Full Project Title

Integration and continuity of primary care: polyclinics and alternatives.

Aims and Objectives

Closer coordination of primary care services to improve continuity of care has been a still imperfectly achieved (Baker et al. 2007; Schoen et al. 2004; Boulton et al. 2006) goal of English health policy since the Dawson report (1926). Currently care for older people with complex needs is usually split across three or more teams: general practices; community nurses and community based therapists; and social care. Each has its own clinical governance arrangements, IT and record keeping systems and are rarely co-located. Third sector providers as well as hospital outreach teams for conditions such as COPD complicate co-ordination further. Similarly care for people with specific diseases is disjointed. For example although shared care for diabetes has been a source of concern and innovation for the last two decades; only recently has it been accepted that primary care should lead and coordinate individual care for most patients, with specialist support when required. Horizontal clinical coordination is therefore a potential means of reducing costs and improving quality, including coordination and continuity of care. For similar reasons, recent health policy has also advocated closer vertical coordination, in particular the substitution of primary for secondary care. Substitution of primary for secondary care is being developed for patients with more immediate needs: community based intravenous antibiotics and fluids for cellulitis and dehydration.

The present proposal stems from the requirement to remedy such deficiencies, which requires high quality evidence about which management practices in which contexts are likely to provide the organisational foundation for achieving better health and social outcomes in the most cost-effective manner. Present-day NHS primary care provides an opportunity to make direct comparisons between differently-structured primary care providers in terms of their relative merits and demerits as means of improving the coordination and continuity of patient care. There is also need and opportunity for NHS managers to learn from experience in attempting meet these aims in other publicly-funded health systems similar to the NHS.

The project aims to provide evidence which will:

- 1. Inform and assist policy makers and managers in establishing closely-coordinated primary and community care through polyclinics or other organisational designs that are well-adapted for English NHS policy objectives and local conditions.
- 2. Identify which management practices within polyclinics and other modes of organising primary care tend to promote high-quality coordinated care.
- 3. Enable NHS managers to learn from experience of polyclinic formation and management in the Swedish health system with its similarities to the NHS.
- 4. Contribute to the development of evidence-based organisational theories with wider applications to health system management.

As explained below, pursuit of the above policy goals has led in England to the development of two main types of governance structure: hierarchical organisations (e.g. PCT-managed services) and networks of providers. The objectives of the project are to answer the following *Research Questions:*

- 1. What differences does the integration of primary care into hierarchical governance structures make, compared with network governance, in regard to:
 - (a) continuity of primary care (horizontal coordination)?
 - (b) substitution of primary for secondary care (vertical coordination)?
 - (c) unit cost of care episodes and management costs?

(d) diversity of primary care services?

- 2. In case of hierarchical governance, what difference does ownership make to 1(a)-1(d) above?
- 3. How much discretion does either type of governance structure allow for managerial and clinician discretion and 'performance'? Within each, which clinical and managerial practices tend to promote continuity of primary care, substitution of primary for secondary care and diversity of primary care services? What other contextual factors (e.g. clinicians' skills, informal networks) influence 'performance' in these terms?
- 4. Do the answers to RQ1, RQ2 and RQ3 tend to support or refute the predictions outlined below about the differences between networked and hierarchical governance in regard to continuity and integration of primary care?
- 5. What are the implications of the above for policy and practice in primary care?

Background

Policy Background

A favoured policy solution for improving continuity of care and service coordination in the NHS has been to introduce new kinds of governance structure, which co-exist. Two main types (with variants within each (Peckham & Exworthy 2003)), have developed:

- 1. Networks:
 - (a) local networks (also found in the Netherlands and elsewhere in the EU) linking independent general practices to GPs with special interests, community nursing and other non-medical services. These networks are based on the co-ordination and sharing of care in an extended primary care team.
 - (b) Case management (Boaden et al. 2006).
 - (c) PBC-based networks of general practices who besides commissioning hospital services (Coleman et al. 2009), also commission community and social services (as does Kaiser Permanente (Feachem et al. 2002)).
 - (d) Health centre 'hubs' for referrals from 'federated', usually smaller, general practices
- 2. Hierarchies:
 - (a) Health centres employing primary health and social care workers except GPs (even if general practices are co-located there).
 - (b) Social enterprises and commercial firms, whose development current policy favours and which will promote the development of quasi-markets in NHS primary care.
 - (c) Health centres employing salaried doctors alongside other primary care professionals. Until the recent advent of PCT-managed general practices the sole English instance to date was in Peckham (Ashton & Seymour 1988).

Although sometimes applied to model 1(d) above, the classic meaning of 'polyclinic' is as a single organisation integrating primary medical care, community health and social services within a hierarchical governance structure (model 2(c) above).

Networks and hierarchies rely on different mechanisms to coordinate primary care. Networks retain separate provider organisations, relying on good practice by clinicians, referral systems, information exchange and, in some cases, a central organising body to co-ordinate care across organisational boundaries. An alternative is to establish a single, integrated hierarchy with unified management to coordinate care.

The English NHS continues to rely mainly upon networked governance structures to coordinate primary care. What were initially termed 'polyclinics' were subsequently re-conceptualised as networked rather than hierarchical structures, as 'GP-led health centres'. They have been promoted as much to increase access to primary medical care as to strengthen service

coordination per se. Nevertheless GP-led health centres are also intended to provide, inter alia, care for care groups such as frail elderly people with complex health care needs i.e. care requiring collaboration by two or more providers. Darzi (2007) argued that by co-locating GPs with other community health and social services (or at least, linking services through better use of information and IT) will promote service coordination. 'Integrating care is also a key driver of personalisation because ... there are likely to be fewer appointments on a typical pathway, greater familiarity between patient and staff, better information for the patient, and a more 'seamless' experience for the patient.' (Darzi 2007: p.32). Alongside the Darzi proposals more closely coordinated systems of health and social care more broadly have been pursued in England with the recently launched 'integrated care pilots', and by more localised initiatives where clinical leaders and progressive managers overcome organisational inertia in order to improve quality and performance. For example in one locality in Plymouth social workers, long term conditions managers, social workers have come together as one tream to work with a cluster of practices.

Elsewhere in Europe polyclinics are a standard means of coordinating services, by means of integrating services into unified hierarchical organisations. Polyclinics employ salaried doctors on essentially the same basis as other primary care professionals. According to country, polyclinics may be operated by municipalities (e.g. Sweden, Finland, Catalonia, former Yugoslavia (Grielen et al. 2000)), health ministry (Italy, Portugal), employers (Russia, Germany) or hospitals (Russia) (Saltman et al. 2006).

Of such health systems, Sweden has the closest parallels to the NHS in terms of level of technical capacity, health system funding and political culture (Øvretveit 2003; Øvretveit 2004). In Sweden much was achieved for continuity within primary health care by the creation of Vardcentral primary healthcare centres. These are hierarchical governance structures where municipally-employed general practitioners, nurses and therapists are managed in one unit and sub-divided into multidisciplinary teams. These organizations are also typically responsible for population-oriented public health activities like maternity and well-baby clinics, vaccinations and care in the community but their main activity is providing primary care services. Hitherto the Vardcentral polyclinics were geographically organised; all residents in a given area were served by one such polyclinic. Recent reforms have introduced a list based system, similar to that in English general practice, where patients choose to join a polyclinic's patient list. Narsjukvard model health centres offer, in addition to primary care, hospital specialist services in major specialties and run the local hospital. Vardcentral and Narsjukvard centres are publicly funded and managed. Both are similar in concept to the English idea of polyclinics, and were one of the sources of this concept in English health policy. On the commissioner side, structures such as the Norrtalie integrated local health and social services organization have developed, acting as purchaser on behalf of cooperating local and regional authorities. Independent cooperatives of medical practitioners; and, increasingly, branches of large private companies also exist. In some areas of Sweden there are also many individual or group private practices, like the UK model of general practice, besides private therapists. In these situations, network governance arrangements have been developed to ensure coordination between different primary care practitioners. Of these variants the two most relevant to the present project are the hierarchical Vardcentral polyclinics and the networked model based on private medical practices, for the Swedish health system is the reverse of the English NHS in terms of coordinating primary care. Sweden relies mainly on hierarchical polyclinics with a minority of networked independent general practices.

These developments allow empirical investigations of their advantages and disadvantages which can give valuable lessons for the UK. For example, the same tension between list-based and geographically-based primary medical care populations arises in both countries.

Research Background

Policy implementation and governance research tends to share policy-makers' assumption that changes to governance structures (markets, hierarchies, networks) (Thomson et al. 1991) produce changes in organisational processes, and hence changes in working practice (Donabedian 1980) including by implication the coordination and continuity of health care.

We conceptualise continuity of care as a product of the activity of coordinating care; 'Continuity is how patients experience integration of services and coordination' (Haggerty et al. 2003, p.1220). A designated clinician (typically, a GP or more recently community matron) coordinates a patient's care by making referrals to other professionals or services and by prescribing (authorising) access to medicines, domiciliary help etc. Continuity of care therefore depends upon how actively and for how long that clinician coordinates the patient's care as whole; upon what resources the clinician has access to, from which to assemble the process of care which the patient needs; on the extent to which the necessary patient information is then communicated to and between the other agents involved; and upon the extent to which the patient is able and willing to engage with each agent in turn.

In general terms governance structures therefore influence continuity of care through the processes of establishing:

- 1. a division of labour for care of patients with complex needs, not least identification of a clinician (if any) responsible for overall coordination and hence continuity of the patient's care.
- 2. clinicians' rights to access certain resources (e.g. in hierarchies, senior clinicians direct subordinates to undertake tasks; network members call upon norms of mutual help in kind) and concomitantly closing other routes of access to resources (e.g. by setting up 'gatekeepers' to certain services). Among these resources are the professionals who provide other parts of the division of clinical labour. These rights are exercised through specific mechanisms for referrals, prescribing and other authorisations.
- 3. policies defining, within these broad rights, which resources (services) may or should be provided for which kinds of patients and under what circumstances (e.g. rules of prioritisation, evidence-based practice).
- 4. incentive systems which reward or penalise specific ways of using the above resources.
- 5. concomitantly, systems for documenting and monitoring what the clinician does.
- 6. channels for communicating knowledge, patient information and requests for treatment between professionals and organisations.

If the above are suitably specified it is possible to have good continuity of care as a result of a governance structure which ensures that a number of individuals carry out non-overlapping responsibilities for all the patient's needs. Even so, governance structures seldom define the above so tightly as to leave the individual clinician no discretion. Non-governance factors such as the practitioner's personality, knowledge or skills, informal relationships, access to 'unofficial' resources and the patient's or informal carers' own preferences and resources co-determine how the clinician selects and uses the resources to which the governance structure gives her access.

Different governance structures are distinguished by their different ways of defining and combining the above factors. Primary care pathways enclosed within a single hierarchy cross no interorganisational boundaries. Compared with networks they would therefore promote continuity of care by obviating 'transaction costs' (Williamson 1975), barriers or delays to treatment arising from:

- 1. the referral process.
- 2. discrepant working practices, treatment protocols, IT systems etc. between different organisations
- 3. different relative priority accorded to different care groups by different organisations'

policies, cultures and incentives

4. delays to decision-making, for hierarchies allow decisions to be made by just one person (the relevant manager) and for subordinates to be held to for implementing these decisions. These decision-making structures contrast with the more discursive, egalitarian structures of networks.

These benefits arise from co-organisation, that is integration into a single organisational hierarchy, (6 2004), rather than co-location. Externally this hierarchy might equally be subcontracted to another organisation (e.g. a PCT or other commissioner) or nested within a larger hierarchy (e.g line-managed by a PCT).

Different ownership generates differences in hierarchies' internal incentives, accountability chains (Day & Klein 1987), organisational culture (Cutcher-Gershenfeld et al. 1998; Scott et al. 2003), managerial activities and resources. Current English policy assumes private sector to be more competent than public sector management (Greener & Powell 2008).

Networks have been predicted (Addicott, McGivern, and Ferlie 2007) to allow:

- 1. multiple, flexible care pathways across networks of diverse primary or social care providers. Hence;
- 2. services tailored more closely to individual clients' needs or wishes.
- 3. easier innovation, by adding new providers to the network.

Coordination of primary care networks originally emerges from the division of labour between health professionals and their individual decisions (Provan & Kenis 2008), although many NHS networks are also overtly managed.

Notwithstanding the above predictions, the mechanisms linking governance structure and organisational working practice are not fully understood. Governance structures are evidently not the sole important influence on clinical practice, including the coordination and continuity of care. The management of patients at clinical practice level also depends, at least, upon how organisations collaborate with external partners (Lewis, Baeza, and Alexander 2008; Provan, Milward, and Isett 2002; Provan, Isett, and Milward 2004); organisational and occupational cultures (Flynn 2002; Sheaff et al. 2004; Mannion et al. 2008); how (and how far) the evidencebasing of practice occurs (Allery, Owen, and Robling 1997; Ferlie, Fitzgerald, and Wood 2000; Sheaff, Pickard, and Dowling 2009); relationships between occupational groups (Ferlie et al. 2005; Currie, Finn, and Martin 2008; Heenan and Birrell 2006), degree of decentralisation (Bihan and Martin 2006), teamwork (Øvretveit 1993; Øvretveit 1996; Øvretveit 2001) and personal affinities among the workers involved (McPherson et al. 2001). Questions also arise about how policy learning and path dependency influence the coordination, continuity and guality of care. Since coordination and continuity of care have long been sought, what factors or interests have prevented such apparently beneficial improvements? And is organisational integration into a single hierarchy necessary for achieving these benefits, or can well-designed networks of organisations also do so?

Need

The health need for patients to experience better-coordinated care is that when care is too complex for diagnosis and treatment by a single clinical act, maintaining longitudinal and relational continuity promotes patient trust (R. Baker et al. 2003; von Bultzingslowen et al. 2006; Donahue et al. 2005), adherence (Dietrich & Marton 1982; Ettlinger & Freeman 1981), enablement (Howie et al. 1999), satisfaction (Donahue et al. 2005; Guthrie & Wyke 2000; Saultz & Albedaiwi 2004) and more efficient resource use (Hjortdahl 1992; Hjortdahl & Borchgrevink 1991). Although they would prefer to avoid such choices (Baker et al. 2007), patients appear willing to sacrifice a certain amount of speed of access to services in order to maintain continuity of care (Turner et al. 2007).

Easier and greater patient access to the full range of primary care services helps prevent avoidable morbidity; avoid unplanned hospital admission (Kane 2002) with its disruptive effects on patients' quality of life; and enable patients to live longer in their own homes, avoiding institutional care. These are important aspects of quality of life for frail older people with chronic, complex health problems. Notwithstanding policy changes towards 'Darzi-style' clinics, there can be little doubt that finding better means to meet the complex care needs of frail elderly (and other) patients for coordinated and continuous care is a substantial and enduring organisational problem. Health care professionals are generally well aware of what factors help them to coordinate and maintain continuity of patients' care across organisations, but a range of practical and organisational factors sometimes enable but often frustrate their attempts to do so.

The study design outlined below is intended to identify and describe these obstructing and enabling factors, explaining how they interact with each other and what organisational (governance) arrangements contribute to them. Various studies (see above) describe aspects of the problem of service coordination, but few (except for Shortell, Gillies and Anderson (2000)) attempt to inter-relate the different aspects of service coordination (or its absence) into a single, coherent explanatory account. Studies which directly compare primary care governance structures in terms of the foregoing policy aims are also scarce (but cp. Gravelle et al. 2007; Salisbury 1997). We know of none attempting the comparison proposed here.

Findings from the proposed study would suggest what has to be done to reduce the obstructions and promote continuity of care. Such findings are likely to have practical ('actionable') implications at a number of levels ranging from health-workers' personal behaviour and knowledge to changed referral decisions, managerial practices, and reforms to governance structures, in particular findings of practical value to the commissioners and managers of GP-led health centres and other providers developing more integrated care.

One indication of the expressed need which NHS managers have for research into this topic is that London SHA has commissioned an evaluation of its 'polyclinics' (West 2009). The House of Commons Health Committee has called for evaluative research into the aspects of primary care organisation which this proposal concerns (House of Commons Health Committee 2009). GPAS survey results between 2003 and 2007 show that patients perceive a decline in continuity of care.

The proposed study builds upon and would exploit past or current SDO research into: organisational form and function (Sheaff et al. 2004); networks (Goodwin et al. 2004); professional partnerships and non-hierarchical organisations; and continuity of care (Freeman et al. 2000); and build on concurrent research in the SDO programme by cross-linking the organisation and management of primary and community health services topic themes and, in part, the quality and outcome measures theme, in call PC254; concurrent SDO studies of networks (Sheaff et al; Goodwin et al; Ferlie et al; Currie et al; Guthrie et al.), decentalisation and local health economies (Exworthy et al.), on professional experience of governance (Ross et al.) and incentives and on continuity of care (Byng et al.)

Of the present applicants Peckham is lead and Sheaff co-researcher of the evaluation of London polyclinics, which will give us up-to-date knowledge, and access to data, about London polyclinics. We have also contacted the RAND evaluators of the Integrated Care Pilot sites, who have agreed comparing findings and methods with the present project, if NIHR adopt it.

Methods

As noted, much governance research (and much current policy) assumes that links obtain between governance structures, core organisational processes (working practices) and policy outcomes.

Governance and implementation research typically explores these links by tracing the sequence from policy changes to governance structures and then changes in working practice. We propose a research design which takes the reverse direction, starting from the coordination of services at clinical practice level and then working back from there towards the organisational, and then the health system, context. In realist terms, our research design will trace the relationships between policies, contexts, mechanisms and outcomes by starting from the intermediate process-of-care 'outcomes' of clinical practice. This approach will allow us to describe and explain how non-governance besides governance factors impact upon the coordination and continuity of care in clinical practice (Mur-Veeman et al. 2008).

We therefore propose a mixed-method (cp.Byng et al. 2008) design of multiple nested case studies to do so and so test the above predictions (Bitektine 2008). We will use:

- Nested in-depth narrative case studies, taking as the fundamental unit of analysis ('case' (Yin 1999)) the model(s) of service available for frail elderly people with complex health care problems in a given study site. By 'model of service' we mean the combination of clinical and organisational activities through which services are delivered and coordinated with each other, or even integrated. For each study site three nested case studies will be made, one for each level in the schema used by Powell Davies et al. (2006) and Epping-Jordan et al. (2004):
 - (a) At <u>service (clinical) level</u> to describe its service model for frail elderly patients and its coordination; and to identify which factors, according to patients and professionals (including managers and non-health service practitioners), promote and which frustrate coordination of services and hence continuity of care.
 - (b) At <u>provider organisation level</u> to describe the ways in which governance structures at provider level contribute to producing (or not) these factors and ways in which other organisational factors (culture, team formation etc; see above) contribute to them.
 - (c) At <u>local health system level</u> to describe similarly the ways in which wider NHS governance structures (e.g. commissioning) outside the care provider organisations produce (or not) conditions which promote continuity of care.
- Cross-sectional comparison, across the study sites described below, of the range of services accessible to patients (and conversely, barriers to access); of patterns of referral and communication between services; and of the factors which promote and frustrate coordination and continuity of care at the three levels of analysis (clinical, organisational, local health system) mentioned above.

Settings

English NHS-funded primary care provided by polyclinics and GP-led health centres which serve an equivalent function of promoting continuity and coordination of complex care; and Swedish polyclinics which serve the equivalent function. Since continuity of care and coordination of services are a key component of service quality for them, as is the substitution of primary for hospital care (Kane 2002), we select as a tracer services for frail elderly people. Swedish comparators are included because Sweden is more closely aligned with the English primary care system and policy than some of the more often-discussed international comparators (Bihan and Martin 2006; Leutz 1999).

Sampling

We will study at least one instance (site) of each of the following six types of primary care provider governance structure described above:

1. English GP-led health centres focusing on integrated care (Darzi 'polyclinics'), or other

initiatives establishing integrated care for frail elderly patients, operated:

- (a) by an NHS organisation, e.g. a devolved PCT provider arm (hierarchy, public ownership)
- (b) on the federated model which address the objectives originally proposed for English 'polyclinics' (networked governance).
- (c) by commercial provider or joint venture (hierarchy, private ownership).
- 2. Swedish polyclinics run by:
 - (a) an integrated <u>Vardcentral</u> provider organisation (hierarchy)
 - (b) a local network of private primary medical practice(s) and (other) community health services organisations (networked governance).
- 3. English independent group general practice with employed and out-posted staff, collaborating with community health services and social services (hybrid hierarchical, partnership and network structure).

The last of these in included as a point of reference, being the standard English governance structure for coordinating primary care.

To identify federated model GP-led health centres which have addressed the original objectives of polyclinics we will carry out an initial scoping study, assembling a simple descriptive data-base of these sites. Study sites will be selected from within the middle two quartiles of such providers in terms of size (so as to eliminate atypically large or small providers). From within that band, we will randomly select one site from each of the above categories. For analysing continuity of care, these sites will then be treated as clusters of patients. This approach to sampling yields a theoretically-driven purposively-selected sample of governance structures and a stratified random cluster sample of patients.

In each site our starting-point will be to make purposive qualitative samples of:

- 1. frail elderly patients with complex care needs (two or more providers), or their carers when necessary as a proxy. These patients will be the focus of the nested micro case studies described below.
- 2. health workers in the professions and services involved in caring for these patients with complex needs. We will seek to recruit medical, nursing and other professional respondents, lead managers responsible for tracer service and including the boundary spanner(s) (Williams 2002) between the related primary care providers. These informants will provide data on both the specifics of clinical care and the organisational factors which facilitate or inhibit good care.
- 3. From these informants we will snowball 'up' the organisations to interview the lead clinician(s), the most senior manager(s) in provider organisations, any other informants suggested by our initial professional informants, and then managers at commissioner level. In this way we will identify (further) informants for the case studies at provider-organisation and local health system levels.

Numbers are not significant in such qualitative studies but we will recruit respondents in each category until (theoretical and empirical) saturation has been reached. On the basis of past studies (e.g. Sheaff et al. 2009) we estimate that this is likely to be 10-15 patients and 20-30 professionals (clinicians and managers) per case-study.

Data Collection

To identify federated model GP-led health centres which have addressed the original objectives of polyclinics we will carry out the initial scoping survey, populating a database characterising GP-led health centres as far as possible using secondary data (e.g. PCT websites), supplementing this with direct enquiries by telephone or e-mail when secondary data are lacking. For this purpose we will collect simple descriptive data about the GP-led health centres' size, setting and range of

services.

Data about governance at organisational and health system level will be collected by interviewing the informants in the samples described above and snowballing from them to others capable of describing which primary care services that provider provides and refers to, how those services are coordinated or integrated, how far continuity of care can be maintained, and average total costs. We will collect data on flexible continuity by describing the range and volume of services which each site makes available to frail elderly patients with chronic, complex health problems.

Continuity of care is considered important in primary care, particularly by patients themselves. Different components of continuity of care (Bacharach 1981; Freeman et al. 2000) have been defined and operationalised. We will focus on:

- Management continuity of care, the co-ordinated and smooth progression between complementary clinicians and services (nursing, medical, physiotherapy etc.) (Fortney et al. 2003; Haggerty et al. 2003). It implies continuity of access (Bacharach 1981), i.e. absence of breaks in contact with services during long-running health problems (Johnson et al. 1997). It also implies flexible continuity, the ability of care to adjust, with minimum disruption for the patient, to changes in a person's life ('comprehensiveness', 'holism', 'cross-sectional continuity') (Byng et al. 2007).
- 2. Relational, i.e. personal and therapeutic, continuity (Haggerty et al. 2003), the provision of care over time from as few professionals as possible.
- Informational continuity, whose components are effectual information transfer and good communications between professional in separate teams, departments and organisations.
 All the above presuppose longitudinal continuity. To broaden the criteria of continuity beyond just the longitudinal aspect encompasses many key markers of quality of care for people with complex needs and long term conditions. We will however also consider other key markers of quality care such as the extent to which evidence informed care can be practised, the involvement of individuals in self care and decision making. We take the following observable features as evidence of continuity and coordination of care:
 - 1. A care manager or case co-ordinator (e.g. GP, community matron) role is explicitly identified (e.g. in policy documents)
 - 2. For a given patient, the same person fulfils this role continuously.
 - 3. Each patient has a shared care plan or goal
 - 4. The case coordinator reviews the patient's circumstances and if they change alters the resources (services etc.) offered.
 - 5. The patient contributes to self-care and decision-making, especially at key transitions.
 - 6. Absence of interruptions or gaps to the provision of care, or of changes of provider, during the period of the care plan.
 - 7. Transfer of information and sharing of records between workers and between organisations

To describe how these components of continuity (and high quality care more generally) were or were not produced, and to identify factors which aid and which impede coordination and continuity of care, qualitative interviews are the necessary means of data collection from health professionals and from patients. We will collect data on these aspects of continuity of care by making nested case studies of individual patients. At the clinical (service) level these case studies will describe the quality of coordination (or coordination) of the patient's care. These micro case studies will collate these data from patient records, interviews with patients and with practitioners. Patient interviews will include completion of a structured questionnaire including a range of organisational and individual indicators and descriptors of continuity; and open questions aimed at unpicking the barriers and facilitators to continuity of care and the specific role of context in achieving it. The practitioner interviews will also contribute to data collection for the organisational level of analysis in the study.

We will recruit patient/carer informants either directly or through the auspices of the respective clinical or service teams. We will emphasise to potential informants that patient participation is voluntary, will not affect their care and they can withdraw at any time without giving a reason and without any change to their care resulting. Ethical approval in these terms will be sought prior to fieldwork (see below). Interviews will be recorded (with permission), last approximately 45-75 minutes and be conducted at a time and location convenient for respondents. Informant anonymity in the dissemination of findings will be guaranteed.

In any London sites, data which are not already collected as part of the London polyclinic evaluation and shared between the projects will be collected for the present project as a supplement to data collection for that evaluation. We have written confirmation that fieldwork for the Swedish cases will be conducted by JO and the Karolinska Institutet.

Data Analyses

For each study site we will analyse the data in the same sequence as data will be collected, moving 'upwards' from clinical practice through the nested levels of the health system 'context', including governance structures (Fulop et al. 2006):

- 1. Clinical care level, equivalent to micro- and meso levels in Powell Davies' et al. (2006) and Epping-Jordan, Pruitt, Bengoa, & Wagner's (2004) schema.
- 2. provider organisation or 'service' level (this level and (3) are together equivalent to 'macro' level in the aforementioned schema)
- 3. health system level (that of whole governance structures and their interactions)

In this way we propose to expose more precisely than in previous studies the links mediating governance structures and clinical practice.

At clinical level we propose the following sequence for identifying and separating the effects of governance and non-governance influences on continuity of care:

- 1. We will identify which health worker(s) if any are responsible for coordinating patients' care; what this coordinating role consists of; and whether for each patient a named clinician undertakes this role.
- 2. We will then ask these coordinators how they undertook this coordination, in particular what relevant resources:
 - (a) they had could refer the patient to or prescribe, and of these, which resources were accessed:
 - i. through health system governance structures?
 - ii. by other means (informally' or 'unofficially')?
 - (b) they lacked, either because governance structures denied access to them or for other reasons (e.g. such resources did not exist in the locality, clinicians did not know about them).

To answer the second question we will collate the data describing care coordination and continuity in each site by using a data grid (already developed for another SDO-funded project) which tabulates patients' contacts with different providers (health care resources) for different problems, revealing specific patterns (or gaps) in the continuity of care. Data collected in response to these questions will indicate what part governance structures played in enabling (or preventing) continuity of care for service users, and what non-governance factors did.

For the purposes of comparing the effects of governance structures on continuity and coordination of care, we will not attempt to combine data about each of the seven observable aspects of continuity listed above into a single measure or score. For that would abstract from any qualitative

differences in the ways in which the different governance structures enable (or impeded) clinicians in producing continuity of care. Rather, we will profile each governance structure in terms of how far it, or other factors, produced (or not) the seven observables listed above.

For each site, we will then use data from the provider-organisation level case study to analyse the ways in which, and the extent to which, the patterns of continuity of care found at the first stage of analysis reflect the governance structures in that site and/or other factors such as those noted above. We will then make a similar but broader analysis to analyse the ways in which, and the extent to which, the provider-level factors which affect continuity of care reflect in turn factors (including but not limited to governance structures) in the local health economy. In doing so we will attempt to elicit the programme theory underlying the specific model of coordination and continuity which each study site represents. To link the three levels of analysis we will apply an analytic framework combining (but elaborating) the conceptual frameworks used in two of the previous SDO studies (Freeman et al. 2000; Sheaff et al. 2004) mentioned above, summarising the data in context -mechanism -outcome matrices. We will also make an Inductive qualitative analysis to reveal any patterns and emergent themes not anticipated in the aforementioned frameworks.

Using the same analytic frameworks in each site will enable us to compare the study sites systematically, revealing similarities and differences in the relationships between continuity of care and governance structures in each or (putting it more concretely) similarities and differences (in terms of continuity of care) between GP-led health centres, commercial providers, independent general practice, case management and polyclinics including the Swedish polyclinics. These analyses will answer RQs 1,2 and 3.

We will also undertake hypothesis-testing by comparing the predictions outlined above with the results of the above analyses, thereby answering RQs 4 and 5. In particular we will distinguish the implications of co-location and of co-organisation (hierarchical integration) of services.

We will compare the above findings with published national data-sets to assess the empirical generalisability the findings across England, but will rely mainly upon the theoretical generalisability of our findings to make (cautious) generalisations from our findings to the wider NHS. The theoretical generalisability of findings from the above analyses is provided by the following methods:

- 1. The analytic framework for the organisation and health system levels is one of medium generality, describing links between organisational environment, structures, productive processes and outcomes. It has been applied in previous SDO studies to compare empirical findings about organisational structures and what policy outcomes they tend to produce across organisations and networks (Sheaff et al. 2009), and across economic sectors and countries (Sheaff et al. 2004).
- 2. The methodology of realistic evaluation is intended to identify the mechanisms which produce (or not) coordination and continuity of care in the different organisations studied (Byng et al. 2005; Pawson & Tilley 1997). The specification of a mechanism is inherently generalisable, as is the analytic concept of a 'programme theory' which we will also apply during the analysis.
- 3. The concepts and analytic framework applied at the clinical level for analysing continuity of care are also of medium generality. They have already been applied in another SDO study (CoCoA; Byng et al.).

In contrast to experimental research designs, realist evaluation seeks to identify (rather than abstract from) any non-governance factors which 'confound' cross-country comparisons of the effects of (in this case) the effects of governance structures upon continuity of care. In comparing across the health systems we will check for points at which English and Swedish study sites have similar governance structures but differences in the observable aspects of continuity of care. Such

differences may then be attributed to differences in the non-governance context (e.g. clinicians' interpersonal skills, local 'cultures' of the patient populations).

Comparison between the English and Sweden institutions can be expected to be meaningful for English health policy in several ways. First, detailed understanding of forms of organisation which do not exist in England provides a 'proof of concept' for these types of organisation and a stimulus to considering organisational options which English policy debate tends to pass by. If it then appears worth attempting experimentally introducing similar organisations in England, a comparison of the two health systems can indicate what governance structures and other conditions (e.g. levels of funding, skill mix, informatics support) the Swedish organisations presuppose, hence what conditions would have to be confirmed, or created, in an English PCT to make such an organisational innovation possible. That is, it would indicate the feasibility of such experiments. Third, where governance structures do appear similar in the two health systems (e.g. management of some non-medical primary care services) the comparison can be used to expose what difference is made to continuity of care by non-structural factors such as the choice of service objectives, management practices, and local micro-political and other informal relationships. Even if it transpires that governance structure has little impact on continuity of care – in that a Swedish polyclinic model and networked provision sustain equal levels of continuity of care - the project would then have evidenced instead the importance of commissioners', clinical leaders' or managers' discretion in deciding that continuity of care is critical, stipulating it in contracts and making sure it is implemented. Confirmation of a null hypothesis about governance structure would also be meaningful for English health policy.

Contribution to collective research effort and research utilisation

The statement of need above notes existing research which the proposal builds upon and complements. Besides the main project report for SDO the following outputs will result:

- 1. Peer-reviewed publications in academic and scientific journals; and conference presentations, including if SDO wish an annual SDO conference.
- 2. Translation and wider dissemination within the UK of Swedish materials describing and evaluating the polyclinic systems found there.
- 3. Briefing reports for policy-makers and practitioners.

To promote knowledge mobilisation and hence research impact on NHS management we proposed:

- 1. Creation of a website with forum for information exchange about GP-led health centres, polyclinics and equivalent organisations. At the end of the project we will offer it to PenCLAHRC for ongoing maintenance.
- 2. During the study we will ask informants at the study sites what focus and presentation of findings would be of greatest practical use to them. We will ask the same question of the CLAHRCs for the study sites.
- 3. Presentation of project-wide findings and their implications for management back to the English study sites, offering sites the option of a seminar per site or a joint cross-site workshop.
- 4. Exchange of findings and background materials with the evaluation of London polyclinics which will run concurrently and in which Peckham and Sheaff are involved; and with the evaluation of the integrated care pilots.

Project Plan of Investigation and Timetable

Our plan of investigation is to undertake sequentially the following phases of work:

- 1. Approvals: Finish obtaining ethical approval, begin desk-based scoping research. Recruit RF (08/2010 01/2011). Approvals have become increasingly time-consuming to obtain.
- Preparation: finish off scoping research (this will continue after ethical approval only if primary data collection is necessary), select English sites, negotiate access and obtain research governance permissions (another increasingly time-consuming step), develop analytical framework and (once we have approvals) pilot data collection instruments. Identify interviewees (England). Set up Swedish fieldwork. (02/2011 - 07/2011)
- 3. Fieldwork: over 18 months, to cover one whole annual planning and management cycle. Translation of Swedish materials as necessary. (08/2011 - 01/2013)
- Analysis: analysis will begin as data start to come in, collecting in parallel any supplementary fieldwork data shown necessary by the ongoing analysis, writing-up (6 months). (01/2013 – 08/2013).

Website formation, feedback to study sites, reports to SDO and other knowledge mobilisation will take place concurrently, mainly during phases 3 and 4. Table 1 gives fuller details and a time-line.

	Months											
Activity	1	2	3	4	5	6	7	8	9	1 0	1	1 2
2010												
Prepare ethics application, obtain approval(s)								•	•	•	•	•
Assemble sampling frame for study sites (scoping)								•	•	•	•	•
Select study sites												•
Negotiate access and RG approval for study sites												•
Document-based policy analysis (of programme theory)								٠	٠	•	•	•
Prepare and pilot data collection instruments								٠	•	•	•	•
2011												
Prepare ethics application, obtain approval(s) (ctd.)	•											
Assemble sampling frame for study sites (scoping) (ctd.)	•											
Select study sites (ctd.)	•											
Negotiate access and RG approval for study sites (ctd.)	•	٠	•	٠								
Document-based policy analysis (of programme theory) (ctd.)	•											
Prepare and pilot data collection instruments (ctd.)	•											
Select patients for interview		٠	•	٠								
Case study fieldwork		•	•	•	٠	•	•	٠	•	•	•	•
Data entry, cleaning, analyses										•	•	•
Set up website							•	٠	•	•	•	•
Report(s) to NIHR-SDO	•						•					
2012												
Case study site fieldwork (ctd.)	•	•	•	٠	٠	•	٠					
Policy-maker interviews		•	•	•	•	•						
Comparative analyses of case studies							•	•	•	•	•	•
Data entry, cleaning, analyses (ctd.)							٠	٠	٠	•	•	•
Supplementary data collection if indicated												•
Report(s) to NIHR-SDO	•						٠					
2013												
Supplementary data collection if indicated (ctd.)	•	٠	•	٠	٠	٠	٠					
Writing-up		٠	٠	٠	٠	٠	٠					
Report(s) to NIHR-SDO	•											
Final report write-up and submission	_						•					
Prepare publications, further dissemination	•	•	•	•	•	•	•	•	•	•	•	•

Table 1: Project Plan and Timeline

Approval by Ethics Committees

Because we will be collecting data from NHS patients and staff on (mainly) NHS premises the English part of the study will require ethical approval which we will seek, with the concomitant applications for research governance approvals, through IRAS. The main ethical requirements of the study are to:

- ensure anonymity of the informants and any organisations which (for purposes of the research) they represent. Pseudonyms will be substituted when the data are cleaned and in all published material. Data will be stored securely, in particular the lists linking informants' identities to pseudonyms.
- 2. obtain informed consent from informants. Only adult patients without serious cognitive impairment will participate in the research. Data collection will be timetabled to allow them time to reflect upon whether they wish to do so. Translation will be offered for any English patient interviewees whose first language is not English. Swedish patients will be interviewed in Swedish by a native speaker.
- 3. make clear to informants their rights to withdraw at any time without adverse consequences and without giving a reason. Participant information sheets will state informants' rights not to participate or to withdraw. Such materials will be included in the IRAS application.

As this is a non-clinical study ethical issues concerning the physical safety of patients due to non/intervention do not arise.

Project Management

Overall project management will be the responsibility of the lead applicant (Sheaff) as will the detailed management of the English element of the research. The Swedish element will be project-managed by Prof. John Ovretveit on behalf of the Karolinska Institutet. The applicants will meet regularly (at project start, then six-monthly or more frequently if circumstances require, and at project end). In between communications will be by telephone or video conferencing, or e-mail, as required.

Engagement with Service Users and NHS Stakeholders

Service users will be involved in the project as informants, indeed as one of the two sets (with practitioners) as key informants. Data collection instruments will include open, free-text questions and all informants will receive information saying how to contact the research team if they have comments, feedback or suggestions to make, either about the services being studied or about the research itself. We will consult the RCGP Quality of Care Group; and follow INVOLVE's guidance (http://www.invo.org.uk/) about engaging with users.

At the outset of the study we will ask the SW Peninsula CLARHC, to comment upon and advise us how they would wish us to elaborate the above research questions and themes. (RS is PenCLARHC executive member.) Through PenCLARHC we will consult not only NHS managers and clinicians, but also representatives of patients and of the general public who participate in the organisations and networks which subscribe to PenCLARHC.

As findings emerge we will share and test them with stakeholders through inviting at least two

stakeholders from each study site (one manager and one clinician) to workshop intended for preliminary 'reality-checking' of the findings. Our invitation will extend to contributors from the Swedish health system and the private sector providers besides NHS stakeholders. These contributors will be invited as speakers.

Expertise and justification of support required

Expertise

In combination, the applicants have substantial experience in researching, and publication about, continuity of care, primary care, health system governance, and international health systems:

JO: Research expertise in quality and safety, health management, organisation, cross-national evaluation, inter-professional cooperation, health reforms, organisation of allied health professions. Has knowledge of Scandinavian forms of polyclinics. JO's publications include study of coordination through integrated primary care teams, health reforms and governance in the UK, Scandinavia and elsewhere.

ME: Research expertise in health system governance, decentralisation of health care, professionalmanagerial relations and policies to tackle health inequalities / social determinants of health. His research has largely focused on primary care and has been mostly funded by the NHS, its research agencies or the Department of Health. He has first-hand research knowledge of the US health system as a Harkness Fellow in health-care policy.

RB: General practitioner in a GP-led health centre and with special interest in mental health, previously a Professional Executive Committee member. Now a medical academic with expertise in continuity of primary care services, realistic evaluation, long term conditions, shared care. RB has research experience and publications on the subject of continuity of primary care for hard-to-reach patient groups such as offenders and people with long-term mental health problems.

RS: Research experience in primary care organisation, health system reform, international health systems, case management, social network analysis. Has knowledge of central and east European polyclinics, including publications about Russian variants. RS has published on consumer research and marketing in health care, and about patient needs.

SA: Has research experience in primary care networks, rural polyclinics, resource allocation mechanisms and formulae for primary medical care, inter-agency collaboration and models of public health, and equity In the provision and distribution of primary health services.

SP: Current research is on decentralisation, access, choice and utilisation of primary care, health system performance and performance indicators, organisation of general practice and diversity of health care provision. He leads the evaluation of London polyclinics.

Justification of support

A research topic of this complexity requires inputs from multiple disciplines (see expertise), which the composition and therefore cost of the research team reflects. These researchers will assist in collecting data from respondents in the field and each will coordinate data collection in one or more sites (i.e. each site will have one lead researcher responsible for coordinating data collection in it). This will require dedicated time. Creation and maintenance of a database and undertaking

fieldwork in possibly widely-dispersed English sites requires a dedicated research fellow. Travel and subsistence costs assume that study sites are dispersed and allow a sum for meetings between the English and the Swedish researchers. The overlap between researchers between this study and the London polyclinics evaluation means that the project obtains some of the English data at marginal cost only.

We will make the Swedish case studies by using Swedish researchers who are already on site and have the health system and linguistic expertise required rather than send British researchers to Sweden to collect data. This is also the most economical way of collecting the Swedish data. The Karolinska Institutet (MMC) will also contributing the majority of the Swedish costs for this project from their own budgets. For the Swedish element of the study, 30% of budget would be contributed from the SDO grant, 70% by MMC internal funds or a separate Swedish research grant. Thus the SDO budget contribution to the Swedish study would be £15,000 (of the total Swedish study costs of £50,000 = SEK 630,000). These costs are a very economical way for NIHR to obtain an international collaboration in the study.

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