Full title: NHS Trusts’ clinical research activity and overall CQC performance – is there a correlation?

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Full title: Clinical research activity and overall NHS Trust performance – is there a link?

Summary

*Objective*: Since the late 2000’s, the creation of the National Institute for Health Research (NIHR) has transformed clinical research activity in the United Kingdom. This study sought to establish if there is a link between clinical research activity and overall NHS Trust performance.

*Study design:* Retrospective cohort study

*Methods*: Data for NHS Trust performance were obtained from public databases, namely the Care Quality Committee (CQC) risk rating for overall performance, and 2012-13 NIHR records for clinical research activity.

*Results*: Applying Spearman’s rank analysis, none of the Trust categories showed a correlation with CQC risk rating: small hospitals, r = -0.062 (p = 0.76; n = 27); medium, r = -0.224 (p = 0.13; n = 47); large, r = -0.008 (p = 0.96; n = 57); academic, r = -0.18 (p = 0.41; n = 24). Similar results were observed when CQC risk rating was compared with the number of different clinical research studies conducted per Trust.

*Conclusion*: The degree of NIHR National Portfolio clinical research activity is not significantly related to a Trust’s overall performance. These results differ from earlier reports where Trusts’ academic output – not all of which would be clinical research - was shown to correlate with improved mortality rates.

**Introduction**

Research is seen as a core part of the NHS; it is mentioned in the NHS constitution.1 The Department of Health (DoH) set out its strategic views in the document ‘Best Research for Best Health’ and NHS England has drafted a follow-up document called ‘Research is everybody’s business’.2,3 Their focus, in terms of healthcare outcomes, is to increase participation in high quality protocols and early access to new intervention and prevention strategies. Research output is still one of the key requirements for consultant posts in (academic) hospitals in particular. There is indeed some evidence that academic output by NHS hospital Trusts is linked with better care outcomes such as mortality rates.4

The establishment of the National Institute for Health Research (NIHR) and related organisations such as the UK Clinical Research Network (UKCRN) and regional Clinical Research Networks (CRNs) has transformed the way clinical research is conducted in the United Kingdom. In virtually every NHS Trust, clinical research activity has increased. More patients are recruited now into a multitude of different research studies and clinical trials involving medicinal products (CTIMPs). To facilitate this increased workload, CRNs fund NHS Trusts to employ research nurses and give physicians protected time to support research activity.

In parallel to the developments around clinical research, the UK government now publishes data on NHS Trusts’ overall performances. The Care Quality Commission (CQC) gives hospital Trusts a risk rating, which is based on the following criteria (not exhaustive): staff feedback, patient surveys, mortality rates, waiting times, avoidable infections, and never events.5 Despite the substantive investments made to increase clinical research activity, thus far, no data has become available on the impact this effort may have on overall NHS Trust performance. Our hypothesis for this study therefore was: Does increased clinical research activity correlate with a lower Trust CQC risk rating?

### Methods

This concerns a retrospective cohort study in which correlation analysis was performed between Trust NIHR clinical research activity with CQC risk rating status. For clinical research, the dedicated Guardian newspaper & NIHR website was consulted and recruitment data for April 2012 to end of March 2013 was obtained (ref website).6 For risk ratings, the CQC website was consulted and the current list as of 22 October 2013 was used, to reflect the period covered by the clinical research.5 Data was further collated and processed using Microsoft Excel 2007, then analysed and interpreted using SPSS Statistical Package for Social Sciences version 17.0 (SPSS Inc. Chicago, IL, USA, 2007)..

### Results

### In order to analyse the data for hospitals, they were stratified into small, medium, large and academic; the NIHR / Guardian websites also uses this categorisation. Acute specialist hospitals (e.g. children’s or orthopaedic hospitals) were classed as a large Trust. This categorisation reflects the typical population covered and size of their hospital(s) for each Trust. The following ranking was devised: level 1, <500 patients recruited; level 2, 500 to 1,000 participants; level 3, 1,001 to 2,000 participants; level 4, 2,001 to 5,000 participants; level 5, 5,000 to 10,000 participants; level 6, >10,000 participants. The number of different studies that Trusts recruited patients into was not categorised. CQC rates for NHS hospital Trusts ranged from 1 (highest risk / poorest performance) to 6 (lowest risk / best performance). Tables 1 and 2 show the outcomes of the Spearman rank analyses. Figure 1 and 2 respectively show the CQC rating versus research activity for patient accrual and different active studies respectively, using a dot-plot graph.

[tables and figures to be inserted here if manuscript accepted]

### Discussion

It is recognised that assessing the interplay between clinical research and its value to its hosting organisations – and therefore patients – is not straightforward.7 Indeed, Buxton et al proposed, what would the NHS have looked like if the research had not been undertaken?8 There are many factors involved in influencing the functioning of NHS hospital Trusts. We tried to encompass as many different relevant factors as possible by using the well established CQC risk rating system, since this comprises data on mortality rates, never events, avoidable infections and patient surveys. A large proportion of NIHR clinical research studies are not designed to directly improve life expectancy or reduce incidents such as myocardial infarctions or strokes, but instead aim to e.g. redesign and improve care pathways and protocols, increase early access to new interventions and prevention strategies, audit patient opinion and decipher the underlying genetic causality for disorders and diseases.9 Therefore, CQC risk ranking data was considered a more suitable indicator of Trust functioning than mortality rates alone, as used by Bennett et al and others.4,10 Based on our analysis, the hypothesis that clinical research activity is linked with overall NHS Trust performance can be rejected. In fact, a weak inverse correlation was observed particularly for the medium-sized recruiters, indicating a potential negative relationship between strong overall Trust performance and Trust research performance.

The results draw the question: why would greater clinical research activity not be related to better Trust performance? The DoH claims that research provides us with the means to tackle the increasing challenges that disease and ill health are placing on our society through early access to new strategies and high quality protocols.1 Indeed, the CQC focus on care pathways as key data to support the trust rating. Hanney et al concluded that a positive impact on health-care performance is more likely to be on improved health-care processes than improve patient outcomes.11

One explanation could be that research activity is too small in comparison to the many factors used to denote the CQC rating, making it hard to statistically show any beneficial impact that it may have. An alternative could that clinical research overall does not have a drastic positive effect on overall quality of care. Both positive and no difference impact have been observed in studies looking at certain specialties.12,13 Furthermore, the impact of some studies may be immediate whereas others may take much longer to have any potential impact. Those trusts with a high CQC rating may have benefitted from historical research efforts. Those with a low rating may feel that heavy investment in research will aid their overall improvement; either scenario may be reflected in the results obtained in this present study.

**Conclusion**

This study failed to demonstrate a statistically significant link between clinical research activity of a NHS hospital Trust and its CQC risk rating. On the positive side, several Trusts that perform poorly from a CQC perspective are performing well in terms of absolute clinical research activity.

Compared to other clinical activities that take place in a NHS Trust, clinical research is a comparatively small component. It may be challenging to measure the impact of clinical research on wider standard clinical care on a Trust level. Analysis of specific groups of studies with their relevant outcomes, e.g. clinical trials with clinical outcomes such as mortality or significant clinical events may be able to show any direct correlation. Because of the significant investments made by the DoH via the NIHR, further evaluative studies are warranted.

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**Ethics Approval**

None sought. Not applicable as this concerns publically available data which does not identify individual patients.

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**Conflict of Interest**

None declared

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Table 1. Patient recruitment and CQC rating.

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| --- | --- | --- | --- |
| **Trust category** | **n** | **rho** | **p-value** |
| Small | 27 | -0.062 | 0.76 |
| Medium | 47 | -0.22 | 0.13 |
| Large | 57 | -0.008 | 0.96 |
| Academic | 24 | -0.18 | 0.41 |

Table 2. Different actively recruiting studies and CQC rating.

|  |  |  |  |
| --- | --- | --- | --- |
| **Trust category** | **n** | **rho** | **p-value** |
| Small | 27 | 0.21 | 0.29 |
| Medium | 47 | -0.29 | 0.052 |
| Large | 57 | -0.020 | 0.88 |
| Academic | 24 | -0.30 | 0.15 |

Figure 1. Distribution of participant recruitment versus CQC risk rating for NHS hospital Trusts.

A, small Trusts B, medium Trusts



C, large Trusts D, academic Trusts



Figure 2. Distribution of different active studies versus CQC risk rating for NHS hospital Trusts.

A, small Trusts B, medium Trusts



C, large Trusts D, academic Trusts

