The Academy of Medical Sciences

Response to NHS England's consultation on 'Supporting research in the NHS' on excess treatment costs and clinical research set-up

January 2018

Summary

- The Academy welcomes NHS England's proposals to better manage Excess Treatment Costs (ETCs) and to clarify and streamline the processes around contracts, costings and reporting for multi-site studies. This proposal is a valuable step in continuing to improve and embed research in the NHS.
- Historically, there has been confusion and debate around what constitutes an ETC and where the responsibility for funding of these lies, which has caused delays to research. We welcome the proposals to clarify funding responsibilities across different stakeholders and budget ownership in the NHS, as well as establishing a threshold which will help prevent delays caused by debate over marginal costs with relatively low impact.
- Standardised costing and contracting processes for clinical research will help address research delays arising from local negotiation of costs and contracts. A standardised process across the UK will increase its global attractiveness for research.
- Ensuring reporting against a set of defined metrics for study set-up and delivery is valuable for potential research partners and sponsors by demonstrating excellence in clinical research capabilities and allowing them to select appropriate sites based on these metrics. It can also drive improvements in clinical research by enabling Trusts to benchmark themselves against the rest of the UK.

Introduction

1. The Academy of Medical Sciences promotes advances in medical science, and supports efforts to see these advances translated into healthcare benefits for society. Our elected Fellowship includes some of the UK's foremost experts in medical science, drawn from a broad range of research areas.
2. We welcome this opportunity to respond to NHS England's consultation on supporting research in the NHS through establishing ways to better manage excess treatment costs and improve clinical research set-up. Our response is based on the views of the Academy's Fellows, many of whom have extensive experience of interacting with, and operating within, the clinical research infrastructure in the UK.
3. Over recent years, NHS England has become increasingly engaged with the research agenda, recognising the value and benefits of health research. Closer working between the National Institute for Health Research (NIHR) and NHS England has helped to support and drive research in the NHS, and we welcome the focus on finding opportunities to promote this further. It is important that there is continued high-level leadership and buy-in to ensure that this positive research culture continues. The steps outlined within the consultation to address challenges around excess treatment costs (ETCs) and the clinical research landscape will support the UK in continuing to compete as a leader in medical research. In addition, there is a further opportunity for relevant bodies to build upon this consultation to clarify the funding and commissioning structure for ETCs in public health research.

Background

4. Studies involving ETCs are highly likely lead to a change in clinical practice as they are answering questions around whether a new approach is an improvement on standard care. Therefore they are a valuable asset for the NHS, particularly as they are most likely to deliver

a 'return on investment' by giving a direct answer as to whether a new approach should be commissioned through the NHS as an alternative to current routine care.

5. Historically, there have been challenges around who is responsible for the financing of ETCs (funders or the NHS, and even within the NHS whether this is centralised or devolved Trust budgets), compounded by a widespread lack of understanding around the contracting and commissioning arrangements for ETCs in the NHS. This has been particularly challenging for the NHS given the current financial environment and constraints in the healthcare system.
6. In addition, ETCs can be very challenging to define and there is a lack of clarity around what constitutes a research cost, ETC and service support cost. This consultation provides a potential opportunity to consider some of the broader issues around research costs such as budgetary impact of research and service support costs, including the fixed-term employment of staff to deliver a study. There can also be disagreement around the 'standard treatment' used to calculate ETCs as the routine care provided may not always mirror standard treatment guidance. The Academy's 2011 report titled *'A new pathway for the regulation and governance of health research'*, noted that the challenges around definition and allocation of research costs were causing a major barrier for Trusts to engage in research, and argued for the need to address these.[1]
7. The challenges around ETCs have led to delays in research, sometimes caused by debate over funding for marginal costs which may have little impact on the system.
8. We also recognise that in some circumstances the cost of running trials can be relatively low but the accompanying treatment costs may be very high, demonstrating the need for clear guidance on responsibility for funding of ETCs.
9. Finally, delays in multi-site trials have previously compromised the attractiveness of the UK for medical research, described by the Academy's report as the *'single greatest barrier to health research'*.[2] This has, in part, been caused by local negotiation of research contracts and disagreement around contracts and costings.
10. Therefore the Academy is highly supportive of NHS England's proposal to enhance the clinical research landscape through clarifying and streamlining the ETC management process and establishing a standardised process for costing, contracting and reporting in clinical research.

Better management of Excess Treatment Costs

11. We welcome the opportunity to establish clear, centralised guidance on ETCs using a framework that reviews these costs in terms of proportionality and impact. It is essential that there is buy-in to the framework from all funders so that full clarity exists around who is responsible for financing ETCs, which in turn will enable the NHS to increasingly engage in research by alleviating concerns and uncertainty around funding. The proposed principles for managing ETCs will support this by creating simplicity and transparency around the processes.
12. Further information is needed around exact timescales for processing ETC study applications and how consistency in decision-making can be ensured.
13. This consultation provides an additional opportunity to consider a single, streamlined funding process for *all* NHS research costs. The process could be potentially managed by the Local Clinical Research Networks (LCRNs) which already manage service support costs. This could be achieved through an amalgamated budget, which not only includes ETCs but also NHS support costs and treatment costs, and would simplify the costing process.[3]

[1] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. https://acmedsci.ac.uk/file-download/35208-newpathw.pdf
[2] *Ibid.*
[3] From the Academy's 2011 report: **Research costs** are the costs of R&D itself and can include the pay and indirect costs of staff employed to carry out the research. **Treatment costs** are the patients' costs which

The role of LCRNs

14. We agree that the LCRNs can better manage ETCs at a sub-regional level than the Clinical Commissioning Groups (CCGs), helping to ensure a more consistent approach and contact between researchers and those administering the process without undue fragmentation. It also removes the need for providers to engage with multiple CCGs on a single study where the patient population may be spread over a large geographical area, thus reducing the risk of one CCG approving ETCs whilst another does not. If LCRNs are chosen to manage the process then they will need associated training and support tools. Furthermore, initial relationships between CCGs and LCRNs will need to be developed, and supported by clear accountability for LCRNs with NIHR to ensure consistency across their decision-making. LCRNs will also need to liaise with other local elements of NIHR infrastructure involved in clinical research such as the Biomedical Research Centres (BRCs) and Collaborations for Leadership in Applied Health Research and Care (CLAHRCs). In addition, it is important to make sure that CCGs remain engaged with the national research agenda if the funding and decision-making processes for ETCs are transferred to the LCRNs, and greater clarity is needed regarding how funding from the CCGs would be distributed to the LCRNs.
15. However, although management by LCRNs would provide a step improvement in the ETC approval process, further coordination at a national level may be preferable with a centralised, national funding arrangement and oversight that only requires one application for the ETCs by the study sponsor. This would simplify procedures for multi-site trials and ensure maximum consistency across decisions on ETC studies compared with a sub-regional process.
16. There is a need for further clarity around arrangements for multi-site studies if a sub-regional approach is taken. It is essential that there is coordination across the LCRNs and for multi-site studies, one LCRN would need to take the lead for reviewing and agreeing the ETCs for the study. This decision would need to be recognised and accepted by all other LCRNs approving applications for local sites. In most cases, the lead LCRN should be where the lead study site is located. Further clarity is needed on how pooling risk across the LCRNs would work in practice as it would help to give reassurance and a degree of flexibility for multi-site trials. There will need to be central oversight – a national register – of the ETCs approved which is visible to all sites so that they can reconcile recruitment data for ETC studies against their threshold. The centralised process proposed in (15) would overcome these more complex arrangements required for multi-site studies if the LCRNs manage the ETC process, such as mutual recognition of decisions and lead coordinators.
17. Fellows agreed that establishing a more rapid, standardised process for ETCs associated with Specialised Commissioning is also valuable, as long as a timeline for decisions of no longer than four weeks was specified. However, this should be further developed into establishing one overarching process for management of all ETCs (rather than separating out specialised and local commissioning), with all applications passing through the same process designated for management of ETCs. This could be supported by pooling funding from Specialised Commissioning alongside the funding from CCGs for local commissioning.

Thresholds

18. Clear, reasonable thresholds for ETCs will prevent delays caused by debate over marginal costs, and so we are supportive of introducing a minimum threshold for ETCs under which providers must absorb these costs, which will ensure a proportionate approach. A nominal

would continue to be incurred if the patient care/service in question continues to be provided after the R&D activity has stopped. **ETCs** are the difference (if any) between the total treatment costs and the costs of standard treatment.

payment cap for primary care may also discourage ETC applications where cost of processing significantly outweighs the cost of the ETC, again ensuring proportionality.

19. For the setting of this threshold, Fellows largely agreed that the proposed 'Options 2 or 4' would be most appropriate. It was noted that 'Option 2' most closely relates the level of activity for a Trust to 'risk', enabling all Trusts to engage with these studies regardless of size because it considers the varying income of Trusts. Options based on per-patient (Option 1) would risk stifling research because a mechanism is needed that supports studies regardless of their individual scale, otherwise a Trust may potentially be required to absorb very high ETCs. Setting thresholds per study may also cause challenges for research as it could again inadvertently select for studies based on their individual scale, and so this would need to be considered for 'Option 4'. In addition, it was noted that 'Option 3' may also impede research through disadvantaging smaller and community Trusts.
20. Other points for consideration to ensure an appropriate threshold included setting these thresholds to overall NHS income such as income received from CCGs or Specialised Commissioning, so that the thresholds are proportionate to the overall 'ETC budget' derived from commissioning funding allocations.

Improving clinical research set-up and reporting

21. To continue positioning the UK as a world-leader in clinical research through accelerating clinical trial set-up and attracting inwards investment, costing and other set-up processes need to be streamlined and simplified at a national level. The Academy's 2011 report recognised the value of providing model agreements, templates and agreed costing structures to help support Trusts and researchers.[4] A multi-stakeholder approach to drafting these standard templates is critical.

Standardised processes for costing NHS provider participation

22. The costing template or guidance must be as simple and clear as possible. Most of our Fellows who responded to the consultation agreed that the principles behind 'Option 1' proposed by NHS England would achieve this aim and increase the attractiveness of the UK for international industry studies. However, some further considerations to improve the utility of Option 1 include:
    a. The National Coordinator for the costing template would need access to appropriate clinical expertise at short notice to expedite completion of the template, and the number of research proposals allocated to each National Coordinator will require careful consideration.
    b. Updates are needed to the NIHR costing template to better provide for calculation or reimbursement of costs, and it needs to include a more exhaustive list of tests, investigations and other non-clinical activities. In addition, there are some particular costs that may vary between research sites and so a one-size-fits-all costing model may not be suitable, for example for archiving costs and cross-tumour site studies.
    c. Sub-contracting requirements need to be considered where a site may need to make local arrangements with another provider (whether NHS or non-NHS) and include these costs within the contract.
23. More broadly, it was noted that the universal use of a standard research contract would be useful for enhancing the UK landscape for clinical research.

[4] Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. https://acmedsci.ac.uk/file-download/35208-newpathw.pdf

Clinical research reporting metrics

24. We agree that it is important for NHS providers to report and publish a standard dataset for performance in clinical research set-up and delivery. This reporting provides a useful benchmark for performance as well as attracting inward investment through demonstrating excellence in clinical research capabilities. One respondent noted that the current metrics of this reporting need to be reviewed to ensure that they incorporate other measures of success that are of value to industry such as recruitment of first patient (UK and global), timely data entry and query resolution within specific timeframes.

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