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Networking

What is the role of local enhanced services in building clinical research facilities in primary care?

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The implementation of a revised government strategy for UK health research led to a reorientation of primary care research, largely focused on recruitment to, and involvement in, clinical trials. This reorientation prompted consideration of new approaches to developing clinical research facilities able to deliver this agenda. The provision of local enhanced services (LES) allow primary care organizations to provide additional services and thereby offer potential for involving primary care staff in clinical research. This paper describes the development and evaluation of one such LES scheme in the East of England, and highlights potential barriers and facilitators to progress.

Key words: clinical research; local enhanced services; primary care; research capacity

Introduction

This paper explores how a recent service innovation – a scheme for local enhanced services (LES) for primary care clinical research – can help to build research within primary care settings and improve access to clinical studies for local populations. We consider how this type of innovation fits with recent national health research policy and describe the development of one such scheme based in the East of England, reporting key findings from an evaluation of the scheme undertaken in 2008. Our intention is to highlight barriers and facilitators to progressing LES schemes and thereby feed into the strategic development of research.

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Why are LES schemes relevant to primary care research?

Local enhanced services officially came into effect in England in April 2004, allowing primary care organizations to provide additional services. At that time, 'clinical research' was not listed within national guidance as one of the options for enhanced payments. However, local organizations soon recognized the potential of LES as a prospective means of developing clinical research facilities in primary care.

During the same period, the government published a new strategy for UK health research (Department of Health, 2006) that led to the reorientation of primary care research around eight clinician-led local primary care research networks (PCRNs; Department of Health, 2005), with a primary goal to increase the number of patients recruited to, or involved in, clinical trials

(Shaw and Greenhalgh, 2008). Implementation of the strategy initially focused on infrastructure, with a growing emphasis on the importance of research at the NHS coalface (National Institute for Health Research, 2008). As a result, local organizations such as comprehensive local research networks (CLRNs) – organizations that act as the primary vehicle for providing infrastructure to support research involvement and wider governance – are increasingly concerned with developing research infrastructure and have directed their attention to LES as one possible means of assisting with this. Local PCRNs and CLRNs work in close collaboration, with local PCRNs facilitating research and CLRNs focused on strategic planning and deployment of research support infrastructure (including channelling of resources). In September 2008, of the 25 CLRNs in England, 14 had a LES scheme or something similar planned, or in place, to support local research practices (Harding, 2008).

Since 2004, government strategy has sought to reorient health research largely around clinical trials (Department of Health, 2005; 2006), with primary care regarded as an important vehicle for recruiting patients into such research (Shaw and Greenhalgh, 2008). Varied approaches have emerged to ensure capacity for such activities, including offering financial assistance to practices in order to facilitate involvement in studies listed on the National Institute for Health Research (NIHR) portfolio (a dedicated database containing details of eligible studies across primary care and other topics such as diabetes). LES schemes typify this approach (see Box 1) and appeal to organizations allied to primary care that are seeking to implement national policy whilst simultaneously building local research capacity. The aim for such organizations is to develop capacity for accessing greater numbers of patients by providing their local health services with the skills, tools and protected time to participate in NIHR portfolio research.

Case study: a pilot LES scheme in Essex and Hertfordshire

So what can LES schemes achieve? To answer this, we present a case study of one such scheme initiated in Essex and Hertfordshire CLRN, the aims of which reflect those outlined in Box 1. Our case study draws on findings from an evaluation of the scheme (Shaw, 2008), involving analysis of 11 practice-specific 'progress logs' (recording information relevant to each practice's involvement within the LES pilot scheme) and 'generic communications logs' (eg, relating to communications around identifying and hosting clinical studies). All anonymized logs were included during the period April to October 2008. Data were analysed for emergent themes and focused on potential barriers or facilitators to achieving the original aims of the LES pilot. Anonymized data excerpts (in italics) are presented below in order to illustrate key points.

Box 1 Example aims for a LES scheme for primary care clinical research

1. To increase local primary care services participation in clinical studies in the NIHR portfolio.
2. To create a quality- and performance-driven sustainable environment for developing primary care clinical research sites.
3. To identify local champions and extend their involvement through 'natural selection' processes.
4. To develop effective ways for collaborating with other research networks and other research organizations.

Early stages: developing the pilot scheme

The first pilot LES for primary care clinical research was established in Essex in May 2007, with a view to building research capacity and expanding access to new populations. Phase One of the pilot focused on bringing local stakeholders – primary care organizations, research networks and support units – on board. This initial phase helped to facilitate joint working and investment of transitional funds to support the scheme and was fundamental to future success.

Phase Two began with a competitive call for practices interested in joining the first wave of the scheme. A panel representing primary care trusts (PCTs) and higher education from across the locality reviewed applications and selected 11

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Box 2 Overview of financial and practical support provided to pilot practices

- Each LES practice was allocated a budget to fund 3.75 hours per week (0.1 whole time equivalent) for a Band 6 Nurse post (approximately £3900), with each funding allocation being weighted against the practice list size (7000 registered patients per 0.1 wte)*. No restrictions were placed on practices to fund nurse time only.
- One-off grant of £500 to set up administrative/archive systems.
- Provision of standard policies and procedures associated with research to ensure compliance with relevant legislation and standards.
- Access to (no fee) training via the NIHR clinical research network.
- Practical assistance from the dedicated LES coordinator (Band 7, CLRN funded) with for example *Research Ready* self-accreditation and study set-up.
- Assistance with developing practice research site profile (including, eg, documents detailing research interests and, capacity to recruit).

*This 'weighting' approach was informed by a review of previous research activity in local primary care, which indicated that practices with a list size of six to eight thousand patients successfully participated in one to two studies if their staff had 2–4 h per week protected for research activities.

practices (one having had no experience of research, seven of student research and qualitative studies, and four of clinical studies). All practices were funded for a period of one year (from 1 April 2008) and provided with practical support and resources via Essex and Hertfordshire CLRN (see Box 2). Practices were required to achieve a number of deliverables (details from authors), the most significant being to recruit patients from at least one clinical study selected from the NIHR portfolio and undertake *Research Ready* self-accreditation (thereby indicating research governance awareness and compliance; Royal College of General Practitioners, 2007).

The appointment of a LES coordinator (0.6 full-time equivalent) brought concrete benefits in terms of providing support to practices (eg, introducing the NIHR portfolio) and interacting with the wider research infrastructure (eg, facilitating research governance processes).

Facilitating research capacity in primary care

At nine months into the pilot, seven practices had passed the *Research Ready* assessment scheme (the others being in progress) and all had at least one clinical representative at a voluntary workshop run for LES practices. In addition, the pilot facilitated involvement in research (eg, getting novice practices involved in undertaking clinical research), aided by the availability of LES staff to actively promote portfolio studies, offer advice and practical support, and sustain local interest in clinical research.

The LES scheme also facilitated research systems and procedures. For instance, the requirement to undertake *Research Ready* assessment helped to effectively manage research governance requirements (eg, making practices address issues such as 'dealing with inducements'). This was particularly important, given that most practices had limited prior involvement in research. A total of 25 practice staff – including general practitioners (GPs), practice nurses and managers – also undertook good clinical practice (GCP) training, ensuring eligibility for participation in available clinical studies.

Study involvement is generally accompanied by funding for research costs but not for development of systems and procedures. Support from the LES scheme was therefore welcome, allowing, for instance, for central development of standard site files and finance templates for use by all practices. However, over half of the practices reported capacity-related issues, such as gaining protected time for research within a busy practice, loss of staff and pressure on clinical services detracting from research time, or lack of space to take on larger studies. Such issues were not insurmountable with one group of three practices establishing a research collaborative, allowing for dedicated staff and space.

Hosting research studies

During the first nine months of the pilot, and following over 30 expressions of interest in

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portfolio studies, 10 practices agreed to host at least one portfolio study (with the remaining practice on the brink of hosting and three practices already hosting two studies). Practices were influenced by a range of factors when deciding to host studies: in line with wider literature on recruitment (eg, Graffy *et al*., 2009) these included clinical relevance, remuneration, enthusiasm of practice staff and available training.

There were significant barriers to hosting studies. Some of these were specific to practices and/or the scheme (eg, lack of practice facilities, complex study design, problems liaising with study teams and securing practice buy-in to research participation). Others were specific to the wider research environment (eg, despite expressions of interest in studies, these were sometimes rejected by the clinical trial team due to practices being considered geographically too far away).

The most significant threat to hosting studies was the availability of national portfolio studies relevant to primary care. Having been accepted to the scheme, practices expected to host a study fairly quickly. However, there were few studies relevant to primary care available via the NIHR portfolio with '*…the choice of ''ready/open'' intervention studies…limited, especially for those GPs with an interest in cardiovascular and diabetes and who would like to take on a role of PI*'. This lack of availability was frustrating for practices, presented a significant barrier to participating in research and raised concerns over developing unusable capacity or skills that, particularly for novice research practices, risked becoming outdated due to lack of applied experience. It also required more of a marketing-oriented approach on the part of the LES team to '[try] *to ''sell'' some of the studies that are desperate for new sites*', using '*''experiential comments'' from sites already involved in particular studies to help with promotion*' and '*inviting trials managers to present their studies*'.

A substantial component of the LES scheme therefore involved proactively communicating with other research organizations to identify potential studies, translating studies into primary care contexts (eg, 'selling' primary care governance systems to study teams) and 'matching' requirements of existing studies with practice interests.

The LES scheme was designed to work in liaison with other research organizations and local networks. It was therefore reassuring that overlap across the LES and local PCRN appeared to facilitate mutually beneficial communication (eg, around emerging recruitment issues for specific studies) and knowledge sharing (eg, regarding governance processes, support costs).

Next steps

The LES scheme offers real potential to assist novice and experienced research practices develop their research activities and to encourage local populations to participate in clinical studies. Discussions since the evaluation suggest that all of the first wave LES practices will continue to be involved in research (at a basic level, at least) with some pilot practices considering options for how they might secure additional *ad hoc* funds (eg, to maintain administrative and nursing infrastructure).

Second and third wave practices have now been appointed, resulting in a pool of over 40 LES practices across the CLRN patch and presenting a significant opportunity to share learning. The focus of the scheme is very clearly on accessing the 408 000 population that it now covers through quality support to local primary care staff. With many practices recruiting to more than one study, it appears that the resources dedicated to involving practices in the LES scheme – £67 875 in the first wave of the scheme – have increased opportunities for local practices and populations to take part in research.

However, there are areas allied to the LES initiative that need further development. In particular, the lack of available studies relevant to primary care needs addressing. This is beginning to happen with numbers slowly increasing; however, those pursuing LES or similar schemes might wish to consider how to strike an effective balance between funding the development of local clinical research activities with availability of studies. They might also consider further facilitating research through establishing closer links with their local PCRN and CLRN in areas of interest or expertise.

Ultimately, by making participation in NIHR portfolio studies a routine and accepted activity, LES schemes can help to facilitate recognition of local staff contributions to enhancing research-based evidence, and more closely align research activities

with clinical priorities. Such activities fit with national health research strategy and should increase opportunities for research to improve services and treatments for patients.

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