Title**: The correlation between NHS Trusts' clinical trial activity and both mortality rates and care quality commission ratings; a retrospective cross-sectional study.**

Running title: **Clinical research and quality outcome measures**

Word count manuscript: 2,400 (excluding title page, abstract, references, tables and figures)

Word count abstract: 220

Type of manuscript: original research article.

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Conflicts of interest: Both LJ and SJF are in receipt of NIHR funding through their regional Clinical Research Network for delivery of NIHR national portfolio studies.

Highlights

- Increased NIHR –adopted clinical trial activity is associated with reduced mortality.
- Increased NIHR-adopted clinical trial activity is associated with better CQC outcomes.
- Particularly the number of clinical trial patients correlates with improved hospital performance.
- The link between clinical trials activity and quality is not Trust-size dependent.

Abstract

Objectives: Evidence supporting the notion that clinical research activity in itself is of benefit to organisations as a whole is inconclusive. In the recent past, a positive association between research activity and reduced mortality has been shown. This study aimed to ascertain if clinical research activity is associated with established organisational outcome measures.

Study design: Retrospective cross-sectional study.

Methods: For 129 English NHS hospital Trusts, National Institute for Health Research (NIHR) study activity data, Summary Hospital-level Mortality Indicator (SHMI) scores and Care Quality Commission (CQC) ratings were collected. Research activity was controlled for Trust size by dividing it by clinical staffing levels. Multiple linear regression and Spearman correlation analyses were performed.

Results: Although there is a significant association between the number of studies and participants with both SHMI score and CQC rating, one particular variable is correlated more significantly than others: the number of participants recruited into interventional studies. It shows a significant correlation with better CQC ratings (standardised coefficient beta 0.26, p-value 0.003) and lower SHMI scores (stand coeff beta -0.50, p-value 0.001).

Conclusions: The mortality-related results corroborate with other published data showing a correlation between increased research and reduced deaths. Furthermore, there is also a statistically significant association between clinical trials activity and improved CQC ratings. However, these tie-ins are predominantly driven by the number of participants in interventional research rather than observational research activity.

Key Words: National Institute for Health Research (NIHR), Care Quality Commission (CQC), Summary Hospital-level Mortality Indicator (SHMI), clinical trials, interventional research, National Health Service (NHS)

Introduction

Since its inception in 2006, the UK National Institute for Health Research (NIHR) has transformed the clinical research landscape in the UK. Its mission, 'To provide a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public', is backed by expenditure of more than 1 billion GBP.[1] Money is primarily spent on provision of research grants for projects and also delivery staff based in National Health Service (NHS) Trusts to deliver both NIHR-funded and other peer-reviewed and funded studies. The sizeable amount of money spent on clinical research in the UK by the NIHR has not increased the number of studies appraising the effect it may have on the overall functioning of the NHS Trusts hosting and conducting its research.[2] Reduced mortality rates have been linked with increased NIHR-adopted clinical research activity and academic output within NHS Trusts respectively.[3,4] Furthermore, one study demonstrated that colorectal patients participating in NIHR-adopted oncology trials survived longer and were at lower risk of death after surgery.[5] Other cohort studies investigating the potential associations between research activity and other patient & organisational outcome measures, including hospital length-of-stay and adherence to clinical guidelines, have produced more mixed results.[6] A more recent review of literature, led to Boaz et al, concluded that there is a positive association between engagement in research by healthcare organisations and improvements in healthcare performance; a caveat being that all 33 source articles in that review involved different specialties rather than whole organisations.[7]

In this study we test the hypothesis that NIHR-adopted clinical research activity in NHS Trusts is associated with improved mortality rates, represented by the Summary Hospital-level Mortality Indicator (SHMI), and better organisational performance, represented by Care Quality Commission (CQC) ratings.

Methods

Ethics statement and data sources

This concerns a retrospective cross-sectional study of English NHS hospital Trusts. All data used in this study is readily available to the public via NHS and NIHR electronic depositories. The NIHR research activity data has been published in the past by the Guardian newspaper's website. No personal identifiable information has been used as part of this study. Therefore, from an ethics point of view this is classed a service evaluation and no formal ethics-clearance is required.

NIHR research activity was obtained from NIHR Open Data Platform website; this information is also published annually on the NIHR website.[8] Totals for the years 2012-13, 2013-14, 2014-15, 2015-16 and 2016-17 were calculated for the total number of studies and recruited participants, and separately for observational & large scale studies ('observational') and interventional & commercial studies ('interventional'). Of the variables included, research activity can be subject to significant year-on-year variability due to e.g. a single high-recruiting study being conducted in a single year. Clinical staffing numbers, determined in August 2016, per NHS Trust were obtained from NHS Digital.[9]

The Care Quality Commission is an independent regulator of health and social care in England. Organisations intending to provide such services have to register with the CQC, and this therefore includes NHS hospitals. Organisations are monitored and inspected based on five key questions that are asked by the CQC, namely whether care is: safe, effective, caring; responsive. Failure to do so may result is registration being revoked.[10] CQC ratings were obtained from the CQC website; the

latest rating for each Trust was used for analysis.[10] The SHMI is the ratio between the actual number of patients who die following hospitalisation at a given NHS Trust hospital and the number that would be expected to die on the basis of average England figures, whilst taking into account the characteristics of the patients treated there. It covers all deaths reported of patients who were admitted to non-specialist acute trusts in England and either die while in hospital or within 30 days of discharge. The statistical models are derived using a three-year dataset from trusts throughout England. Data from the final year of this period are used to calculate the SHMI and accompanying contextual indicators for each individual trust.[11] The average SHMI value for each NHS Trust for the calendar years 2014, 2015 and 2016 was calculated after obtaining data for each calendar year from the NHS Digital web pages.[11] To minimise basing analysis on incidental higher mortality rates for NHS Trusts we applied an average of three years, an approach taken by others in the past.[12]

Data processing and analyses

Data was collected in Excel and transferred to SPSS v20 for analysis. NIHR research activity can fluctuate year-on-year and hence a total of five years was combined to counteract any variance. Trusts can be split by size, since they are officially classed as small-, medium-, large-sized and acute teaching status, which introduces stratification. To maintain one sample, the total research activity (studies and also participants recruited) was divided by the clinical staff number for each Trust to correct for Trust size. This produces a 'studies quotient' and a 'participants quotient' (ie number of active NIHR studies or number of recruited participants divided by the Trust clinical staff number). Spearman correlation analyses and multiple linear regression analyses were conducted. Since CQC rating is an ordinal dependent variable, ordinal regression analysis was performed first for this dependent variable to validate if the results of the ordinal and multiple linear regression analysis

gave comparable outcomes; for the purpose of comparability with the SHMI dependent variable, results from multiple linear regression analysis are presented. Overall number of studies and participants were not included in multiple linear regression analysis models to minimise risk of multicollinearity. A p-value of < 0.05 was considered statistically significant. NHS Trusts often operate more than one hospital; however, the terms 'Trust' and 'hospital' are used interchangeably and are meant to indicate the same throughout the text.

Results.

SHMI and CQC data was available for 129 English NHS Hospital Trust that have existed for the collated five years of NIHR research activity. Specialty NHS Trusts, such as children's, ophthalmology and orthopaedic hospitals, were not included since they do not offer the gamma of services provided in an average acute hospital. First, individual variables were correlated with the SHMI score and CQC rating respectively (see Table 1). Apart from the number of participants recruited into observational studies versus CQC rating and the number of interventional studies versus SHMI, all other variables correlated significantly with CQC rating and SHMI score. Where significantly associated, an increase in research activity is correlated with a better CQC rating and lower SHMI score respectively. Multiple linear modelling of the four independent variables (interventional studies, interventional participants, observational studies, observational participants) established that the variable most associated with improved CQC rating and SHMI mortality score is the number of patients recruited into interventional studies (the interventional participants quotient, see Tables 2 and 3). Figures 1 and 2 visualise the significant correlation between the number of patients enrolled in interventional research studies, which includes clinical trials involving medicinal products but also medical device studies and non-medicinal intervention studies such as counselling, and CQC & SHMI. When the figures for recruitment of participants into interventional studies are appraised per Trust, it shows

that the majority of top performing organisations are acute teaching hospitals. The median interventional participants quotient per Trust size are as follows: acute teaching, 1.72; large, 0.70; medium, 0.60; small 0.45 (for more in-depth overview of performance per Trust size see Supplement 1). Despite correction for Trust size, research activity is still approximately double for acute teaching Trusts compared to smaller sized Trusts. Therefore, analyses were repeated with acute teaching hospitals taken out of the equation, leaving 100 NHS Trusts to analyse. Spearman regression analysis showed that only recruitment of participants into interventional studies is significantly associated with CQC rating (rho 0.23, p-value 0.024); the comparison with SHMI was non-significant (rho -0.093, p-value 0.36). Backward multiple linear regression again resulted in interventional participants quotient being the variable associated the most with both CQC rating (stand coeff beta 0.19, p-value 0.062) and SHMI score (stand coeff beta -0.31, p-value 0.014; see Supplement 2).

Discussion

Ozdemir et al.[4] showed a significant association between NIHR clinical research activity and reduced mortality, with a focus on research funding per Trust to represent research activity. Our results are in agreement with their findings despite some variations in source data and methodology. In their paper NIHR activity data from one year, 2010-11, was used and Trust size was corrected using more than just Trust staff levels; they calculated mortality rates themselves whereas we used the now established SHMI, which was first used in 2010. Our approach of using only staffing levels to control for Trust size does not take into account e.g. vacancy factors (which are only published at regional level). Nonetheless, both studies have produced comparable outcomes. In our study we have addressed two discussion points raised by Ozdemir and colleagues: whether the positive link between NIHR-adopted research activity and mortality persists over time and if there is a difference between different types of research. The positive association persists over time, and only

interventional research shows a persistently significant association with lower mortality rates. The SHMI was originally developed to identify outliers in a cohort of hospitals.[13] There have long been discussions on the merit of a mortality index as an indicator of healthcare quality, and some are of the opinion that they cannot be used as an indicator as such.[12,14] Despite having its critics, the SHMI was deemed the most suitable outcome measure to assess if we could corroborate Ozdemir's findings, because it is available for all English NHS hospital Trusts; an added benefit is that it is published per Trust rather than per hospital. It does however highlight that mortality alone may not be sufficient when assessing the potential impact that clinical research may have on organisation-wide performance.

The positive association between clinical research activity and the healthcare quality indicator CQC rating adds weight to the positive correlation found for mortality through SHMI. A previous publication failed to identify an association between NIHR clinical research activity and CQC ratings.[15] However, unlike in that paper, the present study did not stratify the cohort by Trust size, apart from sub-analysis without teaching hospitals; we instead controlled for Trust size through consideration of Trust staff levels. Furthermore, a longer period of research activity was now used – five versus one year – to minimise the impact of incidental peaks and troughs in activity. The link between research activity levels and CQC ratings suggests that the positive effects clinical research may reach various departments and staff in a NHS Trust. CQC ratings are a compound score of a Trust's performance, aimed to assess if services are safe, effective, caring, responsive (to patient needs) and well-led. They also collate the views from patients and staff alike on how they feel a Trust is performing. Therefore, our data implies that Trusts engaging in clinical research may have low levels of never events and avoidable infections, and high levels of positive staff and patient feedback. To take an example, higher levels of staff engagement have been shown to be significantly associated with better Trust

performance.[16] Engagement in delivery of interventional research certainly requires staff engagement and team work; possibly more so than an average observational study. Nonetheless, caution should be applied in terms of the extent to which clinical research may influence mortality rates and CQC ratings, since the effect size of the associations found here are generally small. Furthermore, human factors would have to be studied in future studies to explore this further.

Since the NIHR funds all acute Trusts in England – along with other specialty, community, and mental NHS Trusts and GP practices – it is encouraging to observe that the positive association between clinical research and CQC and SHMI outcomes goes beyond acute teaching hospitals. This echoes the findings by Downing and colleagues that positive effects research participation are not confined to large regional tertiary centres.[5] Our focus on NIHR-adopted research as a measure of overall research activity means that other non-adopted research, including some commercial research conducted by NHS Trusts in collaboration with pharmaceutical companies, was not considered. The reason for this is two-fold: non-NIHR activity is not published anywhere, and more and more pharmaceutical and medical device companies conduct their research through the NIHR route, and therefore the portion of non-NIHR research is decreasing. The issue of limited data availability – particularly clinical research activity data - may also hamper efforts to replicate the findings of this present study in another country. In the past other correlation studies have been conducted across different European countries, including the association between nursing staff levels and hospital mortality rates[17], and therefore it may not be insurmountable to determine if the association between clinical research and improved quality of care is an international phenomenon.

The findings of this study raise the question: why is interventional research, rather than observational research, associated with increased Trust performance? There may be a number of factors driving this distinction. First, patients enrolled in interventional studies may directly benefit

from being in the study due to a) an improved treatment being offered, and/or b) being treated in accordance to the latest applicable guidelines for the condition in question, and/or c) potentially being monitored more closely as part of the trial. Conversely, an enormous observational study like COSMOS[18] - which has recruited 105,000 participants and investigates the health effects of mobile phone use - is less likely to result in a change in care for those taking part. Secondly, positive outcomes from trials may be incorporated into clinical practice more rapidly when a Trust has participated in those trials. This has been demonstrated in various settings, from oncology units to operating theatres.[19,20] Thirdly, interventional research, which in our analyses included commercial activity, may also generate more income than contributions to observational research.[21] This in turn allows reinvestment in Trust equipment and infrastructure, or investment in staff training, for example. It is, however, unlikely that novel treatment themselves contribute solely and directly to improved mortality rates and Trust performance. NIHR research activity has grown in the last decade, but the total number of recruited patients in 2015-16 for 2,678 interventional studies was still only 0.23% (204,745 participants / 89.4 million attended consultations; data sources NIHR ODP and NHS Digital respectively) of the total out-patient appointments for the year 2016-17. This percentage will be slightly higher when follow-up visits for trial patients are taken into account. Unpicking the exact mechanism, if indeed there are defined causative factors underlying our finding and those by others, remains difficult partly because standard methodological approaches like a prospective randomised trial of engagement in research and a lack of research activity is not feasible.[22] Retrospective studies and outcome research may be indicated to further investigate this phenomenon – termed 'trial effect' by Clarke & Loudon - where interventional clinical research seems to benefit the patients enrolled in the trials and the organisation delivering the research.[6, 23] Due to the retrospective non-controlled nature of this study, and the risk of confounding, one cannot state that the clinical research *per se* drives favourable mortality rates and CQC ratings.[24] Natural

experiment designs, often recommended as a way of understanding the impact of population-level policies on health outcomes, may be indicated to further explore the results shown in this present study.[25] As with prospective trials, controlling for confounders and bias will be key when comparing exposed (high levels of NIHR research) and non- or low-exposed (lower levels of NIHR research) NHS Trusts.[26]

The results of this study strongly support the notion that engagement by NHS Trusts and their staff in delivery of clinical trials, but not necessarily observational research, is positively associated with an improved organisational performance. This does not imply that the correlation is causal. Methodological constrictions mean that conducting prospective (randomised) trials to definitively identify factors contributing to these observations may be difficult.

Funding disclosure: None to declare.

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Table 1, Spearman correlation analysis for individual variables

	SHMI average	**CQC rating**

Variable	**Rho**	**p-value**	**Rho**	**p-value**
Overall studies quotient	-0.21	0.017*	0.23	0.008*
Overall participants quotient	-0.28	0.001*	0.18	0.040*
Observational studies quotient	-0.27	0.002*	0.26	0.003*
Observational participants quotient	-0.25	0.005*	0.12	0.19
Interventional studies quotient	-0.15	0.097	0.21	0.019*
Interventional participants quotient	-0.28	0.001*	0.27	0.002*

*statistically significant correlation (p-value < 0.05)

Table 2, backward multiple linear regression analysis: SHMI score as dependent

Variable	**Standard coefficient Beta**	**p-value**
Interventional studies quotient	0.36	0.030*
Interventional participants quotient	-0.44	0.002*
Observational studies quotient	-0.21	0.13
Observational participants quotient	-0.13	0.25
Most significant variable		
Interventional participants quotient	-0.50	0.001*

*statistically significant correlation (p-value < 0.05)

Table 3, backward multiple linear regression analysis: CQC rating as dependent

Variable	Standard coefficient Beta	p-value
Interventional studies quotient	-0.15	0.40
Interventional participants quotient	0.28	0.056
Observational studies quotient	0.26	0.077
Observational participants quotient	-0.089	0.46
Most significant variable		
Interventional participants quotient	0.26	0.003*

*statistically significant correlation (p-value < 0.05)

Figure 1, Scatter plot number of interventional participant quotient and SHMI score

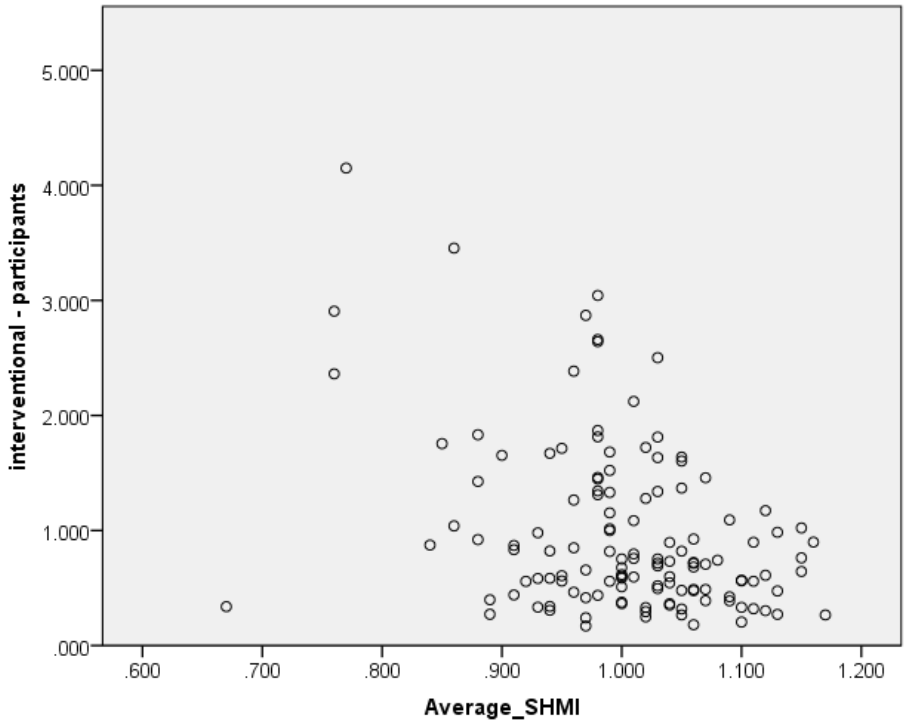
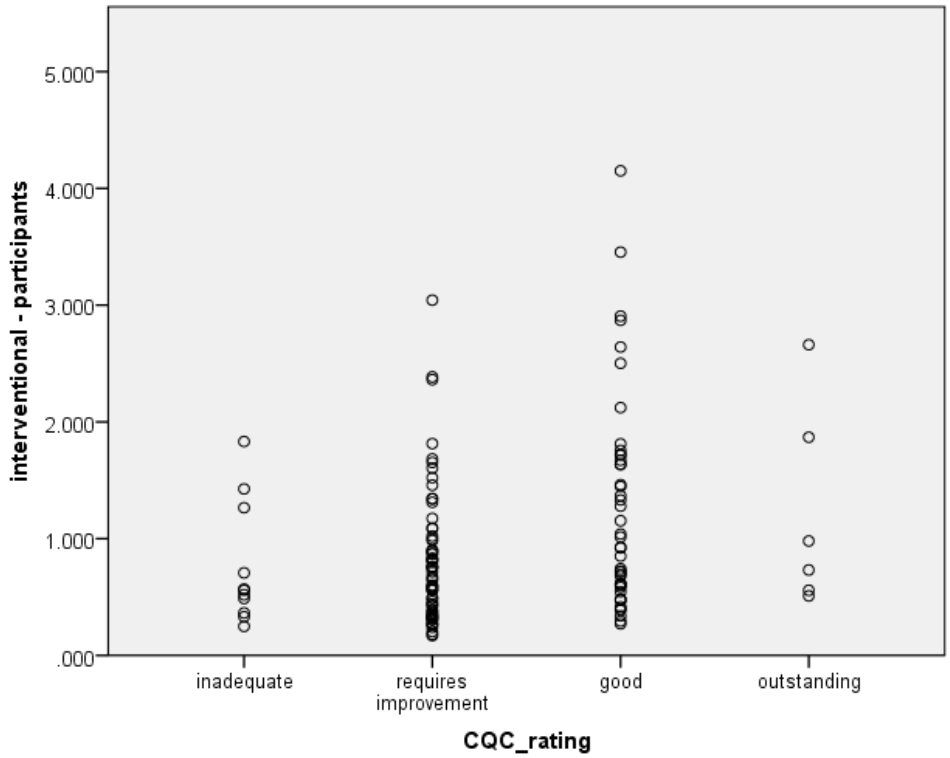


Figure 2, Scatter plot number of interventional participant quotient and CQC rating



Supplement 1, Summary tables of research performance by hospital Trust size

Table 4, Top and bottom five Hospital trusts by size and interventional participants quotient – Acute teaching hospital Trusts

Trust name	**CQC rating**	**Average SHMI score**	**Interventional participant quotient***
GUY'S AND ST THOMAS' NHS FT	Good	0.77	4.15
UNIVERSITY COLLEGE LONDON HOSPITALS NHS FT	Good	0.76	2.91
OXFORD UNIVERSITY HOSPITALS NHS TRUST	Good	0.97	2.87
THE NEWCASTLE UPON TYNE HOSPITALS NHS FT	Outstanding	0.98	2.66
UNIVERSITY HOSPITAL SOUTHAMPTON NHS FT	Good	0.98	2.64
Median values (n = 29)	*Good*	*0.98*	*1.72*
HULL AND EAST YORKSHIRE UNIVERSITY TEACHING HOSPITALS NHS FT	Req. improv.	1.09	1.09
YORK TEACHING HOSPITAL NHS FT	Req. improv.	0.99	1.00
SALFORD ROYAL NHS FT	Outstanding	0.93	0.98
ROYAL FREE LONDON NHS FT	Good	0.88	0.92
CHELSEA AND WESTMINSTER HOSPITAL NHS FT	Req. improv.	0.84	0.87

FT = Foundation Trust; Req. Improv. = requires improvement. *Participants recruited into interventional studies divided by total clinical staff number.

Table 5, Top and bottom five Hospital trusts by size and interventional participants quotient – Large hospital Trusts

Trust name	**CQC rating**	**Average SHMI score**	**Interventional participant quotient***
HEART OF ENGLAND NHS FT	Req. improv.	0.98	3.04
CITY HOSPITALS SUNDERLAND NHS FT	Good	1.03	1.63
PLYMOUTH HOSPITALS NHS TRUST	Req. improv.	0.99	1.52
SOUTH TEES HOSPITALS NHS FT	Good	1.05	1.37
ROYAL CORNWALL HOSPITALS NHS TRUST	Req. improv.	1.03	1.34
Median values (n = 34)	*Req. improv.*	*1.03*	*0.70*
N. LINCOLNSHIRE AND GOOLE HOSPITALS NHS FT	Inadequate	1.1	0.33
EAST SUSSEX HEALTHCARE NHS TRUST	Req. improv.	1.11	0.32
DONCASTER AND BASSETLAW HOSPITALS NHS FT	Req. improv.	1.05	0.27
WIRRAL UNIVERSITY TEACHING HOSPITAL NHS FT	Req. improv.	0.97	0.24

EPSOM AND ST HELIER UNIVERSITY HOSPITALS FT	Req. improv.	0.97	0.17

FT = Foundation Trust; Req. Improv. = requires improvement

Table 6, Top and bottom five Hospital trusts by size and interventional participants quotient – Medium hospital Trusts

Trust name	**CQC rating**	**Average SHMI score**	**Interventional participant quotient***
ROYAL SURREY COUNTY HOSPITAL NHS FT	Good	0.86	3.45
ASHFORD AND ST PETER'S HOSPITALS NHS FT	Good	0.94	1.67
TAUNTON AND SOMERSET NHS FT	Good	0.98	1.45
ROYAL UNITED HOSPITAL BATH NHS TRUST	Req. improv.	0.98	1.34
GATESHEAD HEALTH NHS FT	Good	0.99	1.33
Median values (n = 42)	*Req. improv.*	*0.99*	*0.60*
LEWISHAM HEALTHCARE NHS TRUST	Req. improv.	1.02	0.33
STOCKPORT NHS FT	Req. improv.	0.94	0.31
WARRINGTON AND HALTON HOSPITALS NHS FT	Req. improv.	1.12	0.30
KINGSTON HOSPITAL NHS TRUST	Req. improv.	0.89	0.27
SOUTHPORT AND ORMSKIRK HOSPITAL NHS TRUST	Req. improv.	1.1	0.20

FT = Foundation Trust; Req. Improv. = requires improvement

Table 7, Top and bottom five Hospital trusts by size and interventional participants quotient – Small hospital Trusts

Trust name	**CQC rating**	**Average SHMI score**	**Interventional participant quotient***
YEOVIL DISTRICT HOSPITAL NHS FT	Req. improv.	1.01	1.09
HOMERTON UNIVERSITY HOSPITAL NHS FT	Good	0.86	1.04
DORSET COUNTY HOSPITAL NHS FT	Req. improv.	1.13	0.98
SOUTH TYNESIDE NHS FT	Req. improv.	1.16	0.90
HARROGATE AND DISTRICT NHS FT	Good	0.96	0.85
Median values (n = 24)	*Req. improv.*	*1.03*	*0.45*
MILTON KEYNES HOSPITAL NHS FT	Good	1.02	0.29
TAMESIDE HOSPITAL NHS FT	Good	1.13	0.27
WYE VALLEY NHS TRUST	Req. improv.	1.17	0.27

ISLE OF WIGHT NHS TRUST	Inadequate	1.02	0.25
SOUTH WARWICKSHIRE GENERAL HOSPITALS NHS TRUST	Req. improv.	1.06	0.18

FT = Foundation Trust; Req. Improv. = requires improvement

Supplement 2 , Data analyses without acute teaching hospital Trusts.

Table 8, Spearman correlation analysis for individual variables (without teaching hospitals)

	SHMI average		**CQC rating**	
Variable	**Rho**	**p-value**	**Rho**	**p-value**
Overall studies quotient	-0.10	0.92	0.15	0.15
Overall participants quotient	-0.10	0.32	0.097	0.34
Observational studies quotient	-0.12	0.25	0.15	0.14
Observational participants quotient	-0.057	0.57	-0.009	0.93
Interventional studies quotient	0.092	0.36	0.12	0.25
Interventional participants quotient	-0.093	0.36	0.23	0.024*

*statistically significant correlation (p-value < 0.05)

Table 9, backward elimination multiple linear regression analysis: SHMI score as dependent (without teaching hospitals)

Variable	**Standard coefficient Beta**	**p-value**
Interventional studies quotient	0.39	0.018*
Interventional participants quotient	-0.34	0.008*
Observational studies quotient	-0.20	0.16
Observational participants quotient	0.047	0.65
Most significant variable		
Interventional participants quotient	-0.31	0.014*

*statistically significant correlation (p-value < 0.05)

Table 10, backward elimination multiple linear regression analysis: CQC rating as dependent (without teaching hospitals)

Variable	**Standard coefficient Beta**	**p-value**
Interventional studies quotient	-0.20	0.23
Interventional participants quotient	0.27	0.039*
Observational studies quotient	0.13	0.36
Observational participants quotient	-0.012	0.91

Most significant variable		
Interventional participants quotient	0.19	0.062

*statistically significant correlation (p-value < 0.05)