

SDO Protocol - project ref: 10/1012/07

Version: 1

Date: 26 April 2011

The effective and cost-effective use of intermediate, step-down, hospital at home and other forms of community care as an alternative to acute inpatient care: a realist review

Chief investigator Dr Rob Anderson

Sponsor University of Exeter

Funder NIHR SDO

NIHR Portfolio number

ISRCTN registration (if applicable) -

The effective and cost-effective use of intermediate, step-down, hospital at home and other forms of community care as an alternative to acute inpatient care: a realist review

1. Aims, Objectives and Review questions:

Aim:

To produce a conceptual framework and summary of the evidence of initiatives that have been designed to provide care closer to home in order to reduce reliance on acute care hospital beds.

Objectives:

1. To synthesise relevant documentary evidence, using realist and conventional systematic review methods, in order to develop a conceptual framework for describing and explaining community-based alternatives to acute inpatient care.
2. To draw some provisional conclusions about the likely circumstances in which different types of scheme are likely to be effective, cost-effective, and feasible in the NHS

Review questions:

1. What are the community-based alternatives to acute inpatient care which are specifically designed to reduce the need for acute inpatient care, and what are their main aims (intended outcomes)?
2. What are the mechanisms by which community-based alternatives to acute inpatient care (e.g. hospital at home, virtual wards, etc.) are believed to result in their intended outcomes?
3. What are the important contexts which determine whether the different mechanisms produce intended outcomes?
4. In what circumstances (i.e. with which combinations of mechanisms and contexts) are such schemes likely to be effective and cost-effective if implemented in the NHS?
5. In what circumstances (i.e. with which combinations of mechanisms and contexts) are such schemes likely to generate unintended effects or costs?

2. Background:

Community-based alternatives to acute inpatient care may be described in a number of different ways, e.g. “intermediate care”, which has been defined as:

- a community-based alternative to hospital, either to avoid admission completely or to enable early discharge
- short-term (less than six weeks)
- delivered in one or more settings (e.g. patient’s home, care home,

nurse- or GP-led inpatient unit) (Wilson et al., 2008)

Other models of intermediate care have been labelled as “hospital at home”, “admission avoidance schemes” “early discharge schemes” and “step-down care”; the services offered may also include units such as community hospitals and geriatric day hospitals. This review intends to focus on:

services that replace the need for acute hospital inpatient care, in so much as should the service not be available, the patient would then need to be care for in an acute hospital ward.

It will therefore not seek evidence about assessment tools for identifying patients at risk of (re-)admission, unless they are implemented and evaluated as part of a service change which alters the care provided to those assessed at high or low risk. Most schemes such as “referral management schemes” will probably therefore be excluded from the review, unless they involve planned changes to the type of non-inpatient care received. The review will also therefore not explicitly cover new surgical techniques or medicinal advances which reduce recuperation time or allow day case treatment.

Current evidence

A systematic review and individual patient data meta-analysis of hospital at home schemes for admission avoidance showed a significantly lower mortality at 6 months when compared with standard inpatient care. One explanation for this finding is that the trials included in the meta-analysis were small and publication bias cannot be ruled out. There were no statistically significant differences in functional ability or quality of life outcomes for those receiving admission avoidance hospital at home compared with those admitted to hospital (Shepperd et al. 2008). A second systematic review and individual patient data meta-analysis of early discharge schemes reported no statistically significant differences between groups for mortality, functional ability, or quality of life outcomes, though readmission rates to hospital were significantly increased in older people receiving early discharge hospital at home care (Shepperd et al. 2009).

Community-based alternatives to community care have been reported in a systematic review of older people’s satisfaction to favour “intermediate care” services over hospital care. The convenience, comfort, and ability to remain close to other family members were some of the advantages of community-based care that were identified (Wilson et al., 2008). In addition, a Cochrane review of nurse-led intermediate care units within hospitals showed some evidence of improved outcomes for patients discharged after nurse-led intermediate care, but also increased length of inpatient stay (Griffiths et al. 2007).

Research conducted using a Delphi panel of primary care professionals reported a high degree of consensus regarding conditions that could be managed in the community: dementia, chronic obstructive pulmonary disease, kidney and urinary tract infection, cellulitis, abscess and phlebitis, chest infection, pneumonia and influenza, and congestive heart failure (Purdy et al., 2010). Consensus was also reported regarding the low potential for avoiding hospital admission for mental health conditions and acute illnesses in children (Purdy et al., 2010).

Whilst the evidence of effectiveness suggests there are no compelling reasons why

community-based alternatives to acute inpatient care should not be used for adults with certain identified diagnoses, considerable barriers remain to decision-making about the use of such schemes in the NHS. These barriers include:

- inconsistency in the use of the term “intermediate care” (Wilson, Richards, & Camosso-Stefinovic 2008)
- inconsistency in medical condition terminology and categorisation of conditions; for example, dementia-related conditions are rarely categorised as suitable for community-based care (Purdy et al. 2009;Purdy et al. 2010)
- differences between countries in the way that alternatives to acute inpatient care are designed and implemented; substantial differences may exist because of the existing structure of health care delivery in a country (Shepperd et al., 2008)
- lack of understanding about the ways in which these services change (either through adaptation or evolution) when they are implemented in real-world contexts (Shepperd et al., 2009)
- Uncertainty about the number of patients eligible for these services (Shepperd, Doll et al 2009)
- Uncertainty about how the effectiveness of the different models of care is modified by the type of patients targeted (e.g. elderly medical, general surgical) or the case-mix and disease severity of the overall patient population involved.

Thus intermediate care programmes are complex interventions in the sense that they are usually multi-component, their effectiveness is mediated by how they are implemented, and also by the local health service and wider health system context in which they are delivered, and probably also by the preferences and choices of those patients who receive them (Medical Research Council 2008). Understanding what these factors are for different alternatives to acute inpatient care, and given the heterogeneous nature of relevant research data, is crucial for understanding the real-world effectiveness and cost-effectiveness of complex interventions (Anderson 2008;Medical Research Council 2008). There will typically also be variability in implementation both between different schemes as well as within similar schemes (for example, see (Sheaff et al. 2009)).

While the approach of realist review has mostly been advocated for and applied to explaining the *effectiveness* of interventions, the proposed review team believe the approach can be extended to incorporate the economic aspects of service mechanisms, contexts and outcomes. Writing with colleagues in the Campbell Cochrane Economic Methods Group, the proposed chief investigator has advocated the use of realist review methods for making clearer sense of the economic evidence of complex interventions (Anderson 2010;Anderson & Shemilt 2010).

This may be particularly important for the present review for two reasons. Firstly, the underlying hypotheses or programme theories driving some of the shifts to intermediate and other out-of-hospital care may be inherently economic. That is, such service changes seem often to be grounded in the belief that the community-based alternatives should be *no less effective* (in terms of clinical effectiveness and risk of adverse clinical events) than acute hospital care, but at the same time should be less

costly and/or more acceptable to patients. Moreover, with such shifts from secondary to primary/community care, differences in resource use and opportunity costs will be sensitive to both the local service organisational context and the decision context (Coast et al 2000; Anderson 2010). For example, even with the same service design the opportunity costs of hospital at home may be quite different depending on whether the out-of-hospital care is intended as a *substitute* for acute inpatient care (i.e. shifting the location of care, to reduce use of hospital resources) or is a *supplement or expansion* of services (to accommodate growing demand).

Secondly, both the recent Cochrane reviews (Shepperd et al 2008 & 2009) and another review paper (Viney et al. 2001) found great variation in the cost data related to the reviewed effectiveness studies. We further anticipate that effectiveness and cost-effectiveness may be associated with the scale and scope of the intermediate care programmes (Coast et al 2000), which may require the inclusion of explicitly “economic mechanisms” or “economic contextual factors” within the overall conceptual framework. A realist review should identify the range of such economic factors and suggest how they influence the effectiveness, cost-effectiveness and financial sustainability of different programmes.

3. Need:

This proposal is driven by both the expressed need of the NHS (evidenced by the SDO’s commissioning brief), and also the need to provide:

- A clear conceptual framework **for NHS managers and other decision makers** to design coherent programmes with a clearer idea of how they are supposed to be effective and cost-effective, and when and how they may need to be tailored to different local circumstances (Medical Research Council 2008);
- Some provisional conclusions **for NHS managers and other decision makers** about the circumstances in which different types of scheme are likely to be effective, cost-effective, and feasible in the NHS;
- A clear conceptual framework **for future evaluators** of such programmes, in order to design their evaluations to capture data about the presence and strength of underlying mechanisms and the presence and strength of key contextual factors, so that variations in effectiveness and cost-effectiveness can be better explained (Anderson 2008; Medical Research Council 2008); and,
- A clear conceptual framework **for future systematic reviewers** of such programmes, in order to organise findings according to an evidence-based typology of programmes, and allow re-interpretation of the results of existing systematic reviews and meta-analyses.

There is considerable diversity of practice and terminology of models of care which aim to be an alternative to acute inpatient care. In order for NHS managers and decision-makers to apply this large and growing research evidence base, a more coherent explanatory framework is needed which can enable NHS managers and decision makers to have an integrated understanding of:

- The variety of aims of such programmes
- The dimensions and diversity of the design/organisation of such programmes

- The core underlying mechanisms by which they produce different intended effects
- The key aspects of health service organisation, implementation processes, funding arrangements and professional cultures which hinder or allow these mechanisms to operate successfully

4. Methods:

Search strategy

Locating relevant evidence for a realist review entails using a different logic to that conventionally used in a systematic review. The search for evidence in a realist review is iterative, being progressively extended and re-focused (based on the identified sources) as the review progresses and greater insight is attained into the issues concerned. This means that searching may be needed at multiple points in a review as more data is needed to further understanding. A comprehensive pre-specification of the search strategy and search terms is therefore not appropriate, but the aim of each stage of searching can be summarised as exploratory, mapping, testing, and fine-tuning:

The initial searches in a realist review are very broad. The aim of the searching at this stage is to identify a representative range of papers on the topic so that initial ideas about how programmes work (i.e. mechanisms) can be “surfaced” through discussion within the review team and with the topic expert. For this realist review of community-based alternatives to acute inpatient care, the initial representative range of papers will be identified using the database search strategy used in the two Cochrane effectiveness reviews on the topic (Shepperd, Doll et al 2008; Shepperd, Doll et al 2009). However, the study design methodological filter will be removed from this search so that the broader range of papers appropriate for a realist review will be identified. Reviews, commentaries and editorials will initially be included, for example, as these may contain core definitions and recurrent views on the purpose and mechanisms of different forms of intermediate care.

Mapping of programme theory(ies) relevant to community-based alternatives to acute inpatient care – a search to locate the range of underlying theories that underpinned the design and implementation of those schemes relating to the tracer conditions. Topic expert knowledge is vital at this stage for making sense of the programme theory(ies), clarifying the review question(s) if necessary, and refining the focus of forthcoming searches. However, information about how different programmes were implemented or why it was believed they would be effective may also exist in the introduction or discussion sections of empirical evaluations.

Searching for empirical studies to “test” the programme theory(ies) – “to find primary studies that will help interrogate the explanatory model about how the intervention works” (Pawson 2006, p.84). It may be appropriate at this point to use a purposive sample of studies which report empirical evidence about each stage in the explanatory model and which are focussed on evaluations relating to the chosen tracer conditions; a recent realist review (Wong et al 2010) found a maximum variation sample to provide the richest insights into configurations of contexts, mechanisms and outcomes. We propose to use a similar sampling strategy to attain insights that enable

a conceptual framework to be constructed that explains the patterns of outcomes in the selected studies. This will be followed by a “**fine-tuning**” search – to make use of insights attained later in the course of the review.

The precise combination of strategies to use at each of these stages will depend upon the nature of our findings. Whilst we would expect our search to progressively focus in the order in which the strategies are presented below, this cannot be stated with certainty:

- Electronic database search (to identify the initial representative range of papers) using the database search strategy used in the two Cochrane effectiveness reviews on alternatives to acute inpatient care (Shepperd, Doll et al 2008; Shepperd, Doll et al 2009). The trial methodological filter will be removed.
- Electronic database search (using keywords based on the programme theory(ies) identified) in the following databases: ASSIA (Applied Social Science Index and Abstracts), CINAHL, Database of Abstracts of Reviews of Effectiveness (DARE); NHS EED; HTA (all in the CRD database), EMBASE, HMIC (or Kings Fund catalogue and DH data), MEDLINE, PsycINFO, Social Science Citation Index, Cochrane Database of Systematic Reviews, The Campbell Collaboration, and any other relevant databases identified
- Grey literature search (e.g. of websites) using keywords based on the programme theory(ies) identified
- Sources identified through contact with experts in the field
- Browsing of library shelves
- “Cited by” articles search
- Citations contained in the reference lists of included papers

No restrictions will be placed on study types to be included. There will also, in initial searches, be no restriction by language. This is both because evaluation studies from other countries will provide useful variation in health system organisational contexts and models of service delivery, but also because it is known that countries like France and Italy have pioneered some of the models of hospital at home.

At each stage, a ‘maximum variation sample’ of relevant identified sources will be sought in order to obtain insight into as wide a range of alternative configurations of contexts, mechanisms and outcomes. This method of sampling involves selecting studies on the basis of how widely they represent the relevant dimensions of interest in a study – here, the variety of mechanisms and combinations of mechanisms in different contexts will be the basis for selecting studies. The finalised inclusion criteria (i.e. which key mechanisms or combinations of key mechanisms and contexts, become the focus of the review) will be fully documented. Reasons for excluding studies (at full text stage) will be documented.

Review strategy

Data extraction/processing

Whilst being able to present extracts from the sources of evidence to support the synthesis presented in a realist review is of great importance, this is not achieved by “extracting” the evidence (quantitative or qualitative data and/or findings) into pre-

defined data extraction tables. The “data extraction” stage may more accurately be termed “data processing”. This is because of the way that reviewers actively engage with the sources (through note-taking, annotation and conceptualisation) to identify the data that test the emerging hypotheses in the synthesis (Pawson 2006). Data are not simply “classified” in this process, but are used to begin to develop a line of argument that leads into the final synthesis stage.

‘Quality appraisal’

Since the primary purpose of this review is to develop a conceptual framework of how different models of intermediate care are thought to be more effective or cost-effective in different circumstances, the approach to quality appraisal of included sources of evidence in a realist review differs from a conventional systematic review. Included sources are not appraised in their entirety; instead, the contribution that the source can make to the developing synthesis (its relevance) is the deciding factor. It is important to recognise that, for example, an otherwise poorly conducted study may provide important explanatory insights that a realist review would be able to make use of (and perhaps in its discussion section, rather than its results). The careful use of these aspects of sources of evidence, re-assessed for relevance as well as clarity as the review progressively focuses the synthesis, provide the explanatory insights that mark out a realist review. However, wherever possible, quality appraisals of studies from existing high quality systematic reviews (such as the two by Shepperd et al) will be made use of.

Evidence synthesis

The synthesis stage in a realist review has as its goal explanation building rather than a definitive statement about the effectiveness of particular interventions. The goal of explanation building in the proposed review will be to articulate a conceptual framework which helps describe the diversity of community-based alternatives to acute inpatient care in terms of their functional mechanisms. Synthesis of the diverse sources of evidence included in a realist review is conducted through a process of *reasoning* that is structured around the following activities:

- a) Juxtaposition of sources of evidence - for example, where evidence about implementation in one source enables insights into evidence about outcomes in another source.
- b) Reconciling of sources of evidence - where results differ in apparently similar circumstances, further investigation is appropriate in order to find explanations for why these different results occurred.
- c) Adjudication of sources of evidence - on the basis of methodological strengths or weaknesses.
- d) Consolidation of sources of evidence - where evidence about mechanisms and outcomes is complementary and enables a multi-faceted explanation to be built.
- e) Situating sources of evidence - where outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently.

The transparency of a synthesis in a realist review is achieved by documenting these reasoning processes, the way in which they are grounded in the empirical evidence,

and the justification of inferential shifts that occur through this engagement with the evidence.

There are a number of different approaches that can be taken towards synthesis in a realist review; for example, to identify strengths and weaknesses in an implementation chain, or to understand how context impacts upon interventions. However, in this review, we expect the synthesis to focus on judging between different programme theories about how interventions work - doing so will enable the development of a conceptual framework of community-based alternatives to acute inpatient care.

Design and theoretical/conceptual framework

The aims and methodological approach of realist review have been described above in the Background section and preceding Methods sections. In summary, it is based on the realist notions that complex social programmes are effective through the presence of distinct causal mechanisms operating in conducive contexts. Regardless of the standardisation and quality of included study designs, wide variation in the evaluated effectiveness of programmes is thus usually inevitable; transferrable and useful knowledge can then only be generated by building explanatory (i.e. causal) conceptual models which link hypothetical mechanisms and contexts to likely outcomes .

Setting/context

Assessment of the generalisability of different sources of evidence will be assessed both in terms of the potential transferability of findings (how well the programme aims, programme components and its context were described) and the actual similarity of the evaluated service and health system context to the NHS in the UK.

Data collection

Relevant data/information from included studies and reports will be extracted to a standard data extraction form. A sample of these will be checked by the other reviewer for accuracy, for those data extraction fields which involve quantitative data or key information such as study design.

Data analysis

The main approach for data synthesis will be narrative synthesis, using text, summary tables and where appropriate graphics to summarise individual papers/reports and draw insights across papers/reports. Given the overall purpose and methodological approach of the review, a meta-analysis will not be conducted. However, we will re-examine the results of the two previous Cochrane review meta-analyses in the light of the conceptual framework developed.

7. Project Management:

On a day-to-day basis the review will be run by an experienced lead reviewer who is also a competent research project manager (MP). They will get regular support and direction from the review project's 'director' (in this case the Chief investigator, RA). The lead reviewer will plan the detailed timeline of the review and with the project director monitor progress against it, working closely with the information scientist and second reviewer. Given the location of two of the four co-applicants (Oxford and

Leeds) regular (at least monthly) meetings or teleconferences will be held throughout the project including all co-applicants and all members of the review team.

An early draft of the review will be shared with the Project Reference Group (in association with the PenCLARHC)

8. Service users/public involvement:

We will convene a Project Reference Group in order to consult formally with NHS managers and other relevant stakeholders from local government (including social services) and primary care in Devon and Cornwall. The Project Reference Group will meet two or three times in order (i) to gather 'lay'/professional perspectives on the intended purpose and functional components of intermediate care and similar schemes and, at the later stages of the review, (ii) to get early feedback on the clarity of the emerging conceptual framework and its likely applicability within the NHS.

The Reference Group will be recruited and convened using the South West NIHR CLARHC (Collaboration for Leadership in Applied Health Research & Care) which has the specific remit to link the applied health research and NHS communities in Devon and Cornwall. Through its processes it has already established avoidable admissions as a priority topic, and PenTAG's Director, Prof. Ken Stein, is also Deputy Director of the CLARHC and co-lead for implementation).

9. References:

Anderson, R. 2008, "New MRC Guidance on evaluating complex interventions: clarifying what interventions work by researching how and why they are effective [Commissioned editorial]", *British Medical Journal*, vol. 337, pp. 944-945.

Anderson, R. 2010, "Systematic reviews of economic evaluations: utility or futility?", *Health Economics*, vol. 19, no. 3, pp. 350-364.

Anderson, R. & Shemilt, I. 2010, "The role of economic perspectives and evidence in systematic review," in *Evidence-based decisions and economics: health care, social welfare, education and criminal justice*, 2nd edn, Wiley-Blackwell, ed., Oxford, pp. 23-42.

Berwick, D. M. 2008, "The science of improvement", *Journal of the American Medical Association*, vol. 299, no. 10, pp. 1182-1184.

Coast, J., Hensher, M., Mulligan, J., Shepperd, S., & Jones, J. 2000, "Conceptual and practical difficulties with the economic evaluation of health services developments", *Journal of Health Services Research & Policy*, vol. 5, no. 1, pp. 42-48.

Godber, E., Robinson, R., & Steiner, A. 1997, "Economic evaluation and the shifting balance towards primary care: definitions, evidence and methodological issues", *Health Economics*, vol. 6, pp. 275-294.

Greenhalgh, T., Kristjansson, E., & Robinson, V. 2007, "Realist review to understand the

efficacy of school feeding programmes", *BMJ*, vol. 335, pp. 858-861.

Griffiths, P., Edwards, M., Forbes, A., Harris, R., & Ritchie, G. 2007, *Effectiveness of intermediate care in nursing-led inpatient units. Cochrane Database of Systematic Reviews*. Issue 2. Art. no.: CD002214, DOI: 10.1002/14651858.CD002214.pub3.

Medical Research Council 2008, *Developing and evaluating complex interventions: new guidance*, MRC, London.

Pawson, R. 2006, *Evidence-Based Policy: A Realist Perspective* Sage Publications, London.

Pawson, R., Greenhalgh, T., Harvey, G., & Walshe, K. 2005, "Realist review: a new method of systematic review for complex policy interventions", *Journal of Health Services Research and Policy*, vol. 10, no. S1, pp. 23-34.

Pawson, R., Owen, L., & Wong, G. 2010, "Legislating for health: locating the evidence", *Journal of Public Health Policy*, vol. 31, pp. 164-177.

Purdy, S., Griffin, T., Salisbury, C., & Sharp, D. 2009, "Ambulatory care sensitive conditions: terminology and disease coding need to be more specific to aid policy makers and clinicians", *Public Health*, vol. 123, pp. 169-173.

Purdy, S., Griffin, T., Salisbury, C., & Sharp, D. Prioritising ambulatory care sensitive hospital admissions in England for research and intervention: a Delphi exercise. *Primary Health Care Research & Development* 11, 41. 2010. 50.

Rycroft-Malone, J., Fontenla, M., Bick, D., & Seers, K. 2010, "A realistic evaluation: the case of protocol-based care", *Implementation Science*, vol. 5, p. 38.

Sheaff, R., Boaden, R., Sargent, P., Pickard, S., Gravelle, H., Parker, S., & Roland, M. 2009, "Impacts of case management for frail elderly people: a qualitative study", *Journal of Health Services Research & Policy*, vol. 14, no. 2, pp. 88-95.

Shepperd, S., Doll, H., Angus, R. M., Clarke, M. J., Iliffe, S., Kalra, L., Ricauda, N. A., & Wilson, A. 2008, *Admission avoidance hospital at home. Cochrane Database of Systematic Reviews*. Issue 4. Art. no.: CD007491. DOI: 10.1002/14651858.CD007491.

Shepperd, S., Doll, H., Broad, J., Gladman, J., Iliffe, S., Langhorne, P., Richards, S., Martin, F., & Harris, R. 2009, *Early discharge hospital at home. Cochrane Database of Systematic Reviews*. Issue 1. Art. no.: CD000356, DOI: 10.1002/14651858.CD000356.pub3.

Viney, R., Haas, M., Shanahan, M., & Cameron, I. 2001, "Assessing the value of hospital-in-the-home: lessons from Australia", *Journal of Health Services Research & Policy*, vol. 6, pp. 133-138.

Wilson, A., Richards, S., & Camosso-Stefinovic, J. 2008, "Older people's satisfaction with intermediate care: a systematic review", *Reviews in Clinical Gerontology*, vol. 17, pp. 199-218.

Wong, G., Greenhalgh, T., & Pawson, R. 2010, "Internet-based medical education: a realist review of what works, for whom and in what circumstances", *BMC Medical Education*, vol. 10, no. 12.

This protocol refers to independent research commissioned by the National Institute for Health Research (NIHR). Any views and opinions expressed therein are those of the authors and do not necessarily reflect those of the NHS, the NIHR, the SDO programme or the Department of Health.