organisations with stakeholders and help maximise dissemination and impact of findings. The steering group will comprise a small group of individuals, with a close interest in the topic area, and relevant methodological expertise, representing both university and NHS settings. We will also liaise with the PenCLAHRC's Public Involvement Group (PenPIG) advisor at the University of Exeter to explore the possibility of a PenPIG representative with complementary skills that could contribute to this team (e.g. a professional with an HR background), although we recognise that this would only suit a very specific individual.

The Stakeholder Group has been described previously but, in brief, this group will provide feedback that will help us to: develop and refine the programme theory; optimise our dissemination plans; and produce feasible and practical recommendations for the key audiences.

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Department of Health disclaimer

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.