

# Greater Manchester Rapid Service Evaluation Team: REVAL-GM: Programme-level protocol

## Research team and key contacts

<p><b>Co-Lead</b></p> <p><i>Name</i> Prof Jo Dumville</p> <p><i>Address</i> Division of Nursing, Midwifery &amp; Social Work School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> jo.dumville@manchester.ac.uk</p>	<p><b>Co-Lead</b></p> <p><i>Name</i> Mr Paul Wilson</p> <p><i>Address</i> Division of Population Health, Health Services Research &amp; Primary Care School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> paul.wilson@manchester.ac.uk</p>
<p><b>Co-investigator and PPI Lead</b></p> <p><i>Name</i> Prof Penny Bee</p> <p><i>Address</i> Division of Nursing, Midwifery &amp; Social Work School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> penny.e.bee@manchester.ac.uk</p>	<p><b>Co-Investigator</b></p> <p><i>Name</i> Prof Pete Bower</p> <p><i>Address</i> Division of Population Health, Health Services Research &amp; Primary Care School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> peter.bower@manchester.ac.uk</p>
<p><b>Co-Investigator</b></p> <p><i>Name</i> Prof Dame Nicky Cullum</p> <p><i>Address</i> Division of Nursing, Midwifery &amp; Social Work School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> nicky.cullum@manchester.ac.uk</p>	<p><b>Co-Investigator</b></p> <p><i>Name</i> Prof Evan Kontopantelis</p> <p><i>Address</i> Division of Informatics, Imaging &amp; Data Sciences School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> e.kontopantelis@manchester.ac.uk</p>

<p><b>Co-Investigator</b></p> <p><i>Name</i> Dr Luke Munford</p> <p><i>Address</i> Division of Population Health, Health Services Research &amp; Primary Care School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> <a href="mailto:luke.munford@manchester.ac.uk">luke.munford@manchester.ac.uk</a></p>	<p><b>Co-Investigator</b></p> <p><i>Name</i> Prof Caroline Sanders</p> <p><i>Address</i> Division of Population Health, Health Services Research &amp; Primary Care School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> <a href="mailto:caroline.sanders@manchester.ac.uk">caroline.sanders@manchester.ac.uk</a></p>
<p><b>Co-Investigator</b></p> <p><i>Name</i> Dr Sabine van der Veer</p> <p><i>Address</i> Division of Informatics, Imaging &amp; Data Sciences School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> <a href="mailto:sabine.vanderveer@manchester.ac.uk">sabine.vanderveer@manchester.ac.uk</a></p>	<p><b>Co-Investigator</b></p> <p><i>Name</i> Dr Will Whittaker</p> <p><i>Address</i> Division of Population Health, Health Services Research &amp; Primary Care School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> <a href="mailto:william.whittaker@manchester.ac.uk">william.whittaker@manchester.ac.uk</a></p>
<p><b>Reval Administrator</b></p> <p><i>Name</i> Pip Turner</p> <p><i>Address</i> Division of Nursing, Midwifery &amp; Social Work School of Health Sciences University of Manchester Oxford Road Manchester M13 9PL</p> <p><i>Email</i> <a href="mailto:philippa.turner@manchester.ac.uk">philippa.turner@manchester.ac.uk</a></p>	

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## Scientific Abstract

### Background

Identifying and applying innovative approaches to delivering health and care services is of paramount importance to the long-term sustainability of the NHS. However, innovation without adequate evaluation can lead to the misattribution of effects and adoption of new technologies, roles, practices and ways of working without proven benefits.

Evaluation is critical in informing innovation within the NHS, helping patients and professionals gain access to the most effective and acceptable care. Evaluation also protects services and patients from innovations not yet ready to realise their potential or that widen existing health inequalities. However, evaluation needs to be conducted quickly and efficiently if it is to provide timely information for decisionmakers and policymakers.

### Design and Methods

We are a multidisciplinary team from The University of Manchester with expertise in all aspects of evaluating health and social care. We take an interdisciplinary, pragmatic approach to applied health research and evaluation. Our approach aims to strike the balance between rigour and efficiency and provide timely evidence that is used by all decisionmakers.

Co-production is integral to our approach. We are committed to working closely with providers of services and with patients and the public to make sure research is relevant to all of them. Working within this overarching model of co-production our approach will entail:

- 1. Question specification and prioritisation*
- 2. Establishing what is already known or not known about a given innovation*
- 3. Theory guided evaluation using a range of health services research methodologies*

Our focus will be on selecting the most rigorous, feasible, and rapid approach that we can use for the questions specified. Often no single type of evidence on its own is sufficient to make judgements on whether an innovation is worth pursuing further: each evaluation project we undertaken may include several questions that drive data collection and synthesis. We will draw on a range of methodologies and expect most projects to have a 'mixed methods' or approach.

### Patient and public involvement

We ensure that we actively listen to and involve citizens in all aspects of our work. We will do this by collaborating widely, including with Greater Manchester Patient and Community Involvement and Engagement (PCIE) forums we have worked with previously on multiple projects and with our existing networks of national PCIE groups. These forums have broad based representation from people with varied socio-economic and cultural backgrounds including under-represented communities. Members bring a range of skills, knowledge, voluntary, and lived experience and will ensure that a diverse public voice informs the research that we do and the methods we use.

### Dissemination

Our dissemination and knowledge mobilisation strategy is based around two core strategies (1) timeliness and (2) accessibility. Effective dissemination and knowledge mobilisation relies on timely access to good quality and relevant evidence, and we recognise the need to sustain relationships between researchers and the ultimate users of the research. We will actively engage with key stakeholders at all stages of the evaluation process to ensure

evaluation relevance, efficient use of NIHR resources, and to maximise the impact and use of findings as they emerge.

## Lay Summary

### What is Rapid service evaluation?

Innovation in the NHS means new ways of providing health and care to patients. Innovations can involve re-organising NHS services, bringing in new types of staff, or trying new treatments or technologies. Innovation can benefit everyone by helping the NHS deliver the best possible care at the earliest available opportunity. Ideally this gives patients and staff a better experience, makes care safer, and makes better use of NHS budgets.

However, not all innovations are useful. New ways of doing things may not work as well as expected. Innovations may be too expensive, some changes may not be acceptable to the people they are intended for or they may make care more difficult to access.

To make sure we know which innovations are useful and which are not we need to find out, or evaluate, the impact of any innovation by asking important questions such as:

- Does this innovation improve the way we work?
- Does this innovation offer value for money compared with alternatives?
- Is this innovation acceptable to the people who use it?
- Which elements of the innovation are crucial to its success?
- Does this innovation improve access for those in most need?

The most useful and relevant evaluations (studies to find out answers to these questions) are done by listening to, and working with, people the innovations will affect such as members of the public, health professionals, health and social care service managers and people who make policies about how health and care are delivered.

### Who are we?

We are a multidisciplinary team who undertake evaluations of health and social care innovation. Our knowledge and skills in different study designs means that we are flexible and can answer the evaluation questions in the best way, as quickly as possible. Our team is based in Greater Manchester but embedded in national evaluation activities. We identify and work with the people most relevant for an evaluation. Public involvement in our evaluations is drawn from a strong existing network of individuals and organisations. We are experienced in telling people about evaluation findings in interesting, accessible, and understandable ways.

### What is our proposed approach to Rapid Service Evaluation?

We will use a systematic, collaborative approach based on careful planning and clear communication. We will:

1. Identify innovations that are important to the NHS, by working closely with the funder (National Institute of Health Research), with patients and with NHS services to make sure we evaluate what matters most.
2. Evaluate these innovations using the appropriate methods. This might involve talking to patients and staff, collecting new data and using data the NHS already collects.
3. Share our findings as they emerge in ways that make sure they have impact and are useful to health service providers, people who use services and people who make policy.

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### Service innovation and our evaluation ethos

We adopt the definition of innovation as '*a novel set of behaviours, routines, and ways of working that are discontinuous from previous practice/policy, directed at improving... outcomes...and ...implemented by planned and coordinated actions.*' [1] We interpret this broadly to encompass all aspects of workforce and service re-configuration, implementation and de-implementation and delivery. Introducing innovations into health systems, or indeed removing established but ineffective practices, is a challenging and complex social process [1] and success or otherwise can be impacted by a very wide range of determinants [2-4] Our understanding of service innovation is shaped by diffusion of innovations theory that seeks to explain how, why, and at what rate innovations spread through social systems.[5] Our understanding embraces complexity, recognising that this can arise from the innovation itself, from the context in which it is delivered and from the purposive actions of actors within the system. [6,7] We also recognise that introducing innovations into health systems can have spill over effects and unintended consequences that may exacerbate inequalities. A multi-level exploration of implementation, access, equity, and outcomes will be central to our planned approach. Outcomes will be considered at a system, service, and patient level, encompassing both policy relevance and importance as defined by the public and service users.

Our overarching ethos is one of working with stakeholders to: identify the right questions; collect the right data to address these questions and then report this information in the right way to ensure knowledge is actionable. Work will be highly iterative to meet evidence user needs. We will take formative and summative approaches to evaluation. We are committed to avoiding research waste and are experts in systematic review and evidence synthesis more widely. All our evaluation work involves first learning from current, national, and international evidence.

Our experience means we are familiar with the service issues, tensions, and sensitivities that can arise including:

- *Key stakeholders' reluctance (for various reasons) to engage with evaluation.*
- *Real or perceived overlap between proposed evaluation and existing or on-going work.*
- *Challenges defining service level innovation that may be heterogeneous in nature nationally.*
- *Managing the communication with and input of multiple stakeholders with different viewpoints, which can lead to different views on the focus of evaluation and key uncertainties to explore.*
- *Having to rapidly initiate projects and adapt to changes in the evaluation in response to feedback or changes in evaluation priorities.*

We will use several strategies to manage our evaluative activities, which we present below. These interlinked approaches will also support the rapid nature of the planned evaluations, for example rapid development of new successful collaborations and movement towards agreed evaluation questions and approaches.

**Considered process and governance:** We propose the following operational and governance structure (also see flow chat attachment).

All potential evaluation projects will be explored by the team with activity led by a smaller project-specific group, comprising at least two co-applicant team members, two of the team's research staff and involving engagement with a PCIE link member.

Programme oversight, with advice and guidance for the team, will be drawn from our wider Stakeholder Advisory Pane. The panel will draw together representatives from key national and regional stakeholders including representatives from the network of Applied Research Collaborations (two ARC Directors have agreed in principle to be members of this group as have representatives from the Academic Health Science Network and The Health Foundation). We will also have at least three PCIE representatives on this group.

Project development will then follow a sequential, iterative process ensuring co-production and formative working at all project stages but especially in development. Our planned approach is detailed later in the application but briefly, we anticipate undertaking problem specification and/or prioritisation of evaluation questions with stakeholders (as required), followed by inclusive scoping and specification to guide development of an evaluation plan. The evaluation, which may have multiple inter-linked phases, and dissemination of findings follow.

**Excellence in planning, preparation, and project management:** All project work will be meticulously developed and recorded with a clear audit trail available. Project-related decisions, activities, timetables, and progress will be documented concisely and shared, ensuring people can reflect on activities and feed into these. We will focus on the use of written protocols to enhance shared understanding of proposed work and agree milestones, deadlines and deliverables.

**Clear, consistent, and considered communication:** Clarity of information and appropriate communication lies at the heart of how we interact within the team itself and with wider stakeholders. Whilst evaluations may be rapid, good communication remains essential. We have an ethos of *considering the target audience* when preparing written or verbal material to ensure we take people with us in any conversation and that we link individuals appropriately through project work. This approach will support us as we engage with relevant stakeholders in a timely way, allowing rapid development of relationships. Ultimately across all projects we aim to develop a shared vision and mutual agreement of the evaluation questions; agreement of the contribution of all parties and clear and open lines of communication.

**Considered use of formal, structured meetings:** We aim to hold appropriately structured meetings, informed by pre-circulated, concise material to inform focused discussion. This is relevant for internal team members as well as those with professional and PCIE stakeholder members. We will respect people's time by ensuring meetings are held where there are clear requirements that can be met with group discussion with all appropriate members included.

**Engaging with all stakeholders and 'finding a way forward':** For each evaluation we will build a cohesive relationship with relevant stakeholders enabling meaningful co-production. As a collective we will strive to move evaluation projects forward, shaping, and iterating work to relevant timelines whilst accounting for decisions made with all involved parties. Within this aim, we recognise the potential for differing views and opinions: we will address these proactively and constructively, ensuring all stakeholders are heard. We will facilitate ways forward ensuring transparency and accountability of decision making to relevant parties. As noted, part of our proposed governance structure includes our Stakeholder Advisory Panel, this independent body will serve as a touchpoint for advice and guidance, including where there are any particularly difficult issues to navigate. Whilst we are not anticipating this, we will ensure we have robust processes in place to deal with the eventuality.



**Consideration of health inequalities in all evaluation:** Whilst all health bodies must have due regard to reducing health inequalities and to delivering services based on need, there are deep-rooted and persistent health inequalities within the UK. Our evaluations consider health inequalities at every stage through implementation, access, equity, and outcomes. More specifically we aim to ensure consideration of inequalities due to innovation (assessment of inequalities is built in) alongside a broader consideration of inclusion and diversity in research (aligning research with burden, ensuring inclusive research practice).

We will continue to strive to engage and build research networks with under-served groups and particularly with those population groups highlighted in NHS England's CORE20PLUS5. Team members were involved in the development of the NIHR INCLUDE framework (and continuing to develop this) and are involved in the Manchester Biomedical Research Centre/VOCAL pilot of the Race Equality Framework. We will utilise existing tools associated with these projects to ensure ongoing assessment of equality, diversity and inclusion throughout our work alongside other resources such as the NIHR Research Design Service's EDI toolkit.

## Use of theory in our service evaluations

We are advocates for theoretically informed evaluation and have extensive experience of using theory to plan and guide our evaluations. This approach enables us to offer more efficient and meaningful methods to generalise and predict outcomes and the potential for successful replication in other settings. At this stage, we have not pre-specified one theoretical approach, as the nature of evaluations to be undertaken has yet to be determined and different approaches may be required for each specific project. Whilst we have no specific evaluation-specific theories, there are several core theoretical approaches that run through our work.

Our overarching conceptual framework is grounded in two core ways. First, we are focused on diffusion of innovations theory to explain how, why, and at what rate innovations spread through social systems.[5] Second, we recognise that any service innovation needs to have due regard to reducing health inequalities. Our approach will therefore also be guided by the Health Disparities Framework [13] which recognises that the determinants of health inequalities are multi-level and any evaluation seeking to understand these needs to focus not only on the individual providers and recipients of care but on the ways by which services are shaped by the wider health system in which they are delivered. A multi-level exploration of equity in implementation, access, equity, and outcomes will be core to our planned approach.

All quantitative methodologies and analytical approaches used will be epidemiologically robust and confer maximum rigour within the rapidity constraints imposed. Likewise qualitative and mixed methods will be rigorous in conduct, meeting required standards. All work will be mapped to relevant reporting frameworks. We will use the EQUATOR Network database of reporting guidelines (<http://www.equator-network.org/>) to ensure the evaluations we conduct systematically capture insights and contextual information (which could inform wider spread and learning) in a standardised format. We will use the TIDIER framework to ensure innovations are comprehensively described. [14,15]

## **Collaboration and partnership working**

We will collaborate with a range of stakeholders and use appropriate methodologies to address a variety of uncertainties to meet the needs of evidence users.

We are embedded in relevant regional and national practice and policy networks including primary, secondary, and community care delivery, commissioning, social care and public health, and policy. We will maximize these existing relationships to facilitate the flexibility and responsiveness necessary to act quickly on requests for evaluations.

We are active members of the Northern Health Science Alliance, the health and life sciences partnership between academic and health services mandated to improve the health and wealth of the North of England. We are also part of the NIHR School of Primary Care Research and School of Social Care Research, which brings together academics and practitioners from across the country to collaborate on research that has an impact both at the policy level and in general practice nationally. Several the team are involved in new collaborations across these schools as part of the “3 schools” funding initiatives.

As part of the national network of NIHR ARCs and Academic Health Science Networks, Clinical Research Network, Policy Research Units and Patient Safety Translational Research Centres, we will draw on an established network of support and collaborations that goes beyond our own local geographical boundaries. Being part of these networks provides us opportunities to reach out and rapidly develop new collaborations with stakeholders and to harness additional expertise that may be required to deliver the work at pace. To support this our funding model contains ‘leverage funds’ to access evaluation support, be this in the forms of expertise or activity from our wider collaboration.

### **Co-production**

Our model of co-production is embedded in our collaborative approach, where researchers work in partnership with knowledge users (comprising patients and care givers, clinicians, policymakers, health system leaders, and others) who identify a problem and have the authority or ability to implement the research recommendations.

Co-production is integral to our approach [8] involving: (i) researchers, professionals, and the public working together over the course of a programme or project including the use of participatory research methods; (ii) the co-creation of new knowledge by researchers working alongside other often professional stakeholders and (iii) working to design and develop innovations with intended users and recipients. Our team will strive to follow ‘guiding principles’ of sharing power and ensuring inclusivity.[9] Key to doing this at pace are our established local, regional and national relationships. Co-production is embedded at all stages of our approach, with a range of stakeholders. We will work closely with relevant stakeholders on any potential or agreed projects to ensure the right evaluation is undertaken.

Co-production will be facilitated by (i) our practice and policy networks, which offer extensive content expertise and frontline perspectives and (ii) our extensive community engagement partnerships, ensuring that all specification, scoping, evaluation, and mobilisation is informed by citizens. Our community engagement partnership will use the Greater Manchester PCIE Forum (membership includes representation from over 30 voluntary sector and other community organisations) and the ARC-GM PCIE Panel (18 members) with whom we have worked on multiple projects. Panel members bring a range of skills, knowledge, voluntary and lived experience to ensure that a diverse public voice informs the research that we do and the methods we use. Three Panel members have contributed to this application.

Our engagement of the forum and cross infrastructure work will enable a critical mass for engaging with wider communities and national networks. We will also link as required with PCIE groups that support the Applied Research Collaborations, Schools of Primary Care and Social Care Research and the Patient Safety Translation Research Centres. These linkages also extend beyond the region, for example we have undertaken work linking with PCIE groups from with East Midlands ARC, to wider the scope of our work (in this case on gathering further PCIE input into the use of the INCLUDE framework). These fora have representation from people with varied socio-economic and cultural backgrounds including under-represented communities. Our community engagement partnership approach is able to respond to individual project needs as evidenced by work we have undertaken and also including the convening of citizen juries [10], condition-specific advisory groups [11], work with third sector organisations, public meetings, and open forums.

We also have established relationships with Research for the Future who we have worked with previously to support condition specific and agnostic PCIE. They have over 10,000 people on the register who have signed up to register interest in getting involved in research. Use of this 'consent to contact model' is ideal for rapid evaluation as it allows more rapid access to potential participants.[12] Many people in this community have long-term conditions and contact can be targeted for specific demographic focus.

<https://www.researchforthefuture.org/research-for-the-future/>.

## Research Design /Methods

Working within this overarching model of collaborative evaluation our general approach has four key steps:

### **1. Question specification and prioritisation**

Most evaluation activities will be responsive to topics judged through external processes to be of high priority. As required, we can complement this prioritisation via rapid review and/or engagement with stakeholder networks and community engagement partnerships who may be interested in or impacted. Over time we can explore application of our patient-facing app, which is currently at beta-testing stage, to enable wider service user engagement in research prioritisation (whilst remaining aware of and responsive to issues of digital exclusion). Criteria to consider for question specification and prioritisation include issues relevant to the NHS Long Term Plans and the NIHR strategic priorities.

### **2. Specification and scoping of evaluations**

#### *Specification stage*

We anticipate evaluation topics or decision problems being briefly outlined by the funder. The process of specifying potential evaluations interrogates the decision problem, specific evaluation questions and the perspectives involved. This process requires close collaboration with relevant stakeholders to shape the potential evaluation and associated engagement. A process of decision and informal conversations within the team, funder, and with relevant stakeholders will support development of the evaluation *issue* that will be captured in a short *initial project specification document*. This topic and scope proposed will be agreed with the funder before further, more extensive, scoping work is initiated.

*Formal scoping stage*

It is anticipated that most evaluations will begin with extensive scoping work to support feasibility assessment and protocol development. We have detailed some of the likely approaches below but this list is not exhaustive. From the scoping stage onwards each specific project will be supported by a protocol. This will capture scoping activities as well as further development into a full evaluation. An overview of a starting protocol template is detailed in Box 1, although this is expected to iterate over time.

The end stage of scoping will be a stop/go decision on a full evaluation, made using insights at this stage and in conjunction with funders. Where evaluation is to follow, a full set of evaluation questions will be drafted and agreed based on the scoping work.

*Scoping: rapid evidence review (may include formal scoping reviews):* A crucial element is also to establish, broadly, what is already known or not known about relevant innovations (if this has not been fully assessed at prioritisation stage or if the focus changes during discussion). Our existing rapid review process (developed to support Academic Health Science Networks, take maximum of two weeks) alongside mapping of available national and regional data will inform decision making about appropriate evaluative methodologies to be deployed.

*Scoping: Exploration stakeholder interviews and workshops:* Scoping work may include semi-formal interviews and/or workshops with a range of appropriate stakeholders including citizens representing the public, policy experts, commissioners, representatives from the third sector, health managers and professionals, and potentially representatives from industry.

*Scoping: Exploration of relevant secondary datasets:* Scoping work is likely to include assessment of any relevant datasets available to the team at national, regional, and local levels and an assessment of feasibility of access.

*Box 1: Suggested headings for initial protocol template. This has been informed by assessment of existing protocols for rapid service evaluation. Scoping work is likely to be included as specific work packages with iteration of the overview section as an evaluation develops.*

**Overview**

- *Background*
- *Problem statement*
- *Overarching aims and objectives*
- *Overarching theoretical lens/framework*
- *Tabular overview*

Work Package	Overview of methods	Description	Objectives addressed
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- *Risk and mitigation strategies*
- *Output and dissemination activities*
- *Overview of timelines*
- *Key stakeholders*
- *Equality Impact Assessment*

**Details of work packages which may then contain**

- *Individual aims and objectives*
- *Methods (may include): Sampling, data collection approaches, analyses, synthesis*
- *Approvals requires*
- *Work package timelines*

### **3. Evaluation**

High priority questions will be evaluated using a range of health services research methodologies; seeking a balance between rigour and efficiency, to ensure that the results of evaluations are delivered in a timely and efficient fashion. Our focus will be on selecting the most rigorous, feasible, and rapid approach that we can use for the questions specified. A protocol will be mandatory for all evaluations (Box 1) as will registration with relevant registries including PROSPERO (PROSPERO <http://www.crd.york.ac.uk/prospero/>) for systematic reviews, Research Registry (<https://www.researchregistry.com/>). Where infrastructure support is required, we will also explore adoption onto the NIHR Clinical Research Network Portfolio.

Broadly we anticipate there are five general question types for evaluation focus:

1. Questions about the nature of change involved or required at a service level
2. Questions about the clinical or cost effectiveness of service-level innovation/change on patient, service and staff outcomes
3. Questions about the experience or acceptability of service innovation
4. Questions about implementation activity and barriers and facilitators to adoption and spread of service innovation/change from service and citizen perspectives.
5. Questions about access and equity.

Within questions there may also be focus on certain sub-groups or issues such as impacts on health or digital inequalities.

Often no single type of evidence on its own is sufficient to make judgements on whether an innovation is worth pursuing further: each evaluation project could include several questions that drive data collection and synthesis. We can draw on a range of methodologies and expect most projects to have a 'mixed methods' approach.

We have considerable experience of employing qualitative methods and rapid adaption of these, collecting data via interviews and focus groups, observation, and narrative models. In terms of rapidity, we have used approaches such as rapid assessment procedures (RAP), focused ethnography, and audio diaries. Where appropriate, we will also utilise surveys to gather information on experience, acceptability and feasibility. We recognise that surveys can represent an inefficient means of data collection with a potential risk of bias, but we have a good track record in generating good response rates to carefully targeted questions from clearly defined populations.[17]

We will use theory to inform the design and conduct of each evaluation, to develop mechanism-based explanations for outcomes, facilitate generalisation and to provide a guide for future empirical enquiry. [18] We are also experienced in data linkage processes, crucial for this work.

We are well placed to undertake such work, having expertise in appropriate statistical approaches and good awareness of their strength and limitations. Approaches we have used include matched cohort designs and interrupted time series analyses and we have methodological expertise and experience in numerous aspects relevant to statistical inference from observational data (e.g. propensity score matching or advanced multiple imputations approaches). Appropriate economic modelling follows these statistical analyses.

Such a framework will allow us to use routine data sets to assess impact and effects compared, while considering appropriate counterfactuals. We have extensive experience using national datasets for large scale evaluations (also see Table 2), these include databases of electronic health records, mainly in primary care but linked to other services: Clinical Practice Research Datalink GOLD and Aurum databases or the Royal College of

General Practices database. However, we also have experience in using national registries, like the National Diabetes Audit, or secondary care data, like the Hospital Episode Statistics. As well we have expertise in handling these data and their appropriate analyses. We are also well placed to access data required as rapidly as possible given our familiarity with these processes.

A key concern with evaluations is where important impacts may not be observable within the evaluation timeframe, and/or where embedding of the innovation takes time. Our expertise in linking to administrative data can support on-going assessment of innovations on key impacts like service access. Such approaches help identify potential equity impacts as they emerge and can help identify sub-groups for subsequent outcomes evaluation.

**Table 1: Overview of methodology toolkit the REVAL will draw from across all evaluations.**

**Evidence synthesis**

Evidence synthesis is a vital stage of most evaluations, whether this be via scoping current evidence on a topic or undertaking a fuller synthesis of available evidence via systematic review, using rapid adaptations. We can utilise a range of types of review including: scoping, rapid, interventional, diagnostic test accuracy, prognostic, overviews of reviews, living, mixed methods, and qualitative.

We are also adept at using a range of synthesis approaches including: narrative, meta-synthesis, network meta-analysis, meta-analysis, and analyses involving individual patient data and decision analytical modelling.

**Estimating Effectiveness**

Quasi-experimental methods are increasingly used for rapid assessment of comparative outcomes, prior to or instead of a full trial.[19] Evaluating service innovations with randomised trials is often difficult and resource-intensive. Innovations may be insufficiently well defined or stable to allow formal evaluation, [20] and effects may be unclear, making outcome assessment problematic.

We can deploy a full range of non-randomised methods to allow the most efficient assessment of the effects of innovations against suitable comparators or existing trends, within the resources available.

In doing so, we will use a range of quantitative methodologies including time series analysis,[21] ‘difference in differences’,[22] and lagged dependent variable methods.[23] These methods can be used with a variety of data sources, including data from local services, national datasets from the ONS (e.g. census data), NHS Digital (e.g. QoF and HES data) or other providers (e.g. GP Patient Survey), and bespoke sources such as the Clinical Practice Research Datalink.[24-30]

Service innovation is not without cost or consequences. As with all change, there will be opportunity costs as innovation activity competes with other health-care services for finite health-care resources. In practice however, service change is often predicated on claims that there will be cost savings or released resources. Appropriate measurement of all costs and outcomes is therefore a crucial element of any evaluative pathway. As with other quantitative methods, consideration of costs needs to be rigorous as possible within the resources available. We anticipate the choice of economic evaluation methods will be project dependent and will range from the simplest level of cost-consequences analysis through to more involved methods to inform resource-allocation decision-making including ex ante modelling.

**Exploring experiences, explanations and implementation**

Qualitative methods are crucial to service evaluation, either as a stand-alone method, or as a complement to quantitative methods.[31] Qualitative methods have a variety of functions, including acquisition of early findings when previous research is lacking, providing ‘thick’

description (especially of the nature of interventions and their actual delivery in practice),[32] eliciting the perspectives of those studied, for formative evaluation, the evaluation of process, and for exploring context.[32,33]

Context can be described as patterns of *social relations and structures* that unfold over time and across settings. [6, 34] They make up the implementation environment. Innovation implementation may vary from one context to another or may have different effects in different contexts even if the way it is implemented does not vary. Understanding the role of context will be a key element of each specific evaluation and will inform further decisions relating to continuation or wider spread.

The qualitative methods we may employ include interviews and focus groups, observation, and narrative models. We will use theory and draw on recent MRC guidance on process evaluation [35] to inform the design and conduct of the qualitative component for each evaluation.

All evaluation activity will be theoretically driven where possible. Theory provides a lens through which we can predict, identify and describe the key features that influence the development, evaluation and implementation of any innovation. Its use reinforces the complex and non-linear nature of implementation and emphasises the inter-relationship between aspects of the innovation, the recipients and the context in which change occurs.

#### **Mixed methods**

In some case we may draw on formal, mixed method approaches to synthesise quantitative and qualitative data, each with their own strengths and weaknesses, where this has been pre-specified. Potential approaches include convergent and explanatory mixed methodologies. These methods allow us to develop a more comprehensive picture of the issue at hand or to explore questionnaire or survey outcomes in more depth respectively [36]. Evaluation activity will be theoretically driven where possible and we will draw on existing methods, like the Pillar Integration Process, for data synthesis.[36,37]

## **PCIE engagement plans**

Public and Community Involvement and Engagement (PCIE) underpins the proposed ethos and operational structure of our Greater Manchester Rapid Service Evaluation Team – REVAL

Substantial input at this stage has come from three public representatives of the NIHR Applied Research Collaboration-Greater Manchester PCIE Panel, formed to represent people from different socioeconomic and cultural backgrounds and under-represented communities. These panel members are engaged in our proposed programme as named collaborators and are representatives of different genders and ethnicities. All three are strong advocates of co-production in health and care research and have been instrumental in shaping our operational structure, as well as our PPI approach and written material in this application. We have previously collaborated with these individuals on NIHR-funded research projects, where we have benefited from their knowledge and ability to support research with traditionally marginalised groups.

Following discussion, we will adopt our PCIE representatives' proposition for a hybrid structure to facilitate active and relevant PCIE input across the programme of work, recognising the need for rapidity and need to continue to learn as the programme evolves. Whilst the team is networked into extensive PCIE links via multiple channels across the UK, we recognised the need for a cohesive approach to engagement that can develop productively over time. The proposed model involves partnership with PCIE link members to help support embedded co-production.

We considered that PCIE link members can work with the team to support:

- Co-production of PCIE operational standards and processes.
- Rapid engagement with other established PCIE panels and members, third sector organisations, faith-based groups and community organisations – mindful of the relevant diversity and expertise needed for specific projects.
- Co-production of study design and data collection protocols and
- Output creation and knowledge mobilisation.

We will appoint a group of PCIE link members (n=5-7) who will work with PCIE networks to facilitate coproduced evaluation and dissemination. Members will be supported by a local Public and Community Involvement and Engagement Facilitator, as well as the wider evaluation team.

We anticipate at least three of these PCIE link members being part of local fora. Collectively these groups link to over 30 other groups including: third sector organisations such as the LGBT Foundation, the Independent Mental Health Network and BHA for equality in Health and Social care, Diabetes UK, and community groups and champions representing over 10 different ethnicity and faith-based organisations. This is in conjunction with wider PCIE links we have across NIHR Applied Research Collaborations, Biomedical Research Centres and Patient Safety Translational Research Centres as well as other collaborative links individuals across the team have.

We have co-developed with our PCIE collaborators a 4 stage model of rapid but sustained partnership working. This approach will be iteratively refined throughout our programme.

1. As soon as evaluation topics or uncertainties are allocated by the funder, our PCIE link members will consider, prioritise, and identify the initial regional and/or national PCIE stakeholders to engage with.
2. The team will work with the nominated PCIE link member or members to construct an iterative PCIE co-production plan that reflects the project needs. The plan will outline potential formats for engagement, such as workshops, individual discussion, or surveys, and consider stakeholder mix at sessions.
3. The team will develop introductory material with which to introduce the topic and work with PCIE link members to refine this as required. We will engage relevant PCIE stakeholders at organisational and individual levels, using a combination of established networks and bespoke orientation events.
4. The nominated PCIE link member and other team members will undertake activities planned integrating findings into the project development work. We will ensure ongoing evaluation of all our PCIE activities using multiple methods including informal discussions, structured feedback and Equality, Diversity and Inclusion and auditing.

We will design a training/development strategy for all PCIE representatives on our programme. Penny Bee is our designated PPI Lead. She will be responsible for all PCIE welfare, training and governance and will be supported by Co-applicant Sanders.

## **Dissemination, Outputs and Anticipated Impact**

Effective dissemination and knowledge mobilisation relies on timely access to good quality and relevant research evidence and, close collaboration and on-going relationships with



researchers. Our dissemination and knowledge mobilisation strategy will be based around these two core strategies.

Co-production is integral to rapid uptake of our evaluation findings. By agreeing the features (questions/uncertainties and design) of the evaluation with stakeholder representatives upfront and then co-producing the evaluations (agreeing who will do what), we maximise the likelihood that our findings will be acted upon. Such local, regional and national relationships between research and practice/policy partners plus timely access to good quality and relevant evidence are central to supporting rapid uptake.

We will ensure that selection of specific engagement activities and communication channels are guided by theoretically-informed research into dissemination and knowledge mobilisation, [38-42] whilst also taking account of the needs and preferences of our stakeholders. We can also build on the successful approach developed in our conduct of national evaluations (e.g. DIPLOMA and HEDLINE) that seeks to maximise the impact and use of findings as they emerge. Wherever possible, we will provide timely feedback loops to support policy and service decision making and to provide insights from the evaluation as they emerge.

Working with our stakeholders including our PCIE link members will allow us to create accessible content and summaries. This may include written or animated material: in one recent evaluation we worked with a third sector organisation to create a play based on our research findings (<https://www.youtube.com/watch?v=ZeXyN5n0JHI>). We have costed in time for patient and public contribution through-out, including dissemination.

Each evaluation will produce a lay summary, accessible to service users, which communicates the relevance of the research to patients and carers. It will be co-produced with our PCIE link members and other stakeholders. We are continually developing ways to share, negotiate and apply research, including capacity building and researching the process and will continue to develop this.

We will set up and maintain a website where all our outputs are made available including the lay summary. As a matter of principle, we will produce both a report and an academic peer-reviewed output and make reports available as soon as possible for use.

## **Resourcing and Project management**

Day to day management will be overseen by Paul Wilson and Jo Dumville who have worked successfully together on several projects and programmes. Paul and Jo will be responsible for recruitment, supervision, and direction of resources. Staff will be employed by The University of Manchester and their development supported.

Jo and Paul will co-lead the team, they will have responsibility for how it is operationalised and managed and strategic oversight for how the team functions and develops over time. Jo and Paul will be responsible for working with the team to ensure clear management, governance and reporting structures exist. They will develop a shared vision of how the team operates and nurture the existing strong team dynamics and collegiality to ensure a sense of ownership and identify.

The co-leads will have overall management accountability for the evaluation project portfolio, progress and risk management and troubleshooting across these. They will each lead at least one project per annum and will be responsible for directing external engagement with the funder and other relevant stakeholders. Between them Paul and Jo have one day a week

of funded time and anticipate having a further day between them for this work. Dumville and Wilson will lead on Project Management. Contracts will be managed via the team liaising with The University of Manchester contracts team – as is usual practice.

At any one time we would expect to have up to three live projects but this is likely to vary over time and this will be reflected in a *living Gantt chart* that will be shared with the funder as part of regular progress reports.

For each evaluation project, we will convene a bespoke project evaluation group, drawn from our core team. To support development and maximise use of specific methodological skills we would expect individual researchers to work on two projects at any one time. The core team will meet monthly with regular interim communication between members.

The team will work closely with a Stakeholder Advisory Panel, which will draw together representatives from key stakeholder groups. The group’s role will be oversight of activity as well as supporting the team with advice and guidance at strategic level.

## Project / research timetable

Our timetable schematic gives an outline of our plan of work, it assumes a minimum of 10 evaluations, but we can accommodate more depending on size and scope. We have also assumed a project duration of 12 months, acknowledging that some projects may be shorter and some longer. Our working model of a three-person researcher team with extensive input from Wilson and Dumville, and other co-applicant support, means we have suitable flexibility. Our networks and experience mean we can move rapidly to scoping, in terms of review work, setting up workshops or other fora and survey development as needed as these are all familiar to us.

## Success criteria and barriers to proposed work

A RAG-rated risk register will be developed for the five-year period and for each evaluation project. Overarching risks are detailed below but will be iterated at programme level. All individual evaluations will have separate risk registers generated. (Table 2).

**Table 2: Overview of methodology toolkit the REVAL will draw from across all evaluations.**

Risk	Measurement of success	Risks to proposed research	Mitigation of risk
<b>Knowledgeable and skilled workforce</b>	Appointment of a knowledgeable and skilled workforce to the team	Challenges appointing; periods of staff absence impacting on timelines	Based on the size and skill mix of the current workforce and recruitment experiences, we are confident that we can appoint, internally and externally as required. Where there are staff absences the size and interlinked nature of our team members and the groups they manage mean opportunities for temporary cross-project support work can be explored as required.
<b>Programme operational structure</b>	Development and operationalisation of clear governance structure as a key measure of early success. Including Stakeholder Advisory Panel. Alongside success viewed as adoption and	None anticipated	<b>NA</b>

	implementation of clear processes and overarching project management approaches that will support all work.		
<b>Project activity</b>	Timely conduct of two co-produced evaluations in the first year and a minimum of five evaluations in the first half of the programme as a measure of success.	Normal barriers to research including agreeing the parameters of the evaluation and obtaining relevant approvals. We are also aware of the pandemic and other external events putting additional pressure on staff and delivery and making evaluation more challenging in some cases.	Experience in gaining approvals, where required. Excellent track record working with HRA, good links with several R and D Departments in NHS Trusts as well as Clinical Research Networks.  Extensive experience of obtaining approval to access to routinely available data from multiple sources. Draw on processes and experience in running multiple projects simultaneously and troubleshooting when evaluations run into barriers or delays. Understanding the context of current pressures in relation to specific evaluations will be explored as part of the early evaluation scoping work, allowing subsequent planning to be as realised and responsive as possible.
<b>Dissemination</b>	Production of relevant, accessible, informative, and interesting dissemination material for all projects and measures of impact of these.	Area where time can be squeezed if projects are delayed	Dissemination plans drafted for projects at the start and revisited through-out the work
<b>Impact</b>	Project related impact that can be evidenced for evaluations over the lifetime of the project.	Challenges with capacity in supporting impact whilst maintaining other evaluation activities.	The size and networks of the existing team mean that on-going collaboration will be easier. Development of close working relationship will also support on-going involvement across project areas. Assessment of impact will be an on-going activity through the programme and we can draw on expertise in using routine data in this area where possible.

## Ethics

The need for ethics and approvals more widely will be considered on a project-by-project basis. Our experience with obtaining ethical approval, where required, via the HRA process, is that this is normally straight-forward, especially when the team is familiar with the process and its requirements. Where studies only require institutional approval from The University of Manchester there is a clear process for this with six panels to ensure rapid approvals. The University process also has a proportionate review process to further expedite ethics approvals: <https://www.manchester.ac.uk/research/environment/governance/ethics/approval/>. We have gained experience of achieving both HRA and university approvals quickly for rapid research using innovative and remote methods during the Covid-19 pandemic. Our extensive PPIE networks have also enabled support for rapid patient and public input into ethics applications.

Where we require ethics approval to access secondary data, we can draw in extensive experience and, as has been evidenced in the application, have been able to successfully conduct a number of rapid evaluations using data such as CPRD data, after following the required approval processes, which consider ethical and data disclosure issues.

## **Consideration of equality, diversity and inclusion for study participants in the work of the Rapid Service Evaluation Team**

We are committed to every evaluation we undertaken offering the same opportunity for participant to all eligible people. We will support this by using the NIHR INCLUDE Ethnicity Framework (and wider framework) for all project planning. We have recently worked with the team that developed this material to expand materials to support PCIE engagement and so will operationalise our own guidance in this area. Consideration of study design, target populations and recruitment will be developed with stakeholders. We will complete an Equality Impact Assessment for each project and as noted previously draw on other toolkits that are available.

## References

1. Greenhalgh T, Robert G, Macfarlane F, Bate P, Kyriakidou O. Diffusion of innovations in service organizations: systematic review and recommendations. *Milbank Quarterly* 2004;82:581-629. doi: 10.1111/j.0887-378X.2004.00325.x.
2. Storey J, Holti R. *Possibilities and pitfalls for clinical leadership in improving service quality, innovation and productivity*. Service Delivery and Organisation Programme National Institute for Health Research 2013.
3. Bullock A, Barnes E, Morris Z, Fairbank J, de Pury J, Howell R, et al. Getting the most out of knowledge and innovation transfer agents in health care: a qualitative study. *Health Serv Deliv Res* 2016;4. doi: 10.3310/hsdr04330
4. Kyratsis Y, Ahmad R, Hatzaras K, Iwami M, Holmes A. Making sense of evidence in management decisions: The role of research-based knowledge on innovation adoption and implementation in healthcare. *Health Serv Deliv Res* 2014;2. doi: 10.3310/hsdr02060
5. Rogers EM. *Diffusion of innovations*. 5th ed. New York (NY): Free Press; 2003.
6. Hawe P, Shiell A, Riley T. Theorising interventions as events in systems. *Am J Community Psychol* 2009;43:267-76. doi: 10.1007/s10464-009-9229-9.
7. Skivington K, Matthews L, Simpson SA, Craig P, Baird J, Blazeby JM, et al. Framework for the development and evaluation of complex interventions: gap analysis, workshop and consultation-informed update. *Health Technol Assess* 2021;25. doi: 10.3310/hta25570.
8. NIHR INVOLVE. Guidance on co-producing a research project. 2019. [https://www.invo.org.uk/wp-content/uploads/2019/04/Copro\\_Guidance\\_Feb19.pdf](https://www.invo.org.uk/wp-content/uploads/2019/04/Copro_Guidance_Feb19.pdf); Accessed 10<sup>th</sup> March 2022.
9. Williams O, Sarre S, Papoulias SC, Knowles S, Robert G, Beresford P, et al. Lost in the shadows: reflections on the dark side of co-production. *Health Research Policy and Systems*. 2020;18:43. doi: 10.1186/s12961-020-00558-0.
10. van der Veer SN, Riste L, Cheraghi-Sohi S, Phipps DL, Tully MP, Bozentko K, et al. Trading off accuracy and explainability in AI decision-making: findings from 2 citizens' juries. *J Am Med Inform Assoc*. 2021;28:2128-2138. doi: 10.1093/jamia/ocab127.
11. Knowles SE, Ercia A, Caskey F, Rees M, Farrington K, Van der Veer SN. Participatory co-design and normalisation process theory with staff and patients to implement digital ways of working into routine care: the example of electronic patient-reported outcomes in UK renal services. *BMC Health Serv Res*. 2021;21:706. doi: 10.1186/s12913-021-06702-y.
12. Grady K, Gibson M, Bower P. Can a 'consent to contact' community help research teams overcome barriers to recruitment? The development and impact of the 'Research for the Future' community. *BMC Med Res Methodol* 2019;19. doi.org/10.1186/s12874-019-0843-4
13. Kilbourne AM, Switzer G, Hyman K, Crowley-Matoka M, Fine MJ. Advancing Health Disparities Research Within the Health Care System: A Conceptual Framework. *Am J Public Health* 2006, 96:2113-2121. doi: 10.2105/AJPH.2005.077628
14. Hoffmann TC, Glasziou PP, Boutron I, Milne R, Perera R, Moher D et al. Better reporting of interventions: template for intervention description and replication (TIDieR) checklist and guide. *BMJ*. 2014;348:g1687. doi: 10.1136/bmj.g1687
15. Cotterill, S., Knowles, S., Martindale, AM. et al. Getting messier with TIDieR: embracing context and complexity in intervention reporting. *BMC Med Res Methodol* 2018;18. doi: [10.1186/s12874-017-0461-y](https://doi.org/10.1186/s12874-017-0461-y)
16. Gray TA, Dumville JC, Christie J, Cullum NA. Rapid research and implementation priority setting for wound care uncertainties. *PLoS One*. 2017;12:e0188958. doi: 10.1371/journal.pone.0188958.
17. McManus E, Elliott J, Meacock R, Wilson P, Gellatly J, Sutton M. The effects of structure, process and outcome incentives on primary care referrals to a national

- prevention programme. *Health Economics* 2021; 30:1393–1416. doi: 10.1002/hec.4262
18. Kislov R, Pope C, Martin GP, Wilson PM. Harnessing the power of theorising in implementation science. *Implement Sci.* 2019;14:103. doi: 10.1186/s13012-019-0957-4
  19. Gillies C, Freemantle N, Grieve R, Sekhon J, Forder J. Advancing quantitative methods for the evaluation of complex interventions. In: Raine R, Fitzpatrick R, Barratt H, Bevan G, Black N, Boaden R, et al., editors. *Challenges, solutions and future directions in the evaluation of service innovations in health care and public health.* 2016;4(16). pp. 37–54. London: NIHR; 2016.
  20. Hawe P, Shiell A, Riley T. Complex interventions: how 'out of control' can a randomised controlled trial be? *BMJ* 2004;328:1561-3. doi: 10.1136/bmj.328.7455.1561
  21. Kontopantelis E, Doran T, Springate DA, Buchan I, Reeves D. Regression based quasi-experimental approach when randomisation is not an option: interrupted time series analysis. *BMJ.* 2015;350:h2750. doi: 10.1136/bmj.h2750
  22. Whittaker W, Anselmi L, Kristensen SR, Lau Y-S, Bailey S, Bower P, et al. Associations between extending access to primary care and emergency department visits: a difference-in-differences analysis. *PLoS Med.* 2016;13:e1002113. doi: 10.1371/journal.pmed.1002113.
  23. O'Neill S, Kreif N, Grieve R, Sutton M, Sekhon JS. Estimating causal effects: considering three alternatives to difference-in-differences estimation. *Health Services and Outcomes Research Methodology* 2016;16:1-21 doi:[10.1007/s10742-016-0146-8](https://doi.org/10.1007/s10742-016-0146-8)
  24. Ryan AM, Krinsky S, Kontopantelis E, Doran T. Long-term evidence for the effect of pay-for-performance in primary care on mortality in the UK: a population study. *The Lancet* 2016; 10.doi 10.1016/s0140-6736(16)00276-2
  25. Kontopantelis E, Springate D, Reeves D, Ashcroft DM, Valderas JM, Doran T. Withdrawing performance indicators: retrospective analysis of general practice performance under UK Quality and Outcomes Framework. *BMJ.* 2014;348:g330. doi: 10.1136/bmj.g330.
  26. Kontopantelis E, Reeves D, Valderas JM, Campbell S, Doran T. Recorded quality of primary care for patients with diabetes in England before and after the introduction of a financial incentive scheme: a longitudinal observational study. *Bmj Quality & Safety* 2013;22:53-64. doi [10.1136/bmjqs-2012-001033](https://doi.org/10.1136/bmjqs-2012-001033)
  27. Meacock R, Anselmi L, Kristensen SR, Doran T, Sutton M. Higher mortality rates amongst emergency patients admitted to hospital at weekends reflect a lower probability of admission. *J Health Serv Res Policy.* 2017;22:12-19. doi: 10.1177/1355819616649630.
  28. Kristensen SR, Meacock R, Turner AJ, Boaden R, McDonald R, Roland M, et al. Long-term effect of hospital pay for performance on mortality in England. *New England Journal of Medicine* 2014;371:540-8. doi [10.1056/NEJMoa1400962](https://doi.org/10.1056/NEJMoa1400962)
  29. Kristensen SR, McDonald R, Sutton M. Should pay-for-performance schemes be locally designed? evidence from the commissioning for quality and innovation (CQUIN) framework. *J Health Serv Res Policy.* 2013;18:38-49. doi [10.1177/1355819613490148](https://doi.org/10.1177/1355819613490148)
  30. Campbell SM, Kontopantelis E, Reeves D, Valderas JM, Gaehl E, Small N et al. Changes in patient experiences of primary care during health service reforms in England between 2003 and 2007. *Ann Fam Med.* 2010;8:499-506. doi: 10.1370/afm.1145..
  31. Howarth E, Devers K, Moore G, O'Cathain A, Dixon-Woods M. Contextual issues and qualitative research. In: Raine R, Fitzpatrick R, Barratt H, Bevan G, Black N, Boaden R, et al., editors. *Challenges, solutions and future directions in the evaluation of service innovations in health care and public health.* 2016;4(16). pp. 105-20. London: NIHR; 2016.

32. Palinkas LA. Qualitative and mixed methods in mental health services and implementation research. *J Clin Child Adolesc Psychol*. 2014;43:851-61. doi: 10.1080/15374416.2014.910791.
33. Pope C, van Royen P, Baker R. Qualitative methods in research on healthcare quality. *Qual Saf Health Care*. 2002;11:148-52. doi: 10.1136/qhc.11.2.148.
34. May CR, Albers B, Bracher M, Finch TL, Gilbert A, Girling M et al. Translational framework for implementation evaluation and research: a normalisation process theory coding manual for qualitative research and instrument development. *Implement Sci*. 2022;17:19. doi: 10.1186/s13012-022-01191-x.
35. Moore GF, Audrey S, Barker M, Bond L, Bonell C, Hardeman W, et al. Process evaluation of complex interventions: Medical Research Council guidance; *BMJ*. 2015;350:h1258. doi: 10.1136/bmj.h1258.
36. Creswell JW, Plano Clark VL. *Designing and Conducting Mixed Methods Research*. Second Edition. Sage Publications. 2011.
37. Johnson RE, Grove AL, Clarke A. Pillar Integration Process: A Joint Display Technique to Integrate Data in Mixed Methods Research. *Journal of Mixed Methods Research*. 2019;13(3):301-320. doi:10.1177/1558689817743108
38. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. *The Lancet* 2014;383:267-76. doi: [10.1016/S0140-6736\(13\)62228-X](https://doi.org/10.1016/S0140-6736(13)62228-X)
39. Goodman SN, Fanelli D, Ioannidis JP. What does research reproducibility mean? *Sci Transl Med*. 2016;8:341ps12. doi: 10.1126/scitranslmed.aaf5027.
40. Wilson PM, Petticrew M, Calnan MW, Nazareth I. Disseminating research findings: what should researchers do? A systematic scoping review of conceptual frameworks. *Implement Sci*. 2010;5:91. doi: 10.1186/1748-5908-5-91.
41. Kislov R, Waterman H, Harvey G, Boaden R. Rethinking capacity building for knowledge mobilisation: developing multilevel capabilities in healthcare organisations. *Implementation Science* 2014;9:166. doi: 10.1186/s13012-014-0166-0
42. Davies HTO, Powell AE, Nutley SM. Mobilising knowledge to improve UK health care: learning from other countries and other sectors – a multimethod mapping study. Southampton (UK): NIHR Journals Library; 2015 Jun.