

UKCRN Coordinating Centre

CLRN support for UKCRN primary care research activity: an options paper

1: Background:

A: Primary care and the UKCRN:

Primary care accounts for a substantial proportion of the studies in the UKCRN portfolio activity, and the development of appropriate arrangements to support UKCRN research activity in primary care settings is therefore an important consideration. Such arrangements are influenced by a number of features of primary care:

- NHS primary care provision is characterised by large numbers of small NHS primary care organisations (e.g. a GP practice) which are typically geographically widely dispersed.
- These organisations are for the most part contracted independently to the NHS via primary care trusts (PCTs).
- Practices undertake UKCRN research activity not only in the context of the PCRN, but also in conjunction with TCRNs and other networks such as the GPRF.
- There are currently no standard contractual arrangements for support of research activity in practice.

B: Specific issues relating to research in general practice

For the above reasons, the management of research conducted in general practice can vary from that in an acute hospital based setting and we list below some specific examples of this along with the practical implications:

- The majority of general practitioners work as independent contractors into the NHS with each practice being run as a small business employing staff across several disciplines. Prompt and realistic payment which reflects the full costs incurred is therefore essential if we are to engage practitioners in research and retain their involvement.
- Recruitment into studies often involves the whole primary care team – receptionist, practice managers, practice nurses, GPs and other professionals working within the practice
- Recruitment into studies is sometimes opportunistic but usually involves the searching of records to identify patients who meet the inclusion/exclusion criteria. The cost of contacting and following-up such potential participants (letters, postage, phone calls, administration time) has to be recoverable by the practice. Practice lists can vary in size from 2,500 to 30,000 with 8,000 being typical.
- Historically costs have been calculated on a study by study basis and practices expect funding to be transparent reflecting the work required for the study although they have not generally differentiated between different funding streams for research costs and research support costs, expecting this to be done on their behalf
- The cost of use of space either for storage or research activity may need to be factored into this (may be research or support cost).
- Practices wishing to engage in research may be prevented from doing so by the lack of certain pieces of equipment which are not study specific– e.g. centrifuge, fridge. Limited space availability may also be a critical issue. Flexibility to take this into account may be helpful.
- There need to be flexible and tailored processes in place which will allow practices which regularly take part in research to be compensated appropriately but there is also a need for mechanisms which will compensate practices which might only be interested in participating on an occasional basis. Mechanisms need also to support any changes to recruitment techniques during the course of a study as well as permitting flexible use of staff resources e.g. for the same study some practices may opt to use their own staff whilst others will require support from network funded staff..
- In addition, we need to plan for the use of “hub and spoke” models where “spoke” practices will identify patients for studies being conducted elsewhere i.e. in a “hub”. The “hubs” would normally, but not necessarily, be regular participating sites (primary or secondary settings) referred to above.

“Spoke” practices will need to be resourced to do record searches and initial contact and possibly any contingent follow-up.

- The dispersed nature of multiple small sites in primary care research has consequences in terms of increased travel and time costs, logistics for dealing with samples, staff training, study set-up etc.
- Consideration also needs to be given in the longer term about resourcing arrangements for other primary care practitioners. This will include PCT salaried employees as well as other categories of independent contractors, e.g. dental practices, pharmacists, optometrist where existing (non-research) funding arrangements differ from those of general practice. Whilst the principles for attributing resources remain the same, mechanisms for costings and payments may need to be different.

C: Sessional activity in general practice

For primary care it is more useful to consider recruitment rate (which includes identification, consent and entry into the study) rather than just consent rate. The majority of this work is undertaken by practice admin staff and nurses with the GP reviewing the initial list to ensure the appropriateness of the invitation. Work done by our networks and colleagues in GPRF suggests that taking the additional factors into account, there is agreement with the level of recruitment per sessional payment proposed in the Piers Kotting paper. This reflects time expended by the primary care team up to the second visit for randomisation but does not take into account the extra time needed for patients in the more hard to reach groups or more complex studies.

Given that this suggests time to recruit may be similar in a primary or secondary setting, one simple way in which CLRNs could begin to allocate sessional funding could be based on a ratio of patients accrued from each sector. PCRN LRNs would then assist CLRNs in identifying which practices should receive such payments, based on their knowledge of the current portfolio. This payment would correspond to a certain expected level of activity - to be determined - and anything over and above this would need to be resourced on an activity-related basis.

We suggest that practices which do not qualify for sessional payments but still contribute patients to portfolio studies would continue to be paid on a study-by-study basis. This payment process could be simplified by placing studies in categories based on complexity, although there appears to be concern in the primary care community about moving away from costing each study individually and more work needs to be done on illustrating how this could be applied. A banding structure is particularly unpopular for those studies which have an unusually high screen failure rate (e.g. 70:1 for one recent study on stroke prevention - BAFTA) Information from GPRF suggests that the recruitment to follow-up ratio in terms of time requirement ranges typically from 6:1 to 1:2, and the consequences of this may need some further consideration. It is clear, not only for primary care, that there are requirements for sessional payments to cover study specific activity and activity that which is more generic (for example time for generic training and to ensure compliance with legal and governance issues)

D: Contractual arrangements for general practices engaging in UKCRN research activity - Locally Enhanced Scheme (LES):

Appropriate contractual arrangements for supporting general practice involvement in UKCRN research activity are critical to the successful delivery of the primary care UKCRN portfolio activity. Currently there is no standard agreed contractual framework, but an increasing number of schemes are emerging based on the model of the Locally Enhanced Scheme (LES). In most cases, these make provision for up to three levels of practice engagement with UKCRN activity:

Level 1: Research Responsive Practice – a practice which has a designated research lead, appropriately trained staff, and systems in place to ensure that the practice is able to respond actively to requests for involvement in UKCRN research studies

Level 2: Research Active Practice - a practice which, in addition to the requirements of Level 1, is contracted to actively participate in 2 (or 3) UKCRN studies in each contracted year.

Level 3: Lead Research Practice – a practice which, in addition to the requirements of Level 1, is contracted to actively participate in 4-6 UKCRN studies in each contracted year. In addition, Lead Research Practices may be contracted to function as a research “hub,” undertaking a

degree of outreach work with other practices in their locality They may also act as a primary care clinical research facility, undertaking research assessments and/or interventions for UKCRN studies for patients registered with other practices where such activity cannot readily be accommodated.

The payments for each level of activity are subject to local negotiation and we expect further information to emerge from several pilot schemes which are currently underway. For research activities over and above the provision made in the contractual arrangement, additional resource will need to be identified and made available to the practices.

E: Unblocking the blocks in primary care:

- We have previously identified the potential need for a nurse bank to support primary care research and we believe there is scope for discussions with “NHS Professionals” to develop these ideas.
- As discussed above, the ability to provide small capital equipment to practices would assist networks in engaging new practices which might be willing to be involved but unable to commit funding to essential equipment.
- New practices who wish to engage in research may be prevented from doing so by the lack of appropriate training and/or the absence of procedures to meet regulatory and governance requirements. Whilst training can be provided by UKCRN, the provision of resources to cover time out of practice would encourage practices to release staff to attend. Such activities could be appropriately supported by the use of Flexibility and Sustainability funding,

It should be noted (though it is not appropriate to discuss in detail here), that other blocks to primary care research are systematic and require different solutions. Such factors include incentivisation (over and above the LES – see *below*), VAT on medical research and the complexities of excess treatment costs. A further issue is the limited availability of space in primary care facilities to undertake research activity; on occasion it may be necessary to purchase/lease additional space for this purpose.

F: NIHR Flexibility and Sustainability Funding (NIHR FSF):

PCRN LRNs now receive an annual allocation of network-related NIHR FSF. One of the purposes of this funding stream is to support capacity building and the development of the research workforce, and it may therefore appropriate for it to be used to fund Level 1 contractual activities (see Section D, above). There may be opportunities for local discussions between CLRNs and PCRN LRNs about shared use of NIHR FSF across the networks.

3: Potential models of engagement between CLRNs and primary care organisations:

A: General considerations:

As CLRNs make preparations for setting their budgets for 2008/9, they will need to address a number of key questions in order to make the necessary arrangements to deliver NHS infrastructure support resources to the relevant research active primary care sites:

- How can resources for NHS support for UKCRN research activity be channelled effectively into general practices and other primary care sites?
- How can resource allocations and contractual arrangements for primary care take full account of the role of PCRN and other networks in coordinating UKCRN primary care research activity
- How can the primary care research portfolio activity supported by such resources be effectively managed across a multiplicity of research networks?

There are a number of models for engaging with primary care which CLRNs could potentially adopt:

1. CLRNs negotiate agreements separately with each of their research-active practices and other primary care sites.

This would entail a potentially highly labour-intensive mechanism, which would also largely ignore existing PCRN and other networking arrangements, thus risking fragmentation of UKCRN primary care research activity. Neither does it provide fit with the current arrangements of the membership

agreement. Resources would flow directly from CLRNs to sites informed by portfolio-held information. CLRNs would be the inquiry point for all matters related to primary care payments. Input will be required from PCRN/TCRN/GPRF for sessional payments

2. CLRNs use existing transition-funded RM&G alliances and primary care research consortia to negotiate and administer contractual arrangements on their behalf.

This option would provide a short-term solution, but could not be sustained, as 2008/2009 is likely to be the last year for transition-funded organisational arrangements. CLRNs would need to enter into additional new agreements with the host trusts of a number of organisations with differing capacities and capabilities to allow transfer of resources out to sites. The alliances and consortia would need to be provided with information either from CLRNs, TCRNs/PCRN/GPRF and/or trials units to inform payments.

3. CLRNs liaise closely with the relevant PCRN and TCRN LRNs to identify research-active primary care sites undertaking UKCRN portfolio activity, and identify a single local PCT (or exceptionally an NHS Hospital Trust) within their locality, to establish and manage the contractual arrangements for delivering NHS support to primary care. The trust identified may or may not be the CLRN host.

This option would provide a potential mechanism for standardising the resourcing and contractual arrangements with primary care sites across all 25 CLRNs. It has the advantage that it could support the development of Locally Enhanced Schemes (LES) for UKCRN research in general practice which is being viewed as possible mechanism for incentivisation of practices. It would have the additional merit of involving the PCRN and relevant TCRN LRNs in identifying and working with research-active sites within each CLRN. Resourcing would flow from each CLRN to one nominated trust which would be responsible for all primary care payments. Payments would be based on information provided either by CLRNs, TCRNs/PCRN/GPRF and/or trials units.

4. CLRNs fund dedicated posts within CLRN or PCRN to manage contractual arrangements with all practices within the CLRN

This option is already being discussed in the Northwest. It has the potential to ensure payments are made accurately and appropriately and practices will have the desired one point of contact. However this could increase the level of management responsibility required within PCRN LRNs which cover more than one CLRN and they would require resourcing to manage the funding distribution. Funding would flow from CLRNs to the PCRN host trust and then out to Primary care practices. Payments would be based on information that should be held by or easily accessed by PCRN LRNs.

The model(s) selected must reflect the UKCRN aims of making it possible for more practitioners and patients, wherever they may be located, to be involved in research and also to streamline the research process. A model which permits each CLRN to develop its own independent arrangements for engagement, resourcing and payment mechanisms could result in a primary care researcher having to contact PCRN and up to 25 other sources to find out about local practice capability and capacity and access to support resourcing. Additionally, a PCRN LRN may encompass up to four CLRNs, which provides a powerful driver for ensuring, over time, that models are streamlined and take note of evolving good practice. The goal should be that whatever the individual internal processes are within the CLRNs, the public face/service to researchers and the end results are the same.

It is likely that different models may be more suitable in some networks than in others, and we would strongly encourage CLRNs to work closely with the local PCRN teams who are eager to facilitate the optimum processes in their localities.

UKCRN Primary Care Co-ordinating Team

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