Project title: Understanding new models of care in local contexts: a systematic review using frameworks to examine pathways of change, applicability, and generalisability of the international research evidence

Summary of Research: The NHS has been challenged to adopt new, flexible models of service delivery that are tailored to local populations [NHS England, 2014]. Evidence from the international literature is needed in order to support the development and implementation of these new models of care and to overcome reported potential issues and barriers [Ham & Murray, 2015].

The proposed study aims to support the development of new, flexible models of service delivery in the NHS by carrying out a systematic review of evidence relating to new models of healthcare. It will combine rigorous and systematic methods for identification of literature, together with innovative methods for synthesis and presentation of evidence. The proposed synthesis methods will address the identified need for: firstly, enhanced understanding of the mechanisms whereby new models of service delivery impact on healthcare and patient outcomes; and secondly, greater understanding of ways that models might work in different contexts.

The research team will carry out a systematic search of the international literature on new models of care. We will search electronic databases and use supplementary searching methods such as citation searching and reference list screening [Booth et al., 2013]. This systematic search will advance understanding by privileging **rigour** i.e. by focusing on formal evaluations and empirical designs. At the same time a UK-centric systematic search, with a more inclusive evidence threshold will identify contextually rich ephemeral materials (for example commentaries, editorials, news items, process evaluations, meeting reports) that will privilege **relevance** [Torejeson et al., 2015]. In this way both context and outcomes will receive corresponding attention within this bi-partite review for, as Pawson [2006] has stressed, “outcome patterns are contingent on ... assessments of both rigour and relevance”.

Evidence identified via these means will be synthesised in two ways. Firstly, the study will use data from included studies to develop an evidence-based logic model. Initially UK-based literature will be used to populate the model, which will set out evidence underpinning the pathway from new models of care to long term and system-wide impact. The logic model will detail: the types of service transformation which have been described; short term outcome measures reported; and longer term evaluation tools used to examine impact. The model will also outline the mechanisms of action (i.e. theory of change) for the pathway from these new models of care to different types of impact, together with factors reported as moderating or mediating elements. Following development of the prototype model we will then scrutinise the international literature, making comparisons and contrasts between this evidence and the UK evidence. The logic model will thereby act as a translation tool between multiple and diverse evidence types, and enable a contextually sensitive analysis.

The second method of synthesis in the proposed work will further examine comparisons and contrasts between the UK and international literature in order to develop a framework of factors potentially impacting on generalisability and applicability of the literature. This element of the work will address the need for understanding how particular models might work in different local contexts.

The final phase of the study will use consultation with key stakeholders to examine the clarity and resonance of the developed logic model, and also to gain feedback regarding the assessment of generalisability and applicability. This builds on evidence synthesis methods we previously developed for a systematic review of demand management interventions commissioned by the HS&DR programme and subsequently have used widely and effectively for sharing the findings, in a similarly complex topic area, with practitioners and service commissioners [Baxter et al. 2014; Blank et al. 2014].

Background and rationale: It has been argued that the growing financial and service pressures in the NHS cannot be tackled without transforming how health and care are delivered. The NHS Five Year Forward View Plan [NHS England 2014; 2015] sets out a view on how services need to change and what models of care will be required in the future, with a common thread being the need to break down barriers between services through greater integration of care [Shortell et al., 2015]. It is proposed that there should be new networks of provider organisations (organised horizontally as multispecialty community providers or vertically as primary and acute care systems) which form the bedrock of provision [Long et al., 2015]. Thirty-seven “vanguard sites” have been identified to develop and test new models of care, including enhanced health in care homes and new approaches to urgent and emergency care as well as multispecialty community providers and primary and acute care systems. The rationale underpinning the development of the vanguard sites programme is to evaluate a small number of different models, while allowing flexibility in the way models are implemented to meet local needs.

A study by the Kings Fund [Ham & Murray, 2015] highlighted that change was needed at a whole-system and governance level, with the development and rapid implementation of integrated models of care needing to draw on resources and expertise from across the local health system. This primarily qualitative work analysed five case study sites that have developed more integrated models of care. The work found that significant barriers to implementing changed systems included: a lack of clarification of roles and responsibilities; competition for funding; and challenges in engaging primary care. The authors of this work also highlighted that “one size does not fit all” with different models developed at each of the case study sites. Common themes regarding the requisite types of changes encompassed: delivering more care beyond the hospital walls; changing the future size and shape of acute hospitals; an increased role in prevention and population health; and new organisational models with local partners.

Other studies have similarly reported that cultural and structural barriers have proved difficult to overcome in the drive to provide integrated care [Ahmed et al., 2015]. A key challenge is to create an environment of collaboration between all providers, including primary and secondary care [Long et al.]. Authors have highlighted that there is a need for greater understanding regarding how integrated care can be best delivered, and a requirement for further clarity regarding how new models of integration may impact on patient outcomes [Robertson, 2011].

It has been suggested that models from the United States such as Accountable Care Organizations may be useful frameworks from which the NHS can learn. However, studies have also highlighted that it is important to consider the difference in contexts before implementing the same models in different areas [Ahmed et al. 2015]. The NHS vanguard sites have been encouraged to develop new models of care by adapting systems to local needs and configurations [NHS England, 2015]. However, while individual models should be rooted in local communities and have a “local resonance”, it has also been emphasised that it is important to identify simple standard approaches and products which can be replicated across the country [NHS England, 2015].

The proposed study will add to the existing body of knowledge by providing a critical summary of the international literature on new models of care. The review of the literature will provide knowledge regarding key ingredients of care models and will identify best practice and areas of learning which may be important in contributing to the success of a programme. It will also detail potential outcomes and impacts reported in the literature which will inform the planned multi-faceted approach to measurement and evaluation of new care models in the NHS. The logic model method that will be used to synthesise the review findings is intended to add to the body of knowledge by illuminating complex pathways between models of care and long term health impacts. The method will provide an accessible summary of the literature, and will inform the draft logic models which every vanguard site has been asked to develop as the basis for further development and refinement of local models. The analysis of factors relating to generalisability and applicability in the proposed study, will contribute to knowledge by providing key information to commissioners, service managers and practitioners regarding implementation of care models in their local context, and support understanding of how care models might be replicated in other local care systems.

Evidence explaining why this research is needed now: In order to support the development and introduction of new care models in the NHS via vanguard sites, a rigorous and systematic review of the international evidence is needed. A range of models which are rooted in local communities have been developed, and there is now a need to understand the key ingredients of successful new models of care described in the international literature. This is needed in order to inform evaluation and further replication within the NHS.

The proposed systematic review is particularly relevant in its emphasis on using the international evidence to understand the complex pathways from new models of care to longer term impacts, and also to explore the mechanisms of action underpinning change pathways. It also has as its focus the understanding of components of interventions that influence generalisability and applicability. This focus will directly inform understanding of how models might work in different contexts. The vanguard sites have been asked to develop draft logic models, and the logic model output from the proposed work will be valuable in helping to identify where local models have common characteristics to each other, and to the international literature.

Aims and objectives: The proposed study aims to carry out a rigorous and inclusive systematic review of evidence underpinning new models of healthcare. It will have the following aims:

1. To examine what can be learned from the international literature regarding key elements of implementation, and potential impacts of new models of care.
2. To examine reported mechanisms of change and outcomes and impacts associated with new models of care.
3. To assess how generalisable the findings from the international literature might be to different local populations and contexts, and examine how mechanisms of change might operate differently in differing local services.

4. To explore how the international evidence can be applied in a UK context, and what factors of applicability for the new models of care may be important for local populations and local service contexts.

The work will have the following specific objectives:

1. To carry out a systematic review of the international literature on new models of healthcare.

2. To use a logic model method to outline mechanisms of change underpinning the introduction and outcomes from new models of healthcare delivery, including potential barriers and facilitators.

3. To explore how the developed model resonates with the views and experiences of key stakeholders.

4. To develop a framework which details factors that may impact on the generalisability or applicability of the research literature, and to use this framework to evaluate models of care reported.

Research Plan/Methods: The proposed study will combine established systematic reviewing methods for identification of literature, with innovative methods of analysis and synthesis to examine mechanisms of change, generalisability, and applicability of international evidence to local contexts. The outcomes from this work will be two syntheses: firstly, a logic model synthesis outlining and comparing the UK and international evidence on new models of care; and secondly, an applicability synthesis that will develop and use a methodology of wider value within health service and delivery research.

i) Identification of literature

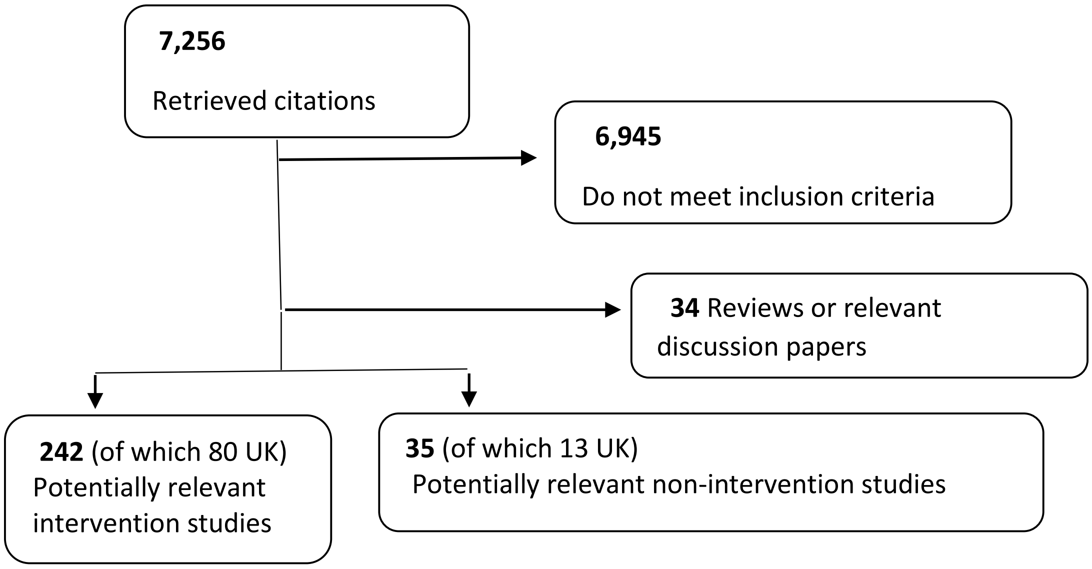
Search strategy: A systematic search of key health, medical and social care databases will be undertaken to identify relevant studies published since the year 2006. We will search from this year as a previous review [Davies et al. 2006; 2008] is available which included studies published up to 2006. Search terms will be developed from keywords with input from the information specialist on the team via an iterative process of scrutinising retrieved papers to inform further searching, and MeSH terms. The initial consultation sessions will also be used to inform keyword identification. Electronic databases searched will include MEDLINE, EMBASE, the Cochrane Library (including the Cochrane

Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effects), PscyINFO, SCI and SSCI, and CINAHL. We will review the titles and abstracts of all articles in a small number of key journals: International Journal of Integrated Care, Journal of Integrated Care, International Journal of Care Coordination. Additionally, Google Scholar will be searched for relevant articles. The search process will be recorded in detail with lists of databases searched, date search run, limits applied, number of hits and duplication as per PRISMA guidelines.

In addition to standard electronic database searching other iterative searching techniques will be employed including citation searches of included articles and authors, searches on any key models of care we identify, additional targeted searching on keywords and concepts identified from the included papers, hand searching of reference lists, and contacting key authors and experts to obtain further relevant published and unpublished material. Relevant review articles will also be used to identify studies. In particular we will examine all articles citing the two published versions of the Powell Davies review [2006; 2008] which provide 78 and 29 citations respectively. In this way a community of citing authors will help us in the definition of “new models of care”.

Initial scoping work: An initial scoping search has been carried out by the information specialist on the team (AS) to gauge the volume of literature and to provisionally test and refine the proposed search strategy. Ovid Medline was searched using the search terms listed below resulting in 7,256 hits. We have carried out some initial sifting and categorisation of these citations (see diagram below).

We have also carried out searching in further databases (Cochrane, PsychINFO, and CINAHL) to estimate the total volume of literature. Across all these databases we have retrieved 20,103 references.



Scoping search

A combination of MeSH subject headings and free-text terms were utilised.

MeSH: Health Care Reform, Organizational Innovation, Quality Improvement, Health Priorities, Accountable Care Organizations, Delivery of Health Care, Integrated

The above MeSH terms were combined with the Floating Subheadings Organization & Administration [og] OR Trends [td]

Free-text terms included (searching in title OR abstract): care model(s) and "new", service delivery model(s), healthcare model(s), transformation of service or care, integrated care, integrated health system(s), vanguard(s), accountable care, future-proofing, service redesign, "five year forward plan"

The search was limited to humans, English language and the publication dates 2006-present.

Additional search for UK evidence: In the proposed study we will carry out a supplementary search process to locate evidence relevant to the development, implementation and evaluation of new models of care in the NHS in England, focusing specifically on the models being implemented by the NHS vanguard sites (or a random/purposive sample). This will involve contact with NHS England and/or vanguard site representatives to obtain as much information as possible about the new models of care being implemented. Starting from information obtained from these sources and/or from published literature, we will apply CLUSTER methodology (Booth et al. 2013), modified if necessary, to understand as fully as possible the context and underlying concept(s) of the intervention(s) under study. For this part of the search process, we will consider evidence for inclusion based on relevance to the process of developing and implementing a new care model, (although discursive papers with little or no data will be excluded).

ii) Inclusion/exclusion criteria: The following inclusion/exclusion criteria will be applied to assess the relevance of studies identified during the searching process.

Target population: Patients receiving a healthcare service and staff delivering services.

Target interventions: We will define new models of care as changes to service delivery which increase integration and coordination within primary health care (PHC) and/and between PHC, health and health related services (including social care). We will include: Polyclinics; Accountable Care Organisations; and Integrated Care Pilots. Based on papers identified during the scoping search, a potential typology outlining the types of intervention that will be included is:

1. Interventions with a focus on service re-design/re-configuration. This may be sub-divided into - single point of access, joint clinics or sessions, integrated care pathways, and re-location of services.

2. Interventions with a focus on workforce changes. This may be sub-divided into changed roles, and further education/training.

3. Interventions with a focus on integration of different services, or working across service boundaries.

4. Greater co-operation between services (for example using common assessments), but without the aim of integration.

5. Interventions with a focus on financial strategies.

6. Information systems or other technology to promote new ways of working.

Control/comparators: The review will examine interventions with comparator groups (such as care networks) and also those with no comparator.

Outcome measures: As one of the objectives of the work is to identify and report measures of outcome and impact that have been used in the literature, we prefer not to specify a priori the outcomes measures that will be included. The review will include studies with any outcome relating to the delivery of services (effectiveness or efficiency) or an impact on patient care, or staff. This will include quantitative measures, together with views/perceptions of patients/service users, staff and other key stakeholders.

Study design: We will carry out a rigorous search of the international literature for all relevant systematic reviews, randomised and non-randomised controlled trials, prospective and retrospective cohort studies with and without comparators, and other before and after/longitudinal studies. With the increasing recognition that a broad range of evidence is needed to inform the depth and applicability of review findings, the review will be inclusive and encompass both experimental and observational studies, together with qualitative work reporting views of service users or staff delivering services. Descriptive or discursive papers will be excluded. A particular focus of the synthesis will be the inclusion of UK formal service evaluations of diverse study types and methodologies.

Other inclusion/exclusion criteria: We will include studies from any country which is a member of the Organisation for Economic Collaboration and Development (OECD). Studies in these developed countries will be of most relevance to UK health systems. We will examine studies published in English, however we will consider translation of any key international papers which have abstracts in English. In order to examine the most relevant studies, the review will include work published since 2006.

iii) Selection of papers: Retrieved citations will be uploaded to EndNote, and title and abstracts (where available) of papers will be independently screened by two reviewers and any queries regarding inclusion will be discussed by the full team. Full paper copies of potentially relevant articles will be retrieved for systematic screening. The screening process will identify papers which are of relevance to answering questions of intervention outcomes, or provide data regarding contextual factors, or perceived barriers and facilitators to successful outcomes.

iv) Data extraction: Studies which meet the inclusion criteria will be read in full and a brief data extraction will be completed. A data extraction form will be developed using the previous expertise of the review team, trialled using a small number of papers, and refined as necessary. Extracted data will include: study population, comparator, baseline characteristics of the population and service provision: details of the model of care: and study findings. In addition to these data we will be identifying elements relating to implementation of care models which may impact on generalisability, or relate to applicability. Data will be extracted by one reviewer and checked by a second.

v) Methods for combining/synthesising findings and different forms of evidence: The literature on new models of care presents two key challenges for systematic review methods. Firstly, it is increasingly recognised that any intervention in healthcare can be considered to be complex, with individual and organisational factors affecting how and if interventions lead to improved outcomes [Rees et al., 2004]. Interventions such as new care models, which act at a system or organisational level, or even across organisational boundaries, provide considerable additional complexity due to their multi-factorial processes. The new care models programme has been described as being “complex in its breadth and depth” [NHS England, 2015]. This complexity presents difficulties for systematic review methodologies which seek to quantify or report clear intervention-outcome effects.

A second challenge to review and synthesis of this literature comes from the extensive variety of models which have been introduced. This diversity in type is particularly apparent as many models have been developed in response to local needs and configurations. New models of care may adopt a number of different approaches and organising principles which respond to the local context. This diversity presents challenges for considering how generalisable the findings from a study may be, and how applicable evidence from varied national and international research may be to a particular local context.

We propose to use two main methods of synthesis to overcome these key challenges, and enable the integration of different forms of evidence. The first method, will be to synthesise the identified UK and international quantitative and qualitative literature using logic modelling techniques, to develop an evidence-based framework of links between new models of care and health impacts. This method, which was developed by the team [Baxter et al. 2010], has been used successfully in previous systematic review studies we have carried out [for example Blank et al. 2014; Allmark et al. 2012], and is ideally suited to the analysis of complex, system-based interventions.

In the logic model method, data from included studies are extracted and analysed to produce an intervention typology, detail regarding the range of outcomes reported, factors which may be influential in the pathway from a new model to health impacts, and reported associations between elements of the model. Both quantitative and qualitative data are used to underpin construction of the elements of the model. The model will outline evidence in the literature regarding different models of care, relationships between contextual factors, inputs, processes and outcomes [Joly et al. 2007;

Anderson et al. 2013]. Lines between each element in the model will demonstrate the logic or theory of the interventions and portray “if......then” relationships in the causal chain from new models of care to system wide health impacts.

Initially, the work will use UK published literature, grey literature and other forms of documentary evidence relating to new models of care to develop an initial or “start” logic model. This will include any available data/documents relating to the Vanguard sites. Following development of the UK-based logic model the second phase of the work will entail examination and synthesis of the international (non UK) literature, making comparisons and contrasts between the primarily internally valid and externally valid domains. We will initially search for and include systematic review level international studies alongside the UK evidence, to underpin a further draft of the model. We will use a “saturation and gap filling” approach to further develop the model via subsequent search iterations, using international primary evidence where we are unable to find reviews to explore gaps in the evidence base. The logic model framework will act as a translation tool between findings from review of the UK evidence and the international literature, and enable contextually sensitive synthesis of multiple and diverse evidence types.

In a further phase of work we will use a second method of synthesis to compare and contrast the UK and international evidence, in order to develop a framework of factors of applicability and generalisability. This additional method will be employed to address the diversity in type of new models of care, and challenges in evaluating generalisability and applicability of the literature to varied local contexts. We will move between the UK and international literature to examine elements of setting, intervention and outcomes. From this analysis we will develop a framework of generalisability and applicability to local NHS contexts in the form of a checklist, which will be used to evaluate the evidence that we find. The framework will be applied to each reported model to provide an evaluation of generalisability and applicability. In addition to detailed analysis, indications of greater/lesser applicability to the UK NHS will be derived from this framework and indicated on the logic model.

vi) Assessment of quality and relevance of studies: The critical appraisal of included evidence is considered a key part of the review process; although remains the subject of debate in the field, with no single recognised tool. There is also variation in views regarding the use of scoring systems and methods for appraising strength of evidence across studies (particularly in qualitative work). Pawson et al. [2003] argued that there is no hierarchy of knowledge, although users of knowledge need to understand that some types of knowledge are more relevant to some purposes than others, and be aware of the quality and reliability of the knowledge. The appraisal of quality and evidence in the proposed study needs to take account of the wide range of study types that we are likely to find, and recognise that a higher number of papers in an area does not necessarily indicate greater strength of evidence; only where more work has been carried out. This is particularly important given that the rigorous evidence base is likely to be dominated by studies from outside the UK, whereas the most relevant studies will be derived from the UK.

Our approach to assessment of strength of evidence will be based not only on the quality and volume of studies, but also consider consistency of the evidence [Hoogendoorn et al., 1999]. We have used this approach successfully in a previous review and logic model study with diverse evidence [Baxter et al., 2014]. We will report where, in the logic model there is greater or lesser strength of evidence for associations and outcomes.

Stronger evidence (Level i) will be defined as: generally consistent findings in multiple higher quality studies.

Weaker evidence (Level ii) will be defined as: generally consistent findings in one higher quality study and lower quality studies, or in multiple lower quality studies.

Very limited evidence (iii) will be defined as: only one study available

Inconsistent evidence (iv) will be defined as: inconsistent findings in multiple studies. Study findings will be considered to be inconsistent if fewer than 75% of studies reported the same conclusions.

Consideration of individual study quality will be based on the hierarchy of design, together with consideration of potential for bias as recommended by the Cochrane Collaboration [2011] (selection bias, performance bias, attrition bias, detection bias, reporting bias). Consideration of systematic review and qualitative evidence will be based on the Critical Skills Appraisal Programme [NHSPRU, 2006] checklists. We will also use emerging methods relating to Confidence in Review Findings (CERQual) that examine relevance, adequacy, and coherence (the qualitative counterpart to consistency) alongside methodological quality of qualitative studies.

Any concerns regarding study quality will be identified and recorded during data extraction. Appraisal of overall strength of evidence will be undertaken by the research team at a series of meetings to establish consensus.

vii) Consultation phase: The final phase of the work will be a period of consultation. This consultation will be carried out via individual and group sessions with stakeholders at local and national levels including: Commissioning Managers, Portfolio Leads, Portfolio Managers, Clinical Executive Directors, members of the Vanguard Evaluation team, together with Service Managers and clinicians from Vanguard sites. This phase of the work will be important in terms of validating the developed model. The consultation will be used to seek feedback regarding the hypothesised causal chains and any areas for amendment, and to explore practitioners' and patients' understanding of the model in order to ascertain the usefulness of the framework as a communication tool. We will also seek feedback regarding the assessment of generalisability and applicability and seek input regarding any further dissemination strategies and/or impact activities.

Design and theoretical/conceptual framework: Logic model methods provide a graphical description of a system and are designed to identify important elements and relationships within that system [Anderson et al. 2013]. They are one form of theory-based evaluation that focuses on relating hypothesised links between an intervention and its constituent parts to its outcomes and long term impacts. Logic models are concerned with examining the processes of implementation, mechanisms of change and participant responses in order to develop hypothesised links or a “theory of change” [Weiss, 2007]. They serve as a tool to represent the causal system of interest, set out proposed causal pathways in the relationship between the intervention and its health and other outcomes, and identify potential moderators of that relationship [Anderson et al. 2013]. Outcomes are conceptualised as being the end of a chain of intermediate changes which the evaluation process seeks to track, with each intermediate point predicting the outcomes that may occur in the future [Dyson & Todd, 2010]. Theory-based approaches focus on assessing the validity of the theory on which an intervention is built and are concerned with opening up the black box of interventions and outcomes to uncover underlying mechanisms [Foss Hansen, 2005]. It is argued that without having a clear understanding of the assumptions underlying an intervention and how it is supposed to work, evaluators cannot ascertain whether it did work and why it did or did not achieve the intended benefits [Rossi et al. 2004].

Logic models, and other theory-based methods of evaluation such as realist synthesis, are becoming increasingly recognised as important additions to conventional methods of evaluating efficacy and effectiveness in systematic reviews. It has been argued that standard approaches can lead to disappointingly inconclusive findings regarding the success or failure of interventions due to their lack of examination of contextual factors [Pawson and Tilley, 1997]. Also, it has been highlighted that factors of process and the fidelity of an intervention may be overlooked in conventional methods of synthesis [Nilsen, 2007]. Theory-based evaluation approaches in contrast view understanding the context of an intervention as vital in attributing causation, and for gaining an understanding of mechanisms and impact. It has been emphasised that contextual factors need to be fully examined if an evaluation is to address issues of external validity [Blamey & Mackenzie, 2007].

The key strength of logic models is in linking complex system processes to system outcomes, and thus guiding the development of strategies and research tools for making system improvements [Handler et al. 2001]. Logic models have been recommended for evaluating highly complex, multi-site interventions with multiple and/or indeterminate outcomes [Connell & Kubishch, 1998] and provide a conceptual basis for explicit reporting of the methods and assumptions used within the synthesis [Anderson et al. 2013]. Health impacts following service re-organisation may be long-term, with evaluation complicated by multiple influential factors. The identification of intermediate impact, indications toward longer term outcomes and understanding processes between them is therefore of key importance. A logic model approach to synthesis is well-suited to analysing and reporting this literature, and examining the mechanisms and impacts underpinning new models of service delivery. A recent multi-author supplement on the systematic review of complex interventions counsels: “Independent of the overall synthesis strategy adopted, integrating diverse types of evidence collected from a wide set of study designs requires a coherent logic or conceptual model that can inform the design (structure and parameters) of narrative and statistical approaches to evidence synthesis” [Anderson et al. 2013]. This approach to synthesis of the international literature will also resonate with the draft logic models that every vanguard site has been asked to develop.

The terms “generalisability” and “applicability” are often considered to be synonymous. However, in the proposed study we are using the term “generalisability” to describe how relevant the results of a study might be to other sites and populations. We use the term “applicability” to refer to information regarding the study processes, and insights into whether and how an intervention may work in other situations. In the proposed study we will draw on work by Burchett et al. [2011] who reviewed published frameworks that included criteria for the assessment of external validity, applicability and transferability. The frameworks identified in this work considered elements relating to setting, intervention, outcomes and evidence. Examples of specific elements include: can the intervention be delivered elsewhere (is it feasible, can adequate coverage of the population be achieved, is the intervention acceptable to recipients); does the intervention meet recipients' needs (do potential recipients have similar needs to those of the original study participants); are investigators explicit about pathways/mechanisms/hypotheses through which an intervention is expected to act and about how intervention processes are influenced by context. The understanding of how evidence (in particular international evidence) can be applied to varying local situation and contexts is a key challenge for systematic review synthesis. The method for evaluating applicability and generalisability that we propose in this work, will assist decision-makers in evaluating how relevant research findings may be to their local organisations and services, and will be of value to future reviews of health services and delivery.

Sampling: For the consultation phase we will use our links with local and national commissioners, service providers and practitioners to gain input from a representative range of stakeholders. We will purposively sample in order to gain diversity in participant role and background. Previous work by the team [Baxter et al., 2014] has indicated that input from around 30-40 individuals should enable a point of saturation in views/perceptions to be reached.

Setting/context: Health care service delivery including primary and secondary care.

Data collection: Not applicable

Data analysis: See methods for analysis/synthesis section.

Dissemination and projected outputs: The main output will be a report providing a critical synthesis of evidence underpinning new models of care. Evidence based practice requires policy makers and practitioners to have readily available access to information on interventions that have shown to work or not work, or have the potential to cause harm. Systematic reviews are an established way of exploring the effectiveness of interventions and a cornerstone of evidence-based practice in order to identify, evaluate and summarise the findings of all available research evidence. The findings of the synthesis will also be presented as an evidence-based framework identifying key aspects of applicability and generalisability which will inform decision-making regarding the transferability of new models to local care contexts. The framework will provide an overview of evidence in an accessible form for stakeholders, and will further the understanding of how elements at a local level and wider organisational structure may enhance or provide obstacles to the implementation and outcomes of new models of care.

The work is expected to have an impact at a number of levels - researcher, practitioner, service managers and commissioners.

Researchers - the synthesis will provide an overview of the current state of knowledge in the field, indicate where further research is needed and the framework is expected to be a useful tool for understanding evidence in other areas of healthcare research. Whatever the findings, the work will highlight the importance of considering the applicability and generalisability of systematic review findings when considering evidence within the academic community. It will be complementary to and enhance other work on review methodology that is ongoing, such as methods of including both quantitative and qualitative synthesis, and incorporation of wider sources of evidence. We envisage that this framework will become a knowledge translation tool for use in future outputs of the NIHR HS&DR Programme where rigour is dominated by non-UK studies, but where relevance is located in lower study designs. Systematic reviews are used by researchers across the health disciplines to summarise current levels of evidence, and the proposed work will add to the methodologies available for ensuring impact on practice and service delivery.

Practitioners and service managers - the work will inform the optimal introduction of new models of care and highlight factors which may be mitigating the effectiveness of any models currently in use. The framework may provide a valuable resource for undertaking local evaluation of implementation and effectiveness and further the understanding of practice and delivery of new models of care. Research currently suggests that practitioners make limited use of available research evidence and find challenges in accessing and understanding systematic review findings due to difficulties in understanding how the review findings may be applied to their particular local context. The work to be carried out in this proposal aims to directly address this challenge and provide practitioners and managers with a framework for understanding the review evidence.

Commissioners - the work will outline evidence underpinning new models of care in use or under consideration, and provide insights into how factors within their local context may influence the implementation and outcomes of particular models.

Impact activities: The findings will be disseminated (in addition to the HS&DR journal) via conferences, as well as high impact peer reviewed journals. The team have a strong track record of publishing previous work in quality journals and of published papers attracting high interest. The University Media Centre will provide support for disseminating research findings via the media, both locally and internationally. Data from the research will be available via a report accessible from the University website. The review will be registered in the PROSPERO database, and in conjunction with the White Rose repository we are able to make journal articles widely available subject to publisher restrictions.

As a University department with a strong teaching and postgraduate research element, the ongoing research and findings will be disseminated via our established teaching for Medical students and other healthcare Masters level courses. Members of the team have current and will have future UK and international students undertaking dissertations and PhD study in the department, which will provide further opportunities to disseminate the findings and build potential future research studies in the area. The team have established links with a wide range of practitioner and commissioning groups from previous and other ongoing research which will be used to provide opportunities for influencing future practice. The work will also be disseminated via training sessions for professionals and researchers. The team and the location where the study will be based have established expertise in providing short courses on secondary research methods to a variety of audiences including medical specialist registrars, other health professionals, PhD students and the research community. Findings from this work will be incorporated into these courses and influence the training of future health researchers.

Plan of investigation and timetable

Month	1	2	3	4	5	6	7	8	9	10	11	12
Protocol development	■											
Searching	■	■	■	■	■	■						
Data extraction			■	■	■	■	■	■				
Synthesis and development of logic model					■	■	■	■	■	■		
Development of applicability and generalisability framework								■	■	■		
Consultation phase									■	■	■	
Report writing and dissemination											■	■

14. Project management: The lead applicant will act as project manager and will oversee timely completion of the project milestones. Team meetings will be scheduled on a fortnightly basis as this has been a proven method of ensuring good communication between team members and co-ordination of work in previous projects. The project team is based within the same University department and in close working locations which will enhance joint working. The previous and current experience of the team in working together has established successful mechanisms of collaboration which will contribute to efficiency of project completion within the rapid timescale. We will establish a PPI group to maximise lay involvement in the study.

Approval by ethics committee: We intend to consult with the University of Sheffield School of Health and Related Research Ethics Committee to gain confirmation that the consultation phases of the work will not require ethical approval. Previous studies with similar consultative components have not required approval as we are not collecting and analysing data beyond receiving verbal and written comments.

Patient and public involvement: We have consulted with a local PPI group which includes lay members with experience of a variety of health and social care services and models of care (the Sheffield Palliative Care Studies Group) to obtain their input regarding writing the lay summary for this grant proposal. In particular, we wanted feedback on how to make the topic area ("new models of care") clear and meaningful to patients and the public. At a meeting with the group some members suggested ways of describing the topic area that might make it easier for lay readers of the proposal to understand. This increased our understanding of what the topic might mean to patients and the public and the importance of using terms and language that is familiar to them. Members of the group were able to ask questions about our proposed methods which allowed us to reflect on the clarity of our study design. Thus, we have used feedback from the group to write the lay summary and to facilitate clarity of the proposal.

During our meeting we asked whether the group would be interested in being involved in the study should we be successful in being awarded funding and also the ways that lay representatives may be involved. The group considered that a key challenge of the topic area for this work was making it clear and meaningful to a lay audience. When we asked what the term “new models of care” meant to them, only one member had heard of the term, few participants were able to make any guesses what it might mean. The group indicated that they would be interested in helping us to produce a piece of research that was meaningful to a lay audience. This would involve PPI input at the design stage as well as continuous input throughout the duration of the project as part of a lay advisory team.

We intend to form a project-specific public involvement advisory group for the duration of the work. One or two individuals from each of the 15 PPI groups co-ordinated by a local NHS Trust have been invited to join the public involvement advisory group (including Cardiology and Cardiothoracic Surgery Research Patient Panel, Community Infections Patient Panel, Bone Research Lay Advisory Panel, Obstetrics, Gynaecology and Neonatology Research, Sheffield Addiction Recovery Research Panel, Sheffield Emergency Care Forum) together with a generic online panel. We intend that this advisory group will have representation across different NHS service users. It is anticipated that this group will meet three times during the project: early phase, middle phase and towards the final phase. The public involvement advisory group will provide input on search terms and existing models and have a particularly important role to play in assessing whether the logic model produced from the work is understandable to a wide audience. PPI will also be important at the stage of writing the report to maximise meaningful messages for lay readers. We will obtain suggestions from the PPI group for disseminating the findings of the study in ways that reach the public, particularly since this topic has the potential to impact on the broad population.

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