



HS&DR Project: 17/06/04 – Remediating Doctors Performance to restore patient safety: A Realist Review

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1.1	February 2017	Investigator team	Final Detailed Project Description document (V0.3) with person for sharing via the HS&DR website.
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1. TITLE

Remediating doctors' performance to restore patient safety: A realist review

2. SUMMARY OF RESEARCH

Tackling underperformance in doctors has been a priority of recent regulatory reform in the UK [1]. Introduced as a statutory requirement in 2012, medical revalidation is the process whereby all UK doctors demonstrate to their regulator (the General Medical Council) that they are fit to practise through submitting evidence every five years from their annual performance appraisal. Early evidence suggests that revalidation is helping to identify poor performance [2 3]. Healthcare organisations have a statutory responsibility to ensure that remediation is available for these doctors. While doctors, who are incompetent, can be stopped from practising, underperformance of doctors is more difficult to remedy. For these doctors, the accepted course of action is remediation, i.e. remedying the underperformance through reskilling or rehabilitation and, wherever possible, returning the doctor to safe practice.

Yet the evidence base for the efficacy of remediation remains exceptionally poor. Three literature reviews conducted on the topic of remediation highlight a lack of research that outlines a firm theoretical base to guide the design and implementation of remediation interventions [4-6]. These reviews were also unable to identify why some remediation interventions were producing different outcomes in different contexts. In order to design high-quality remediation interventions, it is fundamental to understand the theory of how remediation of doctors is supposed to work and the contexts that lead to different outcomes.

Aim

To identify why, how, in what contexts, for whom, and to what extent remediation interventions work for practising doctors, to restore patient safety.

Objectives

1. To conduct a realist review of the literature to ascertain why, how, in what contexts, for whom and to what extent do remediation programmes for practising doctors work to restore patient safety.
2. To provide recommendations on tailoring, implementation and design strategies to improve remediation interventions for doctors

Methods

Remediation is a complex intervention, and realist reviews have been established as an appropriate method of evidence synthesis to explore such complexity.

Underpinning a realist enquiry is the *generative model of causality*, which holds that to infer a causal outcome between any two events requires an understanding of the “causal mechanisms that connect them and the context in which relationships occur” [7]. Remediation activities take place in a range of contexts (e.g. who delivers the intervention and how it is delivered, the characteristics of the doctors, the circumstances surrounding the performance issue, and the tools and techniques utilised), some of which may affect the outcomes. Mechanisms are the way in which an intervention’s “resources or opportunities interact with the reasoning of individuals and lead to outcomes such as changes in behaviour” [8]. By developing and testing a model of how remediation works (its programme theory), the realist review will uncover the underlying mechanisms at work in remediation activity and the contexts that influence how these mechanisms operate to produce desired or undesired outcomes.

This study will be conducted with stakeholder input, including the National Health Service’s (NHS) advisory and remediation service, the National Clinical Assessment Service (NCAS).

Outputs

The outputs of this study will be: 1) a firm evidence base, including evidence of best practice, that can be used to guide and shape remediation practice in NHS organisations, and in particular the development of NCAS remediation and professional support services; 2) the establishment of a professional collaboration with other stakeholders, such as Royal Colleges, for future remediation research; 3) the basis for further empirical research using a full realist evaluation for which we shall seek additional funding upon completion of the review.

3. BACKGROUND AND RATIONALE

“When encountering a [doctor] who is not thriving, it is often difficult to figure out what is wrong and how to help. And when confronted with a serious violation of professional ethics or a repeated threat to patient safety, it is equally unclear what to do.Unfortunately, problems often become worse, and if uncorrected, result in harm to patients, disruption of the healthcare team, and occasional dismissal...”[pg. xiii] [9]

Proficient and safe doctors, operating efficiently within teams, are an essential part of the provision of high-quality and safe care for patients [10]. If the performance of a doctor is lacking, patients may be at risk [10]. Doctors can experience performance issues at any stage in their careers for many different reasons. Examples of performance issues include health/wellbeing, personal reasons, the environment of the workplace, or not keeping up-to date and participating in continuing medical education (CME) [11]. Performance concerns are often complex involving multifactorial issues, encompassing knowledge, skills and professional behaviours [11]. To ensure patient safety, it is vital that if there are questions about the performance of a doctor they are identified quickly and, where appropriate, support for the practitioner is provided through remediation [11].

Remediation is the process by which a doctor’s poor performance is “remedied” and the doctor returned to safe practice [1]. Remediation can be formally defined as “an intervention, or suite of interventions, required in response to assessment against threshold standards” [12]. Threshold standards are set by regulatory bodies to keep patients safe. What actually constitutes a remedial intervention ranges from informal arrangements to complete some reskilling, through to more formal programmes of remediation and rehabilitation [13]. It is generally agreed that there are three necessary components of remediation, including the identification of performance deficit, remediation intervention, and reassessment of performance after intervention [5]. Such practices are widely used to varying degrees to remedy poor performance amongst doctors globally.

In the late 1990s, there was a clear drive to professionalise and standardise the identification and remediation of poor medical performance [1]. Previously there had been quite an ad hoc approach to the identification of poor performance across the United Kingdom (UK),) combined with a reliance on informal mechanisms to address performance concerns [14]. An important first step in addressing this was the establishment of a bespoke advisory and assessment service. The National Clinical Assessment Authority, which later became the NCAS, was set up in the spring of 2001. This NHS body offers advice and guidance to employers on addressing performance concerns related to doctors. Their remit was later expanded to cover dentists and pharmacists. NCAS undertakes extensive clinical performance assessments, if warranted, to ascertain the nature of the performance concerns [15]. However this is in approximately only 10% of cases where advice and support are insufficient [15]. The performance assessments used by NCAS are rigorous and multi-faceted, typically evaluating the clinician’s occupational health, behaviour and clinical competence [15]. In addition, NCAS offers guidance to employing organisations for returning doctors and dentists to safe professional practice [16-18].

It is thought that around 18,000 doctors, at any one time, are falling below the standards that are expected of them at some point in their careers, and it is estimated that around 6,000 of all practising doctors in England and Wales will be undergoing remediation at any one time [13]. These figures are only likely to increase because of the introduction of the regulatory process of revalidation by the General Medical Council (GMC)

[1]. Medical revalidation is the UK's relicensing system for practising doctors [1]. Medical revalidation was introduced in 2012 as a statutory requirement. It is the procedure by which all UK doctors evidence that they are up to date and fit to practise. This is achieved by collating supporting information as part of an annual appraisal. Then, usually every 5 years, a senior doctor called the Responsible Officer (RO) within an associated organisation (known as the designated body), evaluates the portfolio and recommends a revalidation outcome decision to the GMC. If underperformance is identified through the revalidation process (or through any other route) the RO has a statutory responsibility to ensure the designated body offers "training or retraining" [19]. Preliminary data from research evaluating medical revalidation suggest that revalidation is helping to identify such poor performance [2 3].

The real human cost of an underperforming doctor is difficult to measure, but it is estimated that nearly 12,000 patients die in England each year as a result of preventable medical errors [20]. There is also the corresponding financial cost of failure; the NHS paid out more than £1.4 billion in medical negligence claims in 2015/16 alone, up from £1.2 billion the year before [20]. Yet the true societal costs when things go wrong are unknown. Incompetent doctors (of which there are relatively few) need to be stopped from practising; but there is a wider and harder problem to solve: doctors who underperform. Remedying underperformance where possible is both a practical and a financial imperative: doctors are in short supply and are expensive to train (p. 112) [21]. There is a shortage of doctors in particular specialities and geographical areas. The NHS in England, Northern Ireland, Scotland and Wales is under extreme pressure to cut spending. On average it costs £485,390 to train a GP and £726,551 to train a consultant [22]. Thus, offering remediation to retain expensively trained but underperforming doctors is a logical financial solution.

While offering remediation to underperforming doctors makes sense on a practical and financial level, there is another important reason related to the "Duty of Care to Doctors" [23]. Rather than "striking off" or "firing" a doctor who is underperforming, providing the necessary support and remediation and the opportunity to improve is imperative in a caring workplace. The GMC states their aim is to "protect patients and the reputation of the profession". Once this has been achieved the GMC states they also have a parallel duty of care to the doctors to encourage and enable remediation in suitable circumstances [23]. Remediation is, therefore, important for a doctor's personal and professional development as well as their patients.

Despite the importance of remediation in the regulation of doctors and ensuring patient safety, research on remediation is lacking [6]. Three literature reviews have been conducted on remediation within medical education. All three demonstrate the lack of high quality studies on the effectiveness of remediation interventions within the narrow parameters they used to scope the literature.

In 2009, Hauer et al. published a thematic review of the remediation literature across the continuum of medical education (from medical student to practising doctor) [5]. Most the included thirteen studies addressed undergraduate remediation intervention with only four studies involving practising doctors. Learning from these few studies, the authors propose a remediation model involving multiple assessment tools for identifying deficiencies, individualised instruction, feedback and reflection, and reassessment. Overall however, they conclude that there is a paucity of evidence to guide best practices of remediation [5].

In 2013, Cleland et al. conducted a systematic review to identify the theoretical frameworks used in studies of remedial interventions for medical students and doctors in training [6]. Thirty-one studies of undergraduate and early postgraduate medical students were included. Studies involving practising clinicians were excluded. The remediation interventions addressed underperformance on clinical or written examinations. Again, the review found a lack of evidence about the relative effectiveness of remediation interventions. Additionally, the review also found that few of the studies that were included reported having informed their approaches with relevant theory.

While Cleland et al. (2013) focused on remediation interventions to address under performance on clinical or written examinations in medical students or trainee doctors, a Master's dissertation by Brett which was supervised by members of the core research team (Archer and Brennan) conducted in 2016 focused on

remediating doctors' professionalism lapses [4]. Brett's research involved a review of interventions, models and strategies to remediate lapses in professionalism in healthcare professionals. A narrative synthesis of 35 studies identified six common elements in remediation interventions, models and strategies including: 1. insight, reflection and self-remediation, 2. mental health evaluation, 3. mentoring, 4. feedback, 5. spectrum of intervention, and 6. re-teaching the cognitive base. 28 of the included studies related to qualified doctors or medical students. Again, this review found a paucity of high quality studies, with 17 of the 35 included studies being an editorial or opinion piece. Moreover, an even greater proportion of the studies did not undertake any evaluation or exploration of the potential outcomes that their ideas for remediating lapses in professionalism could bring. Therefore, the ability of the review to assess the impact of the remediation strategies, models and interventions was limited.

All three existing literature reviews on the topic of remediating doctors identify a lack of research providing a firm theoretical base to guide remediation interventions [4-6]. They were also unable to identify why particular interventions work for some doctors and not for others i.e. detailed analyses on important contexts were missing. This issue was also highlighted by recently commissioned research by the GMC, which investigated the impact on doctors of undertakings (remediation measures agreed with the doctors), conditions (remediation imposed on the doctors) and official warnings. The study had a small sample size but the outcomes suggested that stipulating remediation in some cases engendered more reflective and safer practice, but in others more defensive or unchanged practice [23]. In other words, the same interventions were producing different outcomes in different contexts and doctors.

In order to design high-quality remediation interventions, it is fundamental to understand the theory of how remediation of doctors is supposed to work, for whom and the contexts that lead to different outcomes. We would argue that, based on the current literature, this is the most important part of the remediation research agenda. Therefore, we propose conducting a realist review of the literature to address this gap. This method of evidence synthesis is specifically designed to understand how and why interventions are supposed to work, in what contexts, and for whom, through the development of a programme theory.

Our research would seek to answer the following research questions:

1. What are the mechanisms by which remediation interventions work to change the behaviour of practising doctors in order to produce their intended outcomes?
2. What are the contexts, which determine whether remediation interventions produce their intended or unintended outcomes?
3. In what circumstances are these remediation interventions likely to be effective?

The proposed research will make an empirical contribution to the existing body of knowledge by developing a programme theory of how remediation of doctors is supposed to work, for whom and in what contexts. Achieving this type of understanding will also enable us to develop recommendations to support the optimal tailoring, design and implementation of remediation interventions for underperforming doctors in order to restore patient safety.

This research will generate new knowledge about a poorly understood area of healthcare delivery that directly affects the standards of care received by patients. It is thus consistent with the organisational focus of HS&DR to improve the quality and the organisation of health services, in this instance within the specific area of improving the design and delivery of remediation programmes in the context of the regulatory changes to UK medicine.

The research will be carried out with the NCAS as a collaborative partner, and so will have a direct impact in terms of shaping NCAS remediation programmes. This collaboration, combined with input from an expert team of stakeholders (a vital aspect of realist review methods – see following sections,) will ensure that the study will deliver findings that will directly feed into policy and practice development within the NHS and will, therefore, directly contribute to the NIHR HS&DR aims of “delivering rigorous evidence to improve the quality, organisation and delivery of healthcare”. The self-evident importance of doctor performance for

patient safety, and the practical, moral, political and financial imperatives of offering underperforming doctors the opportunity to remediate, mean that this will be an area of sustained interest in the NHS for the foreseeable future.

4. EVIDENCE EXPLAINING WHY THIS RESEARCH IS NEEDED NOW

A 2009 systematic review on doctor remediation concluded that there was “a paucity of evidence to guide best practices of remediation in medical education at all levels” [5]. The more recent systematic review in 2013 by Cleland et al. pointed out that most studies focused on medical students who were seeking to, “[improve] performance to pass a re-sit of an examination or assessment” [6]. They noted that, “we cannot delineate precisely what works, and why, in remedial interventions for medical students and doctors” [6] and concluded that “rigorous approaches to developing and evaluating remediation interventions are required” (p.242) [6]. An important issue that has limited our deeper understanding of remediation interventions for doctors has been the way the systematic reviews have been carried out. In particular, the previous systematic reviews on remediation had inclusion criteria that were too restrictive (e.g. by study design, intervention type) and hence were only able to draw on a narrow body of literature.

The advantage of using a realist review is that it is a type of systematic review that allows for evidence synthesis of a wider range of literature. Rather than being restricted to literature on narrow defined populations and interventions, the realist review net can be cast wider to include literature from other fields and other professions where potentially shared mechanisms may be in operation. These mechanisms can then be developed, tested and refined so that they are relevant and more specific for the programme theory of remediation interventions. We have conducted preliminary searches and are confident that an appropriate body of literature exists, in part by taking a wider (realist) approach to the literature than previous systematic approaches.

Better evidence upon which to base remediation practices is long overdue, but the timing of this proposal is also driven by regulatory developments in the UK. As mentioned above, medical revalidation should, if it works as designed, drive up demand on remediation services. However, it is widely recognised that there is no additional funding for remediation programmes [14]. Therefore, it is important to develop a programme theory of remediation in order to ensure that limited resources be directed at developing effective intervention strategies for the right individuals.

This review will be conducted with NCAS as a partner, allowing the development and, ultimately, testing of the programme theory and directly contributing to NCAS’s ongoing evaluation and development of their gold standard professional and remediation services within the NHS.

5. AIMS AND OBJECTIVES

Aim

To identify why, how, in what contexts, for whom and to what extent remediation interventions work for practising doctors, in order to restore patient safety.

Objectives

1. To conduct a realist review of the literature to ascertain why, how, in what contexts, for whom and to what extent do remediation programmes for practising doctors work to restore patient safety
2. To provide recommendations on tailoring, implementation and design strategies to improve remediation interventions for doctors

Review Questions

1. What are the mechanisms by which remediation interventions work to change the behaviour of practising doctors in order to produce their intended outcomes?

2. What are the contexts which determine whether remediation interventions produce their intended or unintended outcomes?
3. In what circumstances are these remediation interventions likely to be effective?

Concise Statement of the Proposed Research

The proposed research uses a realist review methodology to develop, test and refine a programme theory of how remediation interventions work to improve doctor performance. The review will be conducted using Pawson's five steps for realist reviews [8], and will also be informed by the quality and publication standards and training materials for realist reviews [7]. An initial programme theory will be developed through searching the literature and engagement with a stakeholder group. The initial programme theory will then be tested and refined using existing literature on remediation of doctors. Formal searches of the literature will be carried out by an information specialist. Articles used to test the programme theory will be chosen based on relevance and rigour. Data will be organised using NVivo (QSR International Pty Ltd, Doncaster, Vic, Australia) and analysed using a realist logic of analysis.

The review will be conducted by an expert research team with extensive experience of realist reviews, remediation, medical revalidation, performance and assessment. The research will be conducted with input from stakeholder groups, including the National Clinical Assessment Service, which will be a partner in the research project. Through collaboration with NCAS and other professional/regulatory bodies represented in the stakeholder group, the outcomes of this research will feed into the ongoing evaluation and assessment of new professional support and remediation services.

6. RESEARCH PLANS

6.1 Methodology – Realist Review

The proposed study is a realist review of literature on the remediation of doctors. Realist review is a practical methodological approach designed to inform policy and practice. The realist review method is distinct from other types of literature reviews as it is based on an interpretive and theory driven approach, synthesising evidence from qualitative, quantitative and mixed-methods research [24]. The unique contribution of this method is that it yields transferable findings that explain how and why context can affect outcomes [24]. It does so by developing programme theories that explain how, why, in what contexts, for whom and to what extent interventions 'work' [25 26].

Realist reviews are particularly suited to research on the remediation of doctors as they focus on the contextual factors that determine the outcomes of an intervention [27]. Like other interventions that seek to promulgate behavioural change, remediation is highly context dependent, i.e. the same intervention will vary in its success depending, for example, on who delivers it and how it is delivered, the characteristics of the learners, the circumstances surrounding it and the tools and techniques used. Research designs that seek to "strip away" this context limit an understanding of "how, when and for whom" the intervention will be effective [27]. A realist review takes context as central to any explanation by exploring how an intervention manipulates context to trigger mechanisms that induce behavioural change.

The explanation building will ultimately start with the development of an initial realist programme theory of "how remediation of doctors produces its effects". To achieve this, our initial realist programme theory will set out the necessary steps needed to accomplish the final desired outcome(s) from the remediation of doctors. How and why each step (or intermediate outcome) can then be 'made' to happen will then be explained using a realist logic of analysis - i.e. what relationship between context and mechanism(s) might lead to that outcome [24]. This initial programme theory is then challenged and shaped through an iterative process of testing - i.e. parts of it are confirmed, refuted or refined against a range of relevant data from existing literature.

6.2 Plan of investigation

The plan of investigation will follow a detailed realist review protocol, which will be developed by the core research team. We have extensive experience in conducting realist reviews and systematic reviews. The protocol will be designed based on Pawson's five iterative steps in conducting realist reviews [8]. It will also be informed by the quality and publication standards and training materials for realist reviews that was developed by one of the core research team members (Wong) (see www.ramesesproject.org). The protocol will be registered with PROSPERO which is a prospective register of systematic reviews [28].

Objective 1: To conduct a realist review of the literature to ascertain why, how, in what contexts, for whom and to what extent do remediation programmes for practising doctors work to restore patient safety.

Step 1: Locate existing theories

The purpose of this step is to locate existing theories that explain why, how, in what contexts, for whom and to what extent do remediation programmes for practising doctors work. This involves identifying the theories that explain how remediation interventions are supposed to work to bring about behavioural change in clinical settings. While we have already established there is limited theory underlying existing remediation interventions the realist review approach allows for the literature net to be cast wider to include literature from other fields and other professions where potentially shared mechanisms may be in operation.

To identify these theories, we shall iteratively consult with key stakeholders in the remediation process (see below) and search relevant personal libraries we have carefully and purposefully collected on this topic area to identify existing theories. The informal searches conducted in step 1 differ from the more formal searching that will be carried in step 2 as their purpose is to quickly identify the kinds of theory that may be relevant; thus exploratory and informal search methods including citation tracking and snow-balling will be used [29]. Once the theories have been identified, we shall build an initial programme theory to test in the review. Programme theory development will necessitate iterative discussions within the core research team to bring together the different theories into an initial programme theory. A stakeholder group will also be recruited to provide subject knowledge for programme theory refinement (see Table 1). The stakeholder group will include people involved in the remediation process including doctors from both primary and secondary care that have completed a remediation programme, personnel who identify underperforming doctors and initiate involvement in remediation programme, RO's, personnel involved in the delivery of remediation programmes, professional coaches in remediation interventions, members of relevant medical bodies e.g. GMC, British Medical Association (BMA) and researchers involved in research on remediation of doctors. We shall continually assess the constitution of the stakeholder group throughout the study and shall extend the membership if needed. When the initial programme theory has been established by the core research team, the stakeholder group will be asked to provide feedback for further refinement. The plan will be for the stakeholder group to meet six times throughout the review.

Table 1: Stakeholder group members

	Group	Members
1.	Doctors that have completed a remediation programme	2 primary care doctors 2 secondary care doctors
2.	People involved in the delivery of remediation programmes	1 further member of NCAS 2 members involved in delivery of other remediation programmes A professional coach in remediation
3.	People that identify underperforming doctors in the workplace	Responsible Officer Revalidation lead in NHS England NHS Human Resources representative
4.	PPI	Sol Mead – PPI Forum member Stephen Barasi – PPI Forum member Lyndsey Withers, PPI Forum member

5.	Researchers in remediation research/realist reviews	A senior Health Services Researcher at Plymouth University Dr. Jamie Read – Specialist Registrar in Geriatrics/PhD candidate in remediation and professional identity at Plymouth University Mr Joe Brett F1 doctor – completed Masters dissertation on remediation of doctors with professionalism lapses
6.	Members of Relevant Medical Bodies	Dr Andrew Long, The Academy of Medical Royal Colleges GMC representative BMA representative

Named individuals have kindly confirmed their involvement

Step 2: Search strategy

Formal search

In step 2 the goal is to find a body of relevant literature in order to further develop and refine the initial programme theory developed in Step 1. The searches will be designed, piloted and carried out by an experienced information specialist with experience of carrying out iterative searches for realist reviews. The following databases will be searched as required Embase; MEDLINE; CINAHL, PsycINFO, ERIC, DARE, ASSIA. Searches for grey literature will also be conducted in Google, OpenGrey, and Health Management Information Consortium (HMIC).. Citation searching will also be undertaken including 'cited by' searches and searches of citations in the reference lists of relevant documents. We shall also ask the core research team and stakeholders to identify any literature they may think is relevant. The databases will be searched with free text keywords and controlled vocabulary where appropriate using terms such as remedi*, reskilling, and retraining, combined with the concept of doctors. Any literature that is likely to provide conceptually rich data, including grey literature, will be considered for inclusion in the review.. We are confident that there will be sufficient literature to form a 'body of literature' with which to refine the initial programme theory. We believe that following an initial quick search (please see Additional Documentation for a draft Ovid MEDLINE search) the formal stage will yield more than 400 peer review publications for possible inclusion. The searches we develop will also deliberately seek out relevant grey literature.

Screening

When screening the identified literature, the inclusion and exclusion criteria will be deliberately broad as we seek to find quantitative, qualitative and mixed-methods articles. We define remediation as "an intervention, or suite of interventions, required in response to assessment against threshold standards". The following inclusion criteria will be applied:

- Aspect of remediation - all documents that focus on remediation of practising doctors
- Study design - all study designs
- Types of settings - all documents about hospital or primary care settings
- Types of participant - all doctors in primary and secondary care
- Types of intervention - all remediation interventions
- Outcome measures - all remediation-related outcome measures

Screening will be piloted with small samples until high agreement is reached, at which point full screening will be conducted by the Research Fellow (RF) who will be recruited for the study. A random sample of 10% of the citations identified through the formal searches will be reviewed independently by Brennan for quality assurance purposes. If there are disagreements these, will be resolved through discussion between members of the core team. In the event of disagreements remaining they will be discussed and resolved by majority vote amongst the academic steering group (see description in Section 9).

Additional searching

A vital part of conducting a realist review involves searching for additional data to explain particular parts of the programme theory. Therefore, more searches will be conducted if we need more data to develop and

test specific areas of the programme theory. Based on our understanding of remediation to date, these could include areas like feedback on performance, reflection, development of insight. These additional topics will increase the quantity of relevant data available for us to test the programme theory. The searches will be developed, piloted and refined by the core research team with the help of the Information Specialist. These searches will differ from the 'formal searches' outlined above through being more exploratory and purposive, and from a range of different disciplines. Each additional search instigated, along with the inclusion and exclusion criteria, will be discussed by the core research team.

Step 3: Article selection– Review strategy

The literature reviews already conducted on remediation suggest that there exists a substantial literature on remediation but that this is lacking in quality and rigour [6]. However, the realist review approach will enable us to include this literature; as any article, that it can be used, to any extent, to test any part of the programme theory, can be included. Documents will be selected based on relevance (whether data can contribute to theory building and/or testing) and rigour (whether methods used to generate the relevant data are credible and trustworthy) [30]. The RF will read all the included papers and ultimately include all documents or studies that contribute to the development of some part of the programme theory.

A further random sample of 10% of the included articles will first be independently assessed by the RF and Brennan to ensure that there is consistency in the included articles. The remaining 90% of decisions will be made by the RF. If the RF is uncertain over relevance or rigour of an article, it will be discussed by the review team. If there are disagreements these will be resolved through discussion between members of the core team. In the event of disagreements remaining, they will be discussed and resolved by majority vote amongst the academic steering group.

Data – strategy for reviewing literature

The realist review approach synthesises information through note-taking and annotation. Full texts of the included articles will be imported into NVivo. NVivo is a data management system that has been successfully used by the core research team in previous reviews. Data extraction will be carried out by the RF. If required Brennan will provide the RF with NVivo training. Relevant sections of texts relating to one or more part of the programme theory will be coded in NVivo firstly by conceptual 'themes' and then as the review progresses these will be developed into context-mechanism- outcome (CMO) configurations (see Step 5 below). Data on the characteristics of the documents will be extracted separately into an Excel spreadsheet.

Step 5: Synthesising evidence and drawing conclusions

A realist logic of analysis will be used to interrogate the initial programme theory which will be to explain what it is about remediation of doctors that works and for whom, in what circumstances and respect, and why. Interpretive cross-case comparison will be used to understand and explain how and why actual outcomes have happened e.g. by comparing remediation interventions that have been successful against those which have not, in order to understand how context has influenced reported findings [8]. The following analytical approaches are typically used in the synthesis of evidence in realist reviews:

- a) Juxtaposition of sources of evidence e.g. where evidence about behaviour change in one source allows insights into evidence about outcomes in another source
- b) Reconciling of sources of evidence – where results differ in similar situations, these will be further examined to find explanations for these differences
- c) Adjudication of sources of evidence – centred on methodological strengths or weaknesses
- d) Consolidation of sources of evidence – where different outcomes occur in similar contexts, a reason can be developed as to how and why these outcomes happen differently.

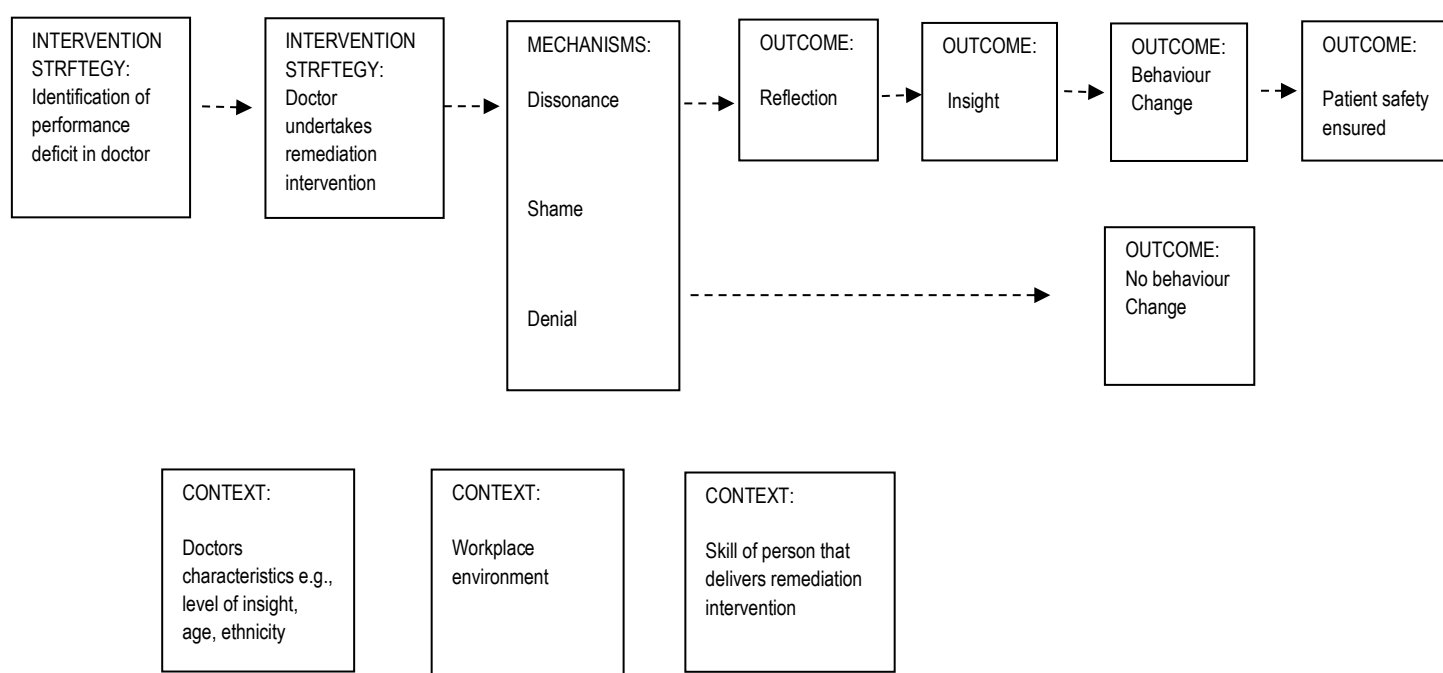
Throughout the review, we shall move iteratively between the analysis of examples, refinement of programme theory, and further iterative searching for data to test specific parts of the programme theory. The final realist programme theory will be presented in a diagram and through a narrative description of CMO configurations.

Example of a preliminary ‘initial’ programme theory

To provide an indication of what a programme theory of remediation might look like in practice, we have developed a preliminary ‘initial’ programme theory of remediation for the purposes of this research proposal (see Figure 1). This theory is based on the core research team’s content expertise on how remediation of doctors could produce its effects. In addition, we have provided details on some CMO configurations to indicate the type of information that a realist review can generate. These CMO configurations are based on three different mechanisms; dissonance, shame and denial. “A mechanism is the way in which a programmes resources or opportunities interact with the reasoning of individuals and lead to changes in behaviour” [8].

While we have set out the processes with our realist review in a linear way, as we have illustrated in our project flow diagram, the review processes are iterative. Once searching has identified potentially relevant full-text articles (i.e., at the ‘end’ of step 2), the subsequent steps often take place at approximately the same time. In other words, once the full text of a document has been retrieved and it is being read and assessed for selection (i.e., at step 3), analysis and synthesis may start. The purpose of analysis and synthesis is to understand how mechanisms behave under the different contexts described within the documents included in the review. During the detailed assessment for inclusion into the review of any content within a potentially relevant article, we will ask a series of questions and make judgements about relevance and rigour based on those set out by Wong et al (see Box 1 in article) [31].

Figure 1: Preliminary ‘Initial’ Programme Theory



A hypothetical CMO Configuration example: Dissonance Mechanism

One possible CMO configuration is based on the mechanism of dissonance, which could be necessary to achieve the desired remediation outcome of behaviour change and therefore ensure patient safety. Cognitive dissonance refers to a situation where a person has conflicting attitudes, beliefs or behaviours. This produces a feeling of discomfort, which leads to an alteration in the person’s attitudes/beliefs behaviours to reduce the discomfort and restore balance. In remediation, the concept of dissonance has the properties of a mechanism. The contents of the remediation intervention/programme or the person delivering the programme (context) may trigger dissonance in the doctor about their current practice compared to best

practice and as a result trigger behaviour change. An important context in this respect is that if the doctor has a high level of insight (context) or the person that delivers the remediation intervention is highly skilled (context) then dissonance (mechanism) will be triggered resulting in behaviour change (outcome) and ensured patient safety (outcome). If we were to find that this hypothetical CMO configuration were to be confirmed against available data from the literature, then we might recommend that people who deliver remediation would need to be highly skilled and understand how to trigger dissonance in a doctor undergoing remediation.

Objective 2: To provide recommendations

Our programme theory will be used to provide recommendations to all organisations designing and implementing a remediation intervention for doctors. However, it will also provide specific recommendations to NCAS on tailoring and implementing their remediation and professional support advice and assessment services. More information is provided in the following section.

7. 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. Representatives of regulatory bodies form part of our stakeholder group, including the NCAS, and we shall work with them to refine our dissemination strategy throughout the study. However, it is clear there will be a number of key audiences, which will each need a slightly different approach to engage. For each audience, therefore, once we have clarified the main players we shall contact the organisation directly to seek advice on their preferred channels and format for optimal dissemination to their members. This will be assisted by our Principal Investigator already having established relationships with both the GMC and NHS England through current research and with NCAS, as an academic advisor, and member of their Education Research Group (ERG).

This dissemination strategy will aim to have impact along three primary trajectories:

Instrumental impact: The study will inform and develop the policy and practice of remediation. This refers to the findings of the review itself and our dissemination of review findings to key stakeholders in order to provide tangible improvement to the practice of remediation in NHS organisations. The purpose of a remediation programme is to produce long-term behavioural change in the participants. In addition, the purpose of a realist review is to understand exactly what conditions create those kinds of behavioural change. Therefore, the findings of our research will directly contribute to improving standards in medical care in NHS.

Conceptual impact: The study will be the first of its kind to conduct a realist review of remediation and to develop a programme theory of remediation. The systematic reviews that exist on this topic are now dated (2009 and 2013) and drew on narrow bodies of literature, and no one has, as yet, conducted a review of remediation to work out what works, for whom, how, why and in what contexts (i.e. a realist review). We are also working to develop our programme theory that will then be refined through our realist review, which will then be used to inform our planned realist evaluation to follow.

Capacity building: The networks that are developed through conducting and disseminating the research will enhance the collective technical expertise in the area for further research and development of remediation practices. Most importantly, it is the intention that this research will establish an expert team and network of professionals that can be used to conduct a full realist evaluation of remediation research in the future. We are already developing a research plan for such a study and have begun to identify appropriate datasets and potential case studies.

We want to ensure that the outputs of this project will be useful to the NHS. To do this we shall use the Knowledge-To-Action Cycle framework provided by the KT Clearinghouse (<http://ktclearinghouse.ca/knowledgebase/knowledgetoaction>). This is a framework that provides knowledge translation resources 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, with input 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;
- adapting knowledge to local context and;
- assessing barriers to knowledge use.

We shall seek to operationalise this framework by:

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

We anticipate that this publication is most likely to impact at an academic level – informing the understanding and theoretical basis of remediation behaviour change interventions.

2) A ‘user guide’ that outlines practical advice to optimise, tailor and implement existing interventions designed to change behaviour through remediation

With this output, we shall aim to impact on the landscape of current remediation provision. This document will be targeted at educational providers and regulators. These include medical schools, Local Education Training Boards and Deaneries, as well as the Health Education England, the NHS, the GMC and NCAS. These bodies are at the delivery end of existing remediation practices that we wish to inform and help improve.

We shall draw on the expertise of the academics and educators within our project team and combine this with the policy expertise of the wider stakeholder group to produce a relevant and practical guide in a direct deliverable language. This will ensure that it can be used to bring about direct change in policy and remediation practice.

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

Stakeholders will be invited to attend presentations on the developing programme theory so that research dissemination can also benefit from their feedback and reflection. In addition to national and regional dissemination, research findings will be presented locally and internationally. Locally, we shall continue to work with researchers across Plymouth, through CAMERA’s monthly meetings to share and promote research. At an international level, established networks in North America and Australasia will continue, allowing international comparisons between practice in the UK and systems for remediating poor performance around the world.

To support PPI beyond the stakeholder group, the research will be summarised in a newly developed website (modelled on a national study website Archer is currently leading www.umbrella-revalidation.org.uk), updated through social media (Twitter, Facebook).

8. PLAN OF INVESTIGATION AND TIMETABLE

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

MONTHS 0-3

- Recruit RF
- Set up and run 1st Steering Group meeting
- Recruit, brief 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
- Initial website development

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 Step 5 of realist review
- Iteratively refine initial programme theory
- Run 5th 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 Stakeholder Group meeting – discussion and refinement of dissemination strategy and project outputs
- Finalise and disseminate project outputs including user guide
- Finalise and publish academic papers
- Write final report

Project timetable

		2018									2019								
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
		Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	July	Aug	Sept
Key review processes	Steering group meetings																		
	Establish stakeholder group																		
	Stakeholder group meetings																		
	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																		

9. PROJECT MANAGEMENT

The core research team will meet monthly and in between these meetings will be in regular contact as needed (e.g. via email, video and tele-conferencing). We shall 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 research team, chaired by Archer, will include Brennan, Wong, our information specialist and the RF– to be employed. We shall use online software 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 research team will be responsible for undertaking the realist review, producing the project outputs and dissemination.

The steering group will include all co-applicants (Cleland, Prescott-Clements and Withers) and representation from finance and research and innovation teams from Plymouth University. It will monitor progress against milestones and oversee research governance and financial management. The group will also provide advice, promote the project, communicate with stakeholders and help maximise dissemination and impact of findings.

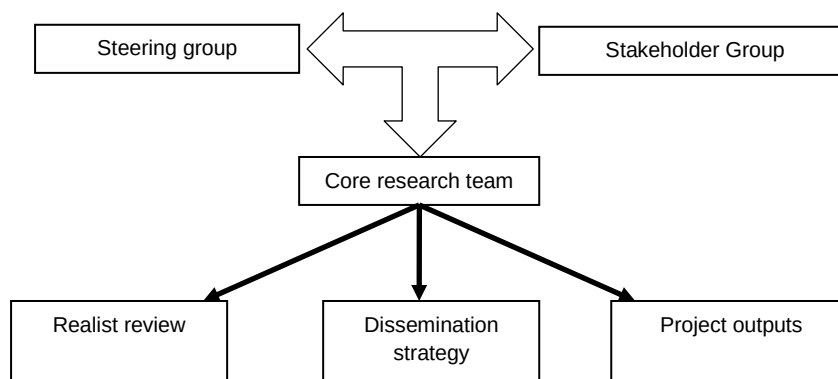
The stakeholder group membership and its roles have been outlined in the Research plan and Dissemination and outputs sections above. In summary, this group consisting of content experts in education, medicine, realist reviews, and importantly with representation from policy leaders and lay people (PPI), it will help us to:

- a) Develop and refine the programme theory on interventions to further develop remediation programmes for behavioural change;
- b) Optimise our dissemination plans;
- c) Produce feasible and practical recommendations for relevant stakeholder groups on how interventions to remediate doctors might be tailored for best effect.

All data will be handled in accordance with the Data Protection Policies of our respective institutions.

Figure 1 below provides an outline of the project's organisational structure.

Figure 1: Project's organisational structure



10. APPROVAL BY ETHICS COMMITTEES

We have confirmed exemption from NHS research ethics approval, through Chair's action, from our University Health and Social Sciences Ethics Committee.

11. PATIENT AND PUBLIC INVOLVEMENT

This study has involved lay representation from the start. As part of two interrelated revalidation studies funded by the GMC and Department of Health (England), we have established a PPI Forum, who as well as contributing to all aspects of the research programmes also work as research partners in the PPI streams. Members include lay 'experts' and national patient representatives involved in GMC and Academy of Medical Royal Colleges revalidation and remediation advisory committees.

During PPI Forum discussions, it became increasingly surprising to the group that this important area that impacts on patient safety was not well researched. This has become a major driver for this application. All PPI Forum members are experienced at supporting and critically reviewing and quality assuring research and have kindly fed back on a number of iterations fundamentally shaping and reshaping its structure, approach and focus. In particular, 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 specifically for this study.

In this project, whilst not strictly members of the public or patients, doctors and policy-makers are also key stakeholders and so will be included as part of our stakeholder group (Table 1). The group will be constituted of members drawn from our existing PPI Forum but also key professional stakeholders; e.g. Academy of Medical Royal Colleges. This group will not replicate the work of other committees, but act as a shared forum to (1) support the project in its focus, applicability and direction, and (2) to feed forward research findings directly into the work of NHS bodies including for example NCAS.

Due to their relatively high levels of experience, it is anticipated that the stakeholders involved in this study, including patients and public representatives, will not require extensive training, but if any stakeholders require briefing on, for example, realist methodologies, this will be provided through internal seminar presentations.

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