The Royal College of Pathologists
Pathology: the science behind the cure

Response from the Royal College of Pathologists to NHS Consultation:

Supporting Research in the NHS:
A consultation covering changes to simplify arrangements for research in the NHS and associated changes to the terms of the NHS Standard Contract

The Royal College of Pathologists' written submission

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1 About the Royal College of Pathologists

1.1 The Royal College of Pathologists (RCPath) is a professional membership organisation with charitable status. It is committed to setting and maintaining professional standards and to promoting excellence in the teaching and practice of pathology. Pathology is the science at the heart of modern medicine and is involved in 70 per cent of all diagnoses made within the National Health Service. The College aims to advance the science and practice of pathology, to provide public education, to promote research in pathology and to disseminate the results. We have over 10,000 members across 20 specialties working in hospital laboratories, universities and industry worldwide to diagnose, treat and prevent illness.

1.2 The Royal College of Pathologists response reflects comments made by Fellows of the Research committee.

2 Response

2.1 Summary

At the end there are really one or two questions with major choices. There is a lot of paperwork but it is mainly about how NHS England, The Department of Health and the Health Research Authority (HRA), working together, will implement changes to simplify NHS research proposals to:

- Manage excess treatment costs better
- Further improve commercial clinical research set-up and reporting

Excess treatment costs are the difference between the NHS Treatment Costs and the cost of the standard treatment is referred to as the NHS Excess Treatment Costs.'
They propose three changes to help with ETCs:

1. Partnering with the 15 Local Clinical Research Networks (LCRNs) to help manage the ETC process on behalf of their local Clinical Commissioning Groups (CCGs),

2. Establishing a more rapid, standardised process for ETCs associated with specialised commissioning

3. Setting a minimum threshold under which ETCs will need to be absorbed by providers participating in studies.

Question 1: There are a few straightforward questions about these changes
Do you agree with the six design principles we have used to develop our proposals?

These are on page and are Capability, Consistency, Cost neutrality, Simplicity, Single point of access, transparency –

All agreed these seem very reasonable

Partnering with 15 NIHR Local Clinical Research Networks (LCRNs) to help manage the ETC process on behalf of their local CCGs

Do you agree that ETCs will be better coordinated by LCRNs at sub regional level with a single point of contact rather than managed by CCGs individually? (Y/N/ Please comment)

There was agreement that ETCs will be better coordinated by LCRNs at sub regional level but some reservations about different activity in Local Clinical Research Networks across the country. There should ideally be sufficient support and monitoring to enable Local Clinical Research Networks to perform these roles.

Do you agree that pooling risk across the 15 LCRNs to manage annual variation in ETCs would be an appropriate approach? (Y/N/ Please comment) Yes seems entirely sensible

All agreed

Will the proposals outlined work for both single site and multi-site studies? (Y/N/Please comment)

All agreed

Establishing a more rapid, standardised process for ETCs associated with specialised commissioning

Do you agree with the proposal to strengthen the process for specialised services? (Y/N/Please comment)

All agreed

Do you agree that applications that fall below the proposed minimum threshold would not be considered by NHS England? (Y/N/Please comment)

All agreed

But some comments. Will sufficient local monies be made available to fund expected ETCs given projected level of funding of clinical work by Research Council and Charities and the clinical research to accompany local audits, surveys and mandated quality improvement schemes?

Are there any additional comments to add to the specialised services proposals?

There were many comments about specialist services

1) **The threshold for ETCs:** There are other problems with specialist assays. Having a reasonable threshold per patient of say £100 would allow some specialist assays to be undertaken in studies under the threshold for ETC.

   On main routine systems problem is often new generation expensive assays- eg BNP for heart failure or cardiac problems; pre-eclampsia markers. These are simply unaffordable for large scale use. So we lack data on many core groups in the NHS. For example, work on major policy papers such as a NICE guideline lacked basic systematic cross-sectional OPD data and data had to be taken from overseas studies and so other populations.

2) **Recompensing these is a real issue.**
   (a) It is felt that often costs on studies are not made explicit and sometimes simply absorbed into routine work. Histopathology may be difficult to cost but pathologists time and lab time should be recognised in the funding scheme. Even if agreed the money sometimes does not reach the laboratory but are absorbed into the Trust budgets.
   (b) At the moment there is difficult getting recompense for small studies and it is felt that in some cases local R&D departments add to delays in starting or agreeing work.

Question 2: Setting a minimum threshold under which ETCs will be absorbed by providers participating in research studies

So the question is what option is best to absorb costs by providers that would be best for the overall community

1. It may be just a small amount per participant (£60 they suggest)
There was agreement that this is the best option but needs to be a higher figure - say £100 to allow funding of laboratory tests for approved studies including observational studies.

2. a fixed amount per Trust (adjusted for Trust income)
No. Generally thought that was large variation in research participation and fixed amount per Trust would discourage large teaching hospital centres or lab hubs at DGHs- they could suffer too. Furthermore, there is no guarantee that this funding would find its way to the laboratories or researchers.

3. a fixed amount per Trust
No. Generally thought that was large variation in research participation and fixed amount per Trust would discourage large teaching hospital centres or lab hubs at DGHs

4. a fixed amount per study - say £2000.
No – larger scale studies should be encouraged.

Any preference for 1/2/3/4?
Option 1

Question 2
The second series of question asks **'What is the best option for costing NHS provider participation in commercial research?'**
Option #1 – National, binding coordination of contract values

For multi-site studies: national co-ordination to avoid re-negotiation and protracted delays by local R&D Depts and to ensure consistency. There should be clear guidance and monitoring of the processes and time to completion to ensure any new system is performing better in terms of speed than the current systems.

Option #2 – First/lead site setting of contract values, with MFF adjustment

For single site studies: the lead site is best placed to do this as researchers know the people they have to deal with. Lead sites often use competitive bids for additional laboratory and clinical services and have a clear responsibility from funders to get costs right and incentive to produce good work. It was felt that national centres might well add to delays and provide little added value.

Question 3
Do you agree that we should reaffirm, through the NHS Standard Contract, the requirement for NHS providers to report and publish a standard dataset for performance in clinical research initiation and delivery?

All agreed yes

Question 4
Are there any additional steps that you think would be helpful on the part of commercial research sponsors and/or their representatives?

Commercial sponsors do not pose a problem: they have clear mechanisms to evaluation and negotiation. The main problem in commercial trials is individual Trust second guessing all costings and demanding renegotiation. This often delays the start of trials for up 6 months. Some national guidance may help here to benchmark reasonable costs for commercial work at individual Trusts.

Question 5.
Do you agree with our proposed wording for a future National Variation to the NHS Standard Contract?

26.3 The Provider commences participation in a Commercial Research Study, it must do so at the NIHR Research Price, on the terms of the NHS Commercial Research Contract, and otherwise in accordance with National Guidance on Conducting Commercial Research Studies
26.4 The Provider must comply with HRA/NIHR Research Reporting Guidance, as applicable.
26.5 The Parties must comply with NHS Treatment Costs Guidance, as applicable.
26.6 The Provider must put arrangements in place to facilitate recruitment of Service Users and Staff as appropriate into Approved Research Studies.

Yes – this will allow changes to the ETC procedures outlined in the consultation