Motivations, mandates, accountability and patient choice in demand management: a realist synthesis

Aims and Objectives

The task of matching fluctuating demand with available capacity is one of the basic challenges in all large scale service industries. It is a particularly pressing concern in modern healthcare systems as increasing demand (aging and growing populations, requests for new treatments, increases in patients' knowledge and expectations, etc.) meets stagnating supply (capacity and funding restrictions on staff, beds and services etc.). Given the complexity of the modern health services, the issue of demand management has come to the fore with the aim of overseeing the interconnection of different points of provision and the harmonisation of different layers of expertise.

In response to these problems a large portfolio of demand management (DM) strategies has developed and the initial **aim of the review** is to chart the many ideas, expectations or 'programme theories' that lie behind the various schemes. Many of these strategies are focused on managing or modifying the process of referral between primary and secondary care and within secondary care. Our **first objective** is to provide a model of the overall 'menu of choices' for regulating and refining demand. Each and every one of these strategies encounters significant challenges in embedding them into existing custom and practice in the NHS. As best practice is always a matter of overcoming or circumventing difficulties and drawbacks, the more specific, **second objective** of the review is to examine four major challenges confronting demand management systems. Our review is thus lead by a quartet of **research questions**:

- How can demand management strategies respond to different and sometimes conflicting motivations that prompt referral?
- How can demand management strategies balance the varied and sometimes uneven expertise and mandates of the participants in referral chains?
- How can demand management strategies promote accountability for costcontainment ambitions in NHS staff groups who traditionally lack such a remit?
- How can demand management strategies regulate provision whilst responding to other initiatives, which provide patients with increased choice of provision?

Background

Scope of the review: key concepts and definitions

As soon as comprehensive health services are introduced, problems of demand management commence. In particular, the wastage accruing because of the considerable variation in referral rates have been the subject of study for many years. In 1985, the then Chief Medical Officer, Sir Donald Acheson expressed a sense of frustration still felt today 'how can a phenomenon so gross continue to defy analysis?' Between 2005 and 2009, GP referral rates to secondary care increased by 19% and consultant to consultant referrals increased by 39% (Imison and Naylor, 2010). There is also wide variation in referral rates both within and between GP practices (Evans et al, 2011). GP referrals for elective care trigger an annual spend of £15 billion pounds. At the same time, the NHS faces a medium-

long term financial crisis with savings of more than £20 billion being required in the next 3 years.

Just as significant is the matter of the appropriateness of referrals. The practice of medicine has become increasingly complex and there is inherent uncertainty in all clinical decision making (Logan and Scott, 1996). Much progress has been made in formalising and codifying decision making tools for referrals in all conditions (e.g. NICE's 2001 advice runs from acne to varicose veins) but these are not a panacea as much of the problem lies elsewhere - in intuitive and tacit decision making as well as in communication and compliance problems. In short, identifying effective ways of managing demand for elective care is a priority for the NHS as is the abundantly clear consideration of ensuring that patients receive the right care at the right time in the right setting and within NHS budgets.

Demand management is often defined as the process of identifying where, how, why, and by whom demand for health care is made and then deciding on the best methods of managing this demand. The problem confronting NHS decision makers is that the permutations of 'wheres', 'hows', 'whys' and 'by whoms' involved in demand and referral decisions are almost limitless and include: 1. Strategic decisions often summarised as the three Cs - curtailing, coping with and creating demand; 2. Organisational reengineering – e.g. referral management centres (RMCs) and clinical assessment centres. 3. Procedural change – such as referral guidelines, substitution of specialists with GPs with a Special Interest (GPSIs); 4. Behavioural change – education and feedback, financial incentives, etc. The result is a formidable level of programme heterogeneity and interdependence.

In this document we use the term demand management (DM) to refer to system level strategies for balancing demand and capacity, whilst referral management (RM) pertains to overseeing the internal balance between different points of provision.

Current evidence and gaps to be addressed

Unsurprisingly against this background, the current evidence base is huge but highly fragmented. Primary research is uneven: i) in coverage, with more work on older and simpler interventions like guidelines and less on recent, complex innovations like RMCs; ii) in the maturity of programmes investigated, with a preponderance of pilot and demonstration projects; iii) in the research strategies involved (and thus research quality), with a high proportion of case studies and relatively few formal trials. A particular bugbear, as noted at the briefing event for this call, is the problem of generalisabilty. Interventions will have been implemented with significant local variation and inserted into systems with different resources, staffing levels, patient profiles, staff demarcations, healthcare histories and so on. Accordingly, outcomes reported in specific localities might not apply elsewhere, especially if evidence is drawn from overseas, where the entire contextual profile is likely to differ (Hadorn and Holmes 1997).

This proposal is for a synthesis of the primary literature, adding to several narrative systematic reviews (e.g. Imison and Naylor, 2010; Akbari et al, 2008 and Roland et al 2006). These have provided some guidance on 'what works' and have highlighted potential limits to the effectiveness of some interventions for certain groups (e.g. in the case of direct access for GPs to tests and services), and the considerable impact of contextual factors on the success of initiatives (e.g. in the case of GPSIs). What is missing from the review literature,

however, are syntheses which address core and generic issues in demand management and which explicitly take account of the contextual issues which may affect its success. For any demand management initiative to work, there has to be some consensus on why the referral should take place, what expertise is required to arrive at decisions, what capacity the system can maintain and what resources and accountability systems are required to maintain it. These generic, system-level ideas, or what are sometimes called 'programme theories' are the unit of analysis in this proposal. We seek to address one broad (I) and four more specific gaps in knowledge (i-iv) that have emerged in our initial reading of the literature and in discussions with practitioner and patient members of our team:

(I). The logic of referral management. The literature reveals considerable levels of ambivalence and uncertainty about demand management. This is captured from title page to conclusions in much of the reportage. For instance, a key paper on referral management into mental health services is entitled: *Controlling the Confusion* (Colgate and Jones, 2007). The conclusion to a report on the referral management pilots in Wales (NLIA, 2007) recommends: 'the Assembly needs to develop greater clarity by what it defines as referral management'. Confusions reign because of the many different types and subtypes of DM, the fact that many of them are combined in practice, and the fact that they are modifications to existing systems rather than fresh interventions. Systematic review always carries a 'ground clearing' function and what assists research in this respect will also meet a clearly expressed practitioner need. Realist synthesis starts by unearthing the 'programme theories' or 'logic models' underlying programmes and policies and the production clear compendium of the logic of the family of DM systems will also have a practical function.

(i) Reasons for and appropriateness of referral. GPs refer for a range of overt and tacit reasons: diagnosis, investigation, specialist treatment, second opinion, patient reassurance, load sharing, buck passing, fear or litigation and direct patient requests (BMA, 2009). There is debate about whether high rates of referral necessarily indicate a large number of inappropriate referrals (Imison and Naylor, 2010; O'Donnell 2000). While PCT managers may agree on what constitutes an appropriate referral (Blundell et al, 2011), this may not be the case for other stakeholders (Pisipati et al 2009; Slade et al, 2006). Other countries have developed standardised criteria in an attempt to achieve greater consistency in referrals, such as the New Zealand priority (Hadorn and Holmes, 1997). However, critics of such systems suggest they do not adequately reflect clinical appropriateness (Seddon et al, 1999) or the patient's ability to benefit from referral (Derrett et al, 2002).

Increases and variations in referrals may be attributable to GP behaviour, but also to patient factors, structural factors and the impact of other policy initiatives such as the Choose and Book system and the Quality and Outcomes Framework (BMA, 2009; Foot et al, 2010). Referral is rooted is a range of triggers – disease prevalence, defensive practice, health literacy, etc. Sophisticated DM systems need to be sensitive to the different motivations behind referral and a key practical requirement is to uncover the underlying drivers and to discover whether different DM systems support or override them.

The specific need addressed in this element of the research is to reconcile the formal apparatus of demand management with the tacit practices acknowledged by the following blogger: 'In my experience, most patients receive high quality consultant care. However, patients are entitled to know that there may be unseen reasons why their physicians choose

specific consultants. We specialists are not entirely righteous either. When we consult other physicians, we are also responding to forces that are *under the radar*. <u>http://www.kevinmd.com/blog/2010/05/doctors-choose-specialists-refer.html</u>

(ii) Substitution of clinical expertise. Linked to the above, many demand management initiatives such as referral management centres, clinical triage, in-house second opinion, referral guidelines and the use of GPSIs involve the substitution of expertise in order to review the appropriateness of referrals and divert referrals away from secondary care. Referral happens at that point when A is reckoned to be better placed than B to make a decision or care for the patient. That calculation is often sensitive one, depending on culture, custom and practice. Clarke et al's SDO report (2010) illustrates some of the dilemmas in conditions, like prostate/urinary tract care, with long treatment sequences. Treatments range from self-management and lifestyle care (the generalist mandate) through to combination therapy and surgery (the specialist mandate). The group responsible for developing referral guidelines to manage this process found it difficult to define the precise point at which mandate A gives way to the mandate B. This is a microcosm for all referral decisions. There can be tensions between mandates (BMA, 2009) and sophisticated DM systems need to be responsive to them. A careful review is needed to search for best practice in how to balance expertise and responsibility across a range of conditions.

The specific need we seek to address here is captured in this furious blog from a consultant physician: 'Just recently I had a referral on a man with diarrhoea but the letter neglected to mention the past history of a hepatico-jejunostomy. How could even the best clinician (and bear in mind that the best clinicians do not work in Referral Management Centres in any case) make any sort of valued judgement on the appropriateness of the referral?' http://www.kingsfund.org.uk/blog/referral_management.html

(iii) Modifying lines of accountability. Accountability has become a watchword in NHS reforms. Changing practice often involves new stakeholders taking on new obligations and responsibilities for the delivery of services. New forms of accountability can be slow to bed down and decision making responsibilities often superimpose old and new accountability regimes (Maybin et al, 2011). All of the potential DM reforms – referral management centres, clinical assessment centres, referral guidelines, substitution of specialists with GPSIs, financial incentives, and so on involve modification to such lines of accountability and a review of the evidence is needed on the feasibility of this aspect of each system. A specific requirement is to discover the opportunities and constraints involved in shifting responsibility to act as their patient's advocate and to manage within a finite budget. There have been a number of studies which have examined the dynamics of such regime changes (Addicot 2009). Revising patterns of accountability appears to be slow and tentative and a priority is to understand the mechanism through which coherent control is achieved and the contexts in which it is most likely.

The specific need we are trying to address in this element of the research is captured in the following discussion on 'who held the purse strings' in the RM pilots in Wales (NLIA, 2007): 'The pilots highlight the great difficulties of diverting resources away from secondary care into different provision or relocating current provision. Where 'reengineering' had taken place it was largely being paid for by Local Heath Boards - without any collateral disinvestment by

them in secondary care. While all pilots were successful to some extent in managing demand from primary care they were less successful in changing what secondary providers chose to supply... Local Health Boards may in theory hold the purse strings but in practice their room for discretionary commissioning (as opposed to funding the historical position) is small'.

(iv) Accommodating the choice agenda. Referral management techniques have been introduced at the same time as the advent of new guiding principles such as 'No decisions about me without me' and major systems change such as 'Choose and Book'. Shared decision-making explicitly recognises a patient's right to make decisions about their care, ensuring they are fully informed about the options they face. The new principles assume, however, that negotiation and compromise are part of the patient centred approach. It is also recognised that clinical expertise and patient preferences meet in different ways in terms of diagnosis, disease aetiology, treatment options, and outcome preferences (Coulter and Collins, 2011).

We already know a great deal about the dynamics of patient choice (Fotaki et al, 2006; Burge et al, 2006). Choice is shaped by provider quality, GP influence, travel costs and logistics, loyalty to local providers as well as socio-economic and demographic factors. We also know that the consumer mentality will vary according to the severity of the illness and the nature of the treatment procedures. Less is known about the system-wide implications of the choice agenda and the constraints involved when demand outstrips capacity. There has been no systematic attempt to map the negotiation and compromise involved when patient choice meets demand management.

The specific need we are seeking to address here is captured in an intriguing finding from the *National Patient Choice Survey*: '88% of patients offered choice were able to go to the hospital they wanted, with a further 5% having no preference. This compares with 47% of patients not offered choice being able to go to the hospital they wanted and 40% having no preference (DOH, 2010). Managing such imbalances is a key task in all DM/RM systems.

Our review will bring together related ongoing and recently completed work funded by the SDO and NIHR programmes (e.g. Hollingworth (09/1006/25), Asthana (09/2000/40), Dowrick (PR-PG-0606-1071), Roland et al (2006), Clarke et al, 2010) and literature from other policy sectors and countries (eg Dew et al, 2005) to understand key contextual and implementation issues that transcend all demand management initiatives.

Need

Demand management is and always has been controversial territory for the NHS. In putting together this application we encountered, first-hand, many forcibly expressed hopes and criticisms for DM from stakeholders at all levels in the system. There is already a considerable and heated debate in blogs and in the practitioner journals and we have taken steps to express some of these concerns. Two particular needs stand out for us and shape the proposed investigation:

 Because there is a degree of confusion about the different modes and sub-types of DM and because any real system will always consist of a pragmatic mix of strategies, there is a need for some basic explanatory research to clarify the practical process involved in implementing the various systems.

(II) Because there is so much interdependency between demand management and other existing priorities with the system, research is needed to examine the knock-on effects and system-wide challenges that confront the introduction of DM regimes.

To assist NHS decision makers, we propose to conduct a realist synthesis (RS) of current knowledge of demand management strategies within the NHS and from other sectors and countries. Our review will not offer 'absolute verdicts' or suggest 'best buys' on particular schemes, as so much depends on how any particular scheme is implemented and where it is implemented. We aim to answer different questions, with more immediate practical relevance to NHS decision makers – what are some of the core expectations, features and problems of all DM systems and what sort of support do they need to work? Specifically our review will provide:

- A clear description of the different demand management strategies and the programme theories underlying these strategies to enable NHS managers and policy makers to have an understanding of:
- The variety of aims of such strategies
- The dimensions and diversity of the design/organisation of such strategies
- The core underlying mechanisms of demand management strategies by which they produce different intended and unintended effects
- (ii) A clear explanation of the assumptions and contextual influences underlying the major challenges to the implementation of demand management strategies to enable NHS managers and policy makers to address these issues locally; specifically:
- The conflicting motivations that prompt referral
- The varied and sometimes uneven expertise and mandates of participants in referral chains
- The promotion of cost containment ambitions in NHS staff groups who traditionally lack such remit
- The need to regulate provision of services at the same time as providing patients with increased choice of services
- (iii) Identification of the key aspects of health service organisation, implementation processes, funding arrangements and professional cultures which hinder or allow these programme theories to operate successfully to enable NHS managers and policy makers design and target demand management activities to their local contexts
- (iv) Some provisional conclusions for NHS managers and other policy makers about the circumstances in which different types of demand management scheme are likely to be effective and feasible in the NHS;
- (v) A clear description of the different demand management strategies and the programme theories underlying these strategies to enable **future evaluators** of DM/RM programmes to design their evaluations to capture comparable data about the presence and strength of underlying mechanisms and the presence and strength of key contextual factors, so that variations in effectiveness can be better explained.

The structure of our project team will enable us to translate review findings into actionable guidance to support Clinical Commissioning Groups. We have worked with a local group

(H3Plus) in developing this bid. As the new structures emerge, a priority will be to decide on the balance and form of demand management initiatives appropriate to the local practice culture, patient needs and the press of other demands on services. NHS decision makers need to know how to adapt services to local circumstances or contexts. Understanding contextual influences is not a central feature of the traditional modes of systematic review; for realist synthesis, however, it is the mainstay. Gathering such contextual knowledge requires a wide-ranging review drawing upon many different studies underpinned by the full range of research methods

Methods

The proposal is for an evidence synthesis and the proposed research strategy is realist synthesis, as developed by the chief investigator of this proposal (Pawson, 2002; 2006). It is an approach which is finding increasing use in the healthcare field and a number of current SDO projects are making use of the approach (e.g. project 10/1012/03 led by Chambers and project 10/1012/07 led by Anderson). Pawson is methodology advisor to the latter and also a team member of another key SDO project 10/101/51, 'Realist and meta-narrative evidence synthesis: evolving standards – RAMESES' (Greenhalgh et 2011). Pawson has recently completed a major synthesis, funded by ESRC and supported by NICE. Much of this has been published in North American outlets (Pawson et al, 2011a and 2011b) and the method is finding a foothold in Canada (Jagosh et al, 2011) and the USA (Berwick, 2008). Each new project brings learning to the method and the present proposal is intended to amalgamate and respond to all of the recent innovations.

Realist synthesis is an approach within the family of systematic review methods, one that assumes that interventions adapt as they are implemented in different settings, and one that is specifically designed to manage the intricate and uneven bodies of evidence that accrue in primary research on complex interventions. Demand management is one such rapidly evolving arena which doesn't yield well to primary investigation by randomised controlled trial (RCT) or review by formal meta-analysis. Results from a previous SDO funded investigation on the use Threshold Assessment Grids to improve mental health referrals (Slade et al 2006) illustrate the typical pitfalls of the traditional methods. Control group practices outperformed those practices that had introduced the grid. The explanation for the perverse result was the very uneven implementation of the scheme and the very different conditions in which the practices operated. As the authors note 'the main weakness is the "black-box" assumption embedded in trial methodology' (2006: 14). All of the multifarious incarnations of demand/referral management allow for and indeed have often encouraged innovation in implementation. They are all heavily shaped by different institutional and management regimes in which they are located. For this reason we have chosen an approach that concentrates on the ideas, aspirations, or 'programme theories' underlying demand management, the purpose of the review being to consider the extent to which these aspirations are met in practice. Primary studies will be reviewed seeking to interrogate the programme theories, examining their strengths and success as well and their problems and pitfalls. The aim is to deliver an evidence base which advises on the implementation and targeting of DM/RM. As ever in realist analysis, we concentrate on the contingencies - what works for whom in what circumstances in what respects and over what duration,

RS operates with an iterative, six-stage study design as outlined in figure 1, which also locates each phase of inquiry on the 18-month timeline required for this study. Each stage is

annotated below, both with an explanation of the various techniques and with examples of how they will be applied in this study. A full account of the realist synthesis protocol may be located in Pawson (2006: ch 4).

Figure1: Template for Realist Synthesis

1. Identifying the review question



1. Identify the review question. The basic unit of analysis in realist synthesis is not the intervention but the programme theories that underpin it. The hypotheses that justify the programme and provide the reasons why it might work are also the hypotheses to be investigated in realist synthesis. Review thus begins by searching primary materials to identify the justifications, arguments and programme logic of the interventions under review. Programme theories are to be found in guidance documentation, resource centre advice, management bulletins, position papers, thought pieces, advocacy pieces, and critical pieces. Our first task will be thus to elicit and map the full range of programme theories that underpin demand management for planned care. A whole range of mechanisms, operating on quite different first principles, has been brought to bear in the attempt to improve referral profiles peer review, target setting, incentive payments, specialist involvement, education and training, guideline implementation, direct access, second opinion, electronic consultation, assessment services and so on. Realist review begins with a ground clearing exercise, which maps the existing set of programme theories to the particular challenges they seek to overcome. The national and international health services stakeholders in our project team (LM, LW, HS and SM) will be actively involved in this process to ensure that our programme theories are drawn from hands on experience of the NHS and international health context. In addition, to make this 'theory elicitation' process as rigorous and transparent as possible,

we will also hold a 'theory building workshop' with a Project Reference Group of practitioners, NHS managers and patients with first-hand experience of referral management (membership described later in the document). In this workshop we will present examples of the theories we have identified and ask the stakeholders to add to these and then rank order the theories in terms of priority and potential explanatory power. In any particular demand management operation in the field, different permutations of these ideas are likely to be brought to bear. Various combinations of them have been tried at the GP, specialist and organisational levels outlined in the research brief. A crucial first stage in realist syntheses is careful deliberation and consultation on which programme theories to prioritise - which are the programme theories whose further investigation is likely to foster the broadest improvement the implementation and targeting of referral management schemes? In developing this bid we have already engaged with this material and an initial reading indicates that the 'four challenges' outlined above (motivations, mandates, accountability and patient choice) may mark fruitful stating points for inquiry. In a complex family of interventions like demand management, the expectations, justifications, debate and potential challenges in play are almost unlimited. With this in mind we should make it clear that the four main research questions identified are provisional. They should be regarded as 'candidate theories', which may be adapted and which will be extended in the inquiry proper. The national and international health service stakeholders in the project team and the theory building workshop will be instrumental in prioritising the core research questions to be tackled by the review.

2. Searching for primary studies. Searching is carried out in two main stages and will be supported by an Information Specialist (JW). The first, described above, is the 'theory search' and its domain is the background policy documentation and the grey literature described above. Once completed and after the subset of theories to be interrogated have been selected, RS commences an 'evidence search', seeking studies that will provide empirical tests of each component of the theory. Here the search domain covers more orthodox research reports and journal papers carrying empirical investigations of DM/RM interventions. There is no limitation on study design; the search aims for a maximal sample of primary studies employing quantitative, qualitative, experimental, documentary and historical analysis. Both UK and international studies will be sourced. Realist synthesis can inform and be informed by ongoing research as well as published evaluations.

Databases for the searches will include the following:- Medline (Ovid), Embase (Ovid), ERIC (CSA), Science Citation Index (Thomson Reuters), The Cochrane Library (Wiley), HMIC (Ovid), UKCRN Portfolio Database, NHS Evidence, Psychinfo (Ovid), The WHO Library, Agency for Healthcare Research and Quality; Dissertation and Theses (Proquest), Science Conference Proceedings Citation Index (Thomson Reuters), Google, Google Scholar.

Initial search terms will include the following (synonyms, truncations, tools and operators excluded here): demand, capacity, backlog, resource utilisation, bottle neck, process mapping, demand management, referral management, referral management centres, triage services, out-of-hospital assessment, clinical assessment, GP referral, referral gateways, referral guidelines, referral protocols, appropriate referrals, referral feedback, referral behaviour, referral motivations, referral audit, referral targets, referral letters, (condition-

specific) referrals, referral rates, referral costs, referral quality, referral delay, referral trials, referral evaluation, service accessibility, patient choice, choice experiments, accountability, financial control, mandates, expertise, defensive practice, health literacy, primary care, commissioning group, NHS and other institutional terms.

Realist synthesis does not rest with comprehensive, pre-specified search strategies. The key to unearthing the appropriate primary studies for a theory-testing exercise is to use techniques variously labelled iterative, purposive, snowball, citation-tracking or pearling. Search strategies and terms evolve as inquiry advances and understanding grows. For instance, if the theory under research requires more evidence on the reactions of different groups of patients to referral management, then the primary research needed to supply that data might be found in a separate body of research whose primary aim was to compare the behaviour of sub-groups of patients under the choice agenda. This might lead our synthesis, for illustration's purpose, to explore studies such as the London Patient Choice Project (Dawson et al, 2004). Since demand management techniques are part and parcel of all public management it also possible that the search radar will be widened to identify key studies in other sectors. Greenhalgh et al (2004) conducted the most painstaking study of the balance of searching methods appropriate to realist reviews and note 52 % of primary studies utilised in their final report were identified through snowballing.

3/4. Data extraction and quality appraisal. These phases are combined in RS. Different programme theories require substantiation in divergent bodies of evidence. Hypotheses about the optimal contexts for the intervention are tested in comparative outcome data; claims about the reactions of particular groups of subjects are tested using qualitative data; implementation ideas are tested in process research, and so on. Primary studies thus contribute specific bodies of evidence but each primary study plays a different role in the final synthesis and so each fragment of evidence needs to be appraised, as it is extracted, for both its relevance for theory testing and the rigour with which it has been produced.

Quality appraisal will be conducted throughout the review process, as described by Pawson (2006) and go beyond the traditional approach that only focuses on the methodological quality of studies. In realist synthesis, assessment of study rigour occurs alongside an assessment of the relevance of the study and occurs throughout the process of synthesis Quality appraisal is thus done iteratively, on a case-by-case basis, as appropriate to the method utilised in the original study. Where appropriate, we will use relevant methodological checklists (eg CASP) to assess the methodological quality of included studies. We will follow guidance emerging from the RAMASES project, funded by SDO (Greenhalgh et al, 2011) that is producing guidance for the conduct of realist reviews, including the issue of study quality appraisal.

Different fragments of evidence are thus sought and utilised from each study. There is no common 'data extraction form'. Both qualitative and quantitative data are compiled as well as the inferences and conclusions drawn from them. Data extraction thus requires active engagement with each document through note taking and text annotation. Evidence will be compiled, stored and annotated using *NVivo*.

5. Synthesis. The role of synthesis in RS is not to offer a verdict, descriptive summary or mean effect calculation on a family of programmes. Outcomes vary considerably according

to how and where programmes are implemented. What is synthesised, therefore, are all the conditions and caveats that make for programme success. Many of these opportunities and stumbling blocks will have been anticipated in the original programme theories but after a total immersion in the data, more refined theories emerge as the key act of synthesis.

Synthesis takes several forms. At its most basic realist synthesis is a form of 'triangulation', bringing together information from different primary studies and different study types. It may, for instance, make use of: outcome data from studies 1, 2 and 3; implementation findings from study 4, 5 and 6; sub-group findings from study 7, 8 and 9; participant interpretations from study 10, 11 and 12; temporal variation from study 13, 14, 15; contextual comparisons using studies 16, 17 and 18; ... and so on.

Another form of synthesis, particularly useful when commentators and stakeholders disagree on the merits of an intervention is to use the review to 'adjudicate' between the contending positions. This is not a matter of providing evidence to declare a certain standpoint correct and another one invalid. Rather adjudication assists in understanding the respects in which a particular programme theory holds and those where it does not. As an example, consider some of the findings from Evans et al's (2011) study of how the practice of peer review influenced GP referrals. In this particular study, there was a decrease in referral rates but the reduction differed markedly according to specialty, with referral rates in neurology dropping by 16% compared to a reduction of 5% for general surgery. In using the example, we are not, of course elevating this finding to the level of the empirical generalisation, merely to show that under adjudication much of the black-and-white antagonism about demand management resolves itself into shades of grey.

The main form of synthesis in the realist perspective is known as 'contingency building'. All DM/RM schemes make assumption that they will work under implementation conditions A, B, C and applied in contexts P, Q, R. Hypotheses of this type abound. To use the same study, Evans (2011:270) notes that peer review 'might be particularly applicable to practices and areas that have particularly large variations within and between practices'. The purpose of the review is to refine many such hypotheses, the evidence synthesis enabling us to say that, more probably, A, C, D, E and P, Q, S are the vital ingredients. Our syntheses will be discussed and refined at a further workshop with our project reference group to ensure that NHS stakeholders have input into this process

6. Dissemination. The purpose of RS is to improve the implementation and targeting of interventions. Accordingly, dissemination will focus on NHS decision makers responsible for designing and implementing DM initiatives and these stakeholders will be involved from the outset of the review (as recommended in all of the 'research utilisation' literature). Outputs will include actionable guidance to assist NHS decision makers to target and implement demand management initiatives within the specific local conditions in their area and workplace, a dissemination event for local NHS decision makers as well as conference presentations and publications in peer reviewed journals, as described in the following section.

Feedback and iteration. Figure one illustrates a final feature of realist synthesis, namely that it does not follow a simple linear plan. Not all lines of investigation can be anticipated from the outset. A good realist synthesis should have an investigative element. Important programme theories are thus often discovered mid-stream and this requires the reviewers to begin another search for a subset of relevant primary studies, so initiating the process of hypothesis testing over and again.

Contribution to collective research effort

Our research will be wide ranging and thus encounter the aims and the deeds of many different stakeholders in demand management. No study and indeed no review can capture the totality of requisite evidence. We have thus taken care to position this proposal in strategically important concerns and we will ensure the study contributes to the collective research endeavour in the following ways:

Our proposal responds to the suggestion, discussed at the briefing event and noted on page 6 of the research brief, that collectively it will be useful to have coverage of the three identified DM domains. Our study, if funded, would review DM schemes across all categories. The unit of analysis in our proposal is the 'programme theory' which allows us to select and review themes that are common to all DM interventions - how schemes distinguish between 'appropriate' and 'inappropriate' referrals, how to manage tensions involved in the substitution of clinical expertise, and so on. A combination of review and primary evaluation is widely regarded as a powerful strategy in the study of complex systems. Realist synthesis can inform and be informed by ongoing research as well as by published evaluations. It might be possible to forge links across studies commissioned in this call, providing a basis for bringing together studies located in particular specialties or settings. If appropriate, early in the project we would make contact with other funded teams to identify such opportunities for collaborative working. There is a significant chance that specific case studies will encounter the generic themes under review in our project and there might be a corresponding opportunity for the mutual exchange and incorporation of evidence. Further joint work on dissemination strategies, and for example, a national conference aimed at NHS decision makers, would also be beneficial.

We have tried to embody the idea of 'collective research effort' in the composition of our project team. The execution of a realist synthesis cannot be left to technical assistants and the core three person review team (RP, JG, LG) has considerable experience of previous systematic reviews, of the NHS policy domain and, most significantly, of realist methodology. We have embedded this review team within a project team comprising a broader cluster of specialist researchers, NHS stakeholders and international health services expertise. In addition, the project team will also be informed by NHS stakeholders within our project reference group and advisory group. The membership and division of labour of these inputs is described in later sections. Here we note their key function, which is to bring urgent and practically relevant questions to the review table and then to help to disseminate our findings along those channels best placed to act upon them. In short, the team is chosen so that we have a member with practical experience of each of the programme theories that will be interrogated in the review, as well as international health services expertise to explore the influence of the international context on these theories.

Our research topic carries generic interest and our dissemination will build outwards from our own clusters of expertise to local bodies and then onto national and international forums. Initial momentum will be informed by our NHS stakeholders in our project team, project reference group and advisory group and our links with the Primary Care Research Network and the West Yorkshire Comprehensive Research Network. They will provide intelligence on which groups should be targeted and how our findings should be disseminated. For senior NHS managers and policy makers we will produce a briefing which summarises our guidance and the implications for the national implementation of demand management activities. We will hold a dissemination event for NHS decision makers to disseminate our guidance, receive feedback from participants about the guidance and crucially provide a forum for networking and exchange of ideas about using our guidance in practice. In addition, we will disseminate our findings via a number of journal publications targeted at a range of stakeholders and through conference presentations at NIHR HS&DR and HSRN network events and conferences. Pawson has presented at a large range of national and international conferences, including King's Fund and IHI (Harvard), and we are confident that this project can receive this level of exposure.

The science of synthesis is undergoing rapid development and the proposed research can also make an important contribution to 'collective methodological effort'. SDO, together with the Canadian Health Service Foundation funded research in 03/04 to pioneer new methods of research synthesis. There is also a current project in the portfolio (10/101/51) seeking to codify methods and establish standards for realist synthesis and meta-narrative reviews. Given its breadth, we consider that the present proposal would constitute the most ambitious realist synthesis ever conducted and as such would provide a stringent test for the development of the strategy.

Plan of investigation and timetable

Realist Synthesis operates with an iterative and flexible study design illustrated in Figure 1. The timetable below provides details of the activities and milestones at each stage. Key programme theories will be explored simultaneously throughout the review, though our design is adaptive and new lines of inquiry will emerge during the course of the review. The review will be managed to ensure that any modifications will be consistent with delivering outputs to an agreed schedule.

Our review will be carried out in collaboration with different stakeholders who are defined below for clarification but explained in more detail in subsequent sections:

- 1. **Project team**: co-applicants of the proposal who will carry out the review (RP, JG, LG, RL, HS, LM, LW, SM) and support from the Information Specialist, JW.
- 2. **Project reference group**: group of local NHS managers, clinicians and patients who will assist in theory development, shaping the focus of the review and interpretation of findings
- 3. Advisory Group: group of stakeholders with expertise in demand management, realist synthesis and NIHR project management who will oversee the management of the project.

Months 1-3

- Initial meeting of project team to establish ways of working and discuss and elaborate upon candidate programme theories outlined in our proposal
- Recruitment of project reference group via project team, PCRN and LBYRA CLAHRC
- Meeting with information specialist (JW) to design initial search strategies

- Setting up Endnote and NVivo databases
- Conducting 'theory' searches to identify the range of sources of evidence
- Reviewing results of searches and selecting and obtaining sources of evidence based on their relevance
- Annotation and initial quality appraisal of sources of evidence to surface theories within our four candidate programme theories
- Hold theory development workshop with the project reference group to present, discuss and refine initial theories and prioritise the focus of the reivew

Key milestones (Months 1-3)

- Initial overview of the DM/RM strategies to establish boundary of our review
- Development of candidate programme theories for detailed review
- Mapping the range of evidence relevant to the programme theories
- Establishment of working relationships with the project team and project reference group

Months 4-6

- Initial Advisory Group meeting to discuss progress to date
- Meeting with project team to review theory development workshop and advisory group meeting and agree programme theories, research questions and scope of the review
- Formalise theories in terms of context-mechanism-outcome configurations and identify potential expected and unexpected outcomes of referral management programme theories
- Meeting with information specialist to design search strategies to identify evidence underlying the programme theories
- Running 'evidence' search strategies and carrying out other search methods to identify sources of evidence underlying each programme theory
- Reviewing results of searches and selecting and obtaining sources of evidence based their relevance and location within the programme theory chain
- Sorting sources of evidence in terms of their location within each programme theory 'chain' (eg, context, mechanism and outcome)

Key milestones (months 4-6):

- Consolidation of programme theories, research questions and scope of the review
- Compendium different demand management strategies and their underlying programme theories
- Identifying and classifying the volume and scope of the evidence relating to the programme theories

Months 7-9

- Annotation, quality appraisal and conceptualisation of sources of evidence in terms of how they contribute to each programme theory and emerging synthesis
- Contact and discussion with project team topic experts as required
- Conducting further searches as necessary

Key milestones (months 7-9):

• Completion of the lion's share of data abstraction and quality appraisal

Months 10-12

- Provisional synthesis through initial testing of posited context, mechanism outcome configurations and identification of expected and unexpected outcomes of our programme theories
- Develop initial outline of the review and draft guidance for review by project team, project reference group and advisory group
- Hold synthesis workshop to discuss provisional synthesis, guidance and methods dissemination with project reference group
- Second advisory group meeting to discuss progress

Key milestones (months 10-12):

- Develop provisional synthesis of posited programme theories
- Develop draft guidance for NHS decision makers
- Review of synthesis and guidance by key stakeholders

Months 13-15

- Meeting of project team to review synthesis workshop and advisory group meeting, identify areas for theory refinement and development and discuss dissemination plans
- Develop initial dissemination plan and begin organisation of dissemination event
- Revisit existing sources of evidence, conduct further searches, annotation and quality appraisal if necessary to refine and further test the theories
- Draft final review and guidance for NHS decision makers for review by project team and Advisory Group

Key milestones (Months 13-15):

• Draft final synthesis/review of programme theories and guidance for review by NHS decision makers

Months 16-18

- Final advisory group meeting
- Final project team meeting to finalise review, guidance and dissemination event
- Completion of final review and submission to SDO
- Production of final guidance for NHS decision makers
- Regional dissemination event
- Begin to draft manuscript of review for publication in peer reviewed journal

Key milestones (months 16-18)

- Production of final synthesis/review integrating theory with empirical evidence for our programme theories
- Production and dissemination of guidance for NHS decision makers
- Completion and submission of final SDO report

Approval by ethics committee

As we are engaging with patients and NHS staff as collaborators in conducting the research, rather than as participants in the research, the INVOLVE statement and IRAS guidance issued in 2011 indicates that we do not need NHS Research ethics approval. However, our sponsor, the University of Leeds, has advised us to seek approval from the University's Research Ethics Committee prior to the project commencing.

Project management

JG has previously successfully led a large and complex rapid review for NICE on electroconvulsive therapy and will be responsible for the day to day management, coordination and quality assurance of the review. JG will receive regular support and direction from the chief investigator, RP. The review itself will be carried out by JG, RP and LG with input and advice from HS, LW, LM, JW, SM and RL throughout the review but specifically in relation to (1) informing the focus of the review; (2) interpreting the findings of the review and (3) advising and planning on the dissemination of the review. To provide a forum for and coordinate this input and discussion, the whole project team (JG, RP, LG, HS, LW, LM, RL, JW, SM) will meet at four points during the review – at the outset (month 1), after the theory building workshop (month 4), after the synthesis workshop (month 13) and at the dissemination stage (month 17). These meetings will also have a project management function and the achievement of key milestones will be monitored and future tasks reviewed and discussed. Support to organise and minute these meetings, assist in organising the theory and synthesis workshops and dissemination event will be provided by Marie Johnson within the Department of Sociology and Social Policy. In addition, HS, LW, LM, JW and RL will also be contacted on an ad-hoc basis to advise on emerging issues relevant to their expertise. Co-ordination of this input will be managed by JG.

JG will also be responsible for co-ordinating the day to day management of the review itself. JG, LG and RP will meet weekly to discuss progress and refine strategy in the review. References will be managed using an Endnote database. The findings of the review will be managed in a shared N-Vivo database which can hold abstracted data and memos in order to manage data synthesis and theory refinement.

To oversee the management of the review, a **project advisory group** will be set up. This will have an independent chair, Professor Ruth McDonald who was part of the team that carried out a previous SDO commissioned review of outpatient services. Dr Geoff Wong, a GP and realist reviewer and Professor Jenny Hewison, Faculty Lead for Health Services Research at the University of Leeds will also sit on this group. The Patient's Association have agreed to identify a representative for our advisory group and Rosemary Young, a local member of Leeds LinK, has also agreed to act as a member of our advisory group. Should our application for funding be successful, we will also enlist the support of a local clinician and NHS manager to be part of this advisory group.

Public users/public involvement

To ensure that our review is informed by knowledge of the international health context and is relevant to NHS stakeholders and decision makers in order to facilitate the uptake of its findings, we will involve key stakeholders in all aspects of the management and conduct of this review. We have representatives from key stakeholder groups on our **project team**; Laurence Wood is non executive director of the H3Plus Clinical Commissioning Group, Leeds and Chair of the H3Plus Public Patient Advisory Group; Hugh Sturgess is a GP with a Special Interest and Clinical Executive Chair of NHS Oldham and Lisa Maginnis is a Practice Based Commissioning Locality Manager for H3Pus Clinical Commissioning Group, Leeds. Steve Montague is a director of Performance Management Network, an incorporated Candadian company focusing on all areas of performance improvement, including performance, planning, measurement and reporting. The project team will meet regularly throughout the review (with SM joining us by Skype for three meetings and in person for one meeting) as described above to inform the content and contribute to its management.

To inform the focus of our review and the synthesis and dissemination of findings, we will form a **project reference group** of patients, NHS managers and clinicians with experience of or an interest in demand management. This group will meet for two, one day workshops during the review. Depending on the wishes of the patients, we may hold separate workshops with them. If this is the case, JG and LW will attend all workshops to ensure that the views of stakeholders can be combined and brought together. The first workshop (Month 3) will focus on surfacing and developing key theories underlying demand management initiatives and help to refine the focus of the review. The second workshop (Month 12) will focus on interpreting emerging findings from our review and informing our dissemination strategy. Potential participants in the group will be identified through our project team, the Yorkshire Primary Care Research Network and the Leeds, York, Bradford Research Alliance CLAHRC, Directed by Professor Steve Smye.

To oversee the performance management of the project, we will also set up a **project advisory group**. This group will comprise specialists in realist synthesis, NIHR project management, the substantive topic area and patients, NHS managers and clinicians, as described above.

Expertise

The review will be led by **Ray Pawson** (University of Leeds) who pioneered the methods of realist evaluation and realist synthesis in an ESRC-commissioned monograph (Pawson et al, 2004), summarised as a short methods paper in the Journal of Health Services Research and Policy (Pawson et al, 2005), and further developed at book length (Pawson, 2006). He has conducted a number of realist syntheses across a range of policy domains, working with both European and UK clients. The review itself will be conducted by an experienced three-person team of Ray Pawson, Joanne Greenhalgh and Liz Glidewell. **Joanne Greenhalgh** (University of Leeds) previously led a large and complex rapid review for NICE on electroconvulsive therapy and has also conducted a theory driven review of feedback of patient reported outcome measures to clinicians in clinical practice. **Liz Glidewell** (University of Leeds) has co-authored Cochrane reviews on interventions to improve outpatient referrals from primary and secondary care and on interventions to implement clinical guidelines. She has also conducted a review of interventions to predict provider

implementation of evidence based practice. This team will build the initial theory, undertake literature searching to identify evidence to underpin the theory, synthesise the evidence, produce the guidance and disseminate policy and methodological lessons of the project.

Our project team also includes five key stakeholders who will provide topic advice and expertise throughout the review - Roberta Longo, Laurence Wood, Lisa Maginnis and Hugh Sturgess. Roberta Longo (University of Leeds) is a health economist with expertise in hospital financing and regulation and inefficiency in the NHS. Laurence Wood is chair of the H3+ Clinical Commissioning Group Public Patient Advisory Group. Laurence has extensive experience of representing the patient's voice in the governance of NHS services; he is a member of Leeds LINks and sits on the board of the Healthy Leeds Joint Strategic Commissioning Board. He also has considerable systems re-engineering experience across the private sector. Lisa Maginnis is a Practice Based Commissioning Locality Manager for H3plus and has worked with GP practices in Leeds and Stockport to review their referral practices. Hugh Sturgess is a GP with a Special Interest and Clinical Executive Chair of NHS Oldham. He has led the development of the Gateway Referral Service (a form of referral management centre) in his locality and is actively involved in the development of Clinical Commissioning. Steve Montague is a Candadian based management consultant and has been involved in the implementation and evaluation of performance and information management systems for the Public Health Agency of Canada and other Canadian and United States Federal and provincial government departments.

Our project team will also be supported by input from **Judy Wright**, a senior information specialist, who will provide guidance on search strategies. Administrative support to organise meetings and the dissemination event will be provided by **Marie Johnson** in the School of Sociology and Social Policy. We have costed in travel and refreshments for our three advisory group meetings. We have also costed in refreshments and travel expenses for two project reference group workshops and time and travel expenses for patient involvement in these workshops. We have estimated the costs of inter-library loans and printing and photocopying in carrying out the review. To disseminate our findings we will produce guidance on our findings, hold a dissemination event, attend the Health Services Research Network and Primary Care conferences and produce peer reviewed publications (including open access journals) and have requested costs to support these activities. We will also make links with other projects funded as part of this call and have costed in attendance at the SDO welcome event for this call plus an individual visit to each project team.

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