Birmingham, RAND and Cambridge Evaluation (BRACE) Centre

Programme Protocol, November 2018

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Plain language summary

Across the NHS, there is much interest in changing what services are provided and, in particular, where they are delivered and the way in which they are organised, in order to improve people's experiences of care and their overall health, and ensure that funding is used as efficiently as possible. Local efforts to change services are widespread, and there is a pressing need to understand if these are working or not and assess whether new services that are effective in one area of the country could work elsewhere. We need to assess whether these new services work (or don't work) as soon as we can, we cannot wait until they are well established to find out if they are effective. We also need to share learning quickly to help improve patient care and outcomes across the health system.

The National Institute of Health Research's Health Services and Delivery Programme is funding a team for five years to carry out rapid evaluations of promising new services. Our team is led by the Health Services Management Centre at the University of Birmingham, in partnership with the independent research institute RAND Europe and the Health Services Research Group at the University of Cambridge. It also includes Richard Kirby (Chief Executive of Birmingham Community Healthcare NHS Foundation Trust and the Black Country Partnership NHS Foundation Trust); Jeremy Taylor (Chief Executive of National Voices); and Katherine Cowan (an expert in developing priorities for research and involving patients and the public in this process).

The team's activities will include: 1) finding and selecting promising services to be studied; 2) designing projects asking: how were these services put into practice; did they achieve their goals; and could they be introduced across the NHS; and 3) sharing our findings in a way that will both interest and inform people, providing the kind of information that frontline NHS and social care staff and managers need to help them change and improve services. We will use a theory-based approach to service evaluation – that is to say we will go beyond a simple assessment of whether something works to look at the reasons for its success or failure: if a service works, how does it work; if it doesn't work, why doesn't it work? To answer these questions, we will bring together evidence from different perspectives, sources and research methods, and we will share what we are learning as our work progresses as well as producing clear and concise summaries of our findings at the end of each project.

We want our evaluations to focus on the things that matter most to people working in and receiving care from the NHS. Throughout our work, we will listen to and involve people who plan, deliver and use health services. We will do this particularly by establishing a Health and Care Panel, which we will consult at all stages of our projects: from decisions about what to evaluate, through to plans for sharing our findings. Patients and the public will also be involved in managing the centre and its work; in the Health and Care Panel; and in delivery of individual evaluation projects. They will be real partners across all the team's activities, and people will receive training, support and payment to ensure that their involvement is meaningful and valued. We have lots of partners and contacts, and will use these when we need extra advice or expertise to support project design and delivery.

1. Background

At a time of unprecedented financial constraint for health and care [Lafond 2017], and policy interest in 'transformation' of service delivery, it is inevitable that local organisations will develop plans to pilot and implement new approaches to care. The evidence base for such innovations may be emerging, partial, contested, or plain unknown, and will often be advocated by its planners as having significant potential to impact on indicators such as levels of emergency or avoidable admissions to hospital, and reductions in health care utilisation [Bardsley, Steventon and Smith et al 2013]. Indeed, a service innovation can appear to gain significant traction when lacking a robust (or only having an emerging and tentative) research evidence base, yet being vaunted as 'what is needed' to improve the NHS, as has arguably been the case with 7-day working in the NHS [Aldridge, Bion and Boyle et al 2016], the use of telecare for people living with complex multi-morbidity [Steventon, Bardsley and Billings et al 2012], and telephone access to general practice services [Campbell, Fletcher and Britten et al 2014]. Such developments are not only questionable from a research standpoint, they also risk significant waste of public money, and the diversion of management and practitioner time and attention away from more effective and evidence-based activities.

Clearly, initiatives should not be assumed automatically to work [Dixon-Woods and Martin 2016], and maximum learning about what works, why, and in what contexts should be obtained from pilot work before moving to scale [Lamont et al 2016, McGlynn and McClellan 2017]. Innovations and developments in health and care services therefore need rigorous, timely and useful evaluation research to be undertaken, so that the risks of such initiatives being assumed 'to work' or rolled out in the face of contradictory evidence can be mitigated [Lamont et al 2016, McGlynn and McClellan 2017]. Investing in evaluation capacity and expertise, as HS&DR is doing, will much better position the NHS to horizon scan, select and undertake rapid evaluative studies of emerging service innovations, and to provide high quality evidence about their performance and potential, including when service development should not be pursued.

The BRACE Rapid Evaluation Centre is a collaboration between the Health Services Management Centre at the University of Birmingham, the independent research consultancy RAND Europe, and the Department of Public Health and Primary Care at the University of Cambridge. BRACE will carry out rapid evaluations of promising innovations in the organisation and delivery and heath and care services. Its work will be guided by three overarching principles:

- 1) **Responsiveness.** We will be to be ready to scope, design, undertake and disseminate evaluation research in a manner that is timely and appropriately rapid, pushing at the boundaries of typical research timescales and approaches, and enabling innovation in evaluative practice.
- 2) Relevance. We will work closely with patients, managers, clinicians and health care professionals, and others from health and care in the identification, prioritisation, design, delivery and dissemination of evaluation research, doing this in a truly co-produced and iterative manner.
- 3) Rigour. We will ensure that all evaluation undertaken by the team is theoretically and methodologically sound, producing highly credible and timely evidence to support planning, action and practice.

2. A theory-based approach to service evaluation

We will employ a theory-based approach to evaluation which opens up the 'black box' of service transformation to identify what *activities and actions* are being undertaken, whether these take place successfully, and *how and why* these activities and actions lead to the outcomes – intended and unintended – of the changes being evaluated. The critical feature of a theory-based approach is that it seeks not only to evaluate whether something has worked or not, but also to explain the underlying mechanisms: if it worked, *how*; if it didn't, *why*. In examining complex, multi-component change programmes evaluators must go 'underneath' the overall programme level to explore what works in relation to constituent interventions or workstreams (which may vary significantly in the nature and extent of their impacts).

An important, early step in each evaluation will be to build a theory of change, described by Davidoff, Dixon-Woods and Leviton et al [2016] as *"the rationale and assumptions about mechanisms that link a*

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programme's processes and inputs to outcomes – both intended and unintended, as well as specifying the conditions (or context) necessary for effectiveness." Our approach will draw on a long tradition of theory-oriented evaluation, including Carol Weiss's list of core questions and tasks for evaluation (Box 1). Weiss's work [2007] points towards the two major reasons why programmes can fail: implementation does not occur or is inadequate (implementation failure), or from faulty logic about how particular effects and impacts will be brought about (theory failure). We will be attentive to both of these possibilities in designing and conducting our evaluations. Another key feature of theory-based evaluation is that it draws attention to the role of contextual influences on how programmes work, the outcomes they achieve and the likelihood that positive changes and their impacts are sustained over time. On this issue, Dixon-Woods' work has been highly influential in calling for 'contextually-sensitive evaluations' which capture the dynamic interaction between programmes and their contexts [e.g. Dixon-Woods 2014] and this will be central to our approach

Box 1. Weiss's logic of analysis in evaluation

- What went on in the programme over time? Describing
- How closely did the programme follow its original plan? Comparing
- Did recipients improve? Comparing
- Did recipients do better than non-recipients? Comparing
- Is observed change due to the programme? *Ruling out rival explanations*
- What was the worth of the relative improvement of recipients? Cost-benefit or cost-effectiveness analysis
- What characteristics are associated with success? Disaggregating
- What combinations of actors, services and conditions are associated with success and failure? Profiling
- Through what processes did change take place over time? Modelling
- What unexpected events and outcomes were observed? Locating unanticipated effects
- What are the limits to the findings? To what populations, places and conditions do conclusions not necessarily apply? *Examining deviant cases*
- What are the implications of these findings? What do they mean in practical terms? Interpreting
- What recommendations do the findings imply for modifications in programme and policy? Fashioning recommendations
- What new policies and programmatic efforts to solve social problems do the findings support? Policy analysis

Source: Portela, Provonost, Woodcock, Carter and Dixon-Woods 2015

A final key consideration is that our approach needs to be rapid. Projects are likely to be undertaken in timescales which are considerably shorter than the 3-5 years that are typical for large-scale programme evaluations. Box 2 outlines the four key features of our *rapid* approach.

Box 2. What is rapid about our approach?

Getting under way quickly: theory-based evaluations require careful preliminary work to develop the theory of change, and stakeholders should be engaged in this process. But these important early tasks also need to be undertaken quickly. This requires project leadership, staff capacity and other resources to be in place at the outset, and calls for an approach where key tasks are often undertaken in parallel rather than sequentially. It means having a strong focus on securing local engagement, building relationships to enable progress to be made quickly but collaboratively. Clear and agreed arrangements for signing off new projects (including budgets)

and timescales) will be essential to enable the team to move rapidly from prioritising innovations to be evaluated to scoping, designing and getting under way with the work.

- Being strong on rigour, while flexible in terms of scope and focus: rapid evaluations should be carried out to the same high standards of scientific rigour as longer-term projects, and our commitment to this through a theory-based approach is paramount. Where flexibility is possible is for the scope of evaluation. The time and resources available may necessitate a tighter focus, for example to specific work streams within large-scale programmes or the selection of a set of core indicators to assess impact.
- Formative feedback alongside formal dissemination: a key goal for HS&DR, and for the BRACE team, is that the evaluations produce *timely* evidence to support real-time learning, decision-making and improvement – both for programmes evaluated and across the wider NHS and social care. We will use multiple vehicles for dissemination, maximising opportunities for formative feedback (including nationally through our diverse networks and activities) alongside more formal methods of dissemination.
- Leaving a legacy for ongoing evaluation: many of the major goals for service redesign programmes within the NHS and social care will only be realised over a period of years. This presents a challenge for shorter term evaluations, and risks negative judgements being made at too early a stage about innovations that may yet be found to be effective. Where appropriate, and in discussion with local teams, our approach will include developing a plan for longer term outcomes and sustainability evaluation, checking with programme teams periodically about data collected locally on a longer term basis and what these are showing.

3. Overarching principles for the BRACE team

3.1 Responsiveness: co-production and flexibility

Central to the BRACE team approach will be its understanding of and closeness to the health and care sectors, and the issues and concerns towards which new service innovations are directed. Our team will have co-production and multiple-stakeholder engagement as core principles underpinning how we work, with our Health and Care Panel forming a central element of this (see section 5.1), along with our approach to patient and public involvement (PPI) (see section 5.2). This co-production will create a shared understanding of how individual evaluations will be undertaken and help secure the associated buy-in and engagement required for the effective implementation of evaluation findings. This will help identify risks and establish risk management strategies in a timely manner, and facilitate a pragmatic evaluation protocol for each project which maximises relevance while minimising time demands on participants.

We are well aware of the challenges of evaluating service innovation and improvement, and these are increasingly acknowledged in the literature [Brewster, Aveling and Martin et al 2015]. Building trust, establishing open dialogue, and having clarity about roles and responsibilities are essential for managing the tensions that can arise, and we will work to create the conditions for successful evaluation during the inception phase of each project.

3.2 Relevance: identification and prioritisation of innovations to evaluate

The BRACE team will adopt a consultative approach to identifying candidate innovations for possible evaluation as part of the overall portfolio of work. We suggest that initial prioritisation work is undertaken at the very start of the contract, and then regularly revisited to ensure service innovations evaluated by BRACE remain aligned with evolving policy and service priorities and emergent needs and opportunities. Sign-off of priorities for service evaluation, and of the team's work plans, would be undertaken in collaboration with the HS&DR Secretariat. The work of our team will involve substantial input in its early stages from Katherine Cowan, bringing James Lind Alliance (JLA) priority setting partnership principles to bear on the processes we use to prioritise service innovations for potential evaluation.

The focus of prioritisation activities will predominantly be on identifying specific interventions to evaluate within acknowledged national and regional priority areas (as documented in policy documents, institutional websites and strategic plans). Our approach to prioritisation will be robust and defensible, and will be undertaken in two stages. The main goals for the first stage of the process are as follows:

- Identifying promising candidate innovations: this will be achieved through both desk-based research and direct consultation with key groups. Desk-based research will include reviewing key publications and the websites of organisations directly involved in and linked to service innovation and improvement within the NHS. This research will be supplemented by consultation with our Health and Care Panel, steering group and wider networks, including HS&DR and The Healthcare Improvement Studies (THIS) Institute. Other key organisations that we would expect to contact at this stage would include: academic health science networks (AHSNs), collaborations for leadership in applied health research and care (CLAHRCs), Department of Health and Social Care, innovation and improvement networks, sustainability and transformation partnerships (STPs), the Department of Health Policy Research Programme (PRP), NHS England, NHS Improvement, medical royal colleges, national bodies representing commissioners (NAPC, NHS Clinical Commissioners, NHS Confederation) and the wider NIHR.
- Developing a multi-criteria decision tool to carry out initial screening of each candidate innovation: an initial screen of candidate innovations identified through the activities described above will be undertaken to produce a long-list of promising topics and initiatives for further consideration. A key consideration in our prioritisation process will be ensuring alignment with national and regional policy developments both in terms of responding to existing policy priorities and shaping future ones. To this end, the desk-based research we describe above will also include reviews of documentation such as Delivering the Five Year Forward View [NHS England 2015], STP plans, and others such as the General Practice Forward View [NHS England 2016], Carter Review of Efficiency [Carter, 2016] and Getting it Right First Time [Briggs 2012] to assess key themes and implied service development priorities within them. The tool will be developed in consultation with HS&DR and the BRACE steering group.

Once we have a screened list of candidate innovations, the second stage of our process will be to prioritise and select amongst these. This will be achieved through a prioritisation workshop with the members of our Health and Care Panel, based on the principles and approach of the James Lind Alliance Priority Setting Partnerships. Participants will be guided through a structured process, involving several rounds of facilitated discussion and prioritisation, which culminates in a ranked list of innovations. The workshop will also be an opportunity to begin the development of key evaluation questions and identify the major, cross-cutting themes across innovations which would inform evaluation design and data analysis.

3.3 Rigour: undertaking high quality evaluation research

A typical evaluation project emerging from the prioritisation process will include: an inception phase; implementation phase; and analysis, synthesis and reporting phase, whilst recognising that reporting may occur in a flexible manner across the project lifecycle. Each project will be rigorous, subject to internal peer review and scrutiny of methodological approach and progress by our 'critical friend' senior academic advisers and steering group.

As part of our commitment to effective use of resources, we will also consider conducting a rapid evaluability assessment (EA) for projects. We envisage this will be particularly useful for very emergent or novel innovations where there is likely to be doubt about the value of conducting an evaluation at such an early stage.

Inception phase

During the inception phase of each evaluation project we will consult with the HS&DR secretariat, our steering group, Health and Care Panel members as appropriate to the topic of the evaluation, and representatives of organisations delivering the intervention being evaluated. Where possible and appropriate, we will – consistent with our co-production principles – hold a scoping workshop with stakeholders to engage them in the design and planning of the project, understand their aims for the service innovation and its evaluation, identify the measures needed to track progress, and select the

most appropriate forms of reporting and dissemination. This will also provide information for an evaluability assessment, should one be carried out.

For each project, we will bring together a bespoke evaluation team, tailored to the project's topic and methodology. This may include drawing in specialist (e.g. content, methodological, PPI) expertise from within our organisations or wider networks, to support project design and/or delivery. We will establish a core project-level advisory group for each specific evaluation, drawn from our steering group, Health and Care Panel, PPI capacity and core evaluation team, and complement this with additional subject-specific expertise as necessary. This would help ensure that each evaluation receives targeted and bespoke input from advisors.

The development of the evaluation protocol and framework for each project will involve specifying research questions and priorities, understanding the intervention logic, the wider context within which it operates, elucidating assumptions about the pathways by which impact is intended to be achieved, considering the management of risks, and (based on this) developing appropriate evaluation indicators, considering also baseline assessment and counterfactual issues. In multi-site evaluations, frameworks may combine core indicators (common to all interventions) and localised indicators (specific to each intervention) – this will provide a common dataset for the purpose of comparison, but ensure that each evaluation plan is tailored to the innovation, goals and needs of the local context, which is vital for local buy-in. Alongside this, we will develop a preliminary dissemination and reporting plan, in consultation with HS&DR and the local organisations involved in the services or programme(s) being evaluated, and drawing in any specialist expertise (e.g. from our patient voice and health management co-applicants, steering group or Panel) where necessary.

Ways of maximising participation by local stakeholders in each evaluation project will also be considered during the inception meetings and in scoping workshop. This will include: how the evaluation team for the project will work with the local site(s); practical arrangements for fieldwork interviews, survey distribution, and collection of routine data; how time demands on participants can be minimised; how to plan meetings to be feasible and acceptable to sites; and what form of local feedback is expected and will aid engagement. It will also include plans for PPI, including details about how patients and the public will be actively involved and arrangements for recruitment, training and payment.

Implementation phase

The core methods for evaluation will allow us to assess progress with implementation of service innovation/redesign activities and realisation of milestones; outputs and impacts; to identify enablers and barriers (internal and external); and examine potential for sustainability, scalability and replicability. The precise nature and mix of methods would be determined on a case by case basis, depending on the evaluation questions and scope, as well as the intended scale of the evaluation. Relevant methods, all of which the evaluation team is highly experienced in, are likely to be drawn from the ones listed below:

- Literature reviews: realist, narrative and rapid evidence synthesis reviews to inform evaluation design and provide contextualising and comparative data for data analysis;
- Qualitative methods: essential for process evaluations and developing theories of change, as well
 as exploring perceptions of programme success and impact. Can include a range of data collection
 methods including interviews, focus groups, ethnographic observation and documentary analysis;
- Surveys: to achieve breadth and engage a wider set of individuals than could be achieved through interviews;
- Participatory approaches: to ensure definitions of programme success are shaped by service users and carers, deepen insights captured from the user perspective, and increase reach to seldom heard groups;
- Case studies: sampling and selection of specific data collection techniques would be dependent on evaluation questions and design;
- Baseline and counterfactual analysis: there are multiple possibilities for designing effectiveness studies, all of which have strengths and limitations [e.g. Portela, Pronovost and Woodcock et al 2015]. Quantitative designs might include controlled studies, before-and-after studies (controlled

and uncontrolled), and time series studies. We would also draw on qualitative insights, which are particular valuable for constructing counterfactuals and exploring causal chains and mechanisms;

- Health economic analysis: encompasses cost analysis, budget impact analysis and economic evaluation. Examples of cost analyses include econometric analysis of large datasets such as hospital episode statistics (HES) and the clinical practice research datalink to estimate associations between exposures and cost.
- Indicator dashboards collecting measurements on key areas supporting the evaluation framework: especially quantitative but also qualitative, to be complemented by interviews, surveys and case studies;
- Multi-criteria decision-making: some situations present multiple problem sets and scales against which performance is evaluated. Multi-criteria decision analysis is a comprehensive, structured process for selecting the optimal alternative in any given situation, drawing from stakeholder preferences and value judgments as well as scientific modelling and risk analysis;
- Delphi techniques: build consensus through iterative questionnaires completed by a panel of experts and are effective in establishing consensus, especially in complex topic areas [de Meyrick, 2003].
- Scenario planning: to help inform future actions given conditions of uncertainty;
- Reflection and learning workshops: to share learning and insights gained and consider implications for adaptiveness and future action and policy, as well as unmet research needs;
- Network analysis: network analysis explores the links between individuals or other actors (websites, organisations, groups) and the information flow between them, numerically and graphically. It enables researchers to illustrate the functioning of complex systems and identify problems with the flow or existence of a network [Hanneman and Riddle 2005].

In order to ensure feasible and effectively managed delivery, each evaluation project will have a designated contact point at an evaluation site who will help coordinate local engagement and work with the evaluation team, helping to ensure that the relevance and quality of evaluation evidence are maximised, but burden minimised, and facilitating participation and buy in. Progress with the evaluation and feedback will be ensured through regular (e.g. monthly or quarterly) meetings or calls with the site core contact point/s, the project advisory group and HS&DR. This will ensure timely planning, support learning and adaptiveness and enable any emerging risks and challenges to be effectively and swiftly managed.

At regular intervals – e.g. mid and end points in each evaluation depending on duration – we would hold **formative feedback and learning sessions**. These would be summative in ensuring a forum for shared learning and reflection on the evaluation evidence gained (e.g. between teams or services within sites, or across different sites) but also formative in terms of informing future action and facilitating scalability, sustainability, the harnessing of identified opportunities and addressing barriers and challenges.

Data analysis, synthesis and reporting

Findings will be analysed with a particular focus on i) assessing whether innovations work, ii) how they have worked fully or in part or why they have failed (including the influence of contextual factors), and iii) the wider lessons (for local programme teams as well as the wider health and care system) about how innovations might be further developed and improved, as well as their potential for replicability, sustainability and scaling up. For the latter of these, we would expect to draw on mid-range theories – such as diffusion of innovation [eg. Greenhalgh, Robert and Macfarlane et al 2004] and normalisation process theory [May and Finch 2009] – to examine the likelihood that effective innovations span the 'translation gap' between initial adoption to long-term acceptance.

Analysis will be conducted at three main levels:

 Examining what works, and how, at project level: for each evaluation, analysis will start with the data gathered at project level. We will adopt a team-based approach to analysis, fostering integration and triangulation between different study components (ensuring our commitment to mixed-methods runs through data collection and analysis) and exploring potential areas of accordance and disagreement between findings from different methods – so-called inter-method discrepancy – which may lead to a better understanding of the evaluation question [O'Cathain, Murphy and Nicholl 2010].

- 2. **Developing cross-cutting themes:** findings will also be brought together in cross-cutting themes, both within and across projects in BRACE's portfolio. Key themes for exploration will be both predefined (for example, following consultation with our Health and Care Panel) and emergent from the data, ensuring we capture both recognised and novel aspects of service innovation and its impact. We envisage that these themes will include wider health system issues such as workforce development, patient experience, payment systems/commissioning new models of care, use of IT, partnership working across services and sectors, and change management approaches.
- 3. **Comparison and synthesis with the wider evidence base:** this will be undertaken in two key ways. First, we will undertake rapid and targeted reviews of the wider evidence base and literature to contextualise findings and deepen the understanding of key themes and programme outcomes. Second, we will work with our colleagues within the health services research and evaluation community to compare and explore the evidence and learning emerging from 'live' evaluations (where published evidence may be limited). Our links with THIS will be of particular value here, enabling findings to be drawn together, compared and interrogated across multiple programmes of innovation and improvement activities across the NHS and care systems, and internationally.

Analysis will be oriented towards the twin goals of project and system learning. In terms of system learning, our patient voice and health management co-applicants (Jeremy Taylor and Richard Kirby), steering group and Panel members will also play a key role in commenting on and contributing to emerging findings, and working with the team to draw out national learning to support practice and service change across the NHS.

4. Dissemination and outputs

All our dissemination activities will be designed with the goal of influencing, informing and supporting NHS practice through evidence that is i) timely; ii) crafted and presented with the end user in mind; and iii) authoritative yet also practical. To this end, our approach to dissemination and impact will be:

- 1. **Designed in consultation with evidence users** so that they meet real needs, and are engaging and appealing. Across the research process, we will consult with our Health and Care Panel about how to maximise the purpose, value and impact of our projects, drawing in specialist expertise where necessary. While recognising and working with capacity constraints at the local level, we will seek to undertake dissemination activities in collaboration with staff and patients from where evaluations are taking place, which we know from experience can enhance both reach and effectiveness.
- 2. Broad-based and tailored to different audiences, recognising that the evidence needed to guide and support ongoing programme delivery at a local level may be different from what is sought by other key audiences. We know from experience that simply sharing evidence (however engagingly it is presented) does not necessarily trigger and support changes in practice. NHS staff benefit from discussing and exploring evidence and thinking through its implications for their services. Opportunities to facilitate the 'evidence into practice' process (eg. workshops, learning events, webinars) will be a core feature of our approach, and we will build on the expertise and previous experience of the team in this area.
- 3. **Carefully planned but also flexible,** allowing us to take advantage of unanticipated or new opportunities. A critical early task for the team will be to develop an impact and dissemination strategy for the centre, which will be annually reviewed and refreshed to take account of the learning from activities undertaken and changes in the wider health and care policy and organisational context. We will also be responsive in our approach, ensuring that key staff have sufficient time to participate in impact activities as part of our ongoing workforce planning.
- 4. Assessed using a range of formal and informal measures, so that we can confidently tell whether the Centre and its projects are having the desired impact. Key metrics for assessing the reach of dissemination activities might include hits on the BRACE website, downloads of electronic

materials, citations of academic papers, presentations given (number and audiences reached) and social media links.

The main dissemination channels for our work are likely to include:

- Formal final reports published in the NIHR Journals Library.
- Papers published in high quality, peer-reviewed, academic journals.
- An 'emerging findings' series, where we will publish slide sets of interim findings, with suitable disclaimers and caveats, prior to final reporting and with a process of rapid (e.g. 2-week) peer review. These slide sets could be made available through the BRACE website, and would be revised and updated as necessary once the project was completed, and/or subsequent insights from ongoing work were gained;
- Concise summaries of findings, highlighting information relevant for decision makers, provided at the conclusion of each evaluation, targeted at appropriate audiences. Such a summary would likely include: i) syntheses across the portfolio of work, drawing together evidence on key outcomes and cross-cutting themes; and ii) short practical guides focusing on key implementation topics, summarising the learning from specific projects about the 'nuts and bolts' of how to plan, make and sustain service transformation;
- Slide sets with creative commons licences that can be used in training and briefing (building on the emerging findings slide sets). These are especially useful, for example, in stimulating discussions at board and directorate level in healthcare organisations and for resourcing local training and activities;
- The three core collaborating organisations in the Centre will actively promote the findings of each project through web distribution (including via the BRACE website), and a press release, a onepage policy brief/blog and a social media campaign if appropriate (Twitter, Facebook, ResearchGate), as well as widespread distribution of the finished reports as appropriate;
- Raising awareness of the work of the team and publicising outputs through our extensive networks and activities, including in the many national and regional leadership development and MSc/Diploma programmes that HSMC delivers for NHS and social care staff and via its online bulletins;
- We propose to capitalise on existing NHS channels such as providing content for *The CCG Bulletin* distributed by NHS England: <u>https://www.england.nhs.uk/email-bulletins/ccg-bulletin/#</u> As a matter of principle, we will aim to work within rather than duplicate existing channels of communication;
- The members of our combined team, especially the PI and co-applicants, collectively have numerous opportunities every year to speak at conferences and participate in roundtables, webinars and the like, where it would be appropriate to present the findings of the evaluations to NHS, social care and international audiences;
- PPI members and our Health and Care Panel will be asked to assist in the production of summaries for non-technical audiences. We will also work through National Voices' extensive networks within the patient charity and voluntary sector in this dissemination. Patients, managers and clinicians involved in individual projects will be encouraged and supported to disseminate through their own networks and activities.

Across all of the above, we would seek to combine more traditional (e.g. written) reporting formats with interactive media and visual content such as infographics.

5. Stakeholder engagement

5.1 Health and Care Panel

The call specification emphasises the importance of producing findings which are useful, timely and relevant, and are therefore more likely to be used to develop and improve health services. The key to

achieving this is to involve evidence users in shaping and designing studies, so that the choice of innovations, development of evaluation questions, selection of research methods and design of dissemination strategies yield information that evidence users need and in a way that they can utilise.

We will establish a **Health and Care Panel** to act as the main source of advice from the health and care sector, and be a sounding board in relation to the choice, design, delivery and dissemination of our evaluation work for HS&DR. The Panel will have around 50 members, which will include representation from system and organisational leaders; middle and operational clinical and general managers; frontline clinicians and other practitioner groups – including hospital and primary care doctors, nurses, allied health professionals and pharmacists; patients and the public; voluntary sector organisations; and health service researchers. We will also recruit to ensure diversity in terms of demographic characteristics such as age, gender and ethnicity.

The Panel's role will include:

- identifying and prioritising innovations to be evaluated: see section 3.2 for more details of our approach to prioritisation;
- shaping research design: for example, supporting the development of evaluation questions; advising on data sources; identifying sensitivities or issues that may affect the conduct of evaluations and supporting the team to develop solutions to these;
- commenting on and contributing to emerging findings: including the learning from evaluation projects – both individual studies and across the portfolio of work as a whole – for the wider health and care system;
- advising on effective strategies for dissemination: including tailoring of messages to different audiences;
- providing subject matter, methodological and other forms of specialist expertise: where we
 need to consult more extensively, or seek input from specific groups and/or on highly specialist
 topics, we will also draw in expertise from our wider networks described above.

Communication with the Panel will be mostly online, to offer convenience to members and enable us to access advice and expertise rapidly. The mode of engagement will be determined by the topic about which we need to consult. For example, prioritisation activities are likely to include all Panel members and be achieved using structured consultation techniques. In other instances, we may seek informal advice from specific Panel members about their area of expertise.

5.2 Patient and public involvement

The principles of meaningful, valued and well supported patient and public involvement is at the heart of our approach. Patients and the public will be our partners across all programme activities and in each of the projects undertaken. Our approach will embed a strong patient and public voice across all the centre's activities:

- Governance and management: membership of the steering group will include Jeremy Taylor (National Voices), Angela Coulter (patient involvement and experience research expert) and Anna Dixon (Chief Executive of the Centre for Ageing Better), helping to ensure that the patient and public perspective guides the work and direction of the centre at a strategic level and that our approach to PPI draws on the latest thinking in the area. As our 'patient voice' co-applicant, a key role for Jeremy Taylor will be to hold the executive team to account and provide constructive challenge to help ensure that our commitment to put patients and the public at the heart of BRACE and its activities is a reality.
- Advisory input and consultation: the Health and Care Panel will include 10 PPI members, who
 will play a central role in the work of the centre. PPI members will be involved across all the Panel's
 core activities, as described in section 5.1 above. They will also work with BRACE staff to select
 outcome measures for evaluating innovations, ensuring that what matters most to patients and the
 public is embedded into how 'success' is defined and measured in each project. The Panel will also
 provide a mechanism for rapidly accessing advice on specific and emerging issues. For example,

we would expect to consult our PPI members about ethical issues; participant recruitment strategies; and effective ways of communicating findings to a diverse audience.

Project delivery: there will be opportunities for co-production within each evaluation project. These opportunities will be tailored to the topics, methodologies, local contexts and timescales concerned, so we would expect involvement to vary from project to project. Involvement could span from consultation (e.g. about evaluation questions, recruitment methods, research tools or emerging findings) through to patients and the public collaborating on the design and delivery of evaluation projects as co-researchers. Good public involvement in research, especially where there is genuine co-production, takes time to do well [INVOLVE 2012]. We will always balance the requirement to work rapidly with a commitment to genuine and meaningful involvement.

Evidence and our experience of PPI demonstrate the importance of involvement being underpinned by training, development and support so that people can participate confidently and effectively [e.g. INVOLVE 2012a]. Support will be tailored to people's needs and the roles they are undertaking, and will be designed on a case-by-case basis, this being important given the likely diversity of PPI collaborators and involvement activities. We will also regularly review our approach to PPI – with the service users and members of the public that we are working with – to support learning and reflection, and identify any areas for improvement and examples of good practice. We would expect the work of the team to contribute to the evidence base about 'what works' in PPI; in particular, providing learning about the factors that promote successful involvement in rapid evaluation projects.

6. Management, governance and quality assurance

6.1 Management and governance arrangements

HSMC at the University of Birmingham will lead and coordinate the evaluation team and be responsible for its performance, project delivery, Centre and project-specific planning, progress monitoring and reporting, contract management, quality assurance, and management of the overall budget. It will also be ultimately responsible for management of risk, however responsibility for management of individual risks will also be allocated through partnership agreements to members of the core team, and we will draw on the collective experience of the central HS&DR team to predict, identify and manage risks in accordance with their expectations and standards. Where individual projects are led by partners, these individuals/organisations will be responsible for day to day management of projects, reporting to the Centre's Deputy Director.

The centre will have an executive team comprising the Programme Director (Judith Smith), Deputy Director (Jo Ellins), Health Economics and RAND/Cambridge lead (Jon Sussex), full-time research fellow and team administrator that will meet on a monthly basis in person, and invite other colleagues from the wider team if required. Jon Sussex will coordinate RAND Europe and HSRG's inputs to the work of the Centre, building on his role as co-director for the Cambridge Centre for Health Services Research. He will also provide senior health economics support. Jon will facilitate rapid access to the team of health service researchers at RAND Europe and the University of Cambridge and will work directly with Judith Smith for the purposes of managing the Centre and co-ordinating inputs to the rapid service evaluations undertaken.

The executive team will represent the 'engine room' of the wider evaluation team and our regular meetings will be held face to face, with additional telephone or video conference discussions in between as required. It will oversee the day-to-day operation of the evaluation team and the projects it is scoping, undertaking and disseminating. It will have responsibility for project and overall team budgets, progress against agreed plans for the team and projects, and identifying and addressing any emerging problems. The Centre will adopt a robust project management approach, overseen by the executive team. At the start of each contractual year, the team – in consultation with wider BRACE staff and the steering group – will develop a detailed project management plan outlining deliverables, expected timescales and allocated leads, and describing any potential risks to delivery and how these will be mitigated. Plans will also be developed for each project. Performance against the targets and deadlines described in these plans will be monitored at the executive team monthly meetings.

The executive team will be supported and challenged by two 'critical friends', Professors Russell Mannion and Mary Dixon-Woods. Their primary role will be to provide peer review criticism, challenge and support to the core evaluation team, ensuring that the overall approach taken is subject to regular academic peer scrutiny, and connected to latest theoretical and methodological developments in the wider health services research and improvement research communities. More specifically, they will undertake peer review of all project proposals, interim outputs and final reports, and support the team in 'reading across' projects and themes and distilling wider learning on both a topic and methodological basis. They will also attend the evaluation team steering group, in order that they hear discussions of the team's plans and work by external PPI, academic and NHS service peers, and can connect this into the critical friend role they will perform for the core team.

The BRACE steering group will meet three times a year in person with communication by email, teleconference or Skype in between, and will: advise on strategic and operational plans for the work of the team; oversee and advise on academic standards; ensure appropriate independence and robustness of research and analysis undertaken within individual projects and across the work of the team; assess and assure the role and extent of public and patient involvement in the work of the team; advise on the approach taken to prioritising and selecting innovations for evaluation; advise on disseminating strategies; suggest how the team can best undertake decision-making in relation to which evaluated innovations are appropriate for scaling up or not.

At the end of each year, we will formally review how the centre is working, including the effectiveness of our management and governance arrangements. This will take the form of a core team away day, supporting a process of reflection and allowing team members to agree and plan any improvements together.

6.2 Managing data and information governance

The rapid service evaluation team will receive and store data from a variety of sources and projects throughout its lifetime, including NHS datasets. All three organisations have in place robust arrangements and institutional policies for storing, managing and sharing data, which are GDPR compliant. These are as follows:

- The University of Birmingham operates an Information Security Policy that is based on the core principles of ISO 27001 and other relevant information security standards including NHS Information Governance. The University's IT department provides a facility 'BEAR DataShare' which enables the secure storing and sharing of data. The University is registered under the Data Protection Act 2018, registration number Z6195856. Details of the current Information Security Policy are at <u>https://intranet.birmingham.ac.uk/it/documents/public/Information-Security-Policy.pdf</u>.
- RAND Europe maintains a strong security governance framework aligned with ISO 27001. All
 research projects are required to comply with internal quality management systems, in line with
 RAND's ISO 9001:2008 certification. RAND Europe adopts good industry practices regarding the
 protection of personal data as part of its obligations as a Data Controller under the Data Protection
 Act 2018.
- The University of Cambridge Clinical School Computing Service operates an ISO27001 certified data security policy and secure data hosting server. The University is registered under the Data Protection Act 2018, registration number Z6641083. Details of the current policy are at <u>https://www.medschl.cam.ac.uk/research/information-governance/sdhs-security-policy/</u>.

Non-personally identifiable data will be held on standard secure, encrypted web servers with password-controlled access, and will be accessible only to staff from the three partner organisations who are specifically working on the evaluations. Transfer of data to servers will be completed via secure (encrypted) methods.

Projects requiring the use of sensitive or higher risk data, such as hospital episode statistics (HES), will be covered by data sharing agreements with the relevant service providers. The lead organisation for each project will have responsibility and be accountable for data management and security relating to that project; they will also act as signatory to any data sharing agreements that need to be put in place. Monitoring of data shall include regular audit of data storage and data transfer procedures; local quality

control checks and procedures undertaken by the centre director; back-up and disaster recovery of any local databases; and validation of data manipulation.

Most data we collect will not be personal data (especially not individual patient data). NHS and social care data will typically be accessed in pseudonymised form. If we do conduct any studies that require the collection of patient identifiable data (PID), it will be subject to a full Health Research Authority ethics review and relevant governance arrangements. All PID collected as part of our research studies will be stored securely (as outlined above).

6.3 Ethical issues raised by the research

All research involving human subjects raises ethical issues including those of voluntary participation, informed consent, maintaining confidentiality and data protection. All work undertaken within the contract will be carried out in accordance with the University of Birmingham's Code of Practice for Research and Data Protection Policy. Projects will be carried out to the highest standards of ethical practice, including clear procedures for securing informed and voluntary participation, to include participant information sheets and written consent.

Research suggests that people's ability to understand information relating to research processes is frequently overestimated, and poor communication around recruitment and consent affects some groups – such as frail older people and people with learning disabilities – more than others [e.g. Harris and Dyson 2001; Goldsmith and Skirton 2015]. For each project, we will design plain language information and consent sheets, tailored to the groups concerned. We will seek advice from the service user members of our Health and Care Panel and local PPI collaborators to support the design of recruitment and consent processes, and address any other ethical issues that may arise.

6.4 Ethical approval and permissions to carry out the research

The type of approvals required will be assessed on a project-by-project basis. In each case, approvals may be required at the following levels:

- University of Birmingham Research Ethics Committee: all projects within the contract are expected to involve human subjects, and therefore will require approval from the University of Birmingham (UoB) research ethics committee. For service evaluation projects involving staff only, we have a fast track approval process set up with the UoB research ethics committee which will enable ethical approval to be secured rapidly. Full ethical approval will be required for any project involving service users or members of the public.
- Health Research Authority (HRA) approval: for each project, we will seek advice from the HRA about whether the project is categorised as 'research' or 'service evaluation'. For those projects categorised as research where only staff are involved, HRA approval will be sought. For any projects categorised as service evaluation, HRA approval is not required and so we will seek local management permissions directly from the relevant research and development (R&D) offices in each area. NHS organisations differ in how they approach service evaluations from an R&D perspective. In our experience, some organisations waiver service evaluation projects, while others require full R&D review. R&D approvals will need to be determined on a project-by-project basis.
- NHS Research Ethics Committee approval: where a project involves NHS patients/service users, we will apply for approval by an NHS and/or Social Care Research Ethics Committee. Where appropriate, we may request permissions for different components of studies separately so that aspects of research requiring fewer checks can commence as quickly as possible.

We will work closely with local clinicians and patients, as well as drawing in expert advice from our Health and Care Panel and wider networks, to address any ethical issues arising from the research in a timely and appropriate manner.

7. Conclusion

The BRACE centre has been brought together with the purpose of undertaking rapid, responsive and rigorous evaluation research that will bring timely and co-produced evidence-based insights to current and planned service innovations in health and social care. We have a very strong commitment to

working in a collaborative, reflexive and innovative manner with PPI and health and care partners, and this will form a 'golden thread' through our research approach. Likewise, our collective experience and expertise in undertaking rapid and impactful evaluation research will define the work of BRACE. Above all, we will ensure that our work is of the highest scientific and ethical standards, and co-produced with NIHR HS&DR colleagues.

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