Title: **Patients admitted to more research-active hospitals have more confidence in staff and are better informed about their condition and medication; results from a retrospective cross-sectional study.**

Running title: **Research activity and information provision to patients.**

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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. DD is the clinical lead for NIHR-funded research within his employing NHS Trust, and has in the past received NIHR grant funding.

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

Summary

Rationale, aims and objectives

Clinical research activity in hospitals is associated with reduced mortality and improved overall care quality. In England, the latter is a compound score of several elements and both staff and inpatient feedback form part of the Care Quality Commission (CQC) ratings. The objective of this study was to determine if NHS Trusts' National Institute for Health Research (NIHR) study activity data correlates with specific outcomes from national NHS staff and patient surveys.

Method

Retrospective cohort design involving data for 129 English NHS hospital Trusts, including scores from recent national NHS staff and inpatient surveys and NIHR data. Statistical approach involved Spearman correlation analyses, with cut-off p-value ≤ 0.01 for qualification for subsequent principal component analysis (correlation coefficient cut-off value 0.20).

Results

Outcomes of one staff survey question (staff recommendation of the organisation as a place to work or receive treatment) and multiple outcomes of inpatient survey questions were positively associated with increased NIHR-adopted clinical research activity. Better quality of information provision to patients was the dominant theme, though a higher degree of observed staff

teamwork, more confidence in the treating doctors, and a better overall inpatient experience also correlated significantly. The number of different studies contributed more to positive associations with survey outcomes compared to the number of recruited participants into research.

Conclusions

Survey elements of the CQC appraisal of English NHS Hospital Trusts are significantly associated with increased clinical research activity levels; it appears to drive better information provision to inpatients – particularly around medicine management - and contribute to a better inpatient experience overall, whilst staff are more likely to recommend their own organisation. Despite clinical research activity forming a very small fraction of overall NHS activity, it has an indirect positive effect on staff and Trust performance that is measurable at patient level.

61 **Introduction**

62 Clinical research can result in gains beyond the direct intended benefits, such as improved efficacy,
63 performance, or safety of a new medicinal product or medical device. Examples of a wider positive
64 impact of clinical research activity at specialty-level are better health outcomes for those
65 participating in clinical trials when compared to patients receiving standard care in obstetrics &
66 gynaecology, and improved survival rates for colorectal cancer patients who attend NHS Trusts that
67 are more research active.[1,2] At an organisation level, studies have shown an association between
68 increased clinical research activity levels - be it National Institute for Health Research (NIHR) activity
69 or academic output - and reduced mortality rates.[3,4,5] Furthermore, engagement in clinical research
70 is associated with improved wider healthcare performance at organisation level.[5,6,7] These
71 developments have spurred the Care Quality Commission (CQC), a national body that inspects NHS
72 Trusts in England, and the National Institute for Health Research (NIHR), the over-arching
73 organisation for management of clinical research in the UK, to work towards incorporating clinical
74 research activity as an outcome measure in CQC inspections for NHS Trusts.[8] Since a CQC rating, and
75 hence a NHS Trust's performance in relation to quality, is based on various elements it would be
76 desirable to identify discrete reasons or elements for seeing higher healthcare standards in more
77 research-active NHS Trusts. To date, unpicking how clinical research may have a positive effect on
78 the performance of a healthcare organisation, or defined clinical specialty, has proven to be difficult
79 to achieve, and it has been suggested that national public database interrogation may shed a light
80 on the 'mechanism of action'.[7]

81 In this study we analyse how NIHR-adopted clinical research activity in NHS Trusts may be linked with
82 improved healthcare quality by correlating it with outcomes from two national NHS surveys: one for
83 inpatients and one for NHS staff. Both surveys form part of CQC rating exercises of NHS Trusts.

84 Potential relationships between clinical research activity and patient and staff perception on
85 healthcare quality in individual NHS Hospital Trusts in England will be explored.

86

87 **Methods**

88 *Ethics statement and data sources*

89 This concerns a service evaluation and therefore no approval was sought from the national
90 research ethics service or health research authority. The data used in this retrospective cross-
91 sectional study of English NHS hospital Trusts is publically available via NHS and NIHR electronic
92 depositories. The methodology for obtaining NIHR research activity, CQC data and SHMI data has
93 been published previously.[5] In summary, NIHR research activity for the accrual years 2012-17 was
94 obtained from NIHR Open Data Platform website.[9] Clinical staffing numbers for each NHS hospital
95 Trust in England were obtained from NHS Digital, whereas CQC ratings for said Trusts as of October
96 2017 were obtained from the CQC website.[10, 11] The average SHMI value for each NHS Trust for the
97 calendar years 2014, 2015 and 2016 was calculated.[12,13]

98 New data added to the existing dataset from the Jonker & Fisher publication includes data from the
99 2016 and 2017 (average score) NHS staff survey and 2017 in-patient survey respectively. Both are
100 available on the NHS survey website.[14] For the NHS staff survey, all questions – called Key Findings
101 by NHS surveys – were included in the analyses. For the in-patient survey, only questions applicable
102 to all in-patients, regardless of route of entry to hospital or treating specialty – thereby excluding
103 admission route questions (via accident & emergency or elective admissions), surgical procedures,

104 and questions on various waiting times - were included. The scoring methodology for each survey is
105 outlined in documents available via NHS surveys web site.

106 *Data processing and analyses*

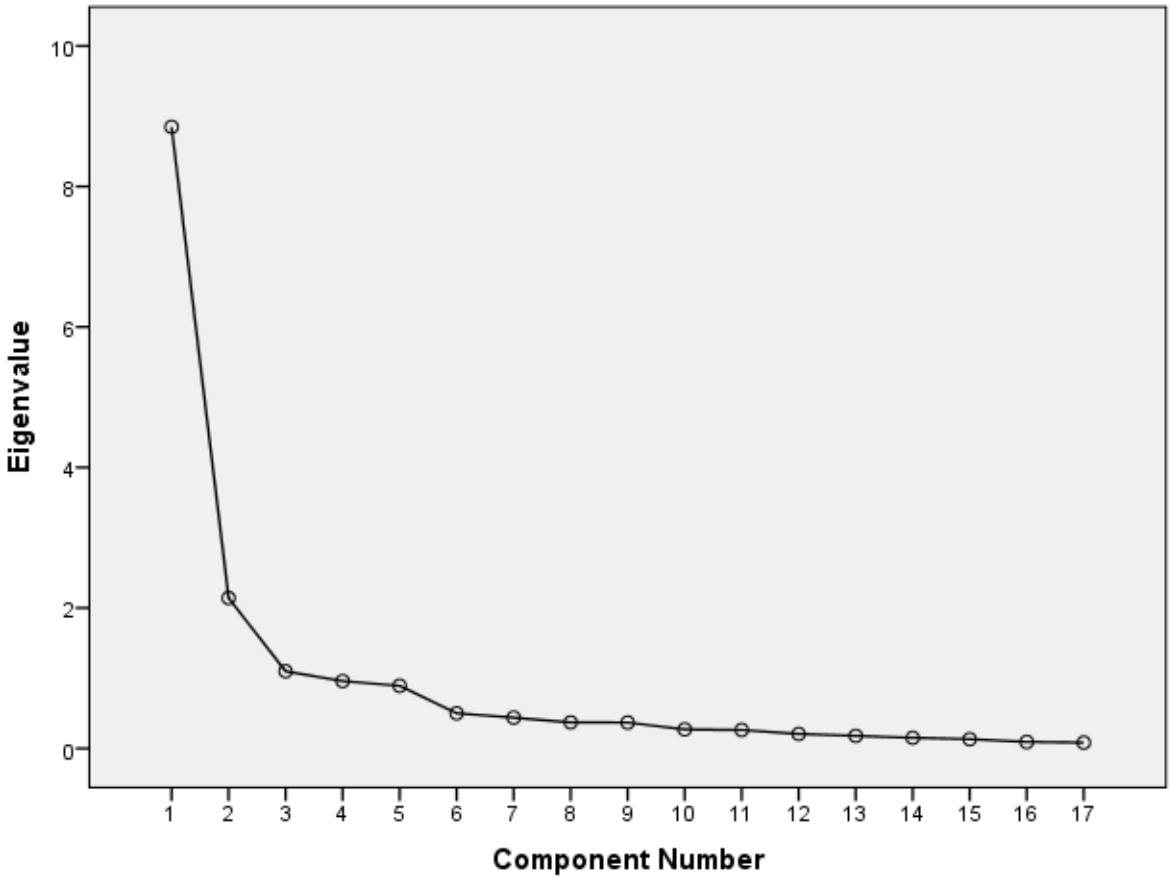
107 Data was collected in Excel and transferred to SPSS v20 for analysis. As outlined previously,[5] a
108 quotient was produced for studies and participants, by dividing the number of studies and accrued
109 participants by the number of clinic staff per NHS Trust. This resulted in six 'research activity
110 quotients': total number of studies, total number of participants, total number of interventional
111 studies, total number of interventional participants, total number of observational studies and
112 total number of observational participants quotients. Spearman correlation analyses were
113 conducted first – the survey outcome measures are based on Likert-scale response options which
114 are then given a weighted score. Only when one of the survey elements was significantly correlated
115 to one of the two 'research activity quotients', ie total number of research studies or total number
116 of participants divided by clinical staff number, was this element then included in the subsequent
117 analysis. A p-value of < 0.01 in the Spearman correlation analyses was considered statistically
118 significant. A stringent p-value was opted for to counteract any multiplicity of testing error that
119 may occur when first applying Spearman correlation coefficient and then a subsequent inferential
120 test to the same data. Subsequent principal component analysis (PCA) was conducted to explore
121 the relationship between the earlier analysed factors of Trust-specific NIHR research activity,
122 mortality (SHMI), CQC rating, and significant results from the two NHS surveys (in-patients and
123 staff). Since the focus was on identifying factors with a shared variance, a correlation coefficient
124 cut-off value of 0.2 was applied for the rotated component matrix table.[15]

125 **Results**.

National survey, SHMI and CQC data was available for 129 English NHS Hospital Trusts that have existed for the collated five years of NIHR research activity. As before, specialty NHS Trusts that cover only one speciality were not included since they do not offer the range of services provided in an average acute hospital. The significantly associated survey questions identified via Spearman analyses are summarised in Table 1, whereas Table 2 gives a full description of how the survey questions were worded in the original NHS survey literature. Although a number of inpatient survey questions are statistically correlated with both research studies and participants quotients, only one staff survey question was linked with NIHR research activity – staff recommendation of their own Trust to others. Some of the staff survey outcomes that were not linked to research activity at all were 'Staff satisfaction with the quality of work and care they are able to deliver' (question KF2; Spearman's rho -0.034, p-value 0.71 for research studies quotient) and 'Staff motivation at work' (question KF4; Spearman's rho -0.11, p-value 0.22). Further Spearman analyses did not identify any survey questions that were correlated specifically with interventional or observational studies, and therefore subsequent analyses used the overall research studies and research participants' quotients. All the outcome elements from the two national NHS staff and in-patient surveys, including questions where correlation was not statistically significant, are presented in Supplement 1 (Table S1-1 and Table S1-2 respectively). The observed correlation between NIHR research activity and staff / in-patient question outcomes was observed even when the data was stratified for the size of a NHS hospital Trust (acute teaching, large, medium, and small hospital Trusts) as outlined in Supplement 2, Table S2-1 through S2-4. The significant association between survey outcomes and research activity is visualised by showing data for staff survey question KF1, inpatient question Q35, and inpatient question Q68 versus the research studies quotient.

149 Any relationship between the NHS staff and inpatient surveys and research activity were
150 subsequently investigated with PCA testing. The significantly associated survey outcome measures
151 from the Spearman analyses, one question in the case of the staff survey and twelve questions from
152 the inpatient survey, were analysed as part of the PCA test. The components identified through PCA
153 were highly significantly correlated, see Table 3. The Kaiser-Meyer-Olkin measure of sampling
154 adequacy was 0.92, whereas the p-value for Bartlett's test of sphericity was <0.001. Three positively
155 correlated components emerged from PCA, namely 1) inpatient survey outcomes, staff survey
156 outcome, and the number of research studies conducted, 2) inpatient survey outcomes, staff survey
157 outcome, CQC rating and SHMI mortality (negative association for the latter), and 3) research activity
158 in terms of studies and patients recruited, mortality (negative association), and inpatient survey
159 outcomes. Component 1 accounted for 52.0% of variance within the model, whereas component 2
160 contributed 12.6% and component 3 accounted for 6.5%. Figure 1 shows the scree plot for this
161 analysis with Eigen values. Therefore, of the three components, component 1 and 3 included
162 research activity components.

163 **Figure 1, Scree plot for principal component analysis of research activity and staff and inpatient surveys**



The relationship between CQC rating, SHMI mortality, and survey questions significantly associated (p-value < 0.01) with research studies or participants quotient were assessed with PCA.

Discussion

Following the recent publications that have shown that clinical research activity is related to a single outcome measure (mortality rates) and a compound score representative of care quality (CQC rating), the current study aimed to further explore the elements that make up the latter. Staff and inpatient surveys give a unique perspective from people who work in NHS hospitals every day, and those who receive care as an inpatient. To assess various outcome measures in a single analysis, including research activity, survey results, mortality and CQC rating, the multi-dimensional analysis

176 tool PCA was performed rather than e.g. linear regression analysis, since this only allows one
177 dependent and it is not known how the significantly correlated independent variables are related.

178 Before appraising and discussing the findings of this study, it is important to emphasise that clinical
179 research activity forms only a fraction of the overall patient activity in the NHS. In England, the total
180 number of recruited patients in interventional studies alone is no more than approximately 1 in 400
181 out-patient contacts; in an inpatient setting this figure will likely be lower still.[5] Therefore, any
182 association between clinical research activity and survey outcomes is likely an in-direct effect (such
183 as a certain organisational culture as a 'side-effect' of conducting clinical research, or vice versa if
184 best practice is considered to be more conducive to conducting clinical research). A shortcoming of
185 this study and any non-controlled retrospective cohort study, due to the high risk of confounding
186 and difficulties untangling cause and effect, is that one cannot conclude with certainty that clinical
187 research drives favourable staff and inpatient survey outcomes. The same applies for the established
188 links between mortality rates and CQC ratings, demonstrated once more in this present study.[5,16]
189 This issue was highlighted in a systematic review by Boaz and colleagues.[7] As a case-in-point,
190 Downing and colleagues found that more research-active colorectal cancer treatment centres have
191 a greater arsenal of diagnostic and therapeutic tools. However, what is not certain is whether
192 research participation contributes to this kind of infrastructure enrichment, or if a pre-existing wider
193 availability of this type of equipment contributes to increased research activity and therefore –for
194 example - improved survival rates.[2]

195 The first observation from the results obtained is that only one element of the staff survey (out of
196 32 questions, or key findings) is significantly associated with clinical research activity, whereas for 12
197 out of 24 questions included in the correlation analysis for the inpatient survey significantly
198 associated with NIHR-adopted research activity. Nonetheless, of all the questions in the staff survey,

KF1 is one of the questions that asks the staff to comment on the performance of the Trust as a whole, as opposed to asking them about how their role impacts on performance or whether they as an individual have experienced bullying or violence, or are being asked to work additional hours. What is perhaps surprising or disappointing, is that staff survey questions related to personal development, including levels of non-mandatory training, and learning, and staff work satisfaction and motivation were not found to be associated with research activity levels. It would be logical for research-active staff to be involved in more training and learning, for example the clinical trial-related Good Clinical Practice training. However, survey responses from (clinical) staff involved in research will have been a small proportion of all the survey responses.

When the questions from the inpatient survey that are significantly correlated with increased research activity are reviewed, a number of themes emerge that can logically be linked to processes related to conducting and engagement in clinical research: high levels of staff teamwork, good quality information provision to patients (including in relation to medicines management), clinical staff involving patients in their care in a respectful manner, and - possibly of a result of these three themes? - patients having confidence in the doctors treating them. Based on the data from the Spearman correlation analyses and PCA, we can conclude that the associations between research activity and survey outcomes can be classed as moderate and statistically highly significant. It should be noted from the PCA data that the number of studies conducted in a NHS Trust is linked to more inpatient survey outcomes than the number of participants recruited. This is also supported by the percentage variance contributed by each of the three identified components; component 1, in which the research studies quotient but not the research participants quotient is associated significantly with positive patient and staff survey outcomes, contributes over half of the variance. Although speculative, this may reflect that more studies will likely mean more specialties in a hospital being

222 involved in clinical research; this in turn would mean more staff being exposed to research and
223 adopting best clinical practice, and therefore would have a larger wider impact than recruiting more
224 patients in fewer studies involving fewer clinical specialties. On a single-specialty level, this has been
225 shown for colorectal patients (all patients even when not participating in a trial) and obstetric &
226 gynaecology patients (patients who participate in research trials).[1,2]

227 Based on the observations from this study, one could ask the question: why would clinical staff in
228 research-active hospital be more competent in the provision of information to patients in an easy-
229 to-understand manner, whilst treating patients in a dignified manner? As with the impact of running
230 more research studies, an explanation to this question is hard to substantiate in the absence of
231 evidence from prospective controlled studies. However, it is conceivable that clinical staff who are
232 used to conducting clinical research, which involves adherence to a protocol, careful and thorough
233 provision of study information to patients and the diligent collection of data, will adopt at least some
234 of these 'good habits' into routine clinical practice. Numerous studies have shown that better quality
235 information provision has a positive impact on patients' well-being and therefore contribute to
236 better quality care.[17,18,19] In parallel, a 'trial' effect of better adherence to guidelines and prescription
237 to latest research evidence was observed in those members of staff who are involved in conducting
238 research.[20] As a result of a review of the literature, Boaz, Hanney and colleagues reported that at the
239 clinician level, engagement in research can positively influence behaviour and attitude and it
240 contributes to staff education. At an organisational level resources and infrastructure used in
241 research trials may be used beyond those studies in standard clinical practice, plus new (beneficial)
242 treatments and practice may be rolled out more readily.[6,7]

243 Data from this present study and previous studies shows that engagement in clinical research is
244 positively – and significantly – associated with reduced mortality and improved quality of healthcare

provision. This observation is not confined to traditional academic hospital Trusts, it is also seen in smaller-sized district hospitals, and it appears that improvements in basic yet essential skills and processes, such as diligent and thorough communication with patients, may contribute to these observations. Furthermore, the 'trial' effect seen in this study is observed beyond patients who participate in clinical trials, or are just treated, in specific specialties such as colorectal cancer, cardiology and obstetrics patients.[1,2,16] Here, a positive effect is observed on an organisational level and it is feedback from patients. The planned inclusion of research as an element of CQC ratings should aid in driving care provision improvements in healthcare provision across more NHS organisations by means of increasing clinical research activity. CQC research elements may benefit from distinguishing between the breadth (number of research studies) and depth (number of research participants) of clinical research activity to get a true picture of how research can make a wider impact. Further research, including longitudinal studies, are indicated to monitor if the NIHR-CQC initiative has an effect on an organisation's performance, including the staff and inpatient survey elements identified in this present study.

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References

1. Nijjar SK, D'amico MI, Wimalaweera NA, Cooper NA, Zamora J, Khan KS. Participation in clinical trials improves outcomes in women's health: a systematic review and meta-analysis. BJOG: An International Journal of Obstetrics & Gynaecology. 2017 May;124(6):863-71

266 2. Downing A, Morris EJ, Corrigan N et al. High hospital research participation and improved
267 colorectal cancer survival outcomes: a population-based study. *Gut*, 2017;66:89-96.
268 3. Bennett WO, Bird JH, Burrows SA, Counter PR, & Reddy VM. Does academic output
269 correlate with better mortality rates in NHS trusts in England? *Public Health*, 2012;126:S40-
270 3.
271 4. Ozdemir BA, Karthikesalingam A, Sinha S, et al. Research activity and the association with
272 mortality. *PLoS One*, 2015;10:e0118253.
273 5. Jonker L, Fisher SJ. The correlation between National Health Service trusts' clinical trial
274 activity and both mortality rates and care quality commission ratings: a retrospective cross-
275 sectional study. Public health. 2018 Apr 30;157:1-6.
276 6. Hanney S, Boaz A, Soper B, Jones T. Engagement in research: an innovative three-stage
277 review of the benefits for health-care performance. Health Services and Delivery Research.
278 2013;1(8).
279 7. Boaz A, Hanney S, Jones T, & Soper B. Does the engagement of clinicians and organisations
280 in research improve healthcare performance: a three-stage review. *BMJ*
281 *open*, 2015;5:e009415.
282 8. NIHR news release: https://www.nihr.ac.uk/news/partners-announce-latest-progress-with-
283 cqc-aimed-at-ensuring-research-is-a-priority-for-quality-patient-care/8496, last accessed 6
284 November 2018
285 9. NIHR Open Data Platform website, https://odp.nihr.ac.uk/ (last accessed 6 November
286 September 2018).
287 10. NHS Digital – Clinical Staffing data for August 2016,
288 https://digital.nhs.uk/catalogue/PUB22340 (last accessed 6 November 2018).
289 11. CQC website, http://www.cqc.org.uk/search/ (last accessed 6 November 2018).

290 12. NHS Digital – SHMI data: https://digital.nhs.uk/catalogue/ (last accessed 6 November 2018).
291 13. Freemantle N, Richardson M, Wood J, Ray D, Khosla S, Sun P, Pagano D. Can we update the
292 Summary Hospital Mortality Index (SHMI) to make a useful measure of the quality of hospital
293 care? An observational study. BMJ open. 2013 Jan 1;3(1):e002018.
294 14. NHS inpatient and staff survey data: http://www.nhssurveys.org/ (last accessed 6
295 November 2018)
296 15. Child, D. (2006). *The Essentials of Factor Analysis*. 3rd edn. New York: Continuum.
297 16. Majumdar SR, Roe MT, Peterson ED, Chen AY, Gibler WB, & Armstrong PW. Better
298 outcomes for patients treated at hospitals that participate in clinical trials. *Archives of*
299 *Internal Medicine*, 2008;168: 657-62.
300 17. Poole K, Moran N, Bell G, Solomon J, Kendall S, McCarthy M, McCormick D, Nashef L,
301 Johnson A, Sander J, Shorvon S. Patients' perspectives on services for epilepsy: a survey of
302 patient satisfaction, preferences and information provision in 2394 people with epilepsy.
303 Seizure. 2000 Dec 1;9(8):551-8.
304 18. Cegala DJ, Street Jr RL, Clinch CR. The impact of patient participation on physicians'
305 information provision during a primary care medical interview. Health communication.
306 2007 May 22;21(2):177-85.
307 19. Smith J, Forster A, House A, Knapp P, Wright JJ, Young J. Information provision for stroke
308 patients and their caregivers. Cochrane Database of Systematic Reviews. 2008(2).
309 20. Clarke, M., & Loudon, K. (2011). Effects on patients of their healthcare practitioner's or
310 institution's participation in clinical trials: a systematic review. *Trials*, 12(1), 16.