Determining arrangements for supporting research in primary and community care

Discussion paper

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Discussion paper

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Introduction

1. This discussion paper aims to support local organisations, working in collaboration with local networks, in considering how to achieve a smooth transfer of capability within the changing NHS for supporting commissioners with their new research roles and for supporting primary care research.

2. It looks in particular at a model of shared services for research which could support, for example, health providers, commissioners and universities. This is particularly relevant at the moment in considering existing Primary Care Trusts (PCT) research services but the principles are relevant more widely and the paper draws on an annex describing potential functions of services to support research across all care settings.

Background

1. From April 2013, the NHS Commissioning Board (CB) and, from the date of their establishment, Clinical Commissioning Groups (CCGs) have new duties to promote research and use of research evidence in the exercise of their functions and Local Authorities can conduct or assist research related to their health functions. Provider organisations will continue to host and deliver research, and some will generate new research. Academic Health Science Networks will have a key role in promoting research participation as part of their role in identifying, adopting and spreading innovation and best practice. The National Institute for Health Research (NIHR) Clinical Research Network continues to support eligible research.

2. A variety of activities and services related to research are currently provided for commissioners and primary care providers, usually by a PCT or consortium. Approaches vary across the country on what services are provided, how they are organised, funded and where they are hosted. Many teams providing such services now find the work they do has diverse potential customers in future. Whatever approach is taken to such support services in future, it is important that they reflect that providers are responsible for research governance.

Future

1. **CCGs are commissioning-only organisations so PCT functions do not directly transfer to them**[1]. Although PCTs have previously issued permission letters for research studies in primary care, this does not mean CCGs have to do so (particularly when doing so could cause them to delay or hinder, rather than promote, research). Responsibility for research governance generally lies with providers of health care services. However, CCGs may want research-related support with their commissioning roles, and examples of such support are in section 1 of Annex A.

2. Independent contractors in primary care will, in future (in the absence of Primary Care Trusts and like other providers in acute, community and mental health care), decide of their own accord whether to participate in research. It will be the **responsibility of providers** to agree a study is suitable for their NHS patients and that they can follow protocol requirements, so they will give permission for studies[2].

3. This does not mean primary care providers need to replicate the activities carried out by PCT research management and/or governance teams. Providers are likely to want to get reliable and proportionate written **advice in deciding whether to participate in a study and may want help facilitating their involvement** such as arranging honorary contracts. Providers could get this from, or by establishing, a support service. They may wish to work together on this to exploit economies of scale and could draw on support

[1] "GP practices, like other providers, will in future be responsible for the governance of research in which they participate and they may wish to work together on this. It is expected that CCGs themselves will have formal responsibility for research governance only in specific, limited circumstances." (page 21) *Towards Establishment: creating responsive and accountable Clinical Commissioning Groups, NHS CBA Feb 2012, NHS CB Oct 2012.* (www.commissioningboard.nhs.uk/files/2012/09/towards-establishment.pdf)

[2] Independent contractors already agree to participate in each study and, in future, this agreement will be sufficient NHS permission. There should be an audit trail (e.g. correspondence confirming agreement, a contract etc) but this need not be a conventional NHS permission letter.

available through the NIHR Clinical Research Network [3]. Such services could also provide other support (see Annex A) such as helping represent primary care research in local forums [4], co-ordinate activity among the local players, influence or help articulate local strategies and disseminate information (e.g. on funding and support).

4. In many areas of the country, existing teams have skills and expertise that could provide valuable support services to future commissioners and providers on research-related roles and activities, and indeed to research sponsors, with their research-related responsibilities and activities. When considering establishing future shared support services for research activities, there is an opportunity to examine which of the current services, and potential related services, will be valuable in the new environment, and to whom (see Annex A). This could help plan what services to retain, to develop and what to stop. For example, there may be potential to review and reduce governance activity of PCTs, such as removing duplication by relying on study-wide reviews of NIHR Clinical Research Network portfolio studies.

5. Local health communities, in planning how functions are transferring between organisations as part of the transition, will wish to review any locally based PCT research services and are encouraged to consider retaining, and finding a suitable host for, skilled teams that can offer supportive services to primary care providers and / or to NHS commissioners with their future duties and activities. Such teams can provide economies of scale and they could be independent or they may be hosted either:

    - within a provider (e.g. acute, mental health, community); or
    - by a commissioner (e.g. CCG, NHS CB Local Area Team or a Commissioning Support Service); or
    - by the NIHR Clinical Research Network or an Academic Health Science Network.

[3] The NIHR Clinical Research Network (CRN) will continue to support research management activities for CRN portfolio studies. There may be benefits, such as economies of scale and strengthening of local expertise, of local services supporting all studies, though other local funding arrangements will be required for non-portfolio research.

[4] Local forums and players could include: NHS and independent healthcare providers, universities, Clinical Commissioning Groups, Local Area Teams of the NHS Commissioning Board, Commissioning Support Services, Local Authorities, Academic Health Science Networks, local groups of the NIHR Clinical Research Network, Collaborations for Leadership in Applied Health Research and Care, a Research Design Service, etc).

Annex A

Sample range of potential research-related services for example for commissioners, sponsors, providers and employers of researchers

Organisations may fulfil more than one role and so be interested in services in more than one category - for example, if a commissioner were sponsoring a study.

1. **Commissioner role in promoting research and the use of evidence – including Clinical Commissioning Groups, Local Authorities, Public Health England, NHS Commissioning Board.**

    a. Supporting the use, access to, identification of the need for, or generation of evidence to support commissioning, including for example considering, commissioning, developing or participating in research or service evaluation.

    b. Promoting research - including developing research culture, capacity and participation among clinicians, managers, patients and the public, as part of efforts to increase the quality of services, including, if they wish, by contributing to potential services for providers as detailed below.

    c. Handling of provider claims for contribution to excess treatment costs for studies.

    d. Participating in, and contributing to, the local Academic Health Science Network, its purpose of identifying, adopting and spreading innovation and best practice and, specifically, promoting research participation. (www.dh.gov.uk/health/files/2012/06/Academic-Health-Science-Networks-21062012-gw-17626-PDF-229K.pdf)

    e. Participating in other strategic initiatives such as NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC) as appropriate.

2. Sponsor of a research study fulfilling their responsibilities – including industry, NHS organisation, university etc.

a. Developing and putting in place agreements and contracts with clear allocation of responsibilities as appropriate, using standard NIHR contracts where they exist. (www.nihr.ac.uk/industry/Pages/model_clinical_trials_agreement.aspx)

b. Overseeing delivery of research studies, including oversight of management, monitoring and safety.

c. Ensuring appropriate funding and resources to deliver the study.

d. Supporting allocation of responsibility, or activity on management, monitoring and audit e.g. for Clinical Trials for Investigational Medicinal Products, meeting requirements of the Medicines and Healthcare products Regulatory Agency.

e. Ensuring appropriate peer review of the research protocol.

f. Ensuring appropriate regulatory approvals are in place, including advising researchers and study co-ordinators on navigating the research process and regulatory and approvals process.

3. **Provider deciding to, and getting help in, participating in research – including independent practitioner, acute, mental health or community trust, independent provider.**

Issues will be different for small / large, complex and NHS/independent providers. The NIHR Clinical Research Network (CRN), which seeks to support research participation, contributes to funding these support services for NIHR CRN portfolio research and may directly provide some of them. In some areas, commissioners seeking to fulfil their duty to promote participation in research might also wish to play a role.

a. Describing capability of the organisation to do research in general, e.g. through Operational Capability Statements. (www.nihr.ac.uk/systems/Pages/OperationalCapabilityStatements.aspx)

b. Identifying suitable studies matching local interests and capability, or from a perspective across many providers, targeting studies to suitable providers.

c. Advising on whether to participate in a particular study to inform the provider's decision, providing information and advice on the specific requirements of each particular study, general provider capability and capacity, feasibility and appropriateness[5] of the particular study and fit with local services and pathways.

d. Supporting local set-up of study to ensure the right people are in the right place at the right time to deliver the study on schedule and supporting local arrangements to enable participants to take part, including adapting standard care pathways / drugs as appropriate.

e. Supporting research delivery for example by administering service support; employing and deploying (team(s) of flexible) research nurses or assistants and or distributing support costs to providers enabling participant recruitment; taking consent; negotiating with commissioners etc.

f. Supporting the management, monitoring and audit of studies e.g. to meet contract requirements.

g. Advising on whether to sign up to any non-standard agreements and contracts with sponsors to inform the provider's decision.

h. Participating in, and contributing to, the local Academic Health Science Network, its purpose of identifying, adopting and spreading innovation and best practice and, specifically, promoting research participation. (www.dh.gov.uk/health/files/2012/06/Academic-Health-Science-Networks-21062012-gw-17626-PDF-229K.pdf)

[5] Note the Health Research Authority is doing a feasibility study to test a simplified and streamlined HRA assessment for all research in the NHS. (www.hra.nhs.uk/hra-news-and-announcements/hra-given-go-ahead-for-feasibility-study-hra-assessment-for-approval-of-research-in-the-nhs/)

i. Participating in other strategic initiatives such as NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRCs) as appropriate.

j. Assessing study-wide governance issues posed by NIHR CRN portfolio studies and others by agreement, to advise other providers, by lead provider.

k. Setting up and hosting honorary contracts and letters of access.

l. Advising on reasonableness of agreements and contracts with sponsors – or how to request they are changed.

m. Providing training e.g. Good Clinical Practice for those leading Clinical Trials for Investigational Medicinal Products regulated by the Medicines and Healthcare products Regulatory Agency.

4. Employer of researcher e.g. university, care provider

a. Managing, distributing and accounting for funding received in the form of research contracts, research grants or other research funding.

b. Advising on and supporting compliance with contractual or grant terms and conditions.

c. Supporting new research grant development, submission and collaboration between researchers.

d. Providing training e.g. Good Clinical Practice for those leading Clinical Trials for Investigational Medicinal Products regulated by the Medicines and Healthcare products Regulatory Agency.

5. Health and Wellbeing Board

a. Advising on basing strategies on evidence and collaborating to contribute to developing research culture and use of research evidence in the system as a whole.

6. Healthwatch

a. Advising on basing strategies on evidence and collaborating to contribute to developing research culture and use of research evidence in the system as a whole.

b. Promoting NHS offering to patients to participate in research studies and equitable access.