**INVESTIGATING THE ORGANISATIONAL FACTORS ASSOCIATED WITH VARIATION IN CLINICAL PRODUCTIVITY IN COMMUNITY PHARMACIES**

## AIMS AND OBJECTIVES

The overarching aim of this study is to inform the commissioning of NHS general pharmaceutical services in England by exploring variation in clinical productivity (levels of service delivery and service quality) in community pharmacy organisations and identifying the organisational factors associated with this variation.

The objectives are to:

(a) explore variation in levels of service delivery across a representative sample of community pharmacies in England;
(b) investigate the relationships between organisational characteristics and levels of service delivery;
(c) investigate the inter-relationships between organisational characteristics, levels of service delivery and service quality;
(d) examine the mechanisms by which organisational factors influence both levels of service delivery and service quality;
(e) develop a toolkit to inform commissioning processes to improve clinical productivity in community pharmacy.

## BACKGROUND

Research into variation in clinical productivity within healthcare, and the organisational factors which influence this, is inconclusive. In their extensive SDO-funded review of the relationship between organisational factors and performance (08/1318/055), Sheaff et al. concluded that, *"There is no consistent or strong relationship between organisational size, ownership, leadership style, contractual arrangements for staff or economic environment (competition, performance management) and performance."* [1] In primary care the evidence is even more limited. More recent studies, however, have been able to utilise data now available from the UK Quality and Outcomes Framework (QOF) to investigate variation in the performance of general practices. Studies have found that some practice characteristics, notably practice size, ratio of practitioners to patients, levels of nurse staffing and team climate may be associated with variation in performance, in addition to local levels of population deprivation and need.[2-6] A subsequent SDO-funded study of the role of incentives in a range of primary care settings (on which one of our research team, KH, was co-applicant; 08/1618/158) concluded that incentives led to higher levels of attainment of quality targets and a reduction in variation in quality relating to deprivation in general practice; a shift towards treatments which pay more in general dental practice; and the provision of increased volumes of incentivised services in community pharmacy. However, it also found that incentives had some unintended consequences in relation to whether the additional investment actually represented value for money with a number of opportunity costs arising out of an increasing focus on incentivised activities.[7] Despite that study's focus on community pharmacy, the extent and causes of variation in clinical productivity within the community pharmacy sector is an otherwise under-researched area.

As private businesses contracted to provide NHS dispensing and medicines-related services, community pharmacies play a key role in healthcare systems. Community pharmacies constitute a range of organisational forms under different types of ownership, from national multiple (chain) pharmacies and supermarkets, to local independent pharmacies operating between one and five premises. The current general pharmaceutical services contract for England was introduced in 2005 (with revisions in 2011) to meet the objectives set out in the White Paper: 'A Vision for Pharmacy in the New NHS'.[8] These included: helping to tackle health inequalities, supporting self care, and

responding to the diverse needs of patients and communities. The contract specifies three levels of service provision. *Essential* services, which all community pharmacies are required to provide, cover dispensing, repeat dispensing and clinical governance requirements. *Advanced* services, including medicines use reviews (MURs), and the new medicines service (NMS) introduced in 2011, are not mandatory and require training and accreditation of the pharmacist. *Enhanced* services are commissioned locally, currently by primary care trusts (PCTs), to meet locally assessed needs and include minor ailments schemes, smoking cessation clinics and medicines management services for long term conditions.

The extension of the community pharmacist's role from traditional dispensing duties into a range of clinical areas once only the remit of family doctors is part of a general move to embrace the philosophy of 'pharmaceutical care' within the profession.[9] It is widely supported by pharmacists[10] – who see it as an opportunity to utilise their extensive clinical knowledge of medicines to greater effect – and service commissioners – who recognise the opportunities to improve service access and quality for patients, reduce some of the burden on GPs' workload, and potentially to save money through role substitution, the reduction of waste medicines (through improved medicines understanding and adherence) and the prevention of medicines-related unplanned hospital admissions.

Medicines use reviews (MURs) aim to help patients manage their medicines more effectively, by increasing their understanding, identifying problems and providing feedback to prescribers. We have produced evidence to suggest that the volume of MUR provision by pharmacy chains is almost twice that of independent pharmacies and that this may be primarily profit driven, prioritising quantity over quality.[11] We have also produced evidence that local enhanced services are more likely to be provided by chain pharmacies than independent pharmacies and that provision is greater in deprived and urban areas.[12] Other research into the implementation of pharmaceutical care services by community pharmacies worldwide has identified a number of organisational barriers and facilitators to their provision, including the physical environment (particularly adequate space and privacy), organisational culture and leadership, having the necessary staffing and skill-mix, relationships with GPs, equipment and technology and work overload/conflicting workloads.[13] Studies of the implementation of MURs in English pharmacies suggest that whilst delegation of dispensing duties to pharmacy technicians or other support staff (to free up pharmacists' time) is supported by pharmacists, constant workload demands and interruptions still prevent pharmacists from conducting MURs.[14] Yet pharmacists, particularly those working for chain pharmacy organisations, are under intense pressure to meet financial targets, including conducting specified numbers of MURs.[11] This may detract not only from the effectiveness of the MURs conducted, which has still to be fully evaluated, but also the extent to which they may represent true role substitution and cost efficiency.

Our recent systematic review of studies describing aspects of organisational culture in community pharmacy, its antecedents and outcomes, highlighted longstanding evidence of the dichotomy in organisational values in this sector (professional vs. business) as a result of community pharmacy services being provided by private sector organisations.[15] Our subsequent survey of community pharmacists provided evidence of a significant relationship between organisational culture, particularly this balance between business and professional values, and pharmacists' work stress and the potentially detrimental effect on patient safety of working within an intensely targets-driven culture.[16] We have also obtained evidence from a number of studies of the influence of workload and working patterns on pharmacists work-related stress,[16-18] and the role of the pharmacist's manager (particularly whether or not they are a pharmacist themselves) in determining job satisfaction.[19] Other research has suggested that organisational factors may be associated with the occurrence of dispensing errors,[20] and qualitative research on locum pharmacists has raised concerns that patients are put at risk because of the increasing reliance on temporary staff.[21] This is of particular importance in a sector of healthcare where over a third of all pharmacists work as self-employed locums.[22]

There is therefore growing evidence for the impact of some organisational characteristics on pharmacists and the volume of delivery of certain types of pharmaceutical service. Whilst some evidence exists for the impact this may be having on service quality and patient safety (dispensing errors), the evidence is still inconclusive, with few studies systematically measuring the impact of different organisational characteristics upon outcomes for patients and the wider healthcare system or, indeed, the link between the volume of services delivered ('quantity') and the benefits for patients ('quality').

**NEED**

One important aspect of recent healthcare policy has been to increase patient choice and access to services. Together with a raft of pro-market policies, this has sought to increase the range and diversity of professionals and provider organisations able to offer advice and services once only the remit of NHS doctors. With the election of the current government and the introduction of further healthcare reforms, the drive towards independent sector provision of healthcare has been stepped up ("any qualified provider"[23]). Concerns have been raised over the quality and safety of patient care delivered by private sector organisations,[24] which need to balance the pressures of delivering quality services within the context of a for-profit business.

Community pharmacies are private businesses, and established providers of NHS funded services. As such, they provide an ideal exemplar in which to begin to unpack concerns over conflicting commercial pressures versus improving quality and safety. This study will contribute to our understanding of clinical productivity in the context of private provision by incorporating measures of both quantity (levels of service provision) and quality.

Another feature of current healthcare policy is the emphasis on achieving quality, innovation, prevention and productivity (QIPP). Service commissioners must ensure that all services, irrespective of whether they are commissioned from NHS or independent sector organisations such as community pharmacies, contribute towards the QIPP agenda. Two areas in which community pharmacies are well-placed to contribute towards the QIPP challenge – improving medicines adherence and reducing medicines wastage – relate to the productivity element: improving efficiency in the NHS, improving clinical outcomes and enhancing the patient experience.

Research suggests that up to 50% of patients with a chronic condition do not take medicines as prescribed.[25] Such non-adherence to medicines is known to cause unscheduled hospital admissions. In the UK, as many as 6.5% of adult hospital admissions are estimated to be medicines-related, 30% of these due to non-adherence to medicines for chronic illness.[26] In 2009/10, £12.6bn was spent on non-elective in-patient costs and £1.8bn on accident and emergency admissions.[27] Therefore, it could be estimated that approximately £28 million was spent on such unplanned hospital admissions in relation to medicines non-adherence.

Another key concern is medicines waste in the primary and community sectors which has recently been estimated to cost the NHS approximately £300 million per year, equivalent to approximately £1 in every £25 spent on primary care and community pharmaceutical and allied products use, and 0.3% of total NHS expenditure.[28] This figure includes an estimated £110 million worth of unused prescription medicines that are returned to community pharmacies over the course of a year and an additional £90 million retained in individuals' homes at any one time.

Community pharmacies are well placed to deliver services to improve patients' understanding of medicines and their use. Interventions such as pharmacist-led medication reviews have been shown to improve adherence,[29] and there is some evidence that increased adherence has a direct impact on treatment success and patient outcomes,[30] thus improving healthcare efficiency. It is for this reason that MURs were originally introduced to ensure patients have a better understanding of their medicines, thus achieving better adherence and avoiding unnecessary waste and unplanned hospital readmissions.

NHS investment in community pharmacy services is substantial and growing. The total budget agreed for the provision of pharmaceutical services in England was £2.5billion in 2011/12,[31] making up a considerable part of the overall NHS budget. Over 850 million prescriptions were dispensed by community pharmacists in England last year, an increase of almost 60% in the last ten years.[32] The number of enhanced services delivered has risen to 30,962 and over 2.1 million MURs were conducted in England in 2010/11, a rise of over 23 percent from the previous year.[32]

The volume of MUR provision is therefore increasing at a rate well above increases in dispensed items. Where service payments are based on a fee-for-service structure, this raises questions over whether the NHS is getting value for money, particularly in light of the concerns raised above that commercial pressures may drive some community pharmacy organisations to prioritise quantity over quality in delivering MURs. To try to address some of these concerns, targeted MURs and the NMS were introduced in 2011.[33] However, these services are new and currently being evaluated and there is still a pressing need for the NHS as service commissioners to gain an understanding of the relationship between the quantity and quality of service provision as key elements of clinical productivity in the context of private businesses such as community pharmacy organisations.

The findings of this study will go some way to addressing this need for service commissioners. An understanding of the organisational requirements for maximising clinical productivity in terms of both quantity *and* quality of service provision could help in the development of a set of organisational standards against which to assess applying pharmacies as part of the pharmacy contract approval process or for commissioning advanced and enhanced services. A better understanding of the interrelationships between the quality and quantity of service provision in private sector organisations could also help to inform improvements in service payment structures and contract monitoring processes to help ensure that the NHS is getting value for money from the services it commissions. With studies of the impact of community pharmacy services on patient outcomes – in particular medicines understanding and adherence – still scarce, the proposed research will provide such insights. Finally, for community pharmacy organisations themselves, knowledge of the organisational characteristics associated with higher levels of productivity (both quality and quantity) are likely to be of benefit to them as businesses and employers without compromising benefits to patients and customers.

## METHODS

### Theoretical framework

The proposed study will draw upon organisational theory, in particular the framework proposed by Michie and West[34] describing the relationships between organisational context (environment, structure and culture) and performance in healthcare. Moreover, it will utilise the theoretical framework we have developed[35,36] for assessing the quality of community pharmacy services in terms of 'accessibility' (influenced by available structures and processes), 'effectiveness' (measured through patient, pharmacy, societal and health outcomes) and 'positive perception of the experience' (both from the patients' and the pharmacists'/staff's perspective). In addition, the study will be informed by our review of the body of work describing the culture of community pharmacy organisations, its antecedents and outcomes.[15]

For the purposes of this study 'clinical productivity' will be defined in terms of both levels of service delivery (i.e. number and volume of essential, enhanced and advanced services delivered) and service quality (e.g. satisfaction with information about and adherence to medicines).

**Context**

The proposed study will be conducted within a purposive sample of five diverse geographical areas (previously described by PCT/PCT cluster administrative boundaries), covering a range of affluent/deprived areas of dense/sparse populations. Provisional agreement to participate had originally been secured from the pharmacy leads of five PCTs or PCT clusters. It is recognised that, by the time this study is due to commence, PCTs will no longer be in existence and there is not yet clarity over the new commissioning arrangements for community pharmacy services. However, we are confident that the continued involvement of an equivalent set of areas based around proposed new commissioning structures can be maintained to ensure the pace and robustness of this research is not compromised. Crucially, PCT pharmacy colleagues have all agreed to include this research in all legacy documents and transition arrangements. Moreover, they have given assurances that, in some cases, existing staff will continue to be employed in similar roles within the new commissioning structures. Given the current upheavals and uncertainties, however, there is a slight possibility that we may lose one or more of these sites over the next year. However, if this happens, we foresee little difficulty in recruiting other areas through existing contacts and with the help of the PCRNs whilst maintaining an equivalent demographic spread. Indeed, we have already received an expression of interest in participating in this study from one other site that we are holding in reserve.

**Design**

**Stage 1:** will combine analysis of existing datasets with primary data collection to examine variation in levels of service delivery across community pharmacies (objective a) and analyse associations between organisational characteristics and levels of service delivery (objective b).

**Sample**

All community pharmacies in the five study areas will be approached to participate (N=632 [provisional figure]). Lists of names and addresses for all pharmacies commissioned to provide NHS services will be obtained from each PCT (or subsequent commissioning body). Based on a 5% level of statistical significance and assuming a non-response rate of 33% (i.e. 420 pharmacies will respond), this study will have in excess of 90% power to detect a correlation as small as 0.16 between organisational factors and clinical productivity. Even if the non-response rate reaches 50%, the study will still have in excess of 80% power to detect such a correlation.

**Data collection**

Unit of analysis: pharmacy premises

a. Primary outcomes: monthly dispensing volume; yearly volume of advanced services (MURs and NMSs).
b. Secondary outcomes: numbers and volume of enhanced services; safety climate.
c. Independent variables: Organisational (ownership, staffing and skill-mix, working patterns, management structure and use of locums, organisational culture, pharmacist/GP integration). Demographic/socio-economic (age; ethnicity; education; employment; limiting long term illness; urban/ rural categorisation; disease prevalence).

Data will be obtained through three major sources:

1. Community pharmacy returns
   PCTs are currently responsible for the routine collection of data from pharmacies in respect of delivery of the general pharmaceutical services contract and this responsibility will be passed to the new commissioning structures. These data include all of the primary outcome variables listed above. Recently proposed changes to routine data collection mean it may also become possible to obtain data on numbers of MURs provided to target

patient groups and also pharmacist-reported outcomes of MURs (better understanding of: what medicine is for; how to take it; side effects; underlying condition) together with detailed information about numbers of interventions provided through the NMS (e.g. provision of advice, information, referrals to GPs) and to which target patient groups. The number and volume of locally commissioned enhanced services (secondary outcome) is also recorded by PCTs although it is recognised that the provision of these services may be as contingent upon local commissioning priorities as the characteristics of the provider organisation. We have already obtained provisional agreement from PCT lead pharmacists that these data will be provided by the study commissioning partners for each pharmacy, identified by postcode. Postcode identifiers will only be used for linkage purposes and no single entity will be identified in published research.

2. Survey of community pharmacies

   A self-completion questionnaire will be distributed to all pharmacies in the five study areas to collect data on organisational characteristics (independent variables) and dispensing errors (secondary outcome). Distribution of the questionnaire will be primarily by post with an option to complete a web-based version, although discussion with local commissioners will determine whether email communication in some areas would be more likely to elicit a response. Pharmacies and their contact details will be obtained from the service commissioners (currently PCTs/clusters) and questionnaires directed towards the lead pharmacist/pharmacy manager (named where possible). Non-responders will initially be sent a second copy of the questionnaire/email and then telephoned to obtain missing information. Information will be collected on key organisational characteristics which have been shown in our previous research to influence care provision.[11,12,16,18,19,21] These include items on:

   - ownership-type (supermarket, multiple, small/medium chain, independent),
   - staffing and skill-mix (numbers and types of pharmacists and support staff, turnover and vacancies),
   - working patterns (length of working day, shift patterns, FT/PT working),
   - management structure (pharmacy manager is pharmacist or not; pharmacist managed by pharmacist or non-pharmacist), and
   - use of locums (number, frequency and regularity of locum use)
   - pharmacist/GP integration

   These items will be developed from items validated through previous community pharmacy surveys conducted by the research team. Organisational culture will also be measured using the Pharmacy Service Orientation (PSO) tool, validated for use in community pharmacies[38], and which has been used successfully in our recent postal survey of English community pharmacies to discriminate between different types of pharmacy organisation.[16] This short tool is scored on the basis of three 1 to 10 semantic differential scales whereby respondents are asked to rate their pharmacy's 'orientation' (patient vs. product), 'focus' (quality vs. quantity) and 'pharmacists' work' (professional vs. technical). The questionnaire will also collect data on safety climate (secondary outcome measure), subject to piloting, using the validated Pharmacy Safety Climate Questionnaire (PSCQ) which captures the pharmacy's collective attitudes and behaviours regarding patient safety.[39] The questionnaire will be piloted with a small sample of community pharmacy managers, recruited through existing contacts, using cognitive interviewing techniques.[40]

3. Secondary demographic and socio-economic datasets

   Determinants of the demographic, socio-economic and health-needs status of the population within the immediate individual pharmacy locality (independent variables) will be obtained from national secondary datasets. These will include: (a) the income deprivation domain of the 2010 English Indices of Multiple Deprivation (IMD), allowing the comparison of relative levels of material deprivation local to community pharmacies; (b) a dichotomous urban or rural indicator of pharmacy location, sourced from the NHS Postcode Directory; (c) Office of National Statistics 2011 Census data reporting the proportion of the local population who,

for example, have a self-reported limiting long-term illness, are aged 65 years or over or consider themselves to be from an ethnic minority background. Local determinants will be attributed to pharmacies by linking pharmacy postcodes to super output areas (SOAs), which are geographical units of approximately 1500 people. SOAs are commonly used to measure and compare the local concentration, extent or weighted averages of population characteristics. Comparative between-PCT health need and pharmaceutical services information will include 2011/12 Quality and Outcomes Framework PCT level disease prevalence for conditions for which community pharmacies (can) provide clinical services (e.g. CHD, asthma, diabetes, smoking).

**Data analysis**

Initially, we will summarise the variation in our primary (monthly dispensing volume; yearly volume of advanced services) and secondary (yearly volume of enhanced services; safety climate) outcome measures using appropriate summary statistics (mean/ standard deviation or median/ inter-quartile range). We will also report these measures by key organisational factors (e.g. ownership; culture; etc). Using STATA software, we will then fit a series of fixed-effects linear regression models to determine whether these outcomes are associated with pharmacy-level organisational variables and/ or areal-specific 'attributed' (by postcode linkage) demographic, socio-economic and health-needs variables. Study area will be treated as a fixed effect. Dependant on the distribution of the outcome variables, we will employ the non-parametric bootstrap re-sampling method of standard error estimation, a logarithmic transformation or categorisation, if appropriate.

**Stage 2:** Quantitative methods will examine the inter-relationships between organisational characteristics, levels of service delivery and service quality (objective c). Qualitative methods will explore issues around levels of service delivery and service quality in community pharmacies, their relationship and the mechanisms by which they are influenced by organisational characteristics (objective d).

**Sample**

Sites: Forty community pharmacies – 2 of each ownership-type (supermarket, multiple, chain, independent) from each NHS area – will be randomly selected from stage 1 respondents to participate in stage 2. Pharmacies will be offered an incentive payment for participating. If any pharmacy declines to participate in stage 2, they will be substituted by another pharmacy of the same type, from the same NHS area, chosen at random.

Subjects (patient survey): Two samples of 30 consecutive walk-in patients following receipt of a) dispensing and b) MUR services from each pharmacy (N=2400). Calculation of the size of the sample required is based on detecting a 2 point difference in patient-average SIMS scores (see description of measure below) between any pair of ownership-types. Assuming that the population standard deviation of SIMS scores is 5 points,[41-43] 30 patients per pharmacy will be required to detect such a difference with 80% power, at the 5% level of statistical significance. Assuming, further, a non-response rate of 50% and an intra-pharmacy correlation coefficient of 0.05, 1,200 patients in receipt of dispensing services and 1,200 patients undergoing a MUR will need to be surveyed.

We have elected at this time not to survey patients on receipt of the new medicines service (NMS) as this is a newly introduced service requiring time to 'bed in'. Furthermore, the NMS is currently undergoing a national evaluation having only been commissioned until March 2013 and will only continue beyond this time if all parties agree that the service has provided demonstrable value to the NHS. We may, however, re-visit this decision nearer the time as more information becomes available about the success and uptake of this service.

We recognise that selecting only walk-in patients excludes those unable to visit the pharmacy themselves (often those more disabled or ill and older people) who account for, on average, about 1 in 4 prescriptions dispensed.[44] Ideally, it would be good to capture this group of patients. However, we have decided to exclude them for a number of methodological reasons. Firstly, in the MUR sample, we know that MURs are conducted opportunistically and in-

store in the vast majority of patients, already excluding those not visiting the pharmacy in person. Secondly, for those using dispensing services by proxy, variation in satisfaction with information received about medicines is far less likely to relate to the quality of the service provided by the pharmacist (e.g. it may relate to the way in which their proxy relayed the information given; the patient may be more likely to rely on a different health professional for information about their medicine). Lastly, including both walk-in patients and those collecting medicines by proxy using consecutive sampling would risk wide variation in the proportions of each type of patient in the samples achieved for different pharmacies (contingent upon population demographics) thus invalidating comparisons of outcomes.

Subjects (qualitative interviews): pharmacists/pharmacy staff and managers and service commissioners. Up to 50 interviewees will be selected purposively to include one service commissioner and up to 8 pharmacy interviewees from each geographical area across all types of pharmacy. As rules of thumb, between 6 and 8 in-depth interviewees are required to reach data saturation in homogenous samples (i.e. no new themes will emerge by recruiting further participants), or between 30 and 50 per study, taking into account the nature and diversity of the population.[45]

**Data collection**

1. Quantitative

   A brief questionnaire will be distributed by the pharmacist/pharmacy staff in each of the 40 selected pharmacies to the two samples of patients described above. To avoid the potential problem of cherry-picking, pharmacists/ pharmacy staff will receive appropriate advance training in questionnaire distribution from the research team. During the training, the importance of distributing questionnaires to consecutive patients to avoid research bias will be stressed and pharmacies will be informed that spot checks will be made on progress. In addition to the training received, pharmacies will be asked to distribute questionnaires over a limited period of time (dependent on dispensing volume/volume of MURs conducted by each individual pharmacy – data available through PCTs) which could well be one day in relation to the dispensing services questionnaire. Checks on progress will be made regularly by the study RA and/or local PCRN assisting with the study and will help to limit the possibility of such cherry-picking. To facilitate this, pharmacists/ pharmacy staff will be required to keep a log of all questionnaires distributed. Payment of the incentive offered to each pharmacy will be dependent upon the distribution of the required number of questionnaires in the allotted time.

   The questionnaire will collect some background data (socio-demographic, existing conditions, medications received), an item asking respondents if they received any information about their medicine(s) and if this information was written, verbal or both and, subject to piloting, items capturing usual pattern of pharmacy use and/or whether or not the patient saw their usual pharmacist on this particular visit. In addition, we will include two self-reported measures of a) satisfaction with information about medicines (SIMS) and b) adherence to medicines (MARS). Both the SIMS (17 items) and MARS (5 items) are of proven reliability and validity and have been widely used in research studies in a number of settings (including pharmacy) across a range of conditions and in several countries.[41-43,46-49] They were therefore selected over the community pharmacy patient questionnaire (CPPQ [50]) already used by English community pharmacies to collect data on patient satisfaction as that tool has not been validated as a measure of patient outcome.[51] This questionnaire will be piloted with a small sample of community pharmacy users, recruited through existing contacts, using cognitive interviewing techniques.[40]

   Participant information sheets will also be provided for patients together with reply-paid envelopes to return the questionnaire directly to the research team. Questionnaires will be anonymous other than a pharmacy identifier and non-responders will not be followed up.

2. Qualitative
   Semi-structured, face-to-face interviews will be conducted with up to 50 pharmacy and commissioning (currently PCT) representatives. Topic guides will be developed from the aims of the research and the research literature and will broadly explore the relationship between the quantity and quality of service provision in community pharmacies, opportunities and barriers to increasing clinical productivity in this setting and the mechanisms by which different organisational characteristics may help or hinder this objective.

**Data analysis**

Quantitative – Initially, we will tabulate the responses to each of the 17 items on the SIMS and the 5 items on the MARS. SIMS items can also be dichotomised to represent satisfaction and dissatisfaction (with medication information): we will report these overall and by ownership type. Individual binary 'ratings' can then be summed to give an overall assessment of satisfaction (ranging from 0 to 17). This 'score' will be used as the outcome in a multi-level linear regression model to determine which patient- (stage 2) and pharmacy-level (stage 1) independent variables are predictors of satisfaction with medication information. Ratings on the 5 items of the MARS can also be summed to produce an overall medication adherence 'score'. This variable will also be used as an outcome in a multi-level linear regression model. However, given the ordinal nature of the original items on this scale, a multi-level ordered logistic regression model will also be fitted and compared with the linear version, by way of a sensitivity analysis. All regression models will be fitted using STATA.

Qualitative – Interviews will be audio-recorded, with permission, fully transcribed and thematically analysed using the framework approach[52] using the NVIVO qualitative analysis software package to manage the process. Themes will be derived from the interview schedule in the first instance and latterly from the data themselves.

**Integration of Stage 1 and Stage 2 findings**

Integration of the findings from the different stages and methodologies employed by the study will be an important final step to building a rounded picture of the factors associated with variation in clinical productivity in community pharmacies and the relationships between the quality and quantity aspects of clinical productivity in this context. Methods of synthesis will incorporate aspects of triangulation of the data, and also illustration and explanation of one set of findings with another.[53] For example, where findings from the survey indicate a significant association between particular organisational characteristics and productivity in terms of quantity of service provided, the qualitative data from interviews with pharmacists and other pharmacy staff will be interrogated to obtain information on the mechanisms of that association. We will also look for alternative explanations where findings from different stages of data collection diverge. In this way we should be able to build up a typology of community pharmacies in terms of their organisational characteristics and the implications for the number and volume of services they can provide and the impact this has on the quality of those services for patients and other service-related outcomes such as medicines wastage and dispensing errors. This will provide the basis for the recommendations we make to service commissioners regarding commissioning processes, to community pharmacy organisations regarding their provision of NHS pharmaceutical services, and to patient/public audiences regarding medicines usage.

**Service commissioners' workshop/toolkit development**

Based on our findings, we intend to develop a toolkit to help service commissioners improve their contracting processes with community pharmacies (objective e) to promote clinical productivity (both quality and quantity) and, hence, value for money. To do this, we will organise a half-day workshop, ideally in partnership with NHS Primary Care Commissioning, to which we will invite community pharmacy/primary care commissioning leads (50 max) from the new local commissioning structures. The workshop will be used to present the findings from the study and invite

discussion and feedback in up to five small group sessions, facilitated by members of the research team, which will each be audio-recorded and transcribed. The facilitators will also record key discussion points and areas where consensus has been reached on flipcharts and these will be brought back to the larger group for final discussion. Transcripts from small group sessions will be analysed thematically and the findings also used to inform the development of the toolkit. The toolkit, which will be made available electronically to service commissioners nationally, will link to the six stages in the NHS commissioning cycle[54] and provide guidance and checklists for commissioners at each stage.

**CONTRIBUTION TO COLLECTIVE RESEARCH EFFORT AND RESEARCH UTILISATION**

The mission of the NIHR is to develop the evidence base to help NHS managers and clinicians improve the care offered to patients, and the proposed study will contribute to that endeavour. The study will add to the growing evidence base around variation in clinical productivity in primary care. In particular, it will extend the reach of this knowledge base into NHS services delivered by for profit organisations, in this case community pharmacies. The earlier SDO-funded study on the impact of incentives on primary care professionals (including pharmacists) demonstrated that while incentivised activities in community pharmacies resulted in increased productivity (e.g. a greater number of enhanced services and MURs), the quality of the work could be compromised, raising questions about the value of paying pharmacies in this way.[14] Recent developments to target MURs to patients who most need them have been introduced to address this issue,[33] and the proposed study will help monitor this change, providing new evidence to commissioners on whether better targeting does improve quality (i.e. better patient outcomes) or whether higher productivity (quantity) is still at the cost of quality. Thus the findings will build on previous work to expand the evidence base for commissioning primary care services around medicines usage.

A report last year by the National Audit Office which examined the financial impact of the new commissioning framework for community pharmacy identified cost savings to the NHS of around £1.8 billion between 2005-06 and 2008-09 (largely through reduced reimbursements to pharmacies for a number of commonly dispensed medicines).[55] With regard to dispensing, the report identified that pharmacies had been more productive in terms of 'quantity' of service provision, with a 17% increase in dispensing volumes being secured for an 8% rise in payments. However, the report took little account of that part of the framework that remunerates pharmacy contractors directly from their PCTs (including payments for MURs), rather than from the global sum. The budget for this in 2008-09 was a substantial £664 million and is likely to be significantly higher now. Moreover, the report took no account of patient outcomes (e.g. whether patients were better able to use their medicines) or the 'quality' aspect of clinical productivity. The proposed study, in collecting this type of activity data and data on patient outcomes alongside dispensing volume data, will enhance the understanding of commissioners about the organisational tradeoffs made between different areas of activity, and between quality and quantity, in achieving the different goals laid out for community pharmacy by government.

The NIHR encourages research involving contributions from a wide range of people with the aim of increasing the relevance and quality of the research it funds. We have deliberately set out to strengthen our research partnerships by directly involving both service commissioners and community pharmacy organisations at all stages of the research process. So the proposed study benefits from having been designed to meet the management needs of both groups and should thus produce findings with a greater likelihood of being adopted. Furthermore, the study will bring together an experienced multidisciplinary research team which draws on expertise in the fields of pharmacy, health services research, sociology, information management, statistics and health service commissioning. It will thus ensure not only that it remains firmly grounded in the needs of service commissioners, but the study will also have a high degree of rigour in the research process, and the way it is managed and conducted.

By producing findings around the role of organisational factors in determining clinical productivity in community pharmacy organisations, not only will community pharmacies benefit in terms of their ability to deliver higher

volumes of NHS pharmaceutical services with improved outcomes for patients but service commissioners will benefit from having robust evidence on which to base improvements in their commissioning processes. Moreover, our study findings will also enable recommendations to be made with regards to the measures that could be taken to improve patients' understanding of and adherence to medicines, thus potentially contributing to an overall reduction in the volume of wastage experienced by the NHS. The strategy for knowledge mobilisation will therefore be multifaceted and target a range of audiences from academics, policy makers and health service managers to community pharmacy professionals and managers and the public. In addition to the research outputs required by the NIHR HS&DR, a number of papers will be prepared throughout the study for presentation at academic, NHS and public/patient conferences as they arise, and for publication in a range of journals targeting professional, managerial and academic audiences.

To target the primary care commissioning community, short articles will be submitted to the Health Services Journal (HSJ) and Practical Commissioning, both of which are widely read by commissioners and health service managers. In addition, a toolkit will be developed to help managers link the six stages in the NHS commissioning cycle[54] with pharmacy productivity. For easy access nationally, it is anticipated that this toolkit will have a hyperlink on the NHS Primary Care Commissioning (NHS PCC) website. Other networks, similar to NHS PCC, will be utilised to disseminate the executive summary and toolkit, such as Public Health Networks. This is important as many of the enhanced services commissioned under the community pharmacy contractual framework currently, are commissioned to meet local public health needs. We also intend to organise a half day workshop for service commissioners, ideally in partnership with NHS PCC, to present and discuss the findings of the study and obtain feedback to inform the development of the toolkit, as detailed in the methods.

To target the community pharmacy audience (those who design pharmacy services, manage pharmacies and negotiate on their behalf) short articles will be submitted to the Pharmaceutical Journal and Chemist and Druggist, both of which are widely read by pharmacists and managers. We will also disseminate findings through the Local Professional Networks (LPNs) which will operate alongside local NCB field forces. It is anticipated that the national negotiating body for pharmacy contractors (PSNC) will also be keen to share the findings and pharmacy-specific recommendations, and we would encourage them to hyperlink these from their website for pharmacy contractors interested in increasing productivity in the manner defined in this study. In addition, all pharmacists and pharmacy technicians providing NHS services in England have access to materials, workshops, webinars and blogs produced by the Centre for Postgraduate Pharmacy Education (CPPE), the national training provider hosted by the University of Manchester and funded by the Department of Health. This research and its findings are ideally placed to be disseminated as elements in CPPE workshops (such as their medicines optimisation workshop), and in their public health modules. Moreover, the involvement of two community pharmacy stakeholders on the project advisory group will help promote the dissemination, and uptake, of the study findings and recommendations by pharmacies.

Finally, to target patient/public audiences, the involvement of two experienced PPI representatives in our project advisory group will be capitalised upon to develop a dissemination strategy appropriate to this audience. Whilst most of the findings will be more pertinent to the pharmacy commissioners and contractors, we will aim to develop those aspects of the findings with the potential to inform and educate members of the public about their use of medicines and pharmacy services and how they can maximise the associated benefits. For example, we may produce leaflets for distribution through patient groups and networks. In addition, we will consider presenting our findings at the Patient Information Forum annual conference.

**PLAN OF INVESTIGATION AND TIMETABLE**

We envisage a 27 month project commencing 1st April 2013 and finishing June 30th 2015. The detailed project timetable is provided in the Gantt chart attached. In the period prior to the project commencing, the preliminary groundwork for the study will be undertaken, including obtaining the necessary research ethics and R&D approvals,

buy-in and endorsement of the study by community pharmacy representative bodies, and full engagement of the project advisory group and service commissioners (currently PCTs) for whom we have already obtained preliminary agreement of participation. Stage 1 of the study will be conducted over the first 10 months and stage 2 over the subsequent 12 month period. The fieldwork for stage 2 of the study will involve site visits to all of the pharmacies recruited for orientation to the study, to train pharmacy staff in the distribution of patient questionnaires and to conduct research interviews. This fieldwork will be conducted by the RA and PI, and supported by the PCRNs. In this way, qualitative and quantitative aspects of data collection will run in parallel. Analysis of stage 1 and stage 2 data will be undertaken during latter 4 months of each stage culminating in the production of interim reports at months 10 and 22. A further 2 months of the project will be dedicated to integration of the findings from the two stages of the fieldwork and preparation of the final report and executive summary. The final 3 months of the study will be required for the organisation and delivery of the half-day workshop for service commissioners, which will feed into the development of a toolkit for service commissioners, and planning the wider dissemination and mobilisation of the findings, as described above.

**APPROVAL BY ETHICS COMMITTEES**

The key ethical concerns and considerations for this project are as follows:

During both stages of data collection, the confidentiality of personal and commercially sensitive data and participants needs to be ensured, and we have established procedures in place to guarantee this, such as separation of identifiers from other data, and the use of locked offices and filing cabinets, as well as storage of identifiable information only on encrypted network drives. All study participants will be provided with detailed information about the project more than 24 hours in advance, thus allowing informed consent to be given. Consent for completing stage 1 and 2 questionnaires will be implied if they respond, and those involved in interviews will provide written and signed consent. There is the potential for insights into poor practice, and these will be handled sensitively. Feedback may be provided to individuals or organisations with poor practice, supporting improvement. However, should any poor practice be identified with a potential to affect patients' care or safety, this would be fed back to the appropriate individuals and organisations, the employer in the first instance.

Consent cannot be obtained easily for the collection of secondary data obtained from PCTs / commissioners of community pharmacy services, who will provide routinely collected data on community pharmacy activity (see primary and secondary outcomes) with postcode identifiers. Although identifiers will only be used for linkage purposes and no single entity will be identified in published research, these data are considered commercially sensitive (particularly dispensing volume), and community pharmacies have not already consented to their being used for research purposes. Therefore, we will endeavour to obtain consent from every pharmacy via the stage 1 survey. To enable this, the Pharmaceutical Services Negotiating Committee (PSNC) – nationally and through their local representatives – have pledged their support. We plan to present the research via the Company Chemists Association (CCA), representing large pharmacy multiples, and the Association of Independent Multiple Pharmacies (AIMp) for the independent multiples/chains, a strategy used successfully in the past, to obtain head office consent from chain pharmacy organisations. This will be supported through approaching each of the Local Pharmaceutical Committees (LPCs) for their buy-in and endorsement which will provide additional reassurance to the independent and small chain pharmacies. The information provided to pharmacies with the stage 1 survey will include a list of those organisations consenting to and endorsing the use of secondary data and will explain that by completing the survey, pharmacies are consenting to the use of both survey and secondary data.

Following submission of an outline of the proposed study to the National Research Ethics Service (NRES) in March 2012, both stages of this project have been considered as not requiring Research Ethics Committee (REC) review. However, this position will need to be confirmed and the University of Manchester ethics committee service (UREC)

expects to review at least stage 2 of this project as it can touch on sensitive issues and we will be surveying patients, who will be recruited as community pharmacy customers.

As the Research Governance Framework for Health and Social Care applies, the research will also require management permission from host care organisations ("R&D approval"), in this case primary care trusts/ clusters (or their equivalents within the new commissioning structures). The Integrated Research Application System (IRAS) allows completion for a research project requiring review by NHS R&D only, and the UREC are supporting this by allowing submission of the IRAS R&D form rather than the university's own ethics committee form. All necessary research ethics/R&D approvals will be obtained prior to commencement of this study, with an amendment submitted once interview topic guides and questionnaires have been fully developed.

**PROJECT MANAGEMENT**

We believe we are in an excellent position to deliver on this project, bringing together a multidisciplinary team of experienced researchers with an excellent understanding of pharmacy policy, commissioning and practice, particularly in relation to community pharmacy. All members of the research team have worked together successfully in different combinations in the past and have an excellent track record in the timely delivery of research and evaluation studies in community pharmacy, including a number of Department of Health (DH, NIHR, National Clinical Assessment Service) and pharmacy (RPSGB, GPhC, Pharmacy Practice Research Trust, Pharmaceutical Trust for Educational and Charitable Objects) funded projects.

The study will be led and managed by the lead applicant, who will take responsibility for delivering all stages of the work. The research team will meet together formally every three months at the University of Manchester throughout the project to discuss the progress of the research and resolve any problems, and to consider emerging findings and their interpretation. Moreover, due to established close working relationships, and co-location of offices in some cases, less formal meetings and other types of communication (conference call, email) will be easily facilitated between all or some of the team on a more frequent basis, particularly at key stages of the study (e.g. at the beginning of each stage), or at very short notice (e.g. to manage difficulties), as the need arises. Project team meetings will be guided by input from the project advisory group.

The study will engage a multidisciplinary project advisory group. Membership of this group will consist of lead pharmacists from each of the PCTs/clusters (or their successors) involved in the study, two senior representatives from community pharmacy provider organisations, an NHS trust PPI manager and two patient/consumer group representatives (described below) and members of the research team. The advisory group will meet together up to four times over the 24 month period and, in addition, individual members will be asked, as appropriate, to comment on various stages of the research process. Convening an advisory group will keep the study grounded in the needs of the different stakeholder groups, provide both academic and professional guidance throughout the study, facilitate access to research sites and it will present wider opportunities for knowledge mobilisation to a range of stakeholder groups.

**PPI**

This study benefits from the involvement of PPI representation at all stages in the research process from the design of the study to analysis and interpretation of the data and dissemination of the findings. We will recruit a PPI manager and two PPI representatives to the project advisory group (above), two of whom are already known to members of the research team and have agreed to participate. Each has read at least a project outline and has been given the opportunity to feed into the full research bid which has helped the research team in their consideration both of the methodology and strategies for dissemination from a patient/public viewpoint. A second lay PPI representative will be recruited through existing contacts. In addition, we plan to link in with local patient support

groups for long term conditions in each of the study areas. Through the PPI manager, we will work with Local Involvement Networks (LINks) to identify appropriate patient support groups in each area who will each be approached to act as a reference group and sounding board for the study. We propose to 'piggyback' onto existing meetings to present material from the research (e.g. study protocol, survey tools, findings) at key stages throughout the study to obtain feedback and guidance and to inform data analysis and interpretation.

The benefits for the research have been, and will continue to be, to maintain a focus on improving patient care in a study which could otherwise drift into focussing solely on outcomes for organisations and commissioners. For example, in designing both the patient questionnaire and interview schedules for community pharmacists and their managers, maintaining a patient perspective will help to ensure that outcomes for patients are fully explored and are a true reflection of patients' expectations of community pharmacy services. PPI involvement will also help to guide our interpretation of the findings – we have found that PPI input during the early phases of data analysis and when composing recommendations from the findings have been particularly fruitful in previous studies undertaken with PPI involvement. Finally, PPI involvement in the project advisory group will provide in invaluable resource for developing strategies for sharing the findings of the research with the wider primary care community and the public. In particular, it will be of great importance to ensure that the findings of the research are shared with LINks in each of the participating areas and that information is made available for Patient Reference/ Participation Groups (PRGs/PPGs) that are associated with the Clinical Commissioning Groups in each of the participating areas. It is hoped that such information can inform and influence local priorities and perhaps contribute to behavioural change amongst the local populations to improve patients' understanding of medicines and their use. PPI involvement in the study has been fully costed including the payment of meeting fees, reimbursement of travel and provision of subsistence.

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