Title: **Appraisal of National Institute for Health and Care Research activity in primary care in England; cross-sectional study.**

Running title: Primary care based clinical research

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Key messages

- One million patients have participated in primary care research between 2013-23
- Research activity is weakly associated with primary care practice performance
- Practice size and staffing levels show a positive link with research activity
- Future research initiatives need to consider primary care practice circumstances

Abstract (currently 242 words)

Background

The National Institute for Health and Care Research (NIHR) was set up to enhance clinical and health research activity in a variety of National Health Service (NHS) healthcare settings, including primary care.

Objective

To appraise how overall General Practitioner (GP) practice performance, location and staffing levels may interact with NIHR Portfolio activity in primary care in England.

Methods

Cross-sectional summary of GP practice research activity and practice descriptors; complete data from 6171 GP practices was collated from NIHR (using data for 2013-23 for Portfolio studies), Public Health England, Care Quality Commission, and NHS Digital sources respectively.

Results

In primary care, 1 million patients have been recruited into NIHR Portfolio studies in the last decade. The top 10% of practices – measured by different studies recruited to – contributed over 50% of that accrual. When the top decile of GP practices is compared to the 20% least active GP practices, research activity is significantly and individually linked with larger GP practices. Furthermore, it is

significantly yet modestly associated with GP practice performance (positive patient feedback, Care Quality Commission rating), lower locality deprivation levels, and lower patient to GP ratios.

Conclusions:

Research activity in GP practices is – as seen previously with hospitals – significantly linked with better GP practice performance and patient feedback. Practice list size and staffing levels in particular interact with the aforementioned. This should be taken into account when determining strategies to increase patient and GP practice participation in NIHR Portfolio research studies.

Key Words: primary care, clinical research, care quality, deprivation, staffing.

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Background

The founding of the National Institute for Health and Care Research (NIHR) in the United Kingdom back in 2006 has allowed more clinical trials and research studies to be delivered at pace and scale in the National Health Service (NHS). In terms of delivery of research, regional NIHR-funded Clinical Research Networks (CRNs) assist to help drive the NIHR's aim to 'improve the health and wealth of the nation through research'.[1] Over £300 million is spent annually on CRNs to have a workforce of research nurses and other delivery and support staff in place for recruitment and follow-up of patients into qualifying studies that have been adopted onto the 'NIHR Portfolio' of studies.[2] At GP practice level, this usually means activity-related back-payments for any studies conducted and patients recruited; remuneration levels depend on study complexity and is arranged through nationally agreed contract models. Occasionally arrangements may be made with a regional CRN to receive block funding for local employment of delivery staff.

Since GPs are a first port of call for patients with a huge variety of conditions and ailments, primary care should be a prime location in which to conduct research. Nonetheless, despite the huge volume of patient consultations and care taking place in general practice (over 300 million patient consultations versus 23 million A&E visits each year) primary care research was not fully integrated into the NIHR's regional CRN model until 2014.[6,7] Recent challenges around workload levels and staff shortages in primary care mean that further development of clinical research delivery in this setting may prove difficult to achieve.[8]

From hospital settings there is a body of evidence that – apart from any direct benefit to patients participating in research studies – more NIHR-adopted clinical research activity is linked with overall reduced mortality rates, better hospital quality metrics, and improved patient experience related to

better clinical practice by staff.[3,4,5] To date, studies have not focused on whether research activity in primary care may be associated with improved wider parameters or quality outcomes for a GP practice. Here we explore how NIHR-adopted clinical research activity in GP practices in England may interplay with (quality-related) descriptors for those organisations.

Methods

The study setup was a retrospective cross-sectional approach involving data from 6231 English GP practices. All data used in this study is readily available to the public via NHS, Public Health England (PHE) and NIHR Digital repositories, and the CQC web site. NIHR research activity was obtained from the NIHR Open Data Platform website and the annual figures for the years April 2013 to March 2023 were combined.[9] The focus was on two measures for each GP practice: the number of different studies that patients had been recruited into, and the total number of patients recruited per 1000 patients registered with said GP practice (the latter to control for differences in GP practice size). The mean patient numbers per GP practice as of each April between 2014 and 2023 were used for the analyses, and these were available from NHS Digital.[10] The number of patients each full-time, or whole time equivalent, GP managed was retrieved from Office for National Statistics based on NHS Digital source data.[11]

The average index of multiple deprivation score for each GP practice was obtained from Public Health England (PHE) records for 2019.[12] Likewise, PHE also has data available for the percentage of patients in each GP practice who have a long-standing chronic health condition.[13] Ethnicity data for patients is available per locality (Integrated Care board sub-locality) rather than individual GP practice; 2023 data was obtained from NHS Digital.[14] There are marked differences for various variables between the North and South of England, for example a difference in hospital-based mortality.[15] To take this into consideration for this present study, predefined regions were used to

divide England into two halves: North (East Midlands, North East, North West, Yorkshire & Humber) and South (East, West Midlands, London, South East, South West).

In England, patients are asked annually about their experience of the GP practice they are registered with. Results for Question 32 of the survey, 'Overall, how would you describe your experience of your GP practice?' were included in the study dataset. Specifically, the percentage of patients in 2022 who had a positive experience of their GP practice (their answer being 'fairly good' or 'very good') was utilised.[16] The CQC is the independent regulator of health and social care in England and failure to comply with monitoring and inspection activities conducted by CQC may result in registration being revoked. As a result of monitoring activities, the CQC will award each GP practice a rating of inadequate, requires improvement, good or outstanding. The published CQC ratings as of May 2023 were included for analysis.[17]

No personal identifiable information has been used as part of this study; since this concerns a service evaluation from a governance perspective, no formal ethics clearance was obtained. Data was collected in Excel and statistical tests run using SPSS v24. Pearson correlation analyses were conducted to assess individual relationships between the research activity variables and GP practice descriptor variables. After establishing if a linear relationship between each variable and research activity was indeed present, multiple linear regression was conducted. To account for any multicollinearity (the presence of high intercorrelations among two or more independent variables in a multiple regression model), Principal Component Analysis (PCA) was performed.[18] Any GP practices that missed data for one or more variables was excluded from regression and PCA. A p-value, *P*, of <0.05 was considered statistically significant.

Results

Since the inception of the NIHR in 2006 and the start of systematic recording of research activity for NIHR Portfolio studies, activity in primary care has gradually grown. Table 1 shows that more than

one million patients have been recruited into NIHR Portfolio studies between April 2013 and March 2023. However, the distribution of contribution is skewed. No recruitment has been recorded for 196 GP practices, and the 20% least research-active GP practices either did not engage in research at all or only recruited to one research study over the period covered. On the other hand, 10% of GP practices contribute over half of all patient accrual (Table 1); those 'top decile' GP practices have all recruited into at least 20 different studies, with the top practice recruiting into 113. There is little difference in the type of research studies conducted when the top decile GP practices are compared to the overall set of GP practices. The percentage patients recruited into interventional studies is 44% (256,364 out of 585,095 participants) for the former and 41% (420,193 / 1,013,975) for the latter. There appears scope to increase the number of GP practices contributing to NIHR Portfolio research, and some patients may not be offered the opportunity to participate in primary care based research.

Table 2 shows that research activity - be it number of different recruiting studies or patient accrual (per 1000 registered patients) as the indicator - is significantly associated with various GP practice descriptors. Independently, increased research activity is significantly associated with: larger GP practices; less deprived areas; the South of England; lower patient to GP ratio. Patients in those GP practices are more likely to have an overall 'good' experience there, and the practices themselves tend to have a higher CQC rating. Since the number of research studies associates better with the GP practice descriptors, this variable was used for subsequent multivariable analyses. To home in on any differences in GP practice characteristics between active and (virtually or completely) non-active GP practices, the top 10% was compared to the lowest 20% of GP practices in terms of research activity. Binary logistic regression analysis indicates that a GP practice's location in the North or South of England is not related to the degree of research activity in a GP practice, whereas larger practice size, lower patient:GP ratio, lower deprivation level, positive GP practice survey response and higher CQC rating are (Table 3). The Nagelkerke R^2 value of 0.56 suggests that the variables account for 56% of variability detected when the top GP practices are compared to the (effectively) non-active GP practices. Principal Component Analysis was performed to establish how the multiple variables

interact. The Kaiser-Meyer-Olkin measure of sampling adequacy indicated that the strength of the relationships among variables was moderate (KMO = 0.60) and the model significant (*P* <0.001), indicating that the data were suitable for PCA. Parallel analysis using varimax rotation recommended that three components be extracted from the data, explaining 57% of the total variance. Three components were detected (see Table 4). The first component has no bearing on research activity; it does however highlight the complicated relationship between regional location and patient characteristics and well-being. Component 2 confirms the earlier regression analysis results; increased research activity associates with a larger GP practice size, fewer patients per GP, and a lower deprivation score. Component 3 is similar to component 2, but instead of practice list size it is the higher functioning of a GP practice (better patient feedback, higher CQC rating) that is linked to research activity here.

Discussion

GP practices have made a significant contribution to clinical research activity in England in the last decade. However, in contrast to secondary care where 100% of all NHS Hospital Trusts are engaged in research, there is a large proportion of GP practices that do not conduct any NIHR Portfolio research. The delivery of clinical research studies in primary care is associated with an overall better performing GP practice. The more research active GP practices employ relatively more GPs per standard size population, tend to be larger practices, and are based in less deprived areas of the England. Despite research activity showing significant links with individual variables, PCA analysis shows that these relationships are likely multifaceted and multidirectional. This likely complex combination of circumstances aligns what is seen in GP practices generally without taking into account research activity: smaller practices in more deprived areas have relatively fewer GPs and perform less well than larger practices.[19, 20, 21] Larger GP practices perform better than smaller GP practices with regards to multiple parameters, such as quality indicator framework score, patient hospital admission rates, and appropriate referral rates to secondary care.[21] Earlier research identified a multitude of factors, some hard to quantify such as ‘team climate’, that may contribute

to GP practice performance.[22] It is therefore not possible to speculate on the direction of associations seen here, and how variables may influence each other.

A strength of the analysis of research activity versus GP descriptors is that data for the vast majority of English GP practices (over 6,000 GP practices) could be included. By averaging 10 years of data on NIHR research activity and also GP practice list sizes, outlier outcomes due major peaks and throughs in research activity and changes in patient numbers due to practice mergers are minimised. For other variables such as GP survey, chronic health prevalence and CQC rating a single most recent outcome measure was used due to the exploratory nature of this study, recognising there may some movement for each of these measures over the years even if it is unlikely to be to the magnitude seen for research activity. Source data for some of the variables may itself also be subject to limitations; for example, ethnicity data is typically based on ~80% of patients, rather than 100%, declaring their ethnicity.[14] With many ethnic sub-categories available, the focus was here on the most prevalent category, White British, and this may not offer sufficient granularity to draw conclusions on any relationship between patient ethnicity and research activity in a GP practice. Since a significant link was found even with just this one category, further work exploring this theme in depth may be warranted. Taken together, some caution is indicated when drawing conclusions from the data. Firstly, NIHR Portfolio studies involve different types of studies, varying from large scale observational studies (involving only a survey to be completed by a patient) to complex clinical trials involving medicinal products. Secondly, studies can be set up in various ways. In primary care, GP practices are often asked to identify, screen and invite patients with the rest of the study conducted by one central site such as a university. In such an instance, a GP practice is acting as a Participant Identification Centre (PIC). As such, although the percentage interventional research is presented here, it does not mean that the logistics and activities at a GP practice level are significantly different from those for a typical observational study. From our personal experience conducting NIHR Portfolio studies in primary care, we recognise why larger GP practices may run more studies. Reasons include more staff capacity, and some research studies target larger GP

practices and exclude smaller ones. A recent example from personal experience is the SAFER trial which remotely screens patients for the presence of atrial fibrillation; only GP practices who had a minimum of 800 eligible patients were allowed to contribute, equating to GP practices with a list size of at least 5,000.[23]

From the results presented here, it emerges that it may not be straightforward to simply ask GP practices to become research active. The wider issues that a GP practice may face will likely contribute to being barriers to engaging in research. One key element is funding to employ staff, or create capacity within a GP practice, to deliver NIHR Portfolio research studies. The CRN is the liaising organisation for GP practices to obtain this income. Unlike in secondary care, where NHS Trust receive a lump sum of CRN money up front at the start of the financial/recruitment year, GP practices typically receive income in arrears once the study work has been completed through an overarching national funding model.[24] This creates a financial risk for the GP practice; it may be challenging to employ a person on a long-term contract when there is no certainty regarding income to cover staff wages. There is also a marked difference in the level of CRN expenditure for hospitals versus primary care; historically, higher levels of funding have been allocated to secondary care providers. As an example, Greater Manchester CRN's 2023-24 budget is £21 million of which £306,000 is allocated for primary care (1.46% of the budget, as published and not taking into account allocation of – for example – funding or delivery staff from a central location or organisation).[25] This again aligns with the overall national picture: a year's worth of GP care per patient costs less than two A&E visits, yet the NHS spends less on general practice than on hospital outpatients. Furthermore, for the past decade funding for hospitals has grown approximately twice as fast as for family doctor services.[6] A recently published primary care strategy by the NIHR recognises that there are challenges to even maintaining the research activity levels seen to date; the specific links presented in this present paper add quantitative evidence of the factors associated with research activity (and conversely with a lack of research activity).[7]

The combination of lack of available GPs and allied staff in primary care and possible limited – particularly when compared to secondary care - funding for research delivery in primary care means that innovative approaches may have to be considered. One of these is for GP practices to collaborate and share staff resources to be research active, and another is for research delivery staff to be deployed from a central point such as a regional CRN. An advantage of managing research (and/or relevant staff) through one organisation is the efficiencies that can be achieved. A single Principal Investigator can lead a study for multiple GP practices, and research governance can be processed and reviewed in bulk. When follow-up is managed by central study teams, as in the case for recent COVID19 trials, research can be delivered without significant staff investment at a local GP practice level.[26] Recently, for some studies the centralised approach has been taken one step further. After sending initial patient invitations from one central location, GALLERI cancer screening trial participants visit a mobile clinic in their own local area.[27]

The above mentioned theme of centralisation of research delivery may have unintended adverse effects. When a central organisation hosts research delivery, (clinical) staff in GP practices will not be actively involved in the research activity. Evidence shows that staff involvement in research activity may improve their overall performance[4,28], hence this may be a missed opportunity for staff to develop and keep up-to-date with the latest developments concerning care and treatments. This may be especially valid for studies that are designed to run in-clinic or intended to change practice instantaneously. On a wider scale, the primary care system itself is an essential cog in deriving new evidence to drive improvements in care and subsequent adaptation of new management and treatment modalities.[29] If this contribution by GPs and their practices is more passive, through allowing research to take place in a GPs practice, this is perhaps still more desirable than research not taking place at all. However, care should be taken when it comes to (clinical) data ownership and processing; transparency towards GPs and patients alike is indicated.[30] Encouragingly, there are pockets of innovation aimed at keeping research alive within the GP practice. A recent published example is the use of non-GP clinical staff to compliment the wider primary care research team.[31]

Conclusion

Staff in GP practices have made a significant contribution to the delivery of NIHR Portfolio research in the last decade, with over one million patients taking part in over seventeen hundred research studies. Association analyses indicate that there is a statistically significant positive association between research activity and GP practice characteristics such as size, GP staffing, performance, and reduced deprivation levels. Changing (practice size through mergers) or improving (increase number of GP WTE employed) some of these variables may potentially aid to improve research activity levels. Other variables may to a large degree be 'fixed entities', for example deprivation level of area in which GP practice is located. Therefore, innovative solutions, and further consideration regarding funding levels, may possibly help drive improvement in research activity in primary care. Accompanying evaluative research could then determine what factors can be effective to increase research activity in primary care.

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Table 1, Overview of NIHR research activity in GP practices (April 2013 to March 2023)

	Different studies recruited to	Participants recruited
Median (IQR) for all 6171 GP practices	5 (7)	16 (109)
Median (IQR) for top 10% GP practices	31 (19)	739 (849)
Median (IQR) for bottom 20% GP practices	1 (1)	2 (1)
Total for all 6171 GP practices	1780	1,013,975
Total for top 10% active GP practices	n/a*	593,155
Total for bottom 20% active GP practices	n/a*	4,316

IQR, Inter-Quartile Range; n/a, not available; * not known how many unique studies amongst specified list of GP practices.

Table 2, Pearson correlation analysis to determine association between measures of clinical research activity and GP practice descriptors (2013-2023).

GP practices, n = 6171 (* n = 6118; # n = 5988)	Number of different studies *r* (*P*)	Patient accrual per 1000 registered patients *r* (*P*)
Number of different studies		0.67 (<0.001)
GP practice size	0.33 (<0.001)	0.08 (<0.001)
Number of patients per 1WTE GP*	-0.15 (<0.001)	-0.07 (<0.001)
Deprivation index score (higher being worse)	-0.16 (<0.001)	-0.09 (<0.001)
% of patients with ethnicity 'White British'	0.05 (<0.001)	-0.003 (0.84)
% of patient responses 'good' or higher (GP survey)	0.10 (<0.001)	0.09 (<0.001)
% of patients with chronic condition	0.02 (0.11)	0.01 (0.49)
GP practice based in North (0) or South (1) of England#	0.08 (<0.001)	0.04 (0.003)
CQC rating#	0.08 (<0.001)	0.06 (<0.001)

Table 3, Binary logistic regression analysis to determine association between clinical research activity and GP practice descriptors (2013-2023)

Dependent: top 10% research active GP practices (versus bottom 20% research active GP practices)	*P*	Odds Ratio	95% confidence interval for Odds Ratio
GP practice size*	<0.001	1.00	1.00 to 1.00
Number of patients per 1WTE GP*	<0.001	1.00	1.00 to 1.00
Deprivation index score (higher being worse)	<0.001	0.96	0.95 to 0.98
% of patients with ethnicity 'White British'	0.01	0.99	0.98 to 0.99
% of patient responses 'good' (GP survey)	<0.001	1.04	1.03 to 1.05
% of patients with chronic condition	0.014	1.02	1.01 to 1.04
GP practice based in North (0) or South (1) of England	0.41	0.87	0.63 to 1.21
CQC rating	0.018	1.64	1.09 to 2.48
GP practices, n = 1765. Nagelkerke R^2 value = 0.56			

Table 4, Principal component analysis to establish relationships between clinical research activity and GP practice descriptors (2013-2023)

GP practices, n = 1765	**Component (% variance contribution in model)**		
	1 (24%)	**2 (20%)**	**3 (13%)**
Research activity (ie top 10% versus bottom 20% GP practices in terms of different recruiting studies)		0.82	0.23
GP practice size		0.89	
Number of patients per 1FTE GP		-0.36	-0.37
Deprivation index score (higher being worse)	0.36	-0.28	-0.66
% of patients with ethnicity 'White British'	0.69		0.35
% of patient responses 'good' (GP survey)			0.84
% of patients with chronic condition	0.74		
GP practice based in North (0) or South (1) of England	-0.77		
CQC rating			0.41
Kaiser-Meyer-Olkin measure of sampling adequacy = 0.60. Bartlett's test of sphericity, Chi^2 2681, 36 degrees of freedom, *P* <0.001. Value cut-off for coefficient inclusion in the model = 0.2			