Building the evidence for the impact of pharmacists in general practice: a multi-method, realistic study

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DECLARATIONS

I, Georgios Dimitrios Karampatakis, confirm that:

-This is my own work and the use of all material from other sources has been properly and fully acknowledged.

-The whole work presented in this thesis was undertaken exclusively during my registration period with the University of Reading.

-No parts of this work have been submitted previously for the award of another degree in my name.

-No parts of this work will be submitted in the future for the award of another degree in my name without approval by the University of Reading.

GEORGIOS DIMITRIOS KARAMPATAKIS

PERSONAL STATEMENT

I am a pharmacist, qualified since 2014 in Greece and registered with the General Pharmaceutical Council since 2016. As a pre-registration pharmacist in Greece, I gained experience in both hospital and community pharmacy settings but had limited exposure to research. It has been my passion since I was an undergraduate student to follow a career in pharmacy practice research. To make my dream in engaging with pharmacy practice research a reality, I arrived in the UK to carry out an MSc in Clinical Pharmacy at University College London. As part of my MSc dissertation, carried out in collaboration with Imperial College Healthcare NHS, I evaluated the impact of a hospital electronic prescribing system on the work of ward pharmacists. After having gained some experience of hospital-based research, I was really keen to also pursue some research in a community setting. At that time (mid-2016), pharmacists in general practice was a very novel idea in the UK and immediately attracted my interest. I therefore managed to find funding, through a postgraduate scholarship, to carry out doctorate level research at the University of Reading in collaboration with Ealing GP Federation and Argyle Health Group in West London. Throughout my research project, I have attempted to attain objectivity by exchanging my pharmacist perspective for a researcher perspective. For example, especially when dealing with patients, I avoided commenting on any choices they had made (even if these actions or decisions sounded wrong to my understanding as a pharmacist) nor to make remarks on any feelings, attitudes, facial expressions or innuendos of participants. However, in cases of immediate risk to the participant, I was prepared to abandon my researcher perspective. For example, I was always ready to terminate or alter the data collection process in cases of distress or report to my supervisors any participant choices or professional care that could have been

dangerous. Fortunately, I did not encounter any instances where retaining my behaviour as a researcher would have been in conflict with my code of practice as a healthcare professional.

The overall aim with my research project has been to generate evidence on the impact of pharmacists working within English general practices. As large numbers of pharmacists are still being integrated into general practices in the UK, and the role is also formally being explored in an increasing number of countries globally, I am very hopeful that my research has something useful to offer to national and international policy makers attempting to establish/shape pharmacist services in general practice, and practitioners in various settings, including general practice-based pharmacists themselves. Figure 1 provides an outline of my thesis, including a summary of the individual studies that I undertook.

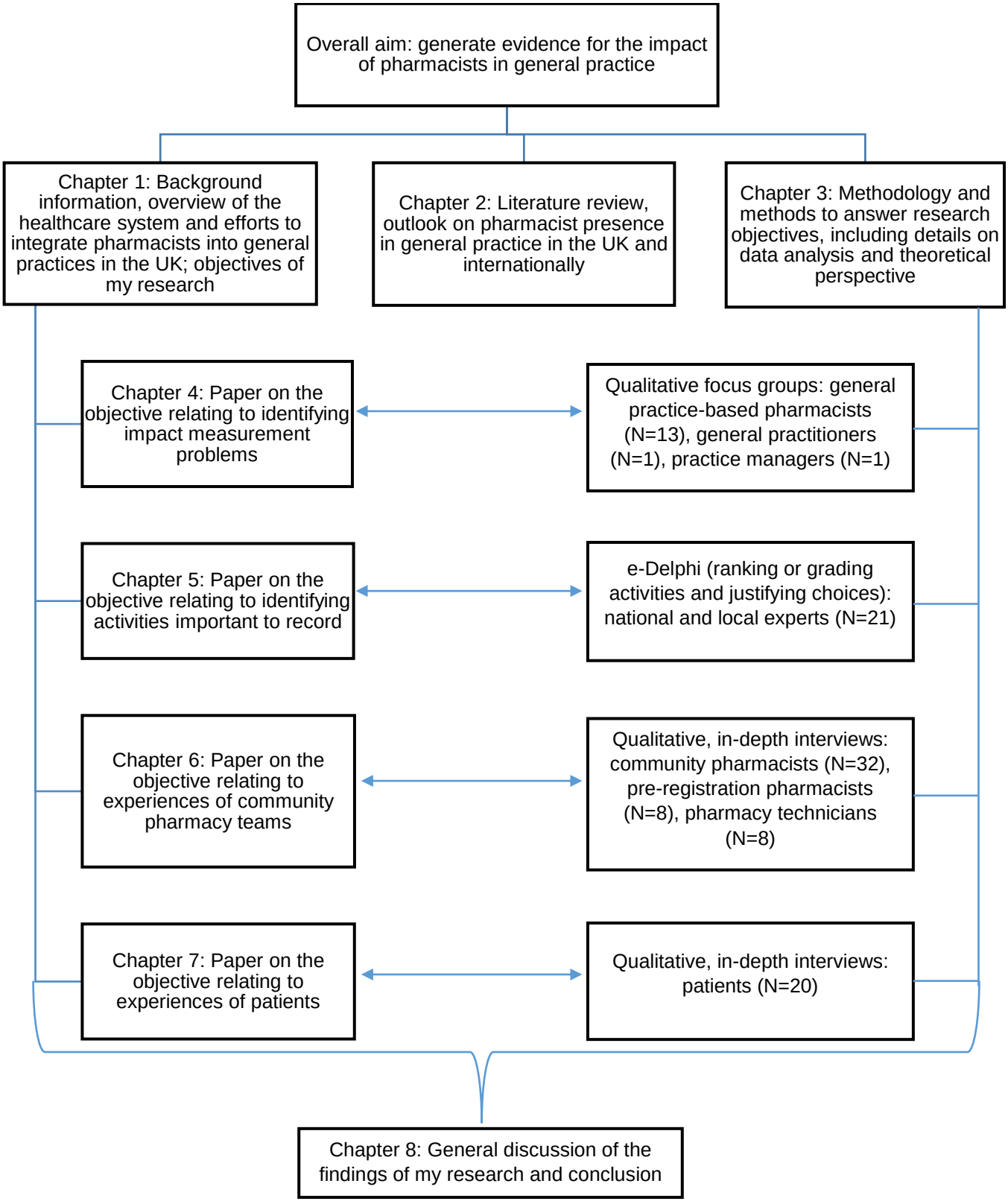

Figure 1. General overview of my research, including thesis structure

LIST OF TABLES

LIST OF ABBREVIATIONS

ACT: Asthma Control Test

A&E: Accident & Emergency

BP: Blood Pressure

CAPTION: Collaboration Among Pharmacists and physicians To Improve Outcomes Now

CCG: Clinical Commissioning Group

COREQ: Consolidated criteria for reporting qualitative research

CPPE: Centre for Pharmacy Postgraduate Education

GP: General Practitioner

GPC: British Medical Association's General Practitioners Committee

HB: Health Board

HEE: Health Education England

HSCP: Health and Social Care Partnership

ICARE: Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care

IMPACT: Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics

INR: International Normalised Ratio

IP: Independent Prescriber

KPI: Key Performance Indicator

MRP: Medication-Related Problem

MUR: Medicine Use Review

NHS: National Health Service

NMS: New Medicine Service

PCMH: Patient Centred Medical Home

PCN: Primary Care Network

PCPA: Primary Care Pharmacy Association

PCPP: Primary Care Pharmacy Programme

PHN: Primary Health Network

PIPPC: Pharmacist-led management of chronic pain in primary care

PIPS: Pharmacists in Practice Study

PIS: Participant Information Sheet

POINT: Pharmacotherapy Optimisation through Integration of a Non-dispensing pharmacist in a primary care Team

QALY: Quality-Adjusted Life Year

QOF: Quality and Outcomes Framework

QIPP: Quality, Innovation, Productivity and Prevention

RCGP: Royal College of General Practitioners

RPS: Royal Pharmaceutical Society

SCRIPT: Successful Collaborative Relationships to Improve PatienT care

STARPU: Specific Therapeutic Group Age-sex weightings Related Prescribing Units

ABSTRACT

Background: There has recently been a drive to integrate pharmacists into UK general practices to tackle workload pressures and enhance patient access to healthcare. Although not a new role, it is the first time that pharmacist presence in general practice is being formally funded and tested. Therefore, little is known about how pharmacists in general practices impact the wider healthcare system.

Aim: To build evidence on the impact of pharmacists in general practice, via in-depth elicitation of stakeholder experiences.

Methods: A multi-method, 'realistic' approach was followed, including qualitative focus groups with general practice-based staff to identify impact measurement problems for pharmacists in general practice; an e-Delphi study to reach consensus, amongst experts, on what pharmacist activities are important to record as part of impact identification; and qualitative interviews with community pharmacy teams and patients to explore their experiences of general practice-based pharmacists. Focus groups and interviews were audio-recorded and transcribed verbatim. Qualitative data was analysed thematically and quantitative data via descriptive statistics.

Results: Pharmacists carry out various valuable services in general practice, however, the majority of existing national measures are not fit for purpose in targeting pharmacist work and capturing the whole spectrum and quality of services. There was agreement on recording primarily funding-related activities, which included medication reviews, high-risk drug monitoring and medicines reconciliations. Pharmacy colleagues in general practices and community pharmacies are willing to develop mutual relationships, which could result in stronger links between the two settings and streamlined workloads. Patients are satisfied with

easy access to a pharmacist in general practice who is able to interact with them at a high standard. Lack of awareness, however, limits uptake of pharmacist-led services.

Conclusions: General practice-based pharmacists could better link different healthcare teams and enhance accessibility to, and quality of, primary care services. Ways to effectively capture pharmacist impact are still needed. Findings will inform policy attempting to frame pharmacist services in general practice as per needs and expectations of stakeholders.

CHAPTER 1.BACKGROUND INFORMATION

1.1. National Health Service in the UK – a brief overview

The National Health Service (NHS) is a public, governmentally funded, medical and healthcare service that all UK residents are entitled to use without having to pay money during or after the delivery of the service (Department of Health & Social Care, 2015). There are four subdivisions of the NHS, one for each of the countries within the UK: NHS England, NHS Wales, NHS Scotland and the 'Health and Social Care Services' which is the local NHS division in Northern Ireland (National Audit Office, 2012). The largest proportion of NHS care is provided through general practice (NHS, 2017). General practice (known as 'family practice' in some countries) is the core structure of primary care in the UK (NHS England, 2013a). Care in general practices is offered based on lists of registered patients (NHS Digital, 2019) and ranges from a consultation (including screening, diagnosis and disease prevention) and treatment to signposting and referring patients to secondary and/or specialist care (Baird et al., 2018; Health Careers, 2015). General practices are also responsible for coordinating and ensuring effective sharing of care with other NHS and non-NHS services as well as social care services (Baird et al., 2018; Royal College of General Practitioners, 2019).

1.2. Pressures on UK general practices

1.2.1. Ageing population and additional services

For several years now, there have been ongoing pressures on service delivery via UK general practices. Firstly, there is an increasingly ageing population. In 1951 about 11% of the English population was aged 65 or over and less than 1% was 85 or over (Health and Social Care Information Centre, 2014). These percentages rose

to 16% and 2%, respectively, by 2011 and the projection is that by early 2050s people aged 65 or over will consist 25%, while those aged 85 or over will be 7% of the population. More recent sources further confirm the rapidly increasing numbers of elderly people, with similar predictions in terms of percentages (Office for National Statistics, 2019). As the prevalence of most long-term conditions increases with age (Age UK, 2017), the ageing population translates to higher numbers of patients with complex co-morbidities who require access to primary care (Centre for Workforce Intelligence, 2014). Furthermore, as part of the attempt to keep people out of hospital, many activities previously carried out in secondary care have been assigned to general practices (Baird et al., 2016; Smith et al., 2013a). Characteristic examples include dealing with residents of care homes, prescribing and monitoring of high-risk drugs and increasing responsibility over out-of-hours care and long-term condition management. Pressures have also stemmed from new vaccination programmes, such as immunising children and pregnant women for influenza, new initiatives relating to disease prevention, for example, as part of the Quality and Outcomes Framework (QOF) which is a programme for English, Welsh and Northern Irish general practices that incentivises clinical excellence, new and complex clinical guidelines and multiple health campaigns urging people to seek frequent, and often unnecessary, checks (Baird et al., 2016).

1.2.2. Increasing workload

As a result of the above-mentioned facts, the workload in general practices has risen considerably. From mid-1990s to 2008, consultations provided by general practitioners (GPs) rose by about 11% whereas those of general practice-based nurses rose by 150% (General Medical Council, 2016). This trend has continued in more recent years as there has been a 16% increase in the total workload of GPs

and nurses between 2007 and 2014 (Hobbs et al., 2016). Similarly, work carried out between 2010 and 2015 reported a 15% rise in the total amount of patient contact with GPs during this period (about 13% rise in face-to-face consultations and 63% in telephone consultations) (Baird et al., 2016). In direct numbers, GPs performed 370 million consultations in 2015, which translates to 60 million additional consultations compared to the beginning of the decade (Roland and Everington, 2016). Apart from the volume, GP workload has also increased in terms of complexity and intensity (i.e. once GPs dealt only with single, common problems whereas nowadays they have to deal with large numbers of complex patient cases experiencing multiple problems and requiring a series of interventions) (Croxson et al., 2017; Gerada and Riley, 2012). A 2015 survey amongst GPs in ten nations revealed that UK GPs felt significantly more stressed at work than their counterparts in other countries and that only 22% of UK GPs believed that the NHS is on the right direction, a much lower percentage when compared to the respective percentage in 2012 which was 46% (Martin et al., 2016). Along the same lines, the 2015 'National GP Worklife Survey' found that job satisfaction for UK GPs was down to its lowest point since the beginning of this century (Gibson et al., 2015).

1.2.3. Decreases in the workforce

In response to the unmanageable workload, in 2016 more than half of the older generation GPs (50 years or older) planned to retire within five years (Sansom et al., 2016) whereas 29% of any age GPs were about to change career within the same period of time (Martin et al., 2016). Part-time employment and/or pursuing a 'portfolio career' (i.e. investing the vast majority of working time to activities other than patient-facing roles, for example, medical education or academia) have tended to become the preferred employment modes for GPs (Nosa-Ehima, 2018). A 2016 survey found

that about 30% of GP partners (i.e. GPs who are shareholders in a general practice and entitled to the respective profits of the practice) had not been able to hire a new GP and fill in their vacancies for at least a period of one year (Byrne et al., 2016). Moreover, applications for GP training dropped by approximately 15% between 2013 and 2014 (Iacobucci, 2014) whereas about 12% and 17% of the total GP training positions remained unfilled in the 2014/15 and 2015/16 recruitment rounds, respectively (Rimmer, 2015). These difficulties in retaining and renewing the workforce of GPs have therefore led to a lack of approximately 8,000 GPs in mid-2015s (The Pharmaceutical Journal, 2015a) which, along with the concomitant shortfalls in the numbers of general practice-based nurses (Smith et al., 2013a), has led to a workforce crisis in general practice.

1.2.4. Impact on patients

This workload and workforce crisis has had a negative impact on patients, particularly around accessing general practice-based services. For example, patients have been experiencing long waiting times for getting an appointment with their practice; difficulties in accessing their practice over the telephone; inability to see their preferred GP, which burdens the continuity of care (i.e. following-up is more efficiently done if they consistently see the same professional); and inadequate length of appointments to satisfy their needs (Healthwatch, 2015; Robertson, 2018; Wellings and Baird, 2017). Patient satisfaction with general practice-based services has been declining, in contrast to other NHS services, reaching historically low levels in different formal surveys done on a regular basis (Robertson, 2018; Wellings and Baird, 2017).

1.3. The potential of pharmacists

To address needs in the primary care workforce, and hence relieve some of the pressures on general practice, NHS England in early 2015 devised a ten-point plan for building the future general practice workforce (NHS England and Health Education England, 2015a). One of the plan's main points referred to the intention to exploit (on a large scale) healthcare professionals other than GPs, such as physician associates, healthcare assistants and pharmacists. Pharmacists were found, as indicated in a 2013 report, to be the third largest profession in healthcare and their numbers were expected to further grow (Smith et al., 2013b). Indeed, in 2015, a projected surplus of 11,000 to 19,000 pharmacists in England by 2040 was announced, generating fears about future unemployment in the profession (The Pharmaceutical Journal, 2015a). Governmental decisions to eliminate restrictions on places in undergraduate pharmacy degrees were quoted as the main reason for this surplus. Despite the available large numbers of pharmacists their full skills, capabilities and potentials in the community (i.e. in settings outside hospitals) have been underutilised, a fact that has been repeatedly emphasised (Department of Health, 2008; NHS England, 2013b, 2016a). A report, published in February 2015, especially highlighted the unexploited potential of English pharmacists within the setting of general practice (Royal Pharmaceutical Society and Royal College of General Practitioners, 2015).

1.4. General practice-based pharmacists in the UK – a historical overview

General practice-based pharmacists are not an entirely new concept for the UK reality. Calls for closer collaboration between GPs and pharmacists have existed since the mid-1980s (Turner, 1986). UK pharmacists have occasionally provided

services in general practice in the past, for example, face-to-face medication review clinics (Lowrie et al., 2012; MacRae et al., 2003; Petty et al., 2003) or note-based medication reviews (Bond et al., 2007). These services, however, were provided for a limited amount of time (sometimes one-off interventions), or were carried out solely for study purposes, or the involved pharmacists were not directly employed by practices and were collaborating local community pharmacists.

1.5. Scheme of integrating pharmacists into general practice – an overview

As part of the NHS ten-point plan, and to make effective use of the available pharmacy workforce by tackling in parallel the shortage of GPs, a national scheme of integrating pharmacists into general practices was announced in July 2015 (Health Education England, 2016). This scheme was co-supported by NHS England, Health Education England (HEE), the Royal College of General Practitioners (RCGP), the British Medical Association's General Practitioners Committee (GPC) and the Royal Pharmaceutical Society (RPS). The scheme expanded pharmacist responsibilities and tested the effectiveness of their role within general practices (NHS England and Health Education England, 2015b). The scheme attempted to make pharmacists full and equal members of the general practice team, similar to nurses (for example) who are already an integral and fully recognised part of general practices. The scheme did not set out to discontinue or downgrade previous efforts of integrating pharmacists into general practice, but rather to identify success of pioneers and accordingly build on previous experiences of having pharmacists working in general practice. In other words, the scheme acted as a learning exercise to explore the potential of pharmacists in general practice and inform future reiterations and/or further roll out of pharmacist presence in general practices.

The overall goal with the scheme was to reduce the workload of overburdened GPs enabling them to focus where they were most needed (e.g. diagnostics and managing patients with very complex conditions) and, in parallel, enhance patient access to healthcare services and checks (NHS England, 2018b). In other words, the scheme for implementing general practice-based pharmacist services was introduced to strengthen three main features in the general practice setting: capacity (i.e. ability to serve larger volumes of patients), expertise (i.e. a medication-related perspective in the care of patients) and safety (i.e. an enhanced use of medications).

The scheme was governmentally-funded by NHS England, with NHS England contracting with general practices. The scheme partially covered the salary costs for co-locating a pharmacist into general practice (i.e. practices received diminishing funding over a three-year period towards the costs of a general practice-based pharmacist salary) (NHS England, 2018a; The Pharmaceutical Journal, 2015b). As with any governmentally-funded service, there were a number of mandatory requirements to be met by the contractor practices, including working at a scale and participating in the scheme under one application; securing appropriate supervision and professional development for pharmacists; maintaining a plan as to how funding for employing pharmacists would be sustained during and beyond the scheme; ensuring pharmacist employment for at least a minimum number of hours per week; ensuring that pharmacists work mainly on patient-facing roles and support the broader community (including nursing home residents); and supporting the evaluation of the scheme, including reporting on national measures for identifying pharmacist impact (see also section 1.8) and coming up with additional impact measures based on local needs. Although NHS England remained at the top of the hierarchy amongst scheme commissioners, the implementation and day-to-day

running of the scheme was very much dependant and led by local players, for example, Clinical Commissioning Groups (CCGs), GP Federations and private providers of pharmacist services. CCGs are legal bodies in the UK, part of the NHS, that design and commission healthcare services for their local area. A GP Federation is a number of practices that operate together as part of a collective union and within a certain geographical area.

In turn, the scheme required pharmacists employed in general practice to pursue leadership and build effective collaborations with healthcare professionals, both at a practice level and across settings, hence supporting the establishment of multidisciplinary care and the better integration of general practices into the broader healthcare system. To account for local needs and individualities, the scheme offered flexibility in terms of its implementation, for example, in the employment models for pharmacists and their specific responsibilities.

1.5.1. The scheme's phases

The scheme was launched in two phases. The first phase, initiated in July 2015, was in the form of a national pilot. Initially, £15 million was invested in this phase with the aim to integrate 250 pharmacists into general practices (NHS England, 2015). In November 2015, however, the investment was scaled up to £31 million to create more than 490 new general practice-based pharmacist posts across England (NHS England, 2016b). Indeed, this first phase recruited more than 490 general practice-based pharmacists across approximately 90 sites which involved about 658 general practices (NHS England, 2020a). A 'pharmacists in general practice' site, formerly 'pilot site', is defined as a number of general practices that joined the scheme under the same application. An example of a site is a GP Federation. In April 2016, the

‘General Practice Forward View’ was announced by NHS England, aiming to further support practices and their associated patients by injecting £2.4 billion each year in primary care services up to 2020 (NHS England, 2016a). In line with this new NHS plan, £112 million was allocated to commence a second phase of the scheme to introduce an additional 1,500 general practice-based pharmacists by 2020/21 (NHS England, 2018a). The ultimate goal with this phase was to establish one general practice-based pharmacist per 30,000 patient population (Sukkar, 2016). This second phase consisted of several application waves (i.e. calls for applications by practices to secure funding for employing a pharmacist). The last wave closed in April 2019 at which point the scheme came to an end having raised the number of general practice-based pharmacists across England to over 1,000 full time equivalent (NHS England, 2020a). Reports have estimated that around 13 million patients will use and benefit from general practice-based pharmacist services by 2020/21 (Jankovic, 2016; Roberts, 2017).

1.5.2. Professional development of pharmacists

Apart from part-funding their salaries, the scheme promoted the personal and professional development of the integrated pharmacists. Mandatory training, tailored to individual learning needs, was ensured for all pharmacists including provision of educational and clinical mentorship (Centre for Pharmacy Postgraduate Education, 2018; Jankovic, 2016). The training programme was designed by the Centre for Pharmacy Postgraduate Education (CPPE) and runs over an 18-month period. It includes a variety of sessions ranging from enriching the clinical skillset (e.g. performing clinical assessments, managing certain long-term conditions and dealing with minor ailments) to developing behaviours necessary for a successful integration into general practice (e.g. acquiring consultation, communication, leadership and

management dexterities). Pharmacists also receive guidance and support in obtaining prescribing qualifications with the expectation that all general practice-based pharmacists would become independent prescribers (Middleton and Wright, 2019).

1.6. NHS Long Term Plan – an overview

In January 2019, the NHS Long Term Plan was released proclaiming an uplift of £4.5 billion in the funding of primary and community care between 2019/20 and 2023/24 (NHS England, 2019a). As part of this plan, general practices are required to work closely with each other by forming Primary Care Networks (PCNs), which are entities serving approximately 30,000 to 50,000 patients but without acting as extra statutory bodies. In terms of size, PCNs are smaller than GP Federations and usually include practices within the borders of CCGs. Approximately 1,300 PCNs were created across England (Baird, 2019). PCNs will act as the foundation on which the various community-based healthcare services will be linked together with mental health, social and hospital services and with the voluntary sector. As a result, integrated care will be gradually established in the community by having community-based multidisciplinary teams. Care in PCNs will focus on a set of clinical areas including cancer prevention; cardiovascular and respiratory diseases; mental health; stroke, diabetes, neonatal and maternity care (Charles et al., 2019).

1.6.1. Hiring of additional staff

To cover the workforce needs that the creation of PCNs generates, the NHS Long Term Plan postulated the hiring of about 20,000 additional primary care staff by 2023/24 (NHS England, 2019b), an amount that was later scaled up to 26,000 staff (NHS England, 2019c). General practices, via a new five-year GP contract, would

have received approximately £1.8 billion of which about £891 million exclusively invested in the employment of new staff (as part of the 'Additional Roles Reimbursement Scheme') and the rest in supporting the day-to-day function of PCNs (Baird, 2019). Some updates to the five-year GP contract, however, elevated these amounts to approximately £2.85 billion and £1.4 billion, respectively (NHS England and British Medical Association, 2020). Examples of professionals to be employed include pharmacists, physiotherapists, social prescribing link workers, paramedics, physician associates and pharmacy technicians. The initial expectation was that NHS funding would suffice for about 70% of employment costs for each professional to be hired, however, the updated GP contract will now fully cover employment costs at recommended pay scales.

1.6.1.1. Hiring of additional pharmacists

From the total amount of money that each PCN will receive in 2019/20, about £38,000 will be allocated exclusively for funding a pharmacist who will work across general practices within the network (Wickware, 2019a). The aim is that all PCNs have at least one general practice-based pharmacist by 2019/20 (The Pharmaceutical Journal, 2019). With the additional funds to arrive post 2020, it is expected that each PCN will have approximately six whole-time equivalent general practice-based pharmacists (Andalo, 2019). This will mean that about 7,500 pharmacists will be hired by PCNs by 2023/24. It is anticipated that general practice-based pharmacists within the PCNs will focus on identifying and managing patients on high-risk medicines or with complex conditions whereas the main contribution of local community pharmacies to PCNs will be the provision of NHS health checks (Wickware, 2019b).

1.7. General practice-based pharmacists in the rest of the UK nations

The drive to integrate pharmacists into general practices continues across England. Similarly to England, the numbers of general practice-based pharmacists are also increasing in Scotland, Wales and Northern Ireland. In Scotland, about £50 million has been invested in primary care since 2015, a large part of which has been specifically directed towards the employment of general practice-based pharmacists to work as part of community-based multidisciplinary teams (Parr, 2018; Torjesen, 2018). By late 2018, about half of Scottish general practices had an in-house pharmacist which translates to about 200 general practice-based pharmacists (Praities, 2018) and the aim is that all practices across Scotland will have access to a pharmacist by 2021. In Wales, the 'plan for a primary care service up to March 2018' allocated funds for integrating pharmacists into general practice (Welsh Government, 2015) and resulted in rapidly increasing numbers of general practice-based pharmacists working as part of the local clusters which are the Welsh version of PCNs (NHS Wales, 2016). Along the same lines, the Northern Irish government has invested approximately £14 million in a five-year pilot (between 2016 and 2021) to expand pharmacist presence in general practice (The Pharmaceutical Journal, 2015c). The anticipation is that there will be 300 full-time equivalent general practice-based pharmacists across Northern Ireland by 2021 (Department of Health, 2019).

1.8. Impact identification

This is the first time (commenced with the 2015 scheme and onwards) that NHS England has attempted to formally expand pharmacist presence in general practice (to a large scale) and explore the effectiveness and the potential of pharmacist roles. The availability of pharmacists in general practice, therefore, can be deemed as a

new healthcare service in English primary care. To justify its continuation, including ongoing funding, every new clinical pharmacy service has historically needed to demonstrate its usefulness including significant contribution to patient care (Delaney, 1999; Scally and Donaldson, 1998). This need for justification originates from the pharmacy profession having struggled to achieve recognition from other healthcare professionals and the public when it comes to clinical, patient-facing roles (Ng and Harrison, 2010). Within this framework of capturing usefulness, at the time of developing the initial phase of the scheme in 2015, NHS England proposed a set of 12 national Key Performance Indicators (KPIs) for identifying the impact of general practice-based pharmacists on patients, practices and the wider healthcare system (NHS England and Health Education England, 2015b). At the time of my research these KPIs were timely and important in trying to capture the impact of pharmacists, but they have now been largely retired. KPIs are defined as quantifiable measures, ideally reflecting quality, and are used to follow and evaluate the progress of a service (or an organisation overall) in terms of certain goals related to the process underpinning the service or its outcomes (Doucette, 2011). Out of the 12 KPIs, ten referred to numerical values and two were based on patient and GP surveys (see Table 1). For the numerical KPIs, general practice-based pharmacists were required to record their day-to-day work on the clinical record systems used in general practices, possibly by using existing electronic (non-pharmacy specific) codes. For example, pharmacists used the ‘medication review done’ and ‘medication management plan in situ’ codes to record completed medication reviews and care plans, as part of the KPIs relating to increasing the total number of medication reviews and developing care plans, respectively. The main clinical record systems used in UK general practice are SystmOne, EMIS and INPS Vision.

Table 1. National Key Performance Indicators (KPIs)

Numerical KPIs

- Number of patient appointments with: General practitioner (GP), Practice Nurse, Clinical Pharmacist, Health Care Assistant/Advanced Nurse Practitioner
- Impact on the percentage of patients who met the achievement indicator within the relevant Quality and Outcomes Framework-QOF (increase in the average QOF score)
- Increase in total number of medication reviews
- Decrease in the percentage of medication reviews undertaken by GPs
- Increase in the total number of patients supported to develop care and support plans, including self-management
- The rate of Accident & Emergency (A&E) attendances per 1000 patients on GP register
- Rate of emergency hospital admissions for selected long-term conditions as a proportion of patients per GP practice
- Reduction in the number of patients attending ≥15 appointments with a GP over the previous two years by age group (0-9, 10-19, 20-39, 40-59, 60-69, 70-89, 90+)
- Reduction in antibiotic prescribing rate (versus national rate per STARPU*)
- Reduction in prescribing rate of anti-psychotic medications for patients with dementia or learning disabilities

Survey-based KPIs

- Patient satisfaction survey (patient experience)
- GP survey (impact on workload, time, utilisation, job satisfaction)

*STARPU (Specific Therapeutic Group Age-sex weightings Related Prescribing Units): a weighting system that takes into account the types of people receiving treatment within a specific therapeutic group to compare drug use between NHS organisations and practices.

1.9. Gaps in knowledge and objectives of my research

As little is known about English general practice-based pharmacist impact, there have been calls for thoroughly exploring the role, for example, in terms of intervention quantity, GP workload, health-related outcomes for patients and views of stakeholders such as patient satisfaction (Bush et al., 2018; Butterworth et al., 2017; Oswald, 2017; Ryan et al., 2018; Wilcock and Hughes, 2015). At the time of commencing my research in September 2016, no transparent evaluation of the impact of English pharmacists in general practice had been announced. The overall aim of my research, therefore, was to contribute to the generation of evidence-based knowledge on general practice-based pharmacist impact to inform policy, at whatever appropriate level, and to inform healthcare practitioners including pharmacists themselves. In other words, my work attempted to identify strengths and

limitations of the integrating pharmacists in general practice (i.e. what works well, what does not work well, areas for improvement and how any changes should be implemented, needs and expectations from the service) as experienced by key stakeholders. I anticipate that my research will provide insights into what the presence of pharmacists in general practice means to the healthcare system (e.g. various providers and patients) and what needs to be done to facilitate the successful integration of pharmacists into general practice, including framing of the service to best meet the needs of the various stakeholders. The specific objectives of my research were the following:

- What are the problems (if any) that pharmacists experience when measuring and recording their impact in general practice?
- What are the most important activities that pharmacists in general practice should systematically record to capture and show their impact in this setting?
- How do community pharmacy teams experience and view the presence of pharmacists in general practice?
- What are the patient experiences of general practice-based pharmacists?

Each of the above-mentioned objectives are presented as individual papers and have been incorporated into my thesis. Impact measurement problems of general practice-based pharmacists were identified by the study presented in Chapter 4 of my thesis. This paper was published in BMC Health Services Research on 14/01/2019. General practice-based pharmacist activities of importance to record, so to show impact, are presented in Chapter 5. This paper was published in BMC Family Practice on 09/09/2019. The experiences of community pharmacy teams are presented in Chapter 6 (this paper was published in BMC Health Services Research on 18/05/2020) and, finally, patient experiences were explored by the study

presented in Chapter 7 of my thesis (this paper was recently accepted for publication in BMC Family Practice).

CHAPTER 2. LITERATURE REVIEW (A NATIONAL AND INTERNATIONAL PERSPECTIVE)

To best inform and ground my research (i.e. checking what is already known on the topic of general practice-based pharmacists, in the international and national literature), I carried out a literature review.

2.1. Existing reviews

At the time of commencing my research, there was a published systematic review on the topic of general practice-based pharmacists (Tan et al., 2014b). Four additional reviews followed, of which one was published in 2018 (Hazen et al., 2018) and the rest in 2019 (Anderson et al., 2019; Benson et al., 2019; Hayhoe et al., 2019). The reviews by Tan et al., Hazen et al., Anderson et al. and Hayhoe et al. collated outcomes from general practice-based pharmacist activities whereas the one by Benson et al. investigated the types of activities carried out by general practice-based pharmacists. Tan et al. found that general practice-based pharmacist medication reviews significantly improved clinical outcomes, such as blood pressure (BP), glycated haemoglobin (HbA1c), cholesterol levels and Framingham score, in 25 out of the 38 randomised controlled trials included in the review. Hazen et al., Anderson et al. and Hayhoe et al. similarly showed positive outcomes from general practice-based pharmacist services. Specifically, Hazen et al. examined 60 studies and reported that long-term condition management by general practice-based pharmacists significantly improved 55 of the 89 outcomes evaluated, for example, mortality, BP and HbA1c, Quality-Adjusted Life Years (QALYs) and medication errors, and had no significant effect on the remaining 34 outcomes. Hayhoe et al., in turn, claimed that pharmacist-led medication reviews, long-term condition

management and patient education reduced numbers of GP appointments, Accident & Emergency (A&E) visits and drug expenditure but did not affect hospitalisations.

None of these reviews, however, has listed the different efforts, across the globe, of integrating pharmacists into general practices or described the processes used for identifying and measuring their impact. Although some of the pre-mentioned reviews accounted for outcomes from general practice-based pharmacist activities, the described outcomes were not based solely on independent measures. In addition, the identified range of general practice-based pharmacist activities (in the review by Benson et al) also included student activity and potential roles, rather than focusing only on existing pharmacist services taking place in reality.

2.2. Literature review questions

To best address knowledge areas that were not examined by the existing reviews and in parallel best inform my research, I sought to answer the following questions with my literature review:

- What attempts have been made internationally to integrate pharmacists into general practice?
- What is the range of activities carried out by general practice-based pharmacists?
- What processes have been used to identify the impact of general practice-based pharmacists on practices and patients?
- What are the independent, quantifiable outcomes from general practice-based pharmacist activities, discovered as part of impact identification processes?
- What is the relationship between community pharmacies and general practice-based pharmacists?

2.3. Inclusion and exclusion criteria

To more effectively carry out my literature review, a number of criteria were developed before conducting the literature search. Articles:

- Should describe original research (with a formal data collection method) or protocols for research studies.
- Should be published in peer-reviewed journals.
- Should be written in the English language.
- Could originate from any country across the globe.
- Should clearly relate to a community-based, general practice or family practice or primary care clinic setting.
- Should refer to pharmacists with some sort of integration into general practice (i.e. pharmacists should clearly have been deemed as part of the practice team) but regardless of the employment model.
- Could relate to general practice-based pharmacist activity undertaken either within the practice or remotely (e.g. patient homes or nursing homes or research sites).

Articles excluded were:

- Letters to the editor, editorials, commentaries, experiences, special features, reports.
- Those describing the activity of student pharmacists in general practice.
- Those relating to pharmacist activity within: community pharmacies, various types of clinics (e.g. memory clinics, occupational health clinics, ambulatory care clinics), outpatient settings that apart from primary care services provided specialist care as well, and family medicine residency programmes.

- Those examining the potential, rather than existing, activities and roles for general practice-based pharmacists.
- Those solely referring to pharmacist-led educational projects or technological tools or manufacturer initiatives in general practice.
- Those evaluating the impact of jointly-delivered interventions (e.g. clinics carried out by general practice-based pharmacists and nurses).

In addition, outcomes of general practice-based pharmacist activities based on stakeholder opinions including patient self-reporting or assumptions (rather than on independent, quantifiable measures) were not included. The quantity of general practice-based pharmacist activities or interventions was also not deemed as an outcome to include.

2.4. Search strategies and selection process

Two databases (PubMed and Web of Science) were searched and the search strategies along with respective hits and the date on which last search was performed are presented in Table 2.

Table 2. Search strategies and respective hits for the literature review

	Search strategy	Hits
PubMed (last search on 11/11/2019)	(pharmacists[Title/Abstract] OR pharmacist[Title/Abstract]) AND (("general practice"[MeSH Terms] OR ("general"[All Fields] AND "practice"[All Fields]) OR "general practice"[All Fields]) OR ("family practice"[MeSH Terms] OR ("family"[All Fields] AND "practice"[All Fields]) OR "family practice"[All Fields]))	2684
Web of Science (last search on 11/11/2019)	#2 AND #1, where #1: TS=(pharmacist OR pharmacists) and #2: TS=(general practice OR family practice)	1748

After removing duplicates between the two databases, the title of all identified articles was screened and articles entirely outside the topic of general practice-based pharmacists were excluded. Then, the abstracts of the potentially relevant articles were read and those articles either turned out to be irrelevant or not meeting the criteria of this review were also excluded. After that, the full-text was read for the remaining articles and only those meeting the inclusion/criteria were included and presented in my literature review. Reference lists of the included articles were also searched for relevant articles. It is worth noting that the screening of titles, abstracts and full-texts was done solely by myself, without supervisor input.

2.5. Brief presentation of the included articles and discussion (where relevant)

Sixty articles met the criteria and were included in my literature review, of which 58 described original research and two were protocols. Eleven articles originated from Australia, eight from Canada, 22 from the UK (14 from England and eight from Scotland), one from the Republic of Ireland, four from the Netherlands, one from New Zealand and 13 from the USA.

2.5.1. Attempts to integrate pharmacists into general practice internationally.

Efforts of integrating pharmacists into general practices have been taking place in seven different countries, since the late 1990s, mainly though short-lived programmes. The UK is the only country with nationwide programmes so far. In the rest of the countries, individual efforts had a local character. Even in Canada where some large-scale schemes took place, most of them related to a certain geographical location (e.g. projects in Ontario and Quebec – see Table 3 below).

A number of funding sources for general practice-based pharmacists were reported. These included local primary care or other clinical structures, research teams, patients, general practices, universities (which is often the case in the USA where practices are commonly run by local universities) and government funds. It is therefore apparent that there is no such thing as a common funding model for general practice-based pharmacists, either inside the same country or globally. Even in the UK where the nationwide government schemes established uniformity to a large degree in terms of funding, many parallel efforts (e.g. the 'Primary Care Pharmacy Programme' in Sheffield or the schemes in Dudley, Slough and Lanarkshire – see Table 3 below) digressed from the norm. In general, programmes led and funded by governments resulted in larger volumes of general practice-based pharmacist posts, with the highest numbers being in Canada and the UK.

A large variety in the models of employment and integration also exists. In most articles, pharmacists were reported to work part-time in their general practice-based role spending the rest of their working time on parallel affiliations such as community pharmacy, hospitals, specialist services and other clinical and non-clinical bodies, including academia. Full-time employment in general practice-based roles was rarely mentioned (e.g. the 'Pharmacotherapy Optimisation through Integration of a Non-dispensing pharmacist in a primary care Team' programme in Netherlands – see Table 3 below). In some cases, pharmacists were directly employed by practices whereas elsewhere pharmacists were officially hired by other structures (e.g. private companies, primary care structures, clinical bodies, specialist services, universities) and integrated into general practices. Coverage of multiple practices (i.e. one pharmacist serving a number of general practices) was also a common phenomenon. General practice-based pharmacists were either directly accessible to

patients, as a choice equal to the GP and other healthcare professionals in general practice, or patients were invited to a pharmacist consultation if they met certain criteria.

Table 3 summarises the various programmes introducing general practice-based pharmacist services worldwide, as presented in the included articles.

Table 3. Programmes integrating pharmacists into general practice internationally (articles grouped by country, in chronological order)

Article reference (author, year, country)	Programme	Details on model
(Freeman et al., 2012), Australia	Local scheme in Brisbane (early 2009).	1 practice; 1 pharmacist; patient identification: via referrals.
(Tan et al., 2013), Australia	The Pharmacists in Practice Study (PIPS), in Melbourne (between 2011 and 2013).	Funded by the research team; 2 practices; 2 pharmacists; part-time employment; patient identification: via referrals.
(Tan et al., 2014c), Australia	PIPS.	Described above (see Tan et al., 2013).
(Tan et al., 2014a), Australia	PIPS.	Described above (see Tan et al., 2013).
(Benson et al., 2018a), Australia	Went West General Practice Pharmacist Project, in Sydney (since 2016).	Funded by local Primary Health Network (PHN*); 13 practices; 4 pharmacists (recruited by PHN and practices); mainly part-time employment; coverage of multiple practices.
(Benson et al., 2018c), Australia	Went West General Practice Pharmacist Project.	Described above (see Benson et al., 2018a).
(Benson et al., 2018b), Australia	Went West General Practice Pharmacist Project.	Described above (see Benson et al., 2018a), plus absence of common funding; patient identification: referrals including patient self-referrals.
(Deeks et al., 2018b), Australia	Local, 12 month pilot in Canberra (between 2016 and 2017).	Funded by local PHN; 3 practices; 5 pharmacists (recruited by practices); part-time employment; flexible roles; patient identification: pharmacists and/or referrals.
(Deeks et al., 2018c), Australia	Local, 12 month pilot in Canberra (same as above).	Described above (see Deeks et al., 2018b).
(Deeks et al., 2018a), Australia	Local, 12 month pilot in Canberra (same as above).	Described above (see Deeks et al., 2018b).
(Baker et al., 2019), Australia	Not applicable, nationwide study.	No common funding; 1 to 5 days/week in the practices; concomitant affiliations.
(Pottie et al., 2008), Canada	Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics (IMPACT), in Ontario (between 2003 and 2006).	7 practices; 7 pharmacists; governmental funds; practices and pharmacists recruited by research team.
(Pottie et al., 2009), Canada	IMPACT.	Described above (see Pottie et al., 2008), plus part-time employment; concomitant affiliations.

Article reference (author, year, country)	Programme	Details on model
(Farrell et al., 2010), Canada	IMPACT.	Described above (see Pottie et al., 2008)
(Young et al., 2011), Canada	Local scheme in Newfoundland and Labrador (2006).	1 practice; 1 pharmacist.
(Farrell et al., 2013), Canada	IMPACT and Family Health Team Initiative.	Not available.
(Bishop et al., 2015), Canada	Local scheme in Newfoundland and Labrador (same as above).	Described above (see Young et al., 2011)
(Gillespie et al., 2017), Canada	IMPACT and Family Health Team Initiative, the latter since 2006.	111 practices (out of the 190 in Ontario); 155 pharmacists, more than 1/2 covered multiple practices; full-time in practices for 1/3 of cases.
(Guénette et al., 2020), Canada	Governmental scheme in Quebec.	Direct, part-time, employment by practices; 1 pharmacist/practice; most working in community too; pharmacists in networks for training and research purposes.
(Rodgers et al., 1999), England	Local, 12 month scheme in Doncaster (in 1996).	Funded by local Health Authority**; 8 practices; 5 pharmacists.
(Chen and Britten, 2000), England	Local effort in South London (late 1990s).	3 pharmacists; patient identification: pharmacists or referrals including self-referrals.
(Zermansky et al., 2001), England	Local scheme in Leeds (late 1990s).	Not available.
(Petty et al., 2003), England	Local scheme in Leeds (same as above).	Not available.
(Bruhn et al., 2013), England	Pharmacist-led management of chronic pain in primary care (PIPPC), in East Anglia (in 2010).	3 practices.
(Neilson et al., 2015), England	PIPPC.	Described above (see Bruhn et al., 2013)
(Langran et al., 2017), England	Local, 12 month scheme in Slough (between 2013 and 2014).	Commissioned by local Clinical Commissioning Group (CCG); 13 practices; 4 pharmacists (employed by CCG but fully integrated); coverage of multiple practices; patients identified by pharmacists.
(Ryan et al., 2018), England	Nationwide, governmental scheme (West London area).	Local effort pre-dated nationwide scheme (GP Federation hiring a private company to integrate pharmacists); 8 practices; patient identification: referrals including self-referrals.
(Marques et al., 2018), England	Primary Care Pharmacy Programme (PCPP), in Sheffield (between 2015 and 2017).	86 practices (of which 9 continued to employ a pharmacist post the scheme); part-time employment.
(Bradley et al., 2018), England	Nationwide, governmental scheme (nationwide study).	Not available.
(Bush et al., 2018), England	Prescribing and Medicines Management Function in Dudley (since 2002).	Funded by local CCG; 49 practices; 23 pharmacists; part-time employment.
(Nabhani-Gebara et al., 2019), England	Efforts in South-East of England.	Not available.
(Hampson and Ruane, 2019), England	Nationwide, governmental scheme (Midlands-east parts).	Not available.

Article reference (author, year, country)	Programme	Details on model
(Nelson et al., 2019), England	Nationwide, governmental scheme (Manchester area).	Not available.
(Cardwell et al., 2018), Ireland	Small, 6-month, nationwide pilot.	4 practices; 4 pharmacists.
(Hazen et al., 2015), Netherlands	Pharmacotherapy Optimisation through Integration of a Non-dispensing pharmacist in a primary care Team (POINT), in Utrecht and Amsterdam (from early 2014 and for 15 months).	10 practices; 10 pharmacists; full-time employment; patient identification: pharmacists, referrals or self-referrals.
(Hazen et al., 2019a), Netherlands	POINT.	Described above (see Hazen et al., 2015), plus a fixed income for pharmacists.
(Sloeserwij et al., 2019). Netherlands	POINT.	Described above (see Hazen et al., 2015).
(Hazen et al., 2019b), Netherlands	POINT.	Described above (see Hazen et al., 2015).
(Campbell et al., 2017), New Zealand	Pharmacy Action Plan (since 2017).	31 pharmacists; funding from various sources, not solely by practices; full-time and part-time employment.
(MacRae et al., 2003), Scotland	Local, 2-year scheme in Glasgow (from late 1999).	Funded by the local Primary Care Trust***; 82 practices; 27 pharmacists; part-time employment.
(Lowrie et al., 2012), Scotland	Large-scale study in Glasgow (between 2004 and 2007).	87 practices; 27 pharmacists.
(Bruhn et al., 2013), Scotland	Described under 'England', in Scotland effort was in Grampian.	Described under 'England'.
(Lowrie et al., 2014), Scotland	Local effort in Glasgow for a year, with ultimate goal to optimise statin prescribing (in 2004).	Funded by local Health Board (HB****); 15 practices; 11 pharmacists; coverage of single/multiple practice(s); part-time employment.
(Neilson et al., 2015), Scotland	PIPPC, in Scotland effort was in Grampian.	Described under 'England'.
(Maskrey et al., 2018), Scotland	Nationwide, governmental scheme (Glasgow area).	16 practices, part of the local Health and Social Care Partnership (HSCP*****); roles developed collectively by HSCP lead and practices.
(Hill et al., 2019), Scotland	Local scheme in Lanarkshire, aiming to reduce opioid prescribing (late 2015).	2 practices; 2 pharmacists (from local addiction services); part-time employment.
(Stewart et al., 2019), Scotland	Nationwide, governmental scheme (study across Scotland).	Coverage of 2 practices/pharmacist; common parallel affiliations; about 70% of pharmacists were independent prescribers (IPs).
(Rothman et al., 2003), USA	Local effort in North Carolina targeting diabetes patients (in 1999).	1 practice (university-affiliated); 3 pharmacists.
(Bungay et al., 2004), USA	Local effort in Boston targeting depression and dysthymia patients (for 18 months).	9 practices; 5 pharmacists; part-time employment; pre-specified frequency for patient contact.
(Harris et al., 2009), USA	Local effort in Minnesota (in 2000).	1 practice (university-affiliated); patient identification by pharmacists.
(Hall et al., 2009), USA	Local effort in South Carolina targeting osteoporosis patients (late 2008).	Funds from local university; 2 practices; 4 pharmacists.
(Vande Griend et al., 2014), USA	Local, 12 month effort in Colorado (in 2011).	1 pharmacist; onsite and offsite employment.

Article reference (author, year, country)	Programme	Details on model
(Gums et al., 2014), USA	Collaboration Among Pharmacists and physicians to Improve Outcomes Now (CAPTION), across 15 States (for 5 years).	32 practices involved, part of the local Patient Centred Medical Homes (PCMHs******).
(Carter et al., 2015), USA	CAPTION.	Described above (see Gums et al., 2014).
(Isetts et al., 2016), USA	CAPTION.	Described above, plus part-time employment; funding in some practices from billing patients.
(Carter et al., 2018), USA	The Improved Cardiovascular Risk Reduction to Enhance Rural Primary Care (ICARE), in Iowa.	6 practices; 3 pharmacists; services provided virtually; patient identification by project facilitators.
(Castelli et al., 2018), USA	Successful Collaborative Relationships to Improve PatienT care (SCRIPT), in Pittsburgh (in 2009).	4 practices (part of the PCMHs); 2 pharmacists; coverage of multiple practices.
(Jun, 2018), USA	Local effort in Southern California (mid-2014).	Funded by local university and a grant; 1 practice (university-affiliated); 2 pharmacists; part-time employment; patient identification by referrals.
(Cowart and Sando, 2019), USA	Local, 12 month effort in Florida (since early 2014).	2 practices; 2 pharmacists; coverage of 1 practice; part-time employment.
(Cariveau et al., 2019), USA	Local effort in Western North Carolina, aiming to optimise naloxone prescribing (mid-2016).	One practice involved.

*Australian Primary Health Networks have a similar function to the English Primary Care Networks.

**Health Authorities were administrative structures of NHS in the period between 1982 and 2000.

***Primary Care Trusts were former structures in the Scottish primary care.

****Health Boards are divisions of NHS Scotland, with a role similar to the English CCGs.

*****Health and Social Care Partnerships are the Scottish version of the English Primary Care Networks.

******Patient Centred Medical Homes are the US version of Primary Care Networks, promoting integrated care and enhanced cooperation between professionals and patients.

2.5.2. Activities carried out by general practice-based pharmacists.

A wide range of general practice-based pharmacist activities was identified, which generally confirms the activities described in the review by Benson et al. (Benson et al., 2019). Medication reviews seem to be the most common task for general practice-based pharmacists, across the globe. This is not a surprise as it has been reiterated that the focus of general practice-based pharmacists should/could be the performance of complex, clinical medication reviews (Ackermann et al., 2010; Stone

and Williams, 2015; Tan et al., 2014d; Turner and Bell, 2013; Williams et al., 2018). In general, activities were quite comparable between different countries. Exceptions included the management of high-risk drugs and engagement with incentive programmes, which were UK features only. Examples of incentive programmes mentioned include the QOF and the Quality, Innovation, Productivity and Prevention (QIPP) which is a combination of programmes in England to ensure that money is spent in a way that maximises quality of care and benefits for patients. In addition, physical assessments and direct ordering of laboratory/clinical tests were also mainly observed in the UK. Overall, UK general practice-based pharmacists appeared to work more independently from GPs compared to other countries in which pharmacist input ended with a number of recommendations awaiting approval and implementation by GPs. This larger degree of independence might be attributed to the independent prescribing concept which has developed in the UK and allows pharmacists to directly make patient- and medication-related decisions (Cope et al., 2016). In contrast, prescribing for pharmacists does not exist or exists under very certain conditions and/or more limited scope of practice in other countries.

Table 4 summarises the activities of general practice-based pharmacists internationally, as presented in the included articles. To help the reader understand Table 4, some key definitions and clarifications are provided below:

- Medication review is the process of optimising (i.e. making more effective) the patient's pharmacotherapy by obtaining medication histories and relevant information (from patients/family or patient notes or both) and initiating, stopping or amending medications or devices as per the patient needs (e.g. contra-indications, interactions and other cautions) (Blenkinsopp et al., 2012).

- Medicines reconciliation is the process of updating medication lists/records so to reflect what patients are actually taking/should be taking, by also taking into consideration various types of correspondence during transfer of care (e.g. hospital discharge letters or outpatient letters) (Aronson, 2017).
- Adherence ascertainment, though not a formal term as such, implies the process of establishing whether or not the patient uses medications or devices as intended (e.g. checking the patient's inhaler technique).
- Patient counselling, as conveyed in Table 4, will refer to providing information to patients on conditions, medications or devices whereas lifestyle advice will relate to advising specifically on lifestyle factors such as diet, weight management and sleep hygiene.

Table 4. Actual activities of general practice-based pharmacists (articles grouped per country, in chronological order)

Article reference (author, year, country)	Activities
(Freeman et al., 2012), Australia	Face-to-face medication reviews (in practices or homes); staff education; patient counselling.
(Tan et al., 2013), Australia	Face-to-face medication reviews; adherence ascertainment; patient counselling; lifestyle advice.
(Tan et al., 2014c), Australia	Described above (see Tan et al., 2013).
(Tan et al., 2014a), Australia	Osteoporosis audit; staff education; patient counselling.
(Benson et al., 2018a), Australia	Face-to-face medication reviews; patient counselling; lifestyle advice.
(Benson et al., 2018c), Australia	Described above (see Benson et al., 2018a).
(Benson et al., 2018b), Australia	Described above (see Benson et al., 2018a).
(Deeks et al., 2018b), Australia	Medication reviews; patient counselling; lifestyle advice; audits; staff education; dealing with practice staff queries; administrative and research duties.
(Deeks et al., 2018c), Australia	Described above (see Deeks et al., 2018b).
(Deeks et al., 2018a), Australia	Asthma management, including asthma medication reviews; patient counselling; developing care plans.
(Baker et al., 2019), Australia	Medication reviews (in practices or homes); adherence ascertainment; patient counselling; de-prescribing; smoking cessation; medicines reconciliations; care liaison; staff education; audits.
(Pottie et al., 2008), Canada	Face-to-face medication reviews; ongoing patient following-up; monitoring; staff education; quality assurance projects.

Article reference (author, year, country)	Activities
(Pottie et al., 2009), Canada	Described above (see Pottie et al., 2008).
(Farrell et al., 2010), Canada	Described above (see Pottie et al., 2008).
(Young et al., 2011), Canada	Telephone consultations with anticoagulation patients, including counselling.
(Farrell et al., 2013), Canada	Dealing with practice staff queries; direct patient care including care plans; medication use projects.
(Bishop et al., 2015), Canada	Described above (see Young et al., 2011).
(Gillespie et al., 2017), Canada	Patient counselling; clinical medication reviews; medicine reconciliations; staff education; dealing with practice staff queries; student supervision.
(Guénette et al., 2020), Canada	Medication reviews; de-prescribing; telephone consultations with patients; dealing with practice staff queries.
(Rodgers et al., 1999), England	Switches to generics; audits; reviewing repeat prescribing; formulary reviews; asthma/gastrointestinal medication reviews.
(Chen and Britten, 2000), England	Medication reviews (in practices or homes).
(Zermansky et al., 2001), England	Face-to-face medication reviews.
(Petty et al., 2003), England	Described above (see Zermansky et al., 2001).
(Bruhn et al., 2013), England	Chronic pain, face-to-face medication reviews; prescribing duties; developing care plans.
(Neilson et al., 2015), England	Described above (see Bruhn et al., 2013). .
(Langran et al., 2017), England	Face-to-face medication reviews for type 2 diabetes; lifestyle advice.
(Ryan et al., 2018), England	Face-to-face medication reviews (in practices or care homes); long-term/acute care; monitoring; spirometry; triage; medicines reconciliation; audits and incentive programmes; prescribing including authorising repeat prescriptions.
(Marques et al., 2018), England	Medicines reconciliations; medication reviews (note-based or face-to-face in practices or care homes); prescription queries from patients and pharmacies.
(Bradley et al., 2018), England	Telephone consultations; triage; medicines reconciliation; medication reviews (face-to-face); ordering tests; physical assessments; long-term/acute care; incentive programmes; prescribing including managing repeat prescription service; producing policies; supporting patient groups; staff education; supervising students; liaison with community pharmacies.
(Bush et al., 2018), England	Medication reviews; long-term care; minor ailments; monitoring; medicine reconciliations; managing high-risk drugs and waste; prescribing duties; audits; facilitating campaigns; multidisciplinary discussions; incentive programmes.
(Cardwell et al., 2018), Ireland	Medication reviews (note-based and face-to-face); checking repeat prescriptions; staff education; dealing with staff queries; clinical audits; participation in practice staff meetings.
(Hazen et al., 2015), Netherlands	Patient care tasks such as medication reviews; quality management tasks such as medication use projects; medicines reconciliation; practice staff education.
(Hazen et al., 2019a), Netherlands	Described above (see Hazen et al., 2015).
(Sloeserwij et al., 2019). Netherlands	Described above (see Hazen et al., 2015).
(Hazen et al., 2019b), Netherlands	Described above (see Hazen et al., 2015), plus care plans.
(Campbell et al., 2017), New Zealand	Staff education; dealing with practice staff queries; writing bulletins; audits; care coordination; medicine reconciliations; medication reviews.
(MacRae et al., 2003), Scotland	Face-to-face medication reviews.

Article reference (author, year, country)	Activities
(Lowrie et al., 2012), Scotland	Medication reviews for left-ventricular systolic dysfunction.
(Bruhn et al., 2013), Scotland	Described under 'England'.
(Lowrie et al., 2014), Scotland	Prescribing project on statins; note-based medication review; education of practice staff.
(Neilson et al., 2015), Scotland	Described under 'England'.
(Maskrey et al., 2018), Scotland	Prescribing tasks; medicines reconciliation; queries from practice staff and pharmacies.
(Hill et al., 2019), Scotland	Opioid medication reviews; prescribing duties.
(Stewart et al., 2019), Scotland	Clinical duties such as medication reviews; population level duties such as audits and care coordination.
(Rothman et al., 2003), USA	Diabetes medication review; patient counselling; patient following-up; elements of physical assessment; care plans.
(Bungay et al., 2004), USA	Depression medication reviews, over the telephone; monitoring; patient counselling.
(Harris et al., 2009), USA	Face-to-face medication reviews; following-up.
(Hall et al., 2009), USA	Osteoporosis, face-to-face medication reviews; counselling; lifestyle advice; monitoring; test ordering.
(Vande Griend et al., 2014), USA	Note-based medication reviews.
(Gums et al., 2014), USA	Face-to-face, asthma medication reviews; telephone support; patient counselling.
(Carter et al., 2015), USA	Note-based and face-to-face hypertension medication reviews; patient counselling; lifestyle advice; following-up.
(Isetts et al., 2016), USA	Described above (see Gums et al., 2014 and Carter et al., 2015), plus education to practice staff.
(Carter et al., 2018), USA	Note-based medication reviews; medicines reconciliations.
(Castelli et al., 2018), USA	Face-to-face medication reviews; patient counselling; staff education; care plans; telephone consultations; population health tasks such as writing policies and protocols.
(Jun, 2018), USA	Face-to-face medications reviews; patient counselling; managing repeat prescription service; practice staff education.
(Cowart and Sando, 2019), USA	Face-to-face medication reviews with patients in diabetes type 2.
(Cariveau et al., 2019), USA	Facilitating naloxone prescribing; patient counselling; practice staff education.

2.5.3. Impact identification processes and independent, quantifiable outcomes, discovered as part of identifying impact.

Various ways of capturing general practice-based pharmacist impact have been employed, such as before-after studies, exploratory studies, controlled trials (often randomised) and descriptive studies including quantification of daily work elements and calculation of acceptance rates of pharmacist recommendations. Outcomes from general practice-based pharmacist activities (explored as part of identifying

pharmacist impact) were overall positive, though very few studies report quantifiable outcomes. Examples of independent, quantifiable outcomes included care in accordance with guidelines; resolution of medication-related problems (MRPs), for example, inappropriate medications or doses or storage conditions, adverse drug reactions, interactions and untreated indications; improvements in clinical values, such as International Normalised Ratio (INR), BP, HbA1c and cholesterol; cost-reductions and time-savings for GPs; reductions in overall medications but increased prescribing rates for agents necessary in certain conditions; and fewer hospitalisations and/or A&E attendances. Although the significance of the measured differences fluctuated (i.e. there were statistically significant changes in some cases and non-statistically significant differences elsewhere), no studies described any negative outcomes for patients and practices following pharmacist integration. These findings confirm previous reviews which similarly concluded positive outcomes from general practice-based pharmacist activities (Anderson et al., 2019; Hayhoe et al., 2019; Hazen et al., 2018; Tan et al., 2014b).

Table 5 summarises the impact identification processes along with the independent, quantifiable outcomes from general practice-based pharmacist activities, captured via these processes.

Table 5. Processes used for identifying the impact of pharmacists in general practice and independent, quantifiable outcomes, captured as part of impact identification (articles grouped per country, in chronological order)

Article reference (author, year, country)	Impact measurement process	Quantifiable outcomes
(Freeman et al., 2012), Australia	Before-after study: number of patients referred for medication review; time to review completion (from referral); financial impact on practices.	Less time to complete reviews and financial savings due to more reviews completed hence billed, unclear statistical significance.
(Tan et al., 2013), Australia	Exploring views of patients and practice staff.	Not applicable.
(Tan et al., 2014c), Australia	Before-after study: number of Medication-Related Problems (MRPs); patient adherence, general health and satisfaction.	Fewer MRPs, statistical significance.
(Tan et al., 2014a), Australia	Before-after study: number of patients on osteoporosis medications, vitamin D and/or calcium.	Significantly more patients on all three aspects.
(Benson et al., 2018a), Australia	Observational study: volume of pharmacist recommendations and percentage actioned.	88% of pharmacist recommendations actioned.
(Benson et al., 2018c), Australia	Mixed methods, quantification of activities and exploration of views of General Practitioners (GPs).	Not applicable.
(Benson et al., 2018b), Australia	Observational study: MRPs spotted and volume of pharmacist recommendations; acceptance rates of recommendations.	1,124 MRPs detected; 70% of recommendations actioned.
(Deeks et al., 2018b), Australia	Exploration of stakeholder views.	Not applicable.
(Deeks et al., 2018c), Australia	Quantification of pharmacist activities.	Not applicable.
(Deeks et al., 2018a), Australia	Quantification of activities; changes in Asthma Control Test (ACT*).	Not applicable.
(Pottie et al., 2008), Canada	Exploring views of GPs.	Not applicable.
(Farrell et al., 2010), Canada	GPs comparing own and pharmacist contributions to practices.	Not applicable.
(Young et al., 2011), Canada	Cohort study with a control: times International Normalised Ratio (INR) within therapeutic and expanded therapeutic range (i.e. range ± 0.3); >5.0 or <1.5.	Statistically significant differences, favouring the intervention group.
(Bishop et al., 2015), Canada	Survey exploring satisfaction of patients and GPs.	Not applicable.
(Gillespie et al., 2017), Canada	Impact on patients, as perceived by pharmacists.	Not applicable.
(Rodgers et al., 1999), England	Controlled trial: changes in prescribing costs; whether savings offset scheme's costs.	Significantly fewer prescribing costs in intervention, which offset scheme's costs.
(Chen and Britten, 2000), England	Audio-recoding consultations to understand content/feasibility.	Not applicable.
(Zermansky et al., 2001), England	Randomised controlled trial: changes in repeat prescriptions; volume of medications prescribed and costs; hospital/practice use.	More prescription changes, less medications and costs in intervention (unclear statistical significance); similar use of hospital/practices.
(Petty et al., 2003), England	Exploration of patients' views.	Not applicable.

Article reference (author, year, country)	Impact measurement process	Quantifiable outcomes
(Bruhn et al., 2013), England	Described below, plus self-reported general health and anxiety levels.	Not applicable.
(Neilson et al., 2015), England	Randomised controlled trail: self-reported pain levels; life quality; costs for hospital/practice visits, medications.	Not applicable.
(Langran et al., 2017), England	Before-after study: patients receiving care following guidelines; those having certain clinical values outside range.	Positive changes, deteriorating after scheme's discontinuation, unclear statistical significance.
(Ryan et al., 2018), England	Exploration of stakeholders' views.	Not applicable.
(Marques et al., 2018), England	Quantifying activities; estimations on time-savings for GPs; exploring patients' and community pharmacists' views.	Not applicable.
(Bush et al., 2018), England	Observational study: quantification of activities; assumptions about savings on GP time and costs.	Not applicable.
(Nabhani-Gebara et al., 2019), England	Identification of changes in the dynamics amongst professionals; eliciting patient satisfaction.	Not applicable.
(Hampson and Ruane, 2019), England	Absence of a common process, different approaches by different practices.	Not applicable.
(Nelson et al., 2019), England	Difficulties in measuring differences on workload of GPs.	Not applicable.
(Cardwell et al., 2018), Ireland	Mixed methods study, without control or before-after design: patient-level data; practice-level data; cost-related data.	Not available, this was a protocol.
(Hazen et al., 2015), Netherlands	Before-after, controlled, study: medication-related hospital admissions; medication errors; drug burden index**; costs for medication, hospital care, tests.	Not available, this was a protocol.
(Hazen et al., 2019a), Netherlands	Ethnographic study to identify pharmacist impact on medication safety as mirrored by their interactions with professionals.	Not applicable.
(Sloeserwij et al., 2019). Netherlands	Described above (Hazen et al., 2015).	Fewer hospitalisations in intervention, unclear statistical significance; no difference on drug burden index and costs.
(Hazen et al., 2019b), Netherlands	Observational study: MRPs spotted; pharmacists' recommendations and proportion actioned; proportion of MRPs resolved.	1292 MRPs; 83% of recommendations actioned; 78% of MRPs resolved.
(MacRae et al., 2003), Scotland	Exploration of GPs' views.	Not applicable.
(Lowrie et al., 2012), Scotland	Randomised controlled trial: use of angiotensin-converting enzyme inhibitors or angiotensin receptor blocker and β-blockers; deaths and hospitalisations.	In intervention arm, significantly more patients on appropriate treatment; similar deaths and hospitalisations.
(Bruhn et al., 2013), Scotland	Described under 'England'.	Not applicable.
(Lowrie et al., 2014), Scotland	Randomised controlled trial: patients achieving target cholesterol; rates of statin prescribing.	Statistically significant differences, favouring intervention arm.
(Neilson et al., 2015), Scotland	Described under 'England'.	Not applicable.
(Maskrey et al., 2018), Scotland	Before-after study on GP time on certain prescribing tasks; exploring GP experiences.	GP time reduced, unclear statistical significance.

Article reference (author, year, country)	Impact measurement process	Quantifiable outcomes
(Hill et al., 2019), Scotland	Volume of records reviewed and patient contact; volume of opioid analgesics prescribed before and after integration of pharmacists.	Volume of opioid analgesics reduced, unclear statistical significance.
(Rothman et al., 2003), USA	Before-after study: HbA1c.	Statistically significant improvements.
(Bungay et al., 2004), USA	Volume of activities and patients; pharmacist time spent with patients and GPs.	Not applicable.
(Harris et al., 2009), USA	Observational study: MRPs spotted and resolved; changes in certain conditions' status, use of certain drugs, number of drugs/patient, clinical goal achievement.	250 MRPs and resolved; Statistically significant changes, except for number of patients achieving clinical goals.
(Hall et al., 2009), USA	Before-after study: adherence to osteoporosis guidelines.	Significantly higher adherence to guidelines.
(Vande Griend et al., 2014), USA	Descriptive study: number of records screened, MRPs, recommendations and acceptance rates, cost savings due to drug switches.	70% of recommendations actioned, 24 serious interactions resolved, savings of about $52,000.
(Gums et al., 2014), USA	Before-after study: hospitalisations and Accident & Emergency (A&E) visits; ACT scores; self-reported life quality.	Significantly fewer hospitalisations and A&E visits, deterioration when scheme discontinued.
(Carter et al., 2015), USA	Cluster-randomised trial, with a control: proportion of patients achieving controlled blood pressure (BP); differences in BP reduction.	Similar proportions achieving controlled BP; significantly higher BP reduction in intervention.
(Isetts et al., 2016), USA	Number of encounters with patients; pharmacists' time on certain activities.	Not applicable.
(Carter et al., 2018), USA	Before-after, controlled, study: adherence to cardiac-related guidelines; certain clinical values. Also, recommendations accepted.	Significantly higher adherence in intervention; similar clinical values; 90% of pharmacists' recommendations accepted.
(Castelli et al., 2018), USA	Number of activities, patients encountered, MRPs.	9,375 MRPs were identified.
(Jun, 2018), USA	Number of patients interacted with pharmacists; hours spent with patients; changes in HBA1c.	Reduction in HbA1c, unclear statistical significance.
(Cowart and Sando, 2019), USA	Matched cohort study, with a control: time to treatment intensification; number of patients with reductions in HBA1c, those achieving HbA1c goals and time for this achievement; changes in HBA1c.	Positive differences, non-statistically significant though, favouring intervention arm.
(Cariveau et al., 2019), USA	Before-after study: prescribing rates of naloxone.	Higher rates, statistically significant difference.

* Asthma Control Test is a patient questionnaire looking at asthma control over the last four weeks.

**Drug burden index is an indicator mirroring the exposure of elderly to anticholinergic and sedative agents.

2.5.4. Relationship between community pharmacies and general practice-based pharmacists.

The relationship between general practice-based pharmacists and surrounding community pharmacies is unclear. Some literature reports that, following pharmacist integration into general practice, there is frequently good communication between pharmacy colleagues in the two settings, stronger links between practices and pharmacies and increased uptake of community pharmacy services due to more referrals from the practices. Conversely, in other cases, competing, business-related interests and/or frictions between the two parts predominate.

Table 6 summarises the relationship between community pharmacies and general practice-based pharmacists, as described in the included articles.

Table 6. Relationship between community pharmacies and general practice-based pharmacists (articles grouped per country, in chronological order)

Article reference (author, year, country)	Relationship with community pharmacies
(Tan et al., 2013), Australia	Good relationships, expressed by general practice-based pharmacists, which were appreciated by practice staff and enhanced continuity of care.
(Tan et al., 2014c), Australia	Referrals to pharmacies when adherence aids needed.
(Benson et al., 2018c), Australia	General Practitioner (GP) fear that general practice-based pharmacists might disrupt existing collaboration between practices and pharmacies.
(Deeks et al., 2018b), Australia	Community pharmacy teams reporting limited communication, doubting the value of general practice-based pharmacists for patient care, expressing fears of losing business and governmental funding.
(Baker et al., 2019), Australia	Mixed views (as expressed by general practice-based pharmacists): better links between practices and pharmacies and more referrals to community pharmacies but also community pharmacy team reluctance to collaborate due to concerns about losing business and governmental funding.
(Pottie et al., 2008), Canada	Tighter links between practices and pharmacies due to pharmacist presence in general practice.
(Guénette et al., 2020), Canada	Limited communication, as expressed by general practice-based pharmacists who occasionally contacted community pharmacies via telephone or in writing (not vice versa due to unawareness of which practice had a pharmacist).
(Ryan et al., 2018), England	Enhanced relationships between practices and pharmacies, as expressed by general practice-based pharmacists and other staff.
(Marques et al., 2018), England	Enhanced relationships between practices and pharmacies, as expressed by both parties, as a result of more respect from practice staff; more referrals to community pharmacies as a result of raised understanding on pharmacist role.
(Bradley et al., 2018), England	Rapidly increasing communication, as reported by general practice-based pharmacists.
(Nabhani-Gebara et al., 2019), England	Existence of significant tensions, expressed by general practice-based pharmacists who viewed community pharmacists as less professionally valuable and criticised them about over-ordering items which doesn't benefit surgeries hence creating tensions plus reducing reputation of profession (hence practices reluctant to hire pharmacists).
(Hazen et al., 2019a), Netherlands	No resistance and tensions observed, as expressed by general practice-based pharmacists, due to complementary roles (i.e. community pharmacies focus on dispensing, basic information on medications and random following-up whereas general practice-based pharmacists on complex medication reviews and structured following-up).

2.6. Relevance to my thesis.

Most articles from the UK relate to the era before the extensive government efforts of introducing pharmacist services into general practice. It is worth noting that England is a pioneer in proposing the use of KPIs for pharmacists in general practice. Although KPIs have been used for hospital pharmacists in the past, such as for pharmacy services in New Zealand and Canadian hospitals (Fernandes et al., 2015;

Ng and Harrison, 2010), this is the first time that KPIs have been employed for identifying the impact of general practice-based pharmacists. However, measuring impact through the KPIs has not been reported.

In July 2018, an evaluation of the English scheme's first phase was announced and published as an online report (Mann et al., 2018). The evaluation explored a wide range of stakeholder opinions in relation to general practice-based pharmacist impact, but did not aim to make any independent measures of activities or outcomes. The evaluation findings suggested that the integration of pharmacists into general practice increased the overall capacity of practices (i.e. ability to serve more patients) as well as the capacity of GPs (i.e. supporting GPs by assigning tasks to pharmacists freed up GP appointment slots) and made GP workload more focused (i.e. GPs dealing with acute care whereas pharmacists dealt with long-term care). In addition, practices saw reduced costs, enhanced performance in terms of safety and greater accomplishment of local or national targets. Patients appreciated the easy access to a professional in the practice and the availability of longer appointments with the same person that enabled in-depth, holistic reviews. As a result, patients reported better medication adherence, raised understanding of their condition/medication, fewer side effects and greater responsibility for their own health including following a healthier lifestyle.

The continuous integration of pharmacists into English general practices, along with the constantly changing models of employment, mean that ongoing research on the topic is required. Literature from overseas, though providing insights, does not necessarily apply to English general practice-based pharmacists due to the scale of the integration efforts in England, the individualities of healthcare systems and the

multiple models of general practice-based pharmacists that exist internationally and even nationally.

In particular, it was unknown at the time of undertaking this work, what a KPI system meant for general practice-based pharmacists. The evaluation of the first phase of the scheme reported resistance from sites to the use of KPIs (Mann et al., 2018), however, the exact problems behind them were not investigated. This absence of knowledge of KPIs led to some exploratory work to determine the exact measurement problems with general practice-based pharmacist impact, which is the first study in my research. In addition, although general practice-based pharmacists were expected to code their activities, there had not been any agreement on what specific activities were important to record. The need to develop an agreed activity coding scheme for English general practice-based pharmacists has been emphasised by participants in the first study of my research. For settings other than general practice, it has been previously reported that the absence of a common activity coding system might lead to inconsistent recordings between different pharmacists hence making difficult any subsequent data extractions (Al-jedai and Nurgat, 2012; McLennan et al., 1999). Therefore, with my second study, consensus amongst general practice-based pharmacists on what activities should be recorded (within the framework of capturing their impact) was determined.

As already mentioned, literature describes mixed attitudes on collaboration between community and general practice-based pharmacists. The initial evaluation by Mann et al. did not offer any further insight on this matter as community pharmacists were not amongst the stakeholders whose views were explored. English community pharmacies provide a range of services, many of which are clinical such as the Medicine Use Reviews (MURs) and the New Medicine Service (NMS)

(Pharmaceutical Services Negotiating Committee, 2019). MURs are annual adherence-focused reviews with patients on certain long-term conditions (such as diabetes, asthma etc.) to verify whether or not they are using their medications as intended. However, MURs are expected to be phased out by 2021, in favour of another service focusing on discharge medications (Pharmaceutical Services Negotiating Committee, 2020). The NMS, in turn, has the ultimate goal to support patients who have been recently initiated on new medications. At the time of commencing my research, there were many anecdotal reports about resistance from English community pharmacies to the introduction of pharmacists into general practice due to fears of competition over certain services (King, 2015; Robinson, 2015). For example, community pharmacy teams were concerned that the comprehensive medication reviews by general practice-based pharmacists might replace MURs by community pharmacists. These anecdotal rumours, along with the conflicting literature findings, led to my next study which attempted to identify the experiences of community pharmacy teams with pharmacists in general practice.

Little work (i.e. only four studies) has been conducted on patient perceptions of general practice-based pharmacists within the UK (Marques et al., 2018; Nabhani-Gebara et al., 2019; Petty et al., 2003; Ryan et al., 2018). Some research with patients was also carried out during the initial evaluation by Mann et al. and by the Patients Association (i.e. an independent UK charity) in collaboration with the Primary Care Pharmacy Association (PCPA) (The Patients Association and Primary Care Pharmacy Association, 2016). In general, patients appear satisfied with general practice-based pharmacist services. Most of the previous UK research efforts, however, either used surveys or qualitative techniques (e.g. focus groups) that investigated only very certain, limited aspects of patient opinions. In addition, all of

the previous studies were restricted to certain regions, hence unlikely to have accounted for the diversity in general practice-based pharmacists' roles, contractual settings and skillsets. None of the previous studies have pursued an in-depth exploration of patient experiences of their contact with general practice-based pharmacists, which is the final study in my research. Mapping patient experiences over time is important because as numbers of UK general practice-based pharmacists keep on rising, patient needs and expectations might also keep on changing. In addition, understanding patient experiences was one of the national KPIs.

I will now move on, in the next chapter (Chapter 3), and describe the methodology and specific methods used for carrying out my four studies to satisfactorily answer the respective objectives of my research.

CHAPTER 3. METHODOLOGY

3.1. Introduction

My research is an evaluation-like project consisting of several related but independent studies. ‘Evaluation’ is defined as a study type employing appropriate research methodologies to assess programmes, with the ultimate goal to inform decision making and result in practical applications (Powell, 2006). The definition of evaluation aligns with the goals of my research in enhancing knowledge on the topic of general practice-based pharmacists in the UK, via the identification of strengths and limitations of the service (see Section 3.2.3 for further explanation).

My research was not theory-driven (i.e. there was not a certain theory that informed the design and the conduction of my research, as such). It was instead a data-driven project (i.e. the choice of methods depended on the data that was to be obtained and subsequently any recommendations made were likewise based on the collected data). According to Michael Crotty, it is very common (and not problematic at all) that methods constitute the starting point for a piece of research rather than the overall theoretical stance of the researcher (Crotty, 1998). It is hard, for example, for a researcher to say that ‘I am an objectivist or constructionist’ (where the objectivism paradigm states that meanings in the social world exist independently of human consciousness, and constructionism seeks to understand the world through the minds of human beings claiming that meanings are only constructed through human minds) and ‘therefore, I will do this, this and that during my research’. In other words, it is usually the problem to be addressed (hence the research questions to be answered) that lead to the selection of methods which of course then need to be

justified. The justification of methods involves the description of the theoretical perspective underpinning the research.

To give the reader a clearer picture on what to expect from the terms used above, some key explanations and definitions are provided here. Methods refer to the specific techniques or activities used in gathering and analysing data during the research process. Methodology relates to the overall plan of action behind the employed methods, in other words, to the overall design or the rationale that shaped the selection of certain methods, which also involves reference to the theoretical perspective. Theoretical perspective implies the overall paradigm taking account of the philosophical viewpoints used to synthesise and bring logic to the findings of a study, including grounding any assumptions made, and the kind and characteristics of the knowledge obtained through a piece of research (i.e. 'how we know what we know').

3.1.1. Chronological series of events in my research

I started by choosing methods that were appropriate for answering my research questions and feasible to be carried out within certain timeframes. Then, my whole research was reviewed and related to a theoretical perspective to explain my findings as well as the actual type of knowledge obtained.

3.2. Theoretical perspective

3.2.1. Paradigms and some preliminary notions

A paradigm is 'a worldview that defines, for its holder, the nature of the world, the individual's place in it, and the range of possible relationships to that world and its parts' (Guba and Lincoln, 1994). Any sort of science, therefore, should be embedded in a belief system described as a paradigm. As mentioned before, I was not guided

by a certain paradigm in the choice of methods. I decided, however, to present my work in light of the realism paradigm hence ascribing to my work the form of a realistic evaluation.

3.2.2. Realism as a paradigm

Realism is an example of a paradigm. The early form of realism, often referred to as ‘naive realism’ or ‘direct realism’, was a synonym of objectivism as it was assumed that realities existed regardless of consciousness (Crotty, 1998; Pawson, 2013). The advocates of ‘naive realism’ claimed that to assume a ‘real’ reality, the stance of the researcher should necessarily be objective, otherwise one cannot explain how things really are or how things really behave in our world. Realism, however, has over the years gradually evolved to what is often called ‘scientific realism’ (Crotty, 1998; Pawson and Tilley, 1997). This contemporary form of realism implies that although a world might exist independently of human consciousness, it would be an inconceivable world. Meanings are brought into existence only when human minds make sense of them. ‘Realities’ in our world, therefore, are always constructed by human minds.

3.2.3. Evaluation prerequisites

Historically, evaluation approaches tended to employ randomised controlled trial and/or meta-analysis designs, largely reflecting the naive form of realism. Evaluation science, however, should always have the realistic ambition to shape real-world practice and policy. As such, evaluation science is well served by the method of realistic evaluation which is considered as a day-to-day inquiry strategy attempting to understand the various flocks of policies (Pawson, 2013). There are three key domains that evaluation is (or should be) based upon, namely ‘real’, ‘realist’ and

‘realistic’ (Pawson and Tilley, 1997). First, evaluation always addresses ‘real’ matters. ‘Real’ does not imply ‘privileged knowledge’ but rather refers to whatever exists in the world (Sayer, 2000). Second, evaluation must adopt a ‘realist’ methodology, rather than one dryly driven by positivistic orthodoxies and statistical diligence, but without this meaning that the need for the methodology to be scientifically sound is denied. In other words, in realistic evaluation, methods are driven by the ‘object of study’ and what is actually desired to be learnt from the study (Sayer, 2000). Lastly, evaluation should be ‘realistic’ hence it should always aim to extend the knowledge of the various stakeholder groups (e.g. decision makers, practitioners, general public) rather than being performed solely for benefitting science.

3.2.4. ‘Scientific realism’ – principles

The key feature of ‘scientific realism’ is the element of explanation, which is believed to gradually result in fresh, scientific knowledge. This explanatory obsession of realism is expressed in the slogan question ‘why a programme works, for whom and in what circumstances’ (Pawson, 2013; Pawson and Tilley, 1997). Realistic research always focuses on the ‘why’ features rather than simply verifying ‘whether’ (e.g. ‘why’ a programme works versus ‘whether’ it works). To achieve its explanatory ambitions, realistic research uses the formula of ‘mechanisms’, ‘contexts’ and ‘outcomes’ (i.e. outcomes, in a programme, are always a result of trigger mechanisms occurring only under certain conditions). It is the responsibility of the realist researcher to identify these mechanisms and contexts that generate certain outcomes, thereby explaining ‘why’ a programme works or does not work. It should be stressed, however, that programmes do not come into existence by having pre-determined mechanisms, contexts and outcomes. These are all concepts that are defined based on their role

in the explanation process of realistic research, in the same way that it is not the ingredients that make a dish but rather the way ingredients get processed (Pawson, 2013). Therefore, the realist approach should not seek to create catalogues of mechanisms, contexts and outcomes associated with a specific programme but rather to present mechanisms, contexts and outcomes in configuration (i.e. Mechanism 1 + Context 1 = Outcome 1, Mechanism 2 + Context 2 = Outcome 2 etc.).

3.2.5. Social factors

To further understand a realistic course of action, it might be worth delving a little bit more into the principles of 'society' (again as viewed by realists). Any 'society' is underpinned by social mechanisms that comprise a constant interplay between 'agency' (i.e. individuals and their reasoning, for example, their choices) and 'structure' (i.e. community-related factors, for example, social norms) (Archer, 1995; Pawson and Tilley, 1997). People's collective reasoning constitutes the underlying mechanism that causes all outcomes in a society. A programme, introduced in a society, is defined as 'its personnel, its place, its past and its prospects' (Pawson and Tilley, 1997). Programmes are therefore social systems attempting to affect people's day-to-day reasoning. Programmes make a 'difference' by generating 'underlying mechanisms' surpassing existing social mechanisms. Society, however, is in a state of constant flux (often referred to as 'morphogenesis') and as part of a society, programmes follow the same principles in terms of undergoing consistent change (Archer, 1995; Bhaskar, 1979; Sayer, 2000). Programmes do mutate (they are 'open systems') and depending on the various social circumstances, which might change from favourable to unfavourable and vice versa, they often have a short 'shelf-life'.

3.2.6. Realistic evaluation

Nevertheless, the aim of realistic evaluation is to capture these ‘underlying mechanisms’ generated by a programme. As social reality is ‘stratified’, these mechanisms are not always observable (Pawson and Tilley, 1997). As a consequence, realistic research needs to ‘penetrate’ into the ‘inner workings’ of a programme and account for both ‘micro’ and ‘macro’ mechanisms, rather than simply acknowledging what appears on the ‘surface’. It is this ‘penetrating’ approach that attributes the exploratory element to realistic research, in the same way that one cannot truly explain how a clock operates by simply observing its face (to use a traditional example of realists). In addition, realistic evaluation does not consider programmes as ‘things’ that ‘work’ or ‘do not work’ (Pawson and Tilley, 1997). It rather seeks ‘ideas’, contained within a programme, that may or may not work. Ideas, however, have ‘their time and place’. Talking about ‘time and place’ equates to taking account of the ‘context’ of a programme. For realists, ‘the relationship between causal mechanisms and their effects is not fixed, but contingent’ (Sayer, 1992). In other words, to use a popular realist example, gunpowder has the potential to blow up but this can only be done when the appropriate conditions exist. ‘Context’ does not only imply the institution or geographical location but also refers to the various social rules or values or interdependencies that may facilitate or hinder a programme.

To summarise the ‘nuts and bolts’ of realistic evaluation, one might say that it is a process seeking to reveal what it is within a programme (mechanisms) that makes people react in a certain way (outcomes) and under what conditions all this occurs (contexts). As previously highlighted, programmes largely target the reasoning of their stakeholders. As a result, the success of a realistic evaluation lies on

understanding the way in which the various subjects (i.e. stakeholders) think and behave (Elster, 2007). In realistic terms, stakeholder reasoning is often described as ‘common sense theory’ or ‘participants’ wisdom’.

The contemporary world is passionate about decision making and hence terms such as ‘value’, ‘worth’, ‘evidence’ etc. are extremely popular (Pawson and Tilley, 1997). Realists, however, strongly believe that research is always susceptible to bias thereby scientific data is always intertwined with uncertainty (Popper, 1992). For realists, there is no universal ‘logic of evaluation’ or ‘scientific key to the truth’ or ‘warranty in decision making’. A favourite example of realists states that ‘when constructing a building on piles, piles are driven down not to any pre-specified base but until builders reach firm ground that can carry the structure’. ‘Evidence’ does not consist of ‘finite chunks’ providing safety to decision making but it rather develops through explanation piling (Popper, 1992). This accumulation of explanation, however, is not a matter of ‘replication’ since programmes undergo constant ‘morphogenetic change’ hence they can never be fully replicated. Progress in ‘evidence’, for realists, is being made via generating and testing theories. In other words, ‘evidence’ is being created via the trial and refinement of ‘mechanisms and contexts which sustain law’.

It is therefore apparent that being realistic in evaluation means to adopt a ‘characteristic modesty’ and be open to ‘attacks on findings’ (Chelimsky, 1995; Pawson and Tilley, 1997). Within this context of modesty, realistic evaluators ‘deny a certain knowledge of the world and accept possibilities of alternative valid accounts of any phenomenon’ (Maxwell and Mittapalli, 2010). Realistic evaluators should also not forget the ‘metallic rules of evaluation’ (Rossi, 1987). These ‘rules’ basically stress that evaluators’ expectations in terms of showing programme effectiveness

should remain low as ‘programmes usually overreach themselves’. What a realistic evaluation offers, in fact, to policy makers is a realisation of a programme for ‘the time being’. Programmes for policy makers are actually a ‘conjecture’ (often referred to as ‘the policy maker’s programme theory’). The evaluation is the ‘test’ of this ‘conjecture’ and has an ‘enlightenment end’ (Weiss, 1986). Realistic evaluation, without being definite, usually sits ‘somewhere in the middle between qualitative and quantitative research’ and promotes collaboration between these two types of research (Greene, 2002; Mark et al., 2000). In any case, realistic evaluators should not be obsessed with a certain methodology/method but rather recognise and accept the defects that each methodology/method might have.

3.2.7. Relevance of ‘scientific realism’ to my research

How realism relates to my research will now be explained by highlighting certain analogies. At first, my whole research project dealt with a ‘real’ matter (i.e. a healthcare service). The presence of pharmacists in general practice and the rapid expansion in their numbers, across the UK, are facts that cannot be argued. The methodology followed was ‘realist’ in the sense that there was no obsession, from my side, to a certain method. Rather, the method that best served each specific objective and addressed my research questions was chosen. At the end, both qualitative and quantitative data was gathered. My research had the ‘realistic’ ambition to extend stakeholder knowledge on the topic, especially decision-makers and general practice-based pharmacists, rather than solely being carried out for the purposes of obtaining an educational degree. The explanatory principle of realism in understanding ‘what works in a programme, for whom and in what circumstances’ is actually illustrated in my attempt to identify strengths and limitations with pharmacist presence in general practice. My research did not seek to answer, at once, why

‘pharmacists in general practice’ might or might not work as a service but rather to identify the elements of the service that work (i.e. strengths) and that do not work (i.e. limitations). Spotting ‘ideas’ that work or do not work within a programme and under what circumstances is exactly the purpose of realistic evaluations. My effort to investigate the service in light of stakeholder experiences coincides with the ‘realistic’ goal of understanding stakeholder reasoning, hence perceiving ‘realities’ as socially constructed. The purpose of realistic research to understand ‘inner workings’ in a programme is depicted in the in-depth approach that I followed throughout my research to make sense of my participant experiences. As such, I did not simply set out to identify the attitudes of participants but rather to capture their day-to-day experiences, views, opinions, needs, feelings and emotions, expectations, preferences, concerns, frustrations, and suggestions.

3.2.8. A reference to epistemology

Epistemology is the concept that seeks to answer what type of knowledge is obtained through a piece of research or, in other words, ‘what it means to know’ (Hamlyn, 2005). As already mentioned, my whole project relied on the experiences of stakeholders. In other words, I sought to understand the world (i.e. the presence of pharmacists in general practice) through the eyes of participants. Therefore, I viewed ‘realities’ in the world as elements constructed by human minds, hence committing to the principles of ‘scientific realism’. The epistemological stance that characterises ‘scientific realism’ is constructionism. Constructionism states that a world without human minds is just an inconceivable world. Meanings are brought into existence only because human minds made a sense of them in a particular way. To use a favourite example of scientific realists, ‘a tree is a tree only because we humans view it as a tree’. Early realists, in contrast, who were adopters of

objectivism believed that a tree is a tree regardless of whether we human beings know about it or not. For scientific realists, ‘realities’ are not perceived as objective truths awaiting to be discovered via a well-designed piece of research. ‘Realities’ are rather constructed by human minds. The knowledge, therefore, obtained via my research project was socially constructed knowledge. Constructionist knowledge does not reflect the reality but it rather creates the reality. Inevitably, socially constructed knowledge accepts the possibility for different accounts of the same phenomenon (i.e. there could be multiple socially constructed realities). In my socially constructed project, for example, nobody can deny the existence of alternative views and experiences with regards to pharmacist presence in general practice. But all these, potentially diverse, constructions will cumulatively provide a good realisation (to speak in realistic terms) of the phenomenon of interest, in my case, the presence of pharmacists in general practice.

So far, I have presented the principles of realistic evaluation and why this is relevant to my work. Linking my specific findings to the realism formula of ‘mechanisms’, ‘contexts’ and ‘outcomes’ and the implications arising from my evaluation when viewed in the prism of realism will be presented in the Discussion chapter (Chapter 8).

3.3. Design and methods

3.3.1. Overall design

A multi-method design was employed, with qualitative elements predominating. As highlighted earlier, it was the objectives of my research that led me to choose certain methods rather than any theoretical stance. Once, quantitative research was strongly associated with the objectivism paradigm (Crotty, 1998). In contrast, qualitative

research was a feature of the constructionism paradigm. These two types of research were therefore once treated as polar opposites. For objectivists at that time, only well-designed, ‘scientific’, quantitative research resulted in validity and sound knowledge, hence achieving objectivity (Sechrest, 1992). Constructionists, on the other hand, rejected quantitative research as they claimed that its outcomes only apply to ‘contextually stripped situations’ and only qualitative research could bring the contextual dimension to any research data (Guba and Lincoln, 1994).

Nowadays, however, this great divide between qualitative and quantitative research no longer exists. Quantitative and qualitative research are intertwined and complementary, rather than competing concepts. For example, even devoted qualitative researchers cannot deny the usability of numbers and counting in their daily lives (Crotty, 1998). Vice versa, devoted quantitative researchers cannot dismiss the concepts of ‘human behaviour’ and ‘theory’ or otherwise their ‘quantitative experiments are blind’ (Bhaskar, 2008). The conclusion is that irrespective of their stance, researchers can use qualitative or quantitative methods or both to serve the purposes of their research (Guba and Lincoln, 1994).

As such, qualitative research is useful when uncovering ‘emic views of individuals, groups, societies etc.’ (Guba and Lincoln, 1994). In other words, qualitative research is appropriate when a researcher sets out to understand ‘human behaviours, desires, needs, routines, emotions, personality characteristics’ to refine a product or service (Madrigal and McClain, 2012). Quantitative research, as implied in the name, is important when measurements are possible/required and seeks to analyse data for trends/relationships and to best understand measurements made (Watson, 2015).

To address the objectives of my research, each time I chose the method that best served my aim/purposes. Table 7 provides an overview of the specific methods used to answer each objective in my research project. Below, I will describe the setting of my research, the specific data collection and analysis methods used and the process which was followed to recruit participants. Please note that what is presented below is a summarised description. Full details can be found in the articles that make up Chapters 4, 5, 6 and 7 of this thesis.

Table 7. Overview of the specific methods used to answer each objective in my research

	Purpose	Data collection method	Data analysis method
Objective 1	To identify impact measurement problems of general practice-based pharmacists.	Two qualitative, semi-structured, audio-recorded focus groups with general practice-based pharmacists and other staff from West London.	Verbatim focus group transcripts analysed thematically.
Objective 2	To identify pharmacist activities of importance to record to demonstrate their impact in general practice.	Three-e-Delphi questionnaire rounds with general practice-based pharmacists and pharmacy technicians from multiple UK locations.	Calculation of agreement percentages in each round; qualitative commentaries on questionnaire rounds analysed thematically.
Objective 3	To identify community pharmacy team experiences of general practice-based pharmacists.	Qualitative, semi-structured, audio-recorded interviews with community pharmacy staff from West London.	Verbatim interview transcripts analysed thematically.
Objective 4	To identify patient experiences of general practice-based pharmacists.	Qualitative, semi-structured, audio-recorded interviews with patients from West London, Surrey and Berkshire.	Verbatim interview transcripts analysed thematically.

3.3.2. Setting

Participants in this research were mainly recruited from a number of West London general practices and/or their local area. These practices were part of two GP Federations (Federations, as defined in Chapter 1, do not exist as structures any

longer) that participated in the English scheme of integrating pharmacists into general practices from its early days. At the time of commencing my research, one of the Federations had eight practices involved in the scheme and the other Federation had seven participating practices. Both Federations, therefore, acted as pioneer 'pilot' and then 'pharmacists in general practice' sites. At the beginning of this research, there were seven general practice-based pharmacists under each Federation. Following the termination of the scheme, all these general practices joined the local PCNs which now have one of the highest numbers of general practice-based pharmacists in England.

These two sites in West London were targeted as recruitment points, due to their working relationships with my institution (University of Reading). For the study with patients, participants were also recruited (apart from the West London sites) from one general practice located in Surrey and another one located in Reading (Berkshire). Both these practices had working connections with the University of Reading and were included to accelerate patient recruitment rates, which had been extremely slow. One of these practices had one pharmacist, at the time of data collection, whereas the other had two integrated pharmacists.

3.3.3. Data collection methods

3.3.3.1. Objective relating to impact measurement problems

To answer the first objective of my research, which involved the identification of specific problems that pharmacists had to overcome when measuring their impact in general practice, I decided to carry out a qualitative study. The qualitative design was preferred to quantitative techniques (e.g. surveys) as the purpose was to undertake an in-depth investigation and follow the implications of any impact

measurement problems, rather than just simply creating a list of potential problems. Focus groups were deemed as the most appropriate method as they are especially useful when participants need to 'build on each other's thoughts hence creating a rich understanding, new ideas and clarifying misunderstandings' (Digital Gov, 2015). For my research, group interactions and discussions were desired during data collection to refine and clearly articulate any impact measurement problems. This need for an interactive process made me select focus groups, rather than individual interviews or stand-alone participant observations which could have been alternative, qualitative data collection methods.

Focus groups are collective interviews in the form of discussion groups, in which a number of participants gather together, and with the help of a facilitator, discuss a certain matter (Eliot & Associates, 2005). In my focus group study, participants included general practice-based pharmacists, GPs and practice managers, all practising across the two West London sites. Participants were all in a position to answer the research question as they were practicing professionals who had been dealing with identifying the impact of pharmacists in general practice since the commencement of the scheme. Two semi-structured focus groups were carried out in late December 2016, one of which was facilitated by myself and the other by one of my academic supervisors (NP). The data collection process lasted approximately two hours and was split into two parts. The first part involved a preliminary seminar, over a period of one hour, in which I (and NP) explained the purpose and the process of the study in detail and answered all questions from the participants. This first part also acted as a rapport building session between the participants and the facilitators. The second part was the actual focus groups, which were conducted concomitantly within one general practice in West London, in nearby rooms.

It is important that hierarchies between co-participants and/or between participants and facilitators are avoided during focus group discussions (Sharken Simon, 1999). To maintain, therefore, a feeling of equality between participants and facilitators in my study, everybody was seated at the same level and in a circular way. As between six and eight participants are recommended for a focus group (Kitzinger, 1995), the focus groups consisted of eight and seven participants, respectively (see Chapter 4). Both facilitators used a focus group schedule (the same for both groups) to keep the discussion on topic and prompt participants to provide specific examples and justifications of their viewpoints. The focus group schedule can be found in Table 8. Each focus group discussion lasted approximately one hour and both were audio-recorded.

Table 8. Focus group schedule

Intro (setting the stage)	Questions	Closing
• Each facilitator to introduce themselves • Re-iterate purpose of the focus group • Go over how the focus group will work, including reminder that session will be recorded • Get participants to sign the consent form (with demographic details: registration year, years in general practice, role)	• Do you have any questions before we start? • Looking at the national Key Performance Indicators (KPIs), are you happy with them? Why and which ones are you not happy with? • List of local KPIs: what do you think of these? • Are there any additional KPIs that you think would be useful in your own scope of practice? • With the KPIs we have agreed upon, what codes do we need to look at for each KPI? (go over each KPI, get an agreement on codes from the list provided and then move on to the next KPI) Probes: • Can you give me an example of that? • You mentioned …… Would you tell me more about this? • Can you explain that a bit more? • Can you be a bit more specific about that?	• Finalise any points about KPIs and codes • Ask if any final questions • Let people know how helpful they have been • Make them aware of how they can reach researchers if they have any questions or additional thoughts

3.3.3.2. Objective relating to activities of importance to record

To answer the second objective of my research, which involved the identification of general practice-based pharmacist activities of importance to record on the general practice clinical record systems for capturing their impact, I decided to conduct an e-Delphi study. The Delphi method is defined as a technique for achieving consensus, amongst experts, on a topic with inadequate evidence (Hasson et al., 2000; Murphy et al., 1998; Okoli and Pawlowski, 2004). I decided, therefore, to identify the activities of importance to record by attempting to reach consensus, amongst a group of experts, on a number of activities. Simple quantitative techniques (e.g. surveys) as

well as qualitative, individual interviews would not have been helpful in establishing consensus as they lack interactions amongst co-participants. Focus groups, in turn, though they allow for interactions between participants and provide 'profound impressions about participant opinions', do not necessarily lead to consensus (Brüggen and Willems, 2009). The Delphi method, in contrast, combines both qualitative and quantitative features and allows for an in-depth understanding of views whilst allowing for statistical calculations to measure the actual consensus levels (Brüggen and Willems, 2009; Habibi et al., 2014). In fact, the Delphi method has the ability to accumulate conflicting opinions or perceptions and, via indirect interactions (see below), to turn them into agreement (Jones and Hunter, 1995; Powell, 2003). Carrying out an e-Delphi study, therefore, seemed to be the ideal method to answer this objective by attempting to achieve consensus on a number of activities or to ascertain that there is no consensus, which is an equally valuable finding (Donohoe et al., 2012).

The Delphi method consists of a preliminary stage where the recruited group of experts (referred to as panellists) identifies the predominant matters/problems on a topic, which are then transformed into statements and graded/ranked in a series of questionnaire rounds. In each round, panellists review their responses in light of their co-panellist views from the previous round (often referred to as feedback which is divulged as an anonymised summary), which is where the indirect interactions between the members of the panel take place. The study terminates when consensus is achieved or after a pre-agreed number of questionnaire rounds.

With my study, I and my practice-based supervisor (GS) screened one of the main clinical computer systems used in general practice (SystmOne) and created a list of activity codes potentially relevant to general practice-based pharmacist work. During

the previously-described focus groups, apart from identifying impact measurement problems, participants were also asked to comment on which activity codes on the list might be useful and to also suggest any additional activities of importance to record. A list of 81 codes was assembled which made up the questionnaire for Round 1.

As literature reports that three Delphi questionnaire rounds usually suffice for achieving consensus (Fan and Cheng, 2006; Hsu and Sandford, 2007), I decided to carry out no more than three rounds (i.e. Round 1, Round 2 and Round 3). All panellists in my study were people with either local or national expertise on the topic of recording general practice-based pharmacist activities, hence fulfilling the definition of expertise in Delphi panels as ‘subjects highly trained and competent within the specialized area of knowledge related to the target issue’ (Hsu and Sandford, 2007). Panellists in the e-Delphi’s rounds included general practice-based pharmacists who participated in the focus groups, pharmacy technicians (again from the West London sites) and national experts on the topic. These national experts were all general practice-based pharmacists who held senior roles in committees responsible for the running of the scheme and were recruited through the Centre for Pharmacy Postgraduate Education (CPPE) and/or the Primary Care Pharmacy Association (PCPA). Senior service commissioners (such as NHS officers or CCG staff) were not invited to avoid generating an unmanageable panel size but also because my focus was to explore the preferences of people who day-to-day had to record their activities, rather than only having a good understanding of the topic. Likewise, international experts on the topic of general practice-based pharmacists were not approached as activity coding systems and processes in other countries

are likely to be quite different to those in the UK, hence international expertise would not have necessarily been fully applicable to the UK reality.

In Round 1, panellists were prompted to report their extent of agreement on the importance of the proposed codes by using a 5-point Likert scale (1 = definitely disagree, 2 = probably disagree, 3 = neither agree nor disagree, 4 = probably agree, 5 = definitely agree).

In Round 2, panellists were asked to classify codes as ‘useful’ or ‘not useful’.

In Round 3, lastly, panellists were asked to grade codes according to importance on a 5-point Likert scale (Very Important, Important, Moderately Important, Slightly Important, Not at all) or rank codes in order of importance (1 = most important and 6 = least important).

In each round, panellists had the chance to justify their choice and provide general comments. Feedback from each previous round included the percentage of panellists in each score or ranking option, all panellist comments and each panellist’s individual choices in that round. Feedback from each previous round was organised in a PDF file and emailed, together with the log in details for the upcoming round, to each individual panellist (see also ‘recruitment’ section below). The e-Delphi’s questionnaire rounds were conducted from September 2017 to March 2018. All questionnaires were designed via the Online Surveys platform (known as Bristol Online Surveys at that time).

3.3.3.3. Objectives relating to community pharmacy team and patient experiences

As for the third and fourth objectives of my research, requiring work with community pharmacy teams and patients respectively, I decided to pursue a qualitative design

to understand in-depth these stakeholder views of general practice-based pharmacists. Quantitative methodologies (e.g. surveys) were excluded as although they could have identified large numbers of participants with a certain attitude (e.g. satisfaction/dissatisfaction with general practice-based pharmacists), they wouldn't have captured the 'voice of participants' (i.e. feelings, inner thoughts etc. and how all these are shaped) (Austin and Sutton, 2014). The qualitative design, in contrast, enabled me to identify how community pharmacy teams and patients actually experience the presence of pharmacists in general practice. Individual interviews, rather than focus groups, were selected because participants might not have felt comfortable to express their honest views in front of other co-participants, especially if there were any areas of dissatisfaction and/or frustration with the service. Stand-alone observations, which could have been an alternative method within a qualitative framework, were not deemed appropriate as they wouldn't have necessarily captured participant experiences of general practice-based pharmacists.

All interviews were face-to-face, semi-structured, audio-recorded and took part in quiet places within pharmacies (for community pharmacy teams) and general practices (for patients). Participants in the study with community pharmacy teams included pharmacists, pre-registration pharmacists and pharmacy technicians. Ten, final year, MPharm project students undertook the interviews of community pharmacy teams whereas all patient interviews were carried out by myself. Interview schedules were used, consisting of open-ended questions and prompts (see Tables 9 and 10 below). Community pharmacy team interviews lasted 30 to 45 minutes whereas those with patients lasted from about 15 minutes to more than one hour (in both cases the duration depended on how much the participant had to share). The study with community pharmacy teams was carried out between October and

December 2017 whereas the study with patients from November 2018 till February 2020.

In the study with community pharmacy staff, where MPharm project students were used as interviewers, a number of steps were taken to assure the quality of the interviews. Specifically, all students were provided with references to read about interviews and qualitative studies in general and a number of project meetings were carried out in which there were thorough discussions about the ethics application submitted for this study, data protection and confidentiality, interview and transcribing techniques, data analysis and interpretation. Mock interviews with all students were also performed as an additional learning exercise. After the first real interview, an individual supervision meeting took place with each student, where the transcript from the first interview was discussed, learning needs with regards to interview technique were identified and satisfied and any questions were answered, hence minimising the chances for incorrect approaches in the subsequent interviews. All students used the same interview schedule, obviously with the required flexibility to explore interesting areas that arose (advice was always given by supervisors as to what areas warranted additional exploration). Throughout data collection, regular debriefing meetings with all students were carried out to address and resolve problems and allow students to exchange experiences, reflect and learn from each other.

Table 9. Interview schedule for the interviews with community pharmacy teams

Thank you for taking the time to contribute to our research project.

1. What are your roles and responsibilities within this pharmacy?
    - Your role, age, years of service
    - Skills and training
    - Day-to-day working life

2. Please tell us about your perceptions of pharmacists working in general practice.
    - Positives/negatives
    - Perceived impact on your own roles, responsibilities
    - Actual experiences or hearsay (where from?)

3. Please tell us about your experiences, if any, of the pharmacists in general practice scheme
    - Relationships – with GPs, pharmacy team members
    - Positive/negatives - examples
    - Impact on own roles, responsibilities

4. Overall view of the GP-pharmacist partnership on your work/services provided
    - Feelings
    - Thoughts about how your work has changed
    - What changes would you like to see made to the scheme?

Table 10. Interview schedule for the interviews with patients

Intro (setting the stage)	Questions	Closing
• Introduce my self • Explain the aim of the study • Explain the process (highlight confidentiality) • Answer questions the participants might have • Ask participants to sign the Consent Form • Collect demographics • Explain that the word 'service' means consultation, or other means of contact, with a pharmacist in the surgery • Switch on the recorder (after gaining permission) – start the interview	• Tell me about your experiences of consulting the pharmacist in the general practice Prompts: a) What did you like about the service? b) What you didn't like about the service? c) What can be improved with the service? How? d) What additional expectations/needs do you have from the service? e) What other preferences do you have in the way the service is offered (e.g. access to the service)? • How do you think pharmacists in general practice could be better accepted by patients? Prompts: a) What do you know about patients' awareness of the service? b) How should the service be best promoted to patients? • Tell me about how would you prefer to give feedback on the service? Probes: • Please give me an example of that. • Please tell me a bit more about that. • Please be a bit more specific about that. • What do you mean by that?	• Ask participants if they have anything else to add (then stop recording) • Inform them how they can reach the research team if they have more questions • Thank them – let them know how helpful they have been

3.3.4. Demographics and consent

Participant demographics were collected in all studies. In the focus group study, the actual focus group discussion began with each participant introducing themselves by stating their time in general practice, their time as a qualified professional and their background before joining general practice. In the e-Delphi study, demographics were collected via the questionnaire in each round which asked panellists to state their overall years as a qualified healthcare professional, their time in general practice, their region of practice and their roles/duties within the general practice environment. In the study with community pharmacy teams, participants were asked (at the beginning of the interview discussion) to report their years of practice in

community pharmacy and their specific role within the pharmacy. In the patient study, participants were asked to fill in a demographics form which asked for their age-group, their gender, their approximate number of visits to the pharmacist in the general practice and their ethnicity.

Written informed consent was collected in the focus group study and in both interview studies, by asking participants to sign a consent form. For the e-Delphi rounds, completion of the questionnaire implied consent and no extra written consent was collected.

3.3.5. Recruitment

In all studies, participation was voluntary (i.e. participants were not pressured, by any means, to take part) and no monetary incentives were provided.

In the focus group study, recruitment was done by the lead pharmacist in each of the West London sites, who sent an email to all general practice-based pharmacists, GPs and practice managers across their site. This email had attached the study's Invitation Letter, Participant Information Sheet (PIS) and Consent Form along with the venue and time for the focus groups. This email also asked potential participants to contact, if they wanted to participate, either the lead pharmacist or myself. No other reminder emails were sent.

For the e-Delphi questionnaire rounds, invitation emails for Round 1 were sent by the lead pharmacists in the two West London sites. These emails included the study's Invitation Letter, PIS and a direction to contact myself should potential panellists be interested in participating. Once confirmatory emails had been received, I sent the individual log-in details for the questionnaire to each potential panellist. In the subsequent rounds, I directly sent the new log-in details for the respective

questionnaires to those panellists who were involved in the previous round(s). Two weeks after the initial invitation, the lead pharmacists also sent an email to the whole potential panel, further encouraging participation.

For the study involving community pharmacy teams, the NHS Choices website was searched to identify all pharmacies within a two-mile radius of the postcodes of the eight general practices of one of the sites in West London. Names, phone numbers and addresses for all pharmacies were retrieved. The identified pharmacies were then equally assigned to the interviewers who, in pairs, phoned each pharmacy, introduced the study to the responsible pharmacist at the time and asked whether any staff member was interested in participating. Community staff members who had expressed interest in getting involved were then provided with the study's documents (Invitation Letter, PIS and Consent Form) either via email or post. After a week, the potential interviewees were again contacted over the telephone to schedule a mutually convenient time for the interview.

Patients were recruited by general practice-based pharmacists working in West London, Surrey and Berkshire. These pharmacists handed out invitation packs, during their face-to-face consultations, to eligible patients. Patients were deemed eligible if they were over 16 years old, able to consent for themselves (as determined by the recruiting general practice-based pharmacist) and were English speakers. The invitation packs were comprised of the study's Invitation Letter, PIS, Consent Form along with a pre-paid, business-reply envelope and a reply form. The PIS asked potential participants to contact myself, if they were interested to be involved, either by email or by filling in the Reply Form and posting it within the business-reply envelope. The Reply Form asked potential participants to provide a contact telephone number. People who expressed their interest to be involved were then

directly contacted by myself (either by telephone or email) to schedule a mutually convenient time for the interview. Recruitment of patients stopped when data saturation was reached (i.e. no new ideas emerging in the interviews).

3.3.6. Data analysis

3.3.6.1. Qualitative data

Qualitative data originated from the focus groups, community pharmacy team and patient interviews and from commentaries in the e-Delphi rounds. Audio-recordings from the focus groups as well as from the patient and community pharmacy team interviews were transcribed verbatim. Recordings from focus groups were transcribed by myself and those from community pharmacy team interviews by the MPharm project students who acted as interviewers. Half of the recordings (ten) from the patient interviews were transcribed by myself and the rest (nine) by a professional transcribing agency registered with the University of Reading. For the transcripts from the community pharmacy team interviews, the accuracy of student transcription was verified by having each pair of students checking the transcripts of another pair.

Focus group transcripts, interview transcripts and e-Delphi commentaries were all analysed thematically by myself. Alternative analytical methods such as grounded theory, content, framework, discourse and conversation analysis were not considered suitable. Grounded theory, content and framework analysis focus on the content of participant statements, similar to thematic analysis (Bennett et al., 2019). Grounded theory, in fact, is a methodology rather than a simple method hence the researcher needs to consistently follow its values. Grounded theory seeks to generate a theoretical model, out of the data, to describe the process of interest and

it differs from thematic analysis in that it seeks to link data categories whereas thematic analysis aims to describe categories. Content analysis sets out to report on the frequency of codes discerned in the data (Hsieh and Shannon, 2005) whereas framework analysis is used to create a matrix into which data is fitted (Gale et al., 2013). Discourse and conversation analysis focus on the language (i.e. 'how things are said') rather than on 'what was said' (Bennett et al., 2019). Since I did not aim to focus on any language aspects but rather on the content of participant views, discourse and conversation analysis were automatically excluded. The purpose of my research was to inform policy. Generating theories and frameworks or reporting on the frequency of codes are all sophisticated processes that would not have enlightened day-to-day policy and practice. Therefore, grounded theory, content and framework analysis were rejected and thematic analysis was used.

Although less sophisticated, thematic analysis is an intuitive process, enabling categories to be discerned directly from the data and allows the formation of trustworthy conclusions which take into consideration the whole spectrum of individual participant views (Guest et al., 2012). The six stages in thematic analysis, as described in the method of Braun and Clark (Braun and Clarke, 2006), were applied to my data (i.e. data familiarization, coding, identifying themes, reviewing themes, defining and naming themes and writing the final report). An inductive, rather than deductive, approach was followed with data analysis (Gabriel, 2013; Web Center For Social Research Methods, 2006). When deduction is followed in qualitative research, the starting point is a hypothesis which guides the whole process and, as such, coding is based on predetermined categories. In induction, in contrast, the starting point is the research question and the inquirer sets out with an entirely open mind, without any preconceptions, to explore new ideas discerned in

the data. Coding in induction is always open and never based on predetermined categories. Although both induction and deduction stand equally as approaches, I chose to pursue an inductive approach as my attitude during my research was always exploratory (i.e. to identify new ideas, as discerned in participant reasoning).

During the coding process, data in each study was analysed as a whole. For example, focus group data was analysed together for both groups, rather than separately. Likewise, commentaries from the e-Delphi rounds were pooled together, rather than analysing data separately for each round. In all studies, I generated as many codes as needed (i.e. every concept/idea was ascribed a different code). Coding for the focus group transcripts and e-Delphi commentaries was done manually, without the use of any electronic software. Codes were annotated on the margins of the hard copies containing focus group transcripts and e-Delphi commentaries. Transcripts from the community pharmacy team and patient interviews, in contrast, were coded by using NVivo 11 software. In all cases, codes were verified by the rest of the research team before developing any categories. Coding refinement was done through extensive discussions during debriefing meetings with my supervisors. When coding was completed, data under the same code was collated together and sorted into potential categories. Each category was graphically depicted (as a large ‘bubble’) on a hard copy and consisted of several codes describing similar concepts that could fit under the same category (each code was placed within one of these ‘bubbles’). Categories were re-assessed and eventually collapsed into potential themes with associated sub-themes (everything was again illustrated on a hard copy). Themes were generated via an ongoing effort to identify patterns in the data, in other words to pool together categories which were underpinned by the same underlying concept. This underlying concept was in fact

the factor that linked categories under the ‘umbrella’ of the same theme. My constant attempt was to create themes which ‘tell the reader something about the shared meaning in them’, rather than simply summarising participant responses on a certain topic (the latter is often described as ‘domain summary’ and, unlike themes, is not characterised by any underlying unifying concept). In each theme, categories usually acted as sub-themes and the various codes constituting the category, after the required merger, acted either as sub-sub-themes or sub-themes. The potential themes developed were then re-examined and re-organised, for example, I changed the way themes were articulated and presented to facilitate the flow. Finally, the whole research team (i.e. my supervisors and I) collectively reviewed, refined and named the themes during debriefing meetings and extensive discussion. Theme refinement, for example, involved merging or splitting themes and sub-themes and restructuring themes by removing elements that actually fitted best under other themes. An attempt was always made to develop themes which were mutually exclusive (i.e. the content under each theme not to overlap with that of other themes).

3.3.6.2. Quantitative data

Quantitative data, which solely originated from the e-Delphi’s questionnaire rounds, was analysed via descriptive statistics. The Online Survey’s platform automatically calculated the percentage of panellists in each score/ranking option, for all rounds. In Round 1, codes in which fewer than 51% of panellists scored 4 (probably agree) and 5 (definitely agree) were eliminated (i.e. not included in Round 2). In Round 2, codes which were not identified as ‘useful’ by at least 70% of panellists were removed (i.e. not included in Round 3). In Round 3, final consensus was defined as at least 80% of panellists scoring ‘Very Important’ and ‘Important’. For codes that were part of the

ranking questions in Round 3, final consensus was defined as 80% of panellists identifying a certain code as belonging in the same order of importance (e.g. 80% identifying a certain code as belonging in position 1, position 2 etc.).

3.4. Ethics

Ethical approval was sought for all studies. For the focus group study, approval was obtained via the Research Ethics Committee of the School of Chemistry, Food and Pharmacy at the University of Reading (Study Number: 37/16). For the e-Delphi study, ethics clearance was gained via the University of Reading Research Ethics Committee (study number 17/21) and the Health Research Authority (Integrated Research Application System Project ID: 228337). For the study with community pharmacy teams, approval was granted by the Research Ethics Committee of the School of Chemistry, Food and Pharmacy at the University of Reading (study number 18/17). Ethical approval for the patient study was obtained from NHS Research Ethics Committee and Health Research Authority (Integrated Research Application System Project ID: 241663).

Ethics applications and all the documentation of the respected studies can be found in the Appendices. In detail, Appendix 1 contains the ethics application for the focus group study, including the study's Invitation Letter, PIS and Consent Form. Appendix 2 consists of the ethics applications for the e-Delphi study, including the study's Invitation Letter, PIS and questionnaires for all rounds. Appendix 3 contains the ethics application for the study with community pharmacy teams, including the study's Invitation Letter, PIS and Consent Form. Appendix 4, lastly, is composed of the ethics application for the patient study, including the study's Invitation Letter, PIS, Consent Form, Reply Form and Demographics Form. Please note that focus group

and interview schedules are not included in the respective Appendices as they are already presented in this chapter (see Tables above).

Every attempt was made to minimise the impact on participant work or other commitments. As such, in the focus group study, time limits on the data collection day were strictly kept. Likewise, the Delphi technique was carried out online as an e-Delphi study. Online Delphi studies offer flexibility as they can be completed remotely and whenever panellists wish, characteristics found to associate with time and cost savings for panellists (Donohoe et al., 2012). In addition, a certain (rather than unlimited) number of e-Delphi rounds was carried out to avoid causing fatigue to panellists. For the study with community pharmacy teams and patients, interviews were always scheduled at a convenient time for participants. Although no sensitive topics were ever included, participants in the focus groups/individual interviews and panellists in the e-Delphi rounds always had the right to refuse to answer any question that they found caused them distress. Other than some demographic data, no sensitive, personal details were collected. Great care was taken to protect the anonymity and confidentiality of all participants. All audio-recordings were made on digital recorders and transferred to University, password-protected computers as soon as possible after the focus groups/interviews. After audio-recordings were transferred, they were deleted from the recorder. Audio-recordings were maintained until the completion of transcription and then deleted. Transcripts were anonymised by removing any identifiable names mentioned during discussion. Electronic versions of transcripts were stored on University, password-protected computers. Hard copies of transcripts, commentaries from the e-Delphi rounds and consent forms were stored in University, locked filling cabinets. The full questionnaires from the e-Delphi rounds were maintained on the secure, Online Surveys platform. Participants were

not individually identified in research outputs as demographics were only reported as a range and a coding system was used to present direct quotations from the focus groups/interviews/e-Delphi commentaries. Where undergraduate students were used as interviewers (i.e. in the study with community pharmacy teams), appropriate training was offered and regular debriefing sessions were carried out (please refer to section 3.3.3.3. for more details) to ensure a rigorous and smooth process for participants and secure data protection. Full details on precaution measures, to reduce risks for participants and prevent/tackle potential ethical issues, are presented in the respective ethics applications (see appendices).

3.5. Rigour

As already mentioned, though 'scientific realism' does not set out to make any distinction between methods in terms of their appropriateness, it does not reject the need to establish a sound methodology when dealing with a piece of research. As an indication of good practice, therefore, I will below present how 'rigour' principles relate to my research in terms of both qualitative and quantitative data.

3.5.1. Qualitative data

3.5.1.1. Preliminary notions

Literature describes a plethora of ways to account for scientific rigour in qualitative research (Anderson, 2010; Bush and Amechi, 2019; Hadi and José Closs, 2016; Johnson et al., 2020). There are several checklists on conducting qualitative studies and reporting their findings. I used the consolidated criteria for reporting qualitative research (COREQ) when synthesising findings (Tong et al., 2007). COREQ guidance consists of 32 points, in the form of a checklist, which aids the qualitative

researcher in assessing and optimising the way aspects related to context, methodology, research teams and findings are presented.

For Amin et al., however, checklists do not always suffice in ensuring ‘quality’ for qualitative studies (Amin et al., 2020). Instead, to maintain rigour in qualitative research, they propose a number of criteria, classified under ‘trustworthiness’ and ‘authenticity’. ‘Trustworthiness’ includes prolonged engagement, persistent observation, member checking, triangulation, peer debriefing, negative case analysis, thick contextual description, external audit, reflexivity and transparency. The term ‘authenticity’ was first introduced by Lincoln and Guba to add the contextual dimension perceived as missing from ‘trustworthiness’ criteria, which were mainly developed with an objectivist stance in mind to deal with methodological matters (Lincoln and Guba, 1986). ‘Authenticity’ encompasses matters such as fairness and values, consent and relationships between inquirer and participants. Although in ideal situations all/most of the above-mentioned criteria should be followed, Amin et al. recognise that this is practically unfeasible and stress that it is up to the researcher to decide what is relevant/applicable to an individual piece of research (Amin et al., 2020). Creswell, in turn, claims that a qualitative researcher should, at least, follow more than one of the ‘rigour’ criteria (Creswell, 2012).

3.5.1.2. ‘Trustworthiness’

In my research, ‘trustworthiness’ is illustrated in prolonged engagement and persistent observations, which imply the processes with which the researcher gets a good feeling of ‘culture’ (i.e. the wider environment in which the research is taking place) and establishes what elements of ‘culture’ are relevant over time (Bush and Amechi, 2019; Lincoln and Guba, 1985). To understand the ‘culture’ of my research,

I have been shadowing a number of general practice-based pharmacists in their day-to-day work, including during face-to-face and telephone consultation clinics and multidisciplinary meetings both in general practice and elsewhere. In addition, I have received various training sessions on the largest clinical record system used in general practice and the ways pharmacists record their activities on it. Visits to general practices have been ongoing hence offering the ability to track how the presence of pharmacists in general practice has been shaping. Literature on the topic has also been systematically followed for any latest updates.

Member checking (e.g. forwarding data categories to participants) might help in verifying that conclusions indeed represent expressed views (Birt et al., 2016). Member checking, however, was not pursued. This was partially because the time requirements would have been detrimental to my research, but also because as a strategy it is often rejected in literature as there are claims that participants might not necessarily be able to spot their own views within data synthesising multiple other views (Morse, 2015).

Triangulation is an approach to secure the credibility of qualitative findings by analysing the research question from multiple angles, including from a methodology, data and investigator perspective (Amin et al., 2020). When the world, however, is viewed as socially constructed (as it was in my research project), credibility arises from crystallisation rather than triangulation (Tracy, 2010). Crystallisation relates to using multiple data, researchers and lenses hence pursuing a more sophisticated understanding of the multiple truths in the world. In my research, from a data point of view, crystallisation was achieved by examining the perspectives of slightly different cohorts in each study. For example, in the focus group study apart from general practice-based pharmacists, who were the main cohort of interest, the views of GPs

and practice managers were also taken into consideration. Likewise, in the e-Delphi study the views of pharmacy technicians, who increasingly contribute to pharmacy-related activities in general practice, were also examined. In the study with community pharmacy teams, the experiences of the whole team were captured and synthesised, including pre-registration pharmacists and pharmacy technicians. Finally, patients registered with a number of general practices were included. These practices were located in different geographical locations and pharmacists had been integrated for different time periods, a fact that enabled the identification of various patient experiences based on different amounts of interaction between the two parties (i.e. patient and general practice-based pharmacist). From an investigator point of view, designing the studies and collecting and analysing qualitative data was always a matter of collective action. There was an established research team (composed of myself, my academic supervisors and external collaborators located in general practices). Frequent meetings, with the whole research team present, were undertaken to verify and refine data collection processes and when developing understanding of data (see also 'reflexivity' below).

Negative case analysis implies the search for 'deviant cases' that appear to contradict findings (Lincoln and Guba, 1985). In my research, negative case analysis was depicted in my effort to account, in the main themes, for participant opinions adding nuances or completely digressing from common viewpoints as well as in reaching data saturation where relevant (i.e. in the patient study). Data saturation implies that the researcher finds no new data that could add extra features in a category (Saunders et al., 2018). Where data saturation was impossible to track (i.e. focus groups and community pharmacy studies), it was ensured that (at least) each participant's views were thoroughly explored. As such, focus groups and interviews

with community pharmacy staff were terminated only when participants did not have anything else to share. The value of data saturation, however, is questionable and, in any case, the ‘one more interview’ should always be regarded as making data just ‘richer’ or ‘more insightful’ rather than ‘rich’ or ‘insightful’ (Saunders et al., 2018).

As qualitative research leaves the responsibility to the reader to ‘transfer’ findings, ‘thick contextual description’ is important in facilitating the reader in this ‘endeavour’ (Lincoln and Guba, 1985). In my research, details about the ‘setting’ and the applicability of the findings were always provided. More importantly, my research findings will be discussed (in Chapter 8) in light of ‘scientific realism’ in which the concept of ‘context’ is one of the three elements in the explanatory formula, which is the core of ‘scientific realism’.

Reflexivity, which is the process of minimising the inherent effect that the inquirer has on data and relates both to the positioning of the inquirer as well as to their attention to knowledge construction (Daly, 2007; Malterud, 2001), was followed throughout data analysis. In detail, personal experiences or feelings that I might have had as a pharmacist, though I have not ever worked as a general practice-based pharmacist, were acknowledged but disregarded and the focus was always on the data. Likewise, categories and themes were collectively developed with supervisors to limit as much as possible assumptions or digressions from what could be evidenced in the data. The potential for individual instances of some personal interpretations during data categorisation, however, could not completely be ruled out.

As for transparency, which relates both to data and the analytical process followed, sources of original data have been always available to readers on reasonable

request. The availability of data has been clearly emphasised in all manuscripts. In addition, why certain collection and analysis methods were chosen in each study was justified. With regards to peer debriefing, this was ensured by having external peers reviewing my manuscripts submitted in scientific journals. No external audits on data were conducted.

3.5.1.3. ‘Authenticity’

Every attempt was made to treat all participants with respect and in fairness, both at the time of data collection and analysis. At data collection, mutual introductions were made to make participants feel more comfortable and foster the expression of honest views. In the focus group, as previously mentioned, an initial session for building rapport between participants and facilitators was carried out. The study process was verbally explained, in all of my studies, and questions were answered to ensure that participants fully understood the study and its implications. In the focus group study, the facilitators ensured that all participants had equal opportunity to contribute to the discussion. Likewise, participants in the individual interviews were not influenced in any way, for example, no responses were pre-empted and silence was not interrupted, leaving participants the necessary time to articulate their thoughts. Informed consent was always obtained and maintained until the end of data analysis. In data analysis, all sorts of views expressed by participants were taken into consideration and summarised in findings. Illustrative quotations from as many participants as possible were reported.

3.5.2. Quantitative data

In the e-Delphi study, quantitative data were solely descriptive and included measures of consensus amongst panellists. It has been occasionally suggested that

to secure statistical validity in Delphi studies (i.e. that any consensus levels are indeed representing consensus by taking into consideration dispersion of responses), the stability of responses between rounds should be assessed using x^2 test formulas which will determine the termination of the study (Dajani et al., 1979). Contrary to these statements, there are claims that Delphi is not a statistical test and its validity is ensured by the expertise of panellists and the fact that wrong conclusions are unlikely after all the 'challenging' views undergo as a result of the feedback process (Hasson et al., 2000). In my case, the primary endpoint of the e-Delphi study was consensus according to a preconceived criterion (agreement ≥ 80%), rather than any statistical validity. The number of rounds to be carried out was predetermined and was not based on any statistical calculations. To promote the achievement of consensus, each round was different in terms of the questionnaire content and also the threshold of agreement was progressively elevated between rounds.

3.6. Summary

In this chapter I started by presenting the way my research was designed. I then moved on by making reference to the theoretical perspective within which my findings will be discussed and why this is relevant to my research. After that, I presented the specific methods used, including data collection and analysis methods. The chapter finished by presenting basic 'rigour' criteria and how these link to my research. The next few chapters (Chapters 4, 5, 6 and 7) will present the papers, in the exact form published, along with my precise contribution to each one of the respective studies.

CHAPTER 4. HOW DO PHARMACISTS IN ENGLISH GENERAL PRACTICES IDENTIFY THEIR IMPACT? AN EXPLORATORY QUALITATIVE STUDY OF MEASUREMENT PROBLEMS

This chapter is the paper from the focus group study, which reports on the impact identification problems pharmacists in general practice experience, as published in BMC Health Services Research (Karampatakis, G.D., Ryan, K., Patel, N., Lau, W.M., Stretch, G., 2019. How do pharmacists in English general practices identify their impact? An exploratory qualitative study of measurement problems. BMC Health Serv. Res. 19(1), 34.). This was the first study in my research project and reports on the experiences and views of general practice-based pharmacists, GPs and practice managers with regards to identification of pharmacist impact in general practice. In particular, with this focus group study I explored what does and what does not work well with the use of KPIs (and impact identification processes in general) for general practice-based pharmacists. With this study, I answered the first objective of my research project, which aimed to unveil problems that general practice-based pharmacists face when measuring and recording their impact. By answering this objective, I sought to inform policy and practice on what needs to be done to effectively identify pharmacist impact in general practice.

Author contributions are presented in the respective section of the paper. Briefly, I contributed to the idea for and design of the study, undertook data collection (i.e. I facilitated one of the two focus groups) and analysis and interpretation of data. I also wrote the manuscript, which was then annotated and approved by all authors.

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How do pharmacists in English general practices identify their impact? An exploratory qualitative study of measurement problems

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Abstract

Background: In England, there is an ongoing national pilot to expand pharmacists' presence in general practice. Evaluation of the pilot includes numerical and survey-based Key Performance Indicators (KPIs) and requires pharmacists to electronically record their activities, possibly by using activity codes. At the time of the study (2016), no national evaluation of pharmacists' impact in this environment had been formally announced. The aim of this qualitative study was to identify problems that English pharmacists face when measuring and recording their impact in general practice.

Methods: All pharmacists, general practitioners (GPs) and practice managers working across two West London pilot sites were invited, via e-mail, to participate in a focus group study. Appropriately trained facilitators conducted two audio-recorded, semi-structured focus groups, each lasting approximately 1 h, to explore experiences and perceptions associated with the KPIs. Audio-recordings were transcribed verbatim and the data analysed thematically.

Results: In total, 13 pharmacists, one GP and one practice manager took part in the study. Four major themes were discerned: inappropriateness of the numerical national KPIs ("whether or not we actually have positive impact on KPIs is beyond our control"); depth and breadth of pharmacists' activity ("we see a huge plethora of different patients and go through this holistic approach - everything is looked at"); awareness of practice-based pharmacists' roles ("I think the really important [thing] is that everyone knows what pharmacists in general practice are doing"); and central evaluation versus local initiatives ("the KPIs will be measured by National Health Service England regardless of what we think" versus "what I think is more pertinent, are there some local things we're going to measure?").

Conclusions: Measures that will effectively capture pharmacists' impact in general practice should be developed, along with a set of codes reflecting the whole spectrum of pharmacists' activities. Our study also points out the significance of a transparent, robust national evaluation, including exploring the needs/expectations of practice staff and patients regarding pharmacists' presence in general practice.

Keywords: Pharmacists in general practice pilot, England, Impact, Activity codes, Qualitative study

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Background

The concept of having pharmacists employed in general practice is increasingly being investigated worldwide. Countries such as Australia, Canada, New Zealand, Malaysia and the USA have formally designed national programmes incorporating a non-dispensing pharmacist (involved in patient-facing activities beyond traditional medication dispensing) into general practice teams [1–5]. Some characteristic examples of services that general practice-based pharmacy teams carry out are: in depth face-to-face medication reviews (i.e. optimising treatment by stopping, amending or initiating medication guided by the patient's current medical condition and the most recent guidelines - consideration is given to contra-indications, cautions and interactions) either inside the practice or in patients' homes; updating medical records to reflect patients' latest medications; education of practice staff around novel trends in pharmacotherapy; responding to general practitioners' (GPs') medication-related queries; quality assurance services to improve prescribing and medication use in the practice (e.g. relevant audits); prescribing tasks (including management of repeat prescriptions); and clinics for certain long-term conditions, such as hypertension, diabetes and asthma [6–8]. The provision of pharmacy services in general practice (e.g. medication reviews; initiation/adjustment of medications; adherence assessment; anticoagulation clinics; health/lifestyle advice; drug monitoring activities) has been found to significantly improve patient outcomes (e.g. systolic and diastolic blood pressure; medication adherence; glycosylated haemoglobin; low-density lipoprotein and total cholesterol levels) and patient safety [9]. It is also reported that pharmacy services in this setting can result in considerable cost savings to national healthcare systems via the prevention of hospital admissions and decreased drug expenditure through the optimisation of medication use [10]. Pharmacists' work in general practice is additionally perceived to lead to considerable reductions in the workload of GPs [11, 12]. Furthermore, the presence of a pharmacist in general practice is often seen as an opportunity for following "precision medicine" patterns by offering patients individualised pharmacotherapy regimens and reducing unnecessary polypharmacy (i.e. concurrent use of multiple medications) [13]. Despite the described benefits, GPs' reluctance to accept clinical interventions by pharmacists originating from historical inter-professional barriers (often characterised as "turf" protection) [14–17], along with patients' unfamiliarity with a pharmacist's role in this environment [18, 19], might significantly hinder pharmacists' integration and subsequent utilisation within general practice. Therefore, it is essential that a pharmacist's impact in this setting is measured and presented (through local evidence) to practice staff, policymakers and the general public [20, 21].

In England, there is a current shortage of approximately 8000 GPs and an oversupply of newly qualified pharmacists with excess numbers estimated to be between 11,000 and 19,000 within the next 20 years [22]. To address the present needs in the primary care workforce, National Health Service (NHS) England along with Health Education England (HEE), the Royal College of GPs (RCGP) and the British Medical Association's GP Committee (GPC) are working in collaboration with the Royal Pharmaceutical Society (RPS) on a 4 year pilot to test the role and the effectiveness of clinical pharmacists in general practice [23]. This pilot is part of a larger national scheme focusing on building the future primary care workforce [24]. The main aim of the pilot is to reduce the workload of overburdened GPs, enabling them to focus on activities where they are most needed (e.g. diagnosis/management of complex patient cases), and offer patients greater access to health services and checks [25]. Within this context, NHS England will partially cover the expenses of co-locating a pharmacist as an equal member of the multidisciplinary team in the general practice environment. The pilot was announced in July 2015 with a budget of £15 million and involved 250 pharmacists [26]. In October 2015, NHS England increased the investment to £31 million which has involved more than 490 pharmacist posts across 90 sites which translates to approximately 698 practices in England [27, 28]. A pilot site is defined as a number of general practices, usually from the same geographical area, which participate in the national pilot scheme as part of the same organisation such as a GP Federation (i.e. a group of practices working together within their geographical area as part of a collective entity). In April 2016, a further £112 million was announced to support 1500 additional pharmacists in general practice by 2020 [29]. At present, the pilot serves over seven million patients and it is estimated that by 2020 a further six million patients will be covered by allocation of at least one clinical pharmacist per 30,000 population [30, 31].

The pilot is expected to be evaluated using Key Performance Indicators (KPIs) so that success and learning is identified and reported [32]. Currently, there are ten national KPIs based on numerical components (e.g. increase in total number of medication reviews) and two survey-based KPIs (requiring patient and GP surveys). Table 1 gives an overview of the national KPIs. For the numerical KPIs, the evaluation plan requires the practice pharmacists to record their day-to-day work on the clinical computer systems (SystmOne, EMIS and INPS Vision are the main computer systems in general practice in the UK). This could be done by using pre-defined electronic activity codes. Activity recording will enable a central investigation of the pilot outcomes by comparing baseline data (gathered at the initial stages or before

Table 1 Overview of the national Key Performance Indicators (KPIs)

Numerical KPIs
• Number of patient appointments with: General practitioner (GP), Practice Nurse, Clinical Pharmacist, Health Care Assistant/Advanced Nurse Practitioner
• Impact on the percentage of patients who met the achievement indicator within the relevant Quality and Outcomes Framework - QOF (increase in the average QOF score)
• Increase in total number of medication reviews
• Decrease in the percentage of medication reviews undertaken by GPs
• Increase in the total number of patients supported to develop care and support plans, including self-management
• The rate of Accident & Emergency (A&E) attendances per 1000 patients on GP register
• Rate of emergency hospital admissions for selected long-term conditions as a proportion of patients per GP practice
• Reduction in the number of patients attending ≥15 appointments with a GP over the previous 2 years by age group (0–9, 10–19, 20–39, 40–59, 60–69, 70–89, 90+)
• Reduction in antibiotic prescribing rate (versus national rate per STARPU - Specific Therapeutic Group Age-sex weightings Related Prescribing Units - a weighting system that takes into account the types of people receiving treatment within a specific therapeutic group in order to compare drug use between National Health Service organisations and practices)
• Reduction in prescribing rate of anti-psychotic medications for patients with dementia or learning disabilities
Survey-based KPIs
• Patient satisfaction survey (patient experience)
• GP survey (impact on workload, time, utilisation, job satisfaction)

pharmacists' integration) with data collected well after the inclusion of pharmacists. Outcomes will then be audited against the KPIs.

Although UK pharmacists have occasionally provided services in general practice in the past [33, 34], this is the first time that NHS England has tried in a formal way to implement and test the role of pharmacists in this setting. Despite the existence of central measures (i.e. national KPIs), as yet (2018) no national comprehensive evaluation of pharmacists' impact in the general practice setting has been formally announced [35]. Therefore, our purpose with this qualitative study was to explore perceptions around the KPIs in two pilot sites in West London and identify problems (if any) pharmacists experience in measuring and recording their input. We anticipate that our findings and practical recommendations will be useful for national policymakers, professional bodies and pilot sites regarding what relevant actions should be taken to assist pharmacists in identifying and demonstrating their impact in the English general practice environment.

Methods

Study design

A qualitative design was chosen for the study to understand participants' views in depth. Semi-structured focus groups, rather than individual interviews, were followed so that participants had the opportunity to collectively interact and to freely express their own ideas for discussion by the group.

Setting

All participants were recruited from two West London GP Federations (both of which constituted pilot sites). These sites were chosen for the study as they both have working connections with the organisation of the research team. At the time of the study, one Federation had eight practices participating in the pilot (employing 36 GPs, nine managers and serving approximately 72,000 patients) and the other Federation had seven practices participating in the pilot serving 60,000 patients. Each Federation employed seven pharmacists who each undertook approximately 40 to 60 face-to-face patient appointments per week, thus, every pharmacist saw between 160 and 240 patients monthly. The pharmacy teams provided a variety of services including face-to-face medication reviews in the practices and in domiciliary settings including surrounding residential aged-care and nursing homes, for example, managing polypharmacy, optimising medications and performing patient monitoring activities; telephone consultations with patients, for example, managing minor ailments such as the common cold; clinics for long-term condition management (e.g. asthma/hypertension/anticoagulation/diabetes); answering GP and patient medication queries; reconciling discharge summaries; completion of prescribing audits; and organising practice education sessions (e.g. updating practice staff on new drugs). They also contributed to prescribing including signing repeat prescriptions. Prescriptions were processed either on site or electronically and authorised only by pharmacists who had completed an independent prescribing course.

Participants and recruitment

To elicit representative and realistic views, only people directly involved in the pilot project (all pharmacists, GPs and practice managers in the two Federations) were invited to take part in the study. One very senior pilot pharmacist was excluded from participation because they are part of the research team and also to avoid discouraging less senior colleagues from expressing their honest views during the discussion. Invitation was via e-mail sent by the lead pharmacist of each of the pilot sites, on behalf of the research team. This e-mail attached an Invitation Letter, a Participant Information Sheet (describing the nature and the process of the study in detail) and a Consent Form. The e-mail also included the time and the venue for the focus groups and asked participants to contact either the lead pharmacist or a member of the research team (GDK) if they wanted to take part in the study. Potential participants had 1 week

to decide whether or not to participate in the study. No follow-up, reminding e-mails were sent. Participation was voluntary and no monetary incentives were provided.

Data collection

Data collection was divided into two parts over a 2 h period. During the first part, which lasted approximately 1 h, a Power-point presentation was given by the researchers to remind the participants of the KPIs at national level and to emphasise the importance of the measurement of pharmacists' involvement in general practice. Additionally, the aim of the study was repeated to ensure that participants fully understood the study process. As the researchers were not known to participants, this preliminary seminar also acted as a rapport building session between researchers and participants (e.g. researchers had the chance to introduce themselves and explain their research interests). Participants had the opportunity to ask questions and put forward ideas for discussion before taking part in the focus groups. The second part of the session was the actual focus group discussions. The researchers split the 15 participants into two focus groups so that each of the participating pilot sites had equal representation in each discussion group. The composition of one focus group was eight participants (all pharmacists), while the composition of the other focus group was seven participants (five pharmacists, one GP and one practice manager). The two focus-groups were conducted concomitantly in different meeting rooms in one general practice which is part of one of the pilot sites. Written consent was obtained from all participants just before participation. The focus group facilitators talked as little as possible during the session, simply adding prompts to keep the discussion on topic. The participants were asked to comment on their thoughts and experiences of the national KPI list, a set of local KPIs developed by the pharmacy team of one of the recruited pilot sites and a list of activity codes extracted from one of the two largest computer systems being used in general practice. In addition, participants were asked to report any additional KPIs that might be useful within their own scope of practice and any day-to-day problems they were experiencing with the measurement of their input. The full focus group schedule (see Table 2) was pilot-tested on the lead pharmacist and pharmacy technician of one of the recruited pilot sites. All areas of the schedule were fully covered during the discussion and the facilitators ensured all participants had equal opportunity to express their opinion. Each of the focus groups lasted approximately 1 h (discussion was completed only when participants did not have anything else to add) and both were audio-recorded with consent from the participants. The facilitators were also keeping field notes when needed.

Two members of the research team (GDK and NP) acted as the facilitators of the focus groups and collected all data. Both facilitators have a pharmacy background (NP holds a Doctor of Philosophy - PhD - and serves as a lecturer in pharmacy practice whereas GDK is a doctoral research student). Both have experience in qualitative research and have undertaken previous training in focus group techniques.

Data analysis

Audio-recordings of the focus group discussions were transcribed verbatim by the researchers (GDK transcribed the audio-recordings and the accuracy of transcription was verified by the rest of the research team) and thematically analysed. Thematic analysis was chosen as it is an intuitive interpretive process, allows for categories to be discerned directly from the data and enables the formation of trustworthy conclusions accounting for the whole range of individual participant experiences [36]. No theoretical framework was applied

Table 2 Focus group schedule

Intro (setting the stage)	Questions	Closing
Each facilitator to introduce themselves Re-iterate purpose of the focus group Go over how the focus group will work, including reminder that session will be recorded Get participants to sign the consent form (with demographic details: registration year, years in general practice, role)	Do you have any questions before we start? Looking at the national Key Performance Indicators (KPIs), are you happy with them? Why and which ones are you not happy with? List of local KPIs: what do you think of these? Are there any additional KPIs that you think would be useful in your own scope of practice? With the KPIs we have agreed upon, what codes do we need to look at for each KPI? (go over each KPI, get an agreement on codes from the list provided and then move on to the next KPI) Probes: Can you give me an example of that? You mentioned …… Would you tell me more about this? Can you explain that a bit more? Can you be a bit more specific about that?	Finalise any points about KPIs and codes Ask if any final questions Let people know how helpful they have been Make them aware of how they can reach researchers if they have any questions or additional thoughts

to the analytical process as the focus of this study was data driven to practically inform policymakers, pilot sites and pilot pharmacists, not to examine any behavioural changes or to interpret perceptions. Analysis was not done separately for each focus group (data from both groups was gathered and each pharmacist was coded, for example, Pharmacist 1, 2, 3 etc.). An inductive approach was followed [37]. The six phases of thematic analysis as described in the method of Braun and Clarke [38] were applied (familiarisation, coding, theme searching, theme reviewing, theme defining and naming, producing the report). The coding process was done manually (codes were annotated on the transcripts' margins). At first, all of the data was systematically coded by GDK generating as many potential codes as needed (i.e. one single code for every different concept/idea identified). Coding was verified by the rest of the research team prior to generating categories and eventually themes. Then, all codes were transferred to a Word® document. Data identified by the same code was collated together and all different codes were sorted into potential categories (each category was highlighted with the same shading). After that, categories were re-examined and collapsed into potential themes with associated sub-themes. Then, the potential themes were re-assessed and re-organised. Finally, the whole research team together reviewed, refined and named the themes. Participants' feedback on the transcripts or the summarised final findings was not sought.

Results

Fifteen people (13 pharmacists including six independent prescribers, one GP and one practice manager) participated in the two focus groups. No participants withdrew during or after the focus groups. Table 3 provides an overview of the range of the participants' demographics rather than the exact details so that anonymity is maintained. Clinical Commissioning Groups (CCGs) in the UK are clinically-led legal bodies responsible for the commissioning of healthcare services for their local area.

Free discussions were observed throughout the focus groups.

Four overarching themes were discerned during analysis of the focus group transcripts: inappropriateness of the numerical national KPIs; depth and breadth of pharmacists' activity; awareness of practice-based pharmacists' roles; and central evaluation versus local initiatives.

Inappropriateness of the numerical national KPIs

The numerical national KPIs were believed to be unsuitable in identifying pharmacists' input into general practice, for various reasons.

Participants claimed that KPIs are mostly designed according to economic priorities (e.g. savings in NHS resources) and that they do not specifically target pharmacists' work. Consequently, it is not within the pharmacist's remit to have an impact on most of the national KPIs and, also, any effect on a particular KPI can be attributed to different people's input rather than to pharmacists specifically.

> *Some of these KPIs, we have no control over. For example, patients attending more than 15 appointments, have we got any control over that? I don't think so.* (Pharmacist 11)

> *It would be very difficult to evaluate at which part of the path the clinical pharmacist's role comes into play, because managing A&E [Accident & Emergency] admissions is disseminated from people involved into different clinical roles.* (Pharmacist 10)

Some of the KPIs (e.g. decrease in medication reviews undertaken by GPs) require coding by more than one healthcare professional (apart from pharmacists) and, subsequently, the existence of (baseline) data for these cases is highly dependent on the degree to which different people record their work.

> *They [GPs] are not using the review codes, there is no way you can see what activity they're doing, what activity we are doing, so in decreasing the percentage of medication reviews done by GPs, you're not going to be able to get a sensible bit of baseline data.* (Pharmacist 2)

Frequent unintentional tick-box exercises by GPs, without a previous in-depth investigation of a patient's medication problems, was thought to negatively affect

Table 3 Participants' demographics

	Time in general practice	Time as qualified professionals	Background before joining general practice
Pharmacists (13)	2 months to 4.5 years	4.4 to 29 years	Hospital pharmacy (5) Clinical Commissioning Group (CCG) work (2) Community pharmacy (3) Unknown (3)
General Practitioner (1)	More than 30 years	More than 30 years	Not applicable
Practice manager (1)	More than 10 years	Not applicable	Not applicable

baseline data by wrongfully elevating activity levels for GPs and thus reducing the visibility of pharmacists' input.

> *The doctors do medication reviews so mainly a tick box exercise, where they might say, "Oh, I can't find medicines, fine, tick" and that's their total baseline numbers, whereas we might do medication reviews and spend half an hour and go into a lot of detail. And that would be like one medication review.* (Pharmacist 6)

According to participants, the KPIs do not account for quality indicators around pharmacists' work (e.g. depth, effectiveness or influence of intervention/consultation) as most of them are purely based on numerical aspects (such as appointment numbers, increase in the total number of medication reviews etc.) and not on any value components.

> *What I'm doing in terms of a consultation is clicking on something. So, for example, I do a care-plan, it's just the number isn't it? I'm just generating numbers, it doesn't show you quality.* (Pharmacist 8)

The national KPI which relates to the Quality and Outcomes Framework (QOF - a voluntary programme for English general practices with the purpose of motivating and rewarding clinical excellence) indicators was deemed by the majority of participants to be irrelevant because QOF measures were thought not always to be based on the latest updated guidelines of the respective health authorities. For example, QOF measures related to diabetes were believed to often include a glycosylated haemoglobin target level significantly different from the one reported on the national diabetes guidelines.

There were also concerns that data collected for the KPIs might, in parallel, be used for comparing the performance of individual pharmacists across the national pilot.

Overall, participants claimed that the whole KPI concept treats pharmacists in general practice unfairly. Pharmacists' continued presence in this setting, they thought, is dependent on whether or not their activities have positive outcomes on certain measures. They thought the role of GPs, in contrast, is well established and secured over and above any impact on any indicators.

> *Whether or not we actually have positive impact on KPIs is beyond our control, but it is providing a staffing base to do roles which the practice needs. I think it's not particularly fair the fact that you're not looking at giving them [general practices] an extra GP and then, for example, seeing admission rates fall, saying "Oh, after all, a GP does have a job role".* (Pharmacist 2)

Despite these general problems, participants recognised aspects of the KPIs where pharmacists could make a difference. For example, the development of comprehensive care-plans was perceived to be directly related to pharmacists' expertise and, thus, a good means of showing impact on patients (e.g. clear administration schedules, instructions on when to seek pharmacist's help, raised levels of patients' understanding around their condition). Reducing unnecessary requests for antibiotic rescue packs, updating practice staff on the latest anti-psychotic medication guidelines and pre-empting frequent appointments and phone calls from high users of GP services were also suggested ways of impacting upon the respective KPIs. Finally, since many pilot sites have nursing homes attached to them, participants said there is an ongoing need for a national KPI accounting for practice-based pharmacists' activities in nursing homes.

> *We thought there may be specific applications of clinical pharmacy into nursing homes. And I still believe that these have been the case. Pilot sites cover 95% of the nursing home patients. I just wonder whether there's something, or some things, we could be measuring around nursing homes, which would be meaningful.* (Practice manager)

Depth and breadth of pharmacists' activity

Practice-based pharmacists were confident that their activities, especially the medication-related ones, bring additional quality to the services provided in general practice and improve the standard of patient care. Pharmacists reported investing time when reviewing a patient, for example during a scheduled consultation for a medication review or a care-plan development, and following a holistic approach which is characterised by an in-depth investigation of every health problem a patient experiences regardless of whether it originates purely from medications or not (e.g. dealing with mental health, dexterity, mobility, lifestyle problems or other situations that individual patients might face).

> *You can assume if a pharmacist is doing a medication review, then there is an inbuilt quality that is not otherwise there.* (Pharmacist 2)

> *We see a huge plethora of different patients and go through this holistic approach - everything is looked at, including medications. In fact [sometimes] when we review a patient, medications play only a small part [in the review process] and the focus is on mobility,*

*mental health, memory [problems], activities of daily living [*etc.*].* (Pharmacist 5)

Participants said, however, that pharmacists' activities are not always being captured and recorded on the electronic systems of general practices, as the available activity codes do not often match actual tasks or they are not specific enough. Therefore, the current electronic codes fail to differentiate work and show all the different activities that pharmacists cover on a day-to-day basis.

Our two pharmacists are just invaluable for the stuff they carry in their heads about medication interactions or complex things that you can phone and ask or e-mail. There's no code for that. But it's actually very, very important. (GP)

There is a general code about [medication] monitoring but not specifics about whether you have adjusted the medication because of the bloods, or checking bloods for monitoring. None of that is captured and I do that nearly every day. (Pharmacist 1)

For this reason, participants referred to the need to investigate the range of pharmacists' work across English general practices and produce a global list of activities widely expected to be carried out by pharmacists in this setting.

We need a global list of activities - core activities of the clinical pharmacist - that [we] are expected to carry out and some other little bits and pieces that we do on a daily basis and around those shape the codes. (Pharmacist 12)

Until then, a general pharmacist code (such as "Pharmacist" or even simply "P") was thought to potentially act as a surrogate for activities that are currently not coded. In addition, as every pharmacist's consultation or other action is automatically time- and name-stamped on the clinical computer systems, searching the system by name (name searches) was perceived to be a complementary method (to the conventional coding-dependent process) of getting an insight into the extent of work a pharmacist does.

Awareness of practice-based pharmacists' roles

Participants commented on the necessity of increasing the awareness of both primary care team members and patients around the role and the capabilities of a pharmacist co-located in general practice.

I think the really important [thing] is that everyone [within the general practice] knows what pharmacists in general practice are doing. And it takes a bit of time. And there is a presumption that everybody knows what pharmacists have been doing. They don't. (GP)

As practice-based pharmacists are in a perfect position to link different professionals and act as the first point of reference in general practice, networking with other practice staff can provide pharmacists ample instances to communicate and promote their role.

Your dieticians, your physios, the in-house smoking cessation services, all these people now come through us. So, we're now dealing with all sorts of prescribing needs, including for care homes. So, it's all these different angles, like the mental health reviews, they all come in [to the general practice] and you do the prescribing. So, you're linking in with all of the teams and you're their contact. (Pharmacist 7)

Especially essential is the building of rapport with the local community pharmacists as this unifies patient care by reducing instances of conflicting interventions from pharmacists in different settings.

I think a really legitimate KPI will be "contact with the local community pharmacy" and it is sort of starting and maintaining a relationship with the community pharmacies, so that's about: how many are there and how many have we spoken to. And the ultimate goal must be to speak to all of them, to interact with, and make sure you [practice-based pharmacists] have a common language to talk [with the local community pharmacists]. (Practice manager)

A close working relationship with community pharmacists was also believed to offer practice-based pharmacists the opportunity to enhance the scope of Medicine Use Reviews (MURs - a service offered by UK community pharmacies which involves adherence-focused reviews with patients, mainly those with a targeted condition such a as asthma, diabetes etc., to confirm that they are taking or using their medications in an optimal way to derive maximum benefit from their therapy) by encouraging their colleagues in community pharmacy to report to the local general practice any outstanding clinical problems they identify. Furthermore, interacting with community pharmacists allows pharmacists in general practice to contribute to reducing medicines waste and thus positively impact overall costs to the NHS.

It would be interesting to investigate the impact of having a pharmacist in a surgery on reducing waste of the NHS in terms of writing prescriptions, medication being out of date so then affecting the cost in the long-

term. So, people keep bringing a bag to [community] pharmacy for disposal and I guess having a pharmacist now in the surgery may influence that by asking the community pharmacist to feedback the amount and the type of wasted medications for each patient where this is clinically relevant. (Pharmacist 12)

Participants said that, as a means of showing self-development, it would be worthwhile for practice-based pharmacists to systematically survey levels of understanding, amongst patients and practice staff, around pharmacists' roles in general practice.

The [pilot] pathway does require us at some stage to do patient satisfaction survey and the GP survey. It would be useful for us and useful in terms of insurance and everything else, to say: "We're actually developing ourselves". (Pharmacist 2)

Participants highlighted the need for a standard patient survey specific to pharmacists' services. Adapting the form that GP trainees use for exploring patients' views on their work and/or using the form of the "friends and family" test (i.e. a single item survey asking patients whether they would recommend the healthcare service they have received to friends and family members) were proposed as contemporary surrogates. The "friends and family" test, however, was thought to hardly distinguish those patients who accessed pharmacy services as it seeks feedback on the practice-based services in general, rather than on individual healthcare professionals.

The problem with the "friends and family test" is that it is very hard to differentiate between a patient who's gonna see a clinical pharmacist and a doctor. So, in order to use "friends and family" specifically for the clinical pharmacist you'd almost have to turn it off for everybody else. (Practice manager)

Despite their importance, patient surveys are often associated with low response rates. Consequently, practice-based pharmacists often face difficulty in showing that they are proactive with the respective national KPI based on patient surveys.

When giving patients the questionnaire, you could always quote [on the electronic system] that you've given this, so you can measure how many patients have received it. But you won't know how many [patient surveys] you've got back. (Pharmacist 9)

Participating pharmacists were also very concerned that patient surveys could contain a powerful bias as they might be dominated by negative views towards the practice-based pharmacist. Several problems were perceived to form reasons for potential patient dissatisfaction. There are instances where patients with a condition unsuitable for pharmacists' knowledge are wrongfully being directed to the practice-based pharmacist (triage problems). As a result, the pharmacist is unable to perform a successful intervention and satisfy their needs or expectations.

Patient satisfaction is quite tricky because it's not always a fair opinion. Just from what I've seen, patients half the time they don't know they're coming to see you [practice-based pharmacist], so they're instantly annoyed because they come with something that you can't actually deal with because it's been wrongly written in reception or something like that, so their satisfaction is going to be poor. (Pharmacist 3)

Patients might negatively link contact with the practice-based pharmacist with undesired amendments to their therapy.

When patients come in [to see the pharmacist in general practice] sometimes, they know they're gonna switch something [medication] or stop it and they're on the defense straight away and they're not going to be satisfied [with practice-based pharmacists' services]. (Pharmacist 7)

Patients who complain are usually keen to fill in surveys and this coupled with the fact that "thank-you" messages (expressed through cards, notes or presents) are not being formally recorded were perceived to further overshadow any positive views.

The typically demanding people are those who will take the time then [after a consultation] to go on and complain [through patient surveys] about what's happened. (Pharmacist 2)

To overcome the bias of unfair negative attitudes and elicit more representative patient feedback, it was suggested that survey forms could be individually handed to those patients who consciously (i.e. aware of the practice-based pharmacist's presence and the respective services provided) experience regular contact with the practice-based pharmacist.

You could focus on getting some kind of a survey for those patients who you are seeing on a regular basis or they are coming in [to the general practice] just for a particular clinic [with the practice-based pharmacist] and so they know that they're going to be seeing you [practice-based pharmacist] in the first place. (Pharmacist 3)

Another identified potential bias is that the structure of the survey form does not take into consideration individual needs that sectors of the patient population have. For example, surveys are often available exclusively in an online version requiring computer skills thus large numbers of patients (e.g. elderly) might be prevented from participating.

> *In each GP practice that's a big problem historically with how feedback is given, I mean patient satisfaction surveys in GP surgeries. The NHS choices [around patient surveys] feed into a computer literate group of people, not typically the elderly with chronic diseases and it massively biases the sort of feedback.* (Pharmacist 2)

Central evaluation versus local initiatives

Participants were certain that NHS England will nationally evaluate the whole pilot project to reveal outcomes for both general practices and patients.

> *The KPIs will be measured by NHS England, regardless of what we think. I see it's a perfectly legitimate thing for them to pull out of their national statistics these particular measures.* (Practice manager)

It was felt obligatory, therefore, for the general practices and the pilot pharmacists to adhere to the national KPIs (despite the inappropriateness of most of them for pharmacists), as NHS England will still follow the relevant measures to satisfy each national KPI.

> *We do have to follow them [national KPIs] because they're national. Some of these don't apply to us but, yes, I think they [NHS England] are gonna be pulling out the [appropriate] figures [to satisfy each KPI], at the end.* (Pharmacist 11)

Practices, however, can additionally create local indicators (taking into consideration local priorities and needs) that will act as supplementary measures to the national KPIs.

> *What I think is more pertinent, are the things - are there some local things? We've got a great opportunity between - among the two boroughs to say "Ok, let's have a simple list of [local] KPIs which we agree we're going to measure", fantastic!* (Practice manager)

Within this framework of local actions, each practice could quantify the work carried out by pharmacists. Examples given were the numbers of medication reviews, therapy amendments or just numbers of patients who contacted the practice-based pharmacist.

> *What would be more specific is to evaluate the work that we actually do, in addition to this [the national KPIs]. What would be more specific to each one of us as pharmacists is that our specific practice, maybe at the end of the year or month, measures our work, to say that "We've actually done this amount of work that has impacted the surgery by this much".* (Pharmacist 13)

Participants reported that recording completed pharmacists' tasks could show pharmacists' involvement in duties that would otherwise have been performed by GPs or other practice staff. Showing a reduction in the workload of GPs was perceived to be the best way of showing pharmacists' impact in general practice.

Pharmacists were very confident that their presence in general practice has positive outcomes for patients and practice staff and that they will maintain their employment in this setting even after the national pilot is over.

> *One thing that's interesting, they [NHS England] think they've come up with a novel idea, the pilot, whereas your pharmacists in practice get it. So, for decades people have known it's worthwhile. Join the club! I was employed for the pilot and will be employed after the pilot, I'm sure, as will probably all of us because it's already there - the role exists.* (Pharmacist 2)

The GP who participated in the focus group was also very optimistic about the pilot and reported that time-savings in GPs' workload are already obvious.

> *A practice-based pharmacist probably saves each GP at the practice an hour per day. I'm very enthusiastic about the idea [of pharmacists in general practice] and I see a real potential.* (GP)

Discussion

Participants believed that the majority of the national KPIs are inappropriate and that pharmacists' day-to-day efforts are not always being captured through the current electronic coding systems. The necessity of raising the levels of knowledge, amongst primary care staff and patients, about practice-based pharmacists' services was highlighted. There was an expectation by participants for a central evaluation of the "pharmacists in general practice" pilot project. The value of creating local indicators was also noted.

Participants reported the inability of pilot pharmacists to show an impact on most national KPIs. In contrast, pharmacists in Australian general practices were able to show their impact within 6 months of their interventions (face-to-face patient consultations) [39]. The impact

measure in the Australian study was the number of patient medication-related problems (MRPs), for example, inappropriate dose or drug interactions that pharmacists were able to resolve. Similarly, practice-based pharmacists of the IMPACT (Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics) project in Ontario, Canada, showed within 1 year of their integration impact on the practice through their contributions around diagnosis (e.g. of untreated indications), prescribing (e.g. of the right drug for the patient's condition) and education (e.g. increasing the awareness of patients around their medications/disease condition) [40].

Although KPIs have successfully been introduced in other countries in the past to investigate different dimensions of the impact of new pharmacy services (e.g. ward pharmacy services in New Zealand public hospitals [41]), England is a pioneer in implementing KPIs for pharmacists in the general practice setting. The English pilot was at the time of the study in its second year and our work shows that the available KPIs are inadequate for explicitly identifying and showing pharmacists' impact in general practice. These national KPIs are not fit for purpose in that they do not properly reflect the definition that Fernandes et al. ascribed to the ideal KPI for clinical pharmacy services: "a measure that reflects quality, relates to pharmacist role and is supported by adequate evidence" [42]. Measuring the quality of a healthcare service, however, appears not to be a straightforward process and the implementation of quantitative measures often leads to a 'quality versus quantity battle' [43]. According to Avedis Donabedian, the quantity of clinical activities itself does not necessarily signify quality unless interventions, in a specific setting, are strongly associated with desirable patient outcomes (in which case the presence or absence of an activity can itself indicate good or bad quality, respectively) [44, 45]. Real impact of a healthcare service, therefore, links with quality which (in turn) relates to outcomes.

Our study emphasises the importance of professional relationships between practice-based pharmacists and other primary care staff. Jorgenson et al. in their guidelines for pharmacists in primary care settings refer to professional interactions as "one of the biggest factors that will dictate the success of the pharmacist" [46]. This is consistent with the perceptions of the Canadian pharmacists in the IMPACT project who refer to interacting and receiving support from other professionals in primary care as one of the most significant facilitators for a smooth integration into general practice [47]. The participants in our study especially noted the necessity of a strong link between practice-based and community pharmacists as a means of unifying patient care which has been echoed elsewhere [48].

Participants in the current study recognised the usability of satisfaction surveys, especially of those targeting patients or GPs. The perceived causes of potential unfair patient discontent (expressed via surveys), however, identify some problems pharmacists in English general practices experience, some of which are fairly similar to those overseas practice-based pharmacists had to overcome. The triage and maintenance of a core of patients (i.e. a consistent number of patients who are aware of the practice-based pharmacists' presence and who visit the practice on a regular basis just for a consultation with the co-located pharmacist) that could benefit from pharmacists' skills seems to be a historical problem at the initial stages of pharmacists' integration into primary care settings [49]. Moreover, associating pharmacists with therapy changes (patients sometimes report that the main reasons behind therapy changes are monetary, for example, introduction of a cheaper alternative medicine) is an established literature finding [18, 50]. For the English reality, the latter point could be explained as a feature of culture which is often GP-orientated and not always fully informed about what a pharmacist can or cannot do for the patient [51].

Pharmacists employed in various South-West English environments viewed the relief of GPs' work pressure as a prerequisite for undertaking any general practice roles [52]. Similarly, GPs in another English qualitative study point out that pharmacists should "demonstrably reduce GPs' workload" to disprove any negative perceptions amongst practice staff peers and successfully incorporate into general practice [53]. This opinion is congruent with the perceptions of our participants who deemed the shift in GPs' workload as the greatest factor in showing pharmacists' impact and success of the pilot.

The current study did not reveal any initial "outsider feeling" which was the case for Canadian pharmacists in this environment [54]. In contrast, our participating pharmacists were confident about the high standard of their activity and their continuing presence in general practice (post the national pilot). It should be mentioned, however, that though the vast majority of our participating pharmacists were relatively new in their current general practice roles within the pilot, some of them had previous experience (up to 4.5 years) of some sort of work in general practice. Therefore, this may have been the reason for different confidence levels between our pharmacists and the pharmacists in the Canadian study by Pottie et al. [54].

Study strengths and limitations

To our knowledge, this is the first study investigating problems around the measurement of pharmacists' input in English general practices. The results can be extrapolated to various pilot sites nationwide and might also be

useful for overseas policymakers and practice-based pharmacists. The free and extensive discussions observed meant that participants' views were understood in depth. The study also accounted for perceptions of other practice staff members apart from pharmacists as it had knowledgeable representatives from the GP and managerial groups who explored the topic from different angles. Our study achieved a very high participation rate for pharmacists since all eligible pharmacists from the recruited pilot sites participated in the focus groups and, thus, we obtained the full range of possible pharmacists' views from these sites. Another strength is that demographic characteristics of participating pharmacists were quite broad and so the findings reflect different levels of experience, backgrounds and roles.

One of the study limitations is that the overall number of participants was small and originating only from two pilot sites. Therefore, there may be more or different problems with the measurement of pharmacists' input arising from different models of interaction and practice that exist across the country (e.g. different ways of employing practice-based pharmacists or different make-up of the general practice team or different pharmacists' roles or contributions/services or different patient populations or other local features). The research team, however, mixed the participants from the two sites during the focus groups to encourage trans-site interactions and a wide exchange of different experiences. The views from the GP and practice manager must be regarded as an indication only (i.e. GPs' and managers' views were not exhaustively explored) because there was only one participant from each group. The purpose of the study, however, was not to compare perceptions between different professionals but to understand the overall opinions in depth (quotes from the GP and practice manager were chosen as they reflected the opinions of the group). A reflexive method of data interpretation was followed throughout data analysis as the researchers ignored any personal experiences and results were collectively analysed and discussed. Some unavoidable instances of personal assumptions during categorisation of the data, however, might still exist. Finally, there might have been facilitation differences amongst the two focus groups which possibly translates to some divergence in the depth and breadth of topics explored in the discussions. Both facilitators, however, followed the same focus group schedule to ensure that all main questions were adequately covered.

Implications for practice and research

Our findings contain several useful points for NHS policymakers (both at a national and local level) and practice-based pharmacists. The most pertinent points are summarised below.

Policymakers should

- Determine national measures (explicitly based on key pilot stakeholders' opinions) that will ultimately mirror the quality of practice-based pharmacists' services.
- Develop complementary local indicators as per the needs or goals of individual practices.
- Produce electronic activity codes encompassing the whole range of pharmacists' activity (across different work models) to encourage a more consistent and effective coding of work.
- Consider including amongst the KPIs activities relating to pharmacists' capabilities in nursing homes, MURs, medicinal waste and interactions with community pharmacies.
- Develop clearly defined policies and task descriptions for the whole multidisciplinary team (e.g. conditions under which a certain task is considered satisfactorily complete) to limit instances of tick-box exercises and gradually build sensible data for any comparisons to be made.
- Design and validate, in conjunction with patient groups, standardised patient surveys specific to practice-based pharmacists' work.
- Arrange booking systems of the practices to filter patient cases that could benefit from contact with a pharmacist.

Practice-based pharmacists should

- Use effective means to strengthen their utilisation and professional networks, such as participating in all multidisciplinary team meetings, liaising with other practice staff and interacting with nearby community pharmacies.
- Increase their visibility to patients by engaging with Patient Participation Groups; adding their name/face to the Practice notice boards and websites; producing leaflets or waiting room videos.
- Survey patients with regular contact with a general practice pharmacist and ensure that all kinds of feedback are formally recorded.

Future research should include the perceptions of larger cohorts of pilot pharmacists practising in multiple locations across England to identify any further problems that different models of practice-based pharmacists might experience.

Conclusions

The participants in this study thought that the national KPIs are not fit for the purpose of identifying and demonstrating pharmacists' impact in general practice.

Therefore, it is important that generalisable measures, specific to pharmacists' roles and reflecting the effectiveness and depth of their work and expertise, are developed along with a set of new activity codes accounting for the whole spectrum of pharmacists' responsibilities. Our findings also constitute a forceful call for a transparent, robust and fully supported, by all stakeholders, national evaluation of all aspects of the pilot, including exploring the needs and the expectations of patients and GPs regarding the presence of pharmacists in the general practice setting. Every feasible method should be employed to extract the required data for the evaluation, including quantifying pharmacists' work at a local level and obtaining data through searching the electronic systems by pharmacists' names. An acknowledged evaluation will unveil strengths and limitations of the national pilot and will explicitly determine any further expansion of pharmacists' roles and integration into this environment.

Abbreviations

A&E: Accident & Emergency; CCG: Clinical Commissioning Group; GP: General Practitioner; GPC: British Medical Association's General Practitioners Committee; HEE: Health Education England; IMPACT: Integrating Family Medicine and Pharmacy to Advance Primary Care Therapeutics; KPI: Key Performance Indicator; MRP: Medication-Related Problem; MUR: Medicine Use Review; NHS: National Health Service; QOF: Quality and Outcomes Framework; RCGP: Royal College of General Practitioners; RPS: Royal Pharmaceutical Society; STARPU: Specific Therapeutic Group Age-sex weightings Related Prescribing Units

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Availability of data and materials

The datasets generated and analysed during the current study are not publicly available because that would compromise participants' anonymity and the researchers are still publishing findings. Reasonable requests for information, however, can be made to the corresponding author.

Authors' contributions

GDK, KR, NP and WML contributed to the study concept and design, analysis and interpretation of data and writing of the manuscript. GS was involved in the recruitment of participants. All data was collected by GDK and NP. Audio-records were transcribed verbatim by GDK. All authors have approved the manuscript.

Ethics approval and consent to participate

The study received a favourable opinion from the Research Ethics Committee of the School of Chemistry, Food and Pharmacy at the University of Reading (Study Number: 37/16). The research team also gained verbal governance approval from the respective Clinical Commissioning Groups (CCGs) to which the Federations, in which the study was carried out, belong (i.e. the NHS Ealing CCG and the NHS Hammersmith & Fulham CCG). All participants signed an informed consent form.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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CHAPTER 5. CAPTURING PHARMACISTS' IMPACT IN GENERAL PRACTICE: AN E-DELPHI STUDY TO ATTEMPT TO REACH CONSENSUS AMONGST EXPERTS ABOUT WHAT ACTIVITIES TO RECORD

This chapter is the paper from the e-Delphi study, attempting to reach consensus on what general practice-based pharmacist activities are worth recording, as published in BMC Family Practice (Karampatakis, G.D., Ryan, K., Patel, N., Stretch, G., 2019. Capturing pharmacists' impact in general practice: an e-Delphi study to attempt to reach consensus amongst experts about what activities to record. BMC Fam. Pract. 20(1), 126.). The need for this e-Delphi study was strengthened after my focus group study in which participants emphasised the importance of developing an agreed activity coding scheme for general practice-based pharmacists, within the framework of impact identification. With this study, therefore, I set out to explore what does and what does not work well with regards to activity coding for general practice-based pharmacists, with the ultimate goal to identify a number of activities deemed broadly as important to record. With this e-Delphi study, I answered the second objective of my research project, which set out to identify the most important activities that pharmacists in general practice should systematically record to capture and demonstrate their impact in this setting. By answering this objective, I aimed to inform policy and general practice-based pharmacists attempting to align activity coding processes with options widely deemed as useful.

Author contributions are presented in the respective section of the paper. Briefly, I contributed to the concept and design of the study, undertook data collection (i.e. I managed the Delphi's questionnaire rounds), analysis and interpretation of data. I also wrote the manuscript, which was then annotated and approved by all authors.

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Capturing pharmacists' impact in general practice: an e-Delphi study to attempt to reach consensus amongst experts about what activities to record

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Abstract

Background: In the UK, there is ongoing integration of pharmacists into general practice as a new healthcare service in primary care. Evaluation of the service involves national measures that require pharmacists to record their work, on the general practice clinical computer systems, using electronic activity codes. No national agreement, however, has been established on what activities to record. The purpose of this study was to attempt to reach consensus on what activities general practice-based pharmacists should record.

Methods: The e-Delphi method was chosen as it is an excellent technique for achieving consensus. The study began with an initial stage in which screening of a general practice clinical computer system and discussion groups with pharmacists from two 'pharmacists in general practice' sites identified 81 codes potentially relevant to general practice-based pharmacists' work. Twenty-nine experts (pharmacists and pharmacy technicians from the two sites along with experts recruited through national committees) were then invited by e-mail to participate as a panel in three e-Delphi questionnaire rounds. In each round, panellists were asked to grade or rank codes and justify their choices. In every round, panellists were provided with anonymised feedback from the previous round which included their individual choices along with their co-panellists' views. Final consensus (in Round 3) was defined as at least 80% agreement. Commentaries on the codes from all e-Delphi rounds were pooled together and analysed thematically.

Results: Twenty-one individual panellists took part in the study (there were 12 responses in Round 1, 18 in Round 2 and 16 in Round 3). Commentaries on the codes included three themes: challenges and facilitators; level of detail; and activities related to funding. Consensus was achieved for ten codes, eight of which related to activities (general and disease specific medication reviews, monitoring of high-risk drugs and medicines reconciliation) and two to patient outcomes (presence of side effects and satisfactory understanding of medication).

Conclusions: A formal consensus method revealed general practice-based pharmacists' preferences for activity coding. Findings will inform policy so that any future shaping of activity coding for general practice-based pharmacists takes account of pharmacists' actual needs and preferences.

Keywords: Pharmacist, General practice, UK, Key performance indicators, Delphi study, Activity codes

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Background

In England, there is an ongoing drive to incorporate pharmacists into general practice (known as 'family practice' in some countries) which has been co-supported by the National Health Service (NHS) England, Health Education England, the Royal College of General Practitioners, the British Medical Association's General Practitioners Committee and the Royal Pharmaceutical Society. In 2015, a national pilot scheme was introduced that partially covered the expenses of co-locating pharmacists into general practices as equal members in the multidisciplinary teams [1]. An amount of £31 million was invested in the pilot which formed a component of a wider plan [2] aiming to address needs in the primary care workforce (i.e. a shortage of roughly 8000 general practitioners (GPs) and, by 2040, an oversupply of 11,000 to 19,000 newly qualified pharmacists [3]). The pilot led to approximately 490 new general practice-based pharmacists' posts across 90 sites which included approximately 658 general practices [4]. A pilot site, now 'pharmacists in general practice' site, includes a number of general practices participating in the pilot scheme as part of the same organisation. An example of a pilot site is a GP Federation (i.e. a group of practices, in the UK, working together within their geographical area as part of a collective entity). Following the pilot, the number of general practice-based pharmacists has increased as a result of a second roll-out phase [5]. The ultimate purpose with this second phase has been to integrate an additional 1500 pharmacists into general practices by 2020/21 thus having approximately one pharmacist per 30,000 patient population. The overall goal of the 'pharmacists in general practice' scheme is to reduce the workload of overburdened GPs (thus enabling them to manage their time-demands and focus where they are most needed, for example, diagnostics or treating patients with rare or very complex conditions) and ease patients' access to healthcare services and checks [6]. Integrating pharmacists into general practice is also expanding to Wales, Scotland and Northern Ireland [7–10].

Historically, the pharmacy profession has been striving, across the globe, to gain recognition of pharmacists' clinical roles by other healthcare professions and the public [11]. Every new clinical pharmacy service has therefore needed to demonstrate its effectiveness, efficiency and contribution to patient care to justify its necessity and continued funding [12, 13]. Internationally, the greatest challenges when integrating pharmacists into general practices have been overcoming GPs' reluctance to accept pharmacists' clinical interventions [14, 15] and patients' unfamiliarity with pharmacists' roles in this environment [16, 17]. To capture the impact of general practice-based pharmacists, and thus show their usefulness, a number of approaches have been employed internationally. In Australia, for example, the number of medication-related problems experienced by patients (such as incorrect medication or dose, adverse drug reactions and interactions) was measured before and six months after a consultation with a general practice-based pharmacist [18]. Measurements were done by interviewing patients and auditing their records. Results showed significant reductions in medication-related problems with pharmacists' intervention. In Canada, a postal questionnaire was sent to GPs (at the 3rd, 12th and 19th month of pharmacists' integration into general practices) asking them to grade their own and pharmacists' contributions to a number of general practice-based activities [19]. Findings revealed the increasing contributions of pharmacists to diagnosis, prescribing, monitoring, medication reviews and education.

In the UK, NHS England has proposed a set of ten national Key Performance Indicators (KPIs) to evaluate the impact of the introduction of general practice-based pharmacists on patients, GPs and the wider healthcare system [20]. Eight of the KPIs are based on numerical components and two are survey-based (see Table 1). For the numerical KPIs, UK general practice-based pharmacists are required to record their day-to-day work on the

Table 1 National Key Performance Indicators (KPIs)

Numerical KPIs
• Number of patient appointments with: General practitioner (GP), Practice Nurse, Clinical Pharmacist, Health Care Assistant/Advanced Nurse Practitioner
• Impact on the percentage of patients who met the achievement indicator within the relevant Quality and Outcomes Framework-QOF (increase in the average QOF score)
• Increase in total number of medication reviews
• Decrease in the percentage of medication reviews undertaken by GPs
• Increase in the total number of patients supported to develop care and support plans, including self-management
• The rate of Accident & Emergency attendances per 1000 patients on GP register
• Rate of emergency hospital admissions for selected long-term conditions as a proportion of patients per GP practice
• Reduction in the number of patients attending ≥15 appointments with a GP over the previous two years by age group (0–9, 10–19, 20–39, 40–59, 60–69, 70–89, 90+)
• Reduction in antibiotic prescribing rate (versus national rate per STARPU*)
• Reduction in prescribing rate of anti-psychotic medications for patients with dementia or learning disabilities
Survey-based KPIs
• Patient satisfaction survey (patient experience)
• GP survey (impact on workload, time, utilisation, job satisfaction)

*STARPU (Specific Therapeutic Group Age-sex weightings Related Prescribing Units): a weighting system that takes into account the types of people receiving treatment within a specific therapeutic group to compare drug use between NHS organisations and practices

clinical computer systems in the general practices by using pre-existing, non-pharmacy specific, electronic activity codes. SystmOne, EMIS and INPS Vision are the main clinical record systems used in UK general practices. At the time of writing, there has been no national agreement on what general practice-based pharmacists' activities are worth capturing on a regular basis. A recent paper (2019) found that UK general practices still do not have a formal and/or common process for measuring the impact of their pharmacists (practices informally looked for reductions in their GPs' workload or their improved performance in terms of quality inspections and national targets) [21]. A formal evaluation of the initial pilot scheme, based on the opinions of healthcare staff and patients, reported benefits for the practices (such as increased capacity, more focused workload for GPs and reductions in costs) and patients (such as availability of longer appointments with the same person in the practice) [22]. Although the evaluation looked at pharmacists' perceptions about their roles, it made no quantitative measures of their activities. Moreover, a UK qualitative study revealed that the current coding options are not tailored to pharmacists' work (available coding having pre-dated the 'pharmacists in general practice' scheme) and concluded that they are not fit for purpose to effectively identify the spectrum of pharmacists' tasks within the general practice environment [23]. The purpose, therefore, of this study was to reach a broad consensus amongst experts on what general practice-based pharmacists' activities should be recorded on the general practice clinical computer systems.

Methods

Study methodology

The Delphi method was selected for the current study because it enables consensus amongst experts (panellists) on a topic that lacks evidence [24–26]. The Delphi method involves an initial stage in which the recruited panel of experts identifies the spectrum of predominant problems which are then transformed into statements and ranked in a succession of consecutive questionnaire rounds. In each round, responses are influenced by controlled feedback from the previous round (i.e. panellists are offered an anonymised summary of their counterparts' views). The study completes when a pre-defined agreement percentage is reached or after a pre-agreed number of rounds [27].

Initial stage

Because there was no recent UK literature on pharmacists' activities in general practice at the time of beginning this study, two members of the research team (GS-service lead and GDK-doctorate research student) screened the largest general practice computer system (SystmOne) and built up a list of 69 codes potentially relevant to general practice-based pharmacists' work. The vast majority of codes were related to activities but there were also a few codes concerning patient outcomes that were included due to their potential high relevance to pharmacists' activities in this setting as determined by GS. Face-to-face focus groups were then conducted with general practice-based pharmacists (from two West London sites) in which participants were asked to discuss which codes on the list might be useful and suggest any other pharmacists' activities worth considering as coding options. These focus group discussions were audio-recorded, transcribed verbatim and analysed thematically (for detail, see reference [23]). A further 12 codes were generated from the focus group discussions. In total, a collection of 81 codes was assembled which made up the questionnaire for Round 1 of the Delphi study. An additional file presents all 81 codes (see Additional file 1). Each code formed a different item in the questionnaire. Two general practice-based pharmacists and one pharmacy technician pilot tested the questionnaire for Round 1 and any modifications made thereafter. All questionnaires were created using the platform of Online surveys (formerly known as Bristol Online Surveys).

Expert panel

Clayton (1997) recommends 15 to 30 panellists as an ideal size for Delphi panels [28]. Twenty-nine people were identified as potential panel members for the current study, using the following criteria: pharmacists or pharmacy technicians working in general practice and involved in coding general practice-based pharmacists' activities either at a local or national level. Invitees included all pharmacists and pharmacy technicians working across two West London sites (at the time approximately 17 eligible staff members) along with other national experts (12) holding senior general practice-based pharmacists' roles and widely engaged on national committees. The West London sites were targeted for recruitment because both have working connections with the research team's organisation (invitees from the West London sites included most of the focus group participants). The national experts were recruited through the Centre for Pharmacy Postgraduate Education and the Primary Care Pharmacy Association.

Recruitment process

Participation was voluntary and all 29 experts were invited to participate in each round. All invitation e-mails for Round 1 were sent, on behalf of the research team, by the lead pharmacists in the two West London 'pharmacists in general practice' sites. The invitation included

a direction to e-mail a member of the research team (GDK) if they wanted to be involved in the study. Once confirmatory e-mails had been received, the log-in details for access to the questionnaire were individually e-mailed (by GDK) directly to potential panellists.

In each subsequent round, GDK directly e-mailed the new log-in details of the updated questionnaires to those panellists involved in one of the previous round(s). Two weeks after the initial invitation, the lead pharmacists sent a follow-up invitation e-mail to the whole potential panel encouraging them to take part in the study.

e-Delphi rounds

The study's endpoint was consensus according to a preconceived criterion (agreement ≥80%). As literature reports that three Delphi iterations suffice for achieving consensus [29, 30], it was decided in advance to carry out a succession of three e-Delphi rounds in the current study. To foster the achievement of consensus, each round was different in terms of the questionnaire's content and the threshold of agreement was progressively elevated (see Analysis of quantitative data below). In each round, panellists had the chance to explain their choice for each item and/or to provide general comments. Feedback from each previous round (see Fig. 1 for what it included) was organised into a PDF document and e-mailed, alongside log-in details, to panellists. Demographic data was collected in each round including overall years of practice as qualified healthcare professional, years of practice within the general practice environment, region of practice and roles/duties within general practice.

Round 1

The questionnaire for this round asked panellists to report the extent to which they agreed that each of the proposed codes was important to record by using a 5-point Likert scale (1 = definitely disagree, 2 = probably disagree, 3 = neither agree nor disagree, 4 = probably agree, 5 = definitely agree). The questionnaire for this round can be found as an Additional file (see Additional file 2).

Round 2

In this round, codes were grouped as per their context (e.g. codes relating to medication review, monitoring, patient outcomes etc.). Panellists were asked to characterise each code as 'useful' or 'not useful'. The questionnaire for this round can be found as an Additional file (see Additional file 3).

Round 3

In this round, codes were grouped similarly to Round 2 and panellists were asked to grade them according to their importance on a 5-point Likert scale (Very Important, Important, Moderately Important, Slightly Important, Not at all). For codes related to patient's ability to manage medication, where duplication existed (i.e. multiple codes for the same meaning), panellists were instead asked to rank the available options in order of importance (1 = most important and 6 = least important). The questionnaire for this round can be found as an Additional file (see Additional file 4).

Analysis of quantitative data

Descriptive statistics were employed to analyse quantitative data. In each round, the percentage of panellists in each score/ranking option was calculated automatically by the Online Surveys platform. The threshold of agreement was progressively elevated (51% in Round 1, 70% in Round 2 and 80% in Round 3). In detail, Round 1 codes in which fewer than 51% of panellists scored 4 (probably agree) and 5 (definitely agree) were removed. In Round 2, codes not characterised as 'useful' by at least 70% of panellists were removed. Final consensus was defined as at least 80% of the panellists in Round 3 scoring within the 'importance' area (i.e. 'Very Important' and 'Important'). Similarly, for the ranking question in Round 3, consensus was implied if 80% or more of the panellists identified a certain option as belonging in the same position of the order of importance (i.e. at least 80% of panellists ranked an option as number 1, number 2 etc.).

Figure 1 summarises the process followed in this study, including the analysis process for the quantitative data.

Analysis of qualitative data

Panellists in all Delphi rounds were given an identifier based on round, for example, Round 1, Panellist 1; Round 1, Panellist 2 etc. Panellists' commentaries from all rounds were pooled together (on a hard copy) and analysed thematically. The six stages of thematic analysis as described by Braun and Clark were employed (familiarisation with data, coding, identifying themes, reviewing themes, defining themes and writing the report) [31]. In detail, commentaries were coded by GDK (the term 'code' or 'coding' in this context refers to the coding step of qualitative analysis [32] rather than to activity codes which formed the questionnaire items in each Delphi round). Codes were developed on the margins of the hard copies containing all commentaries and a single code was ascribed to every different meaning. Codes were confirmed by the whole research team before developing categories. All different codes were transferred to a Word® document and sorted

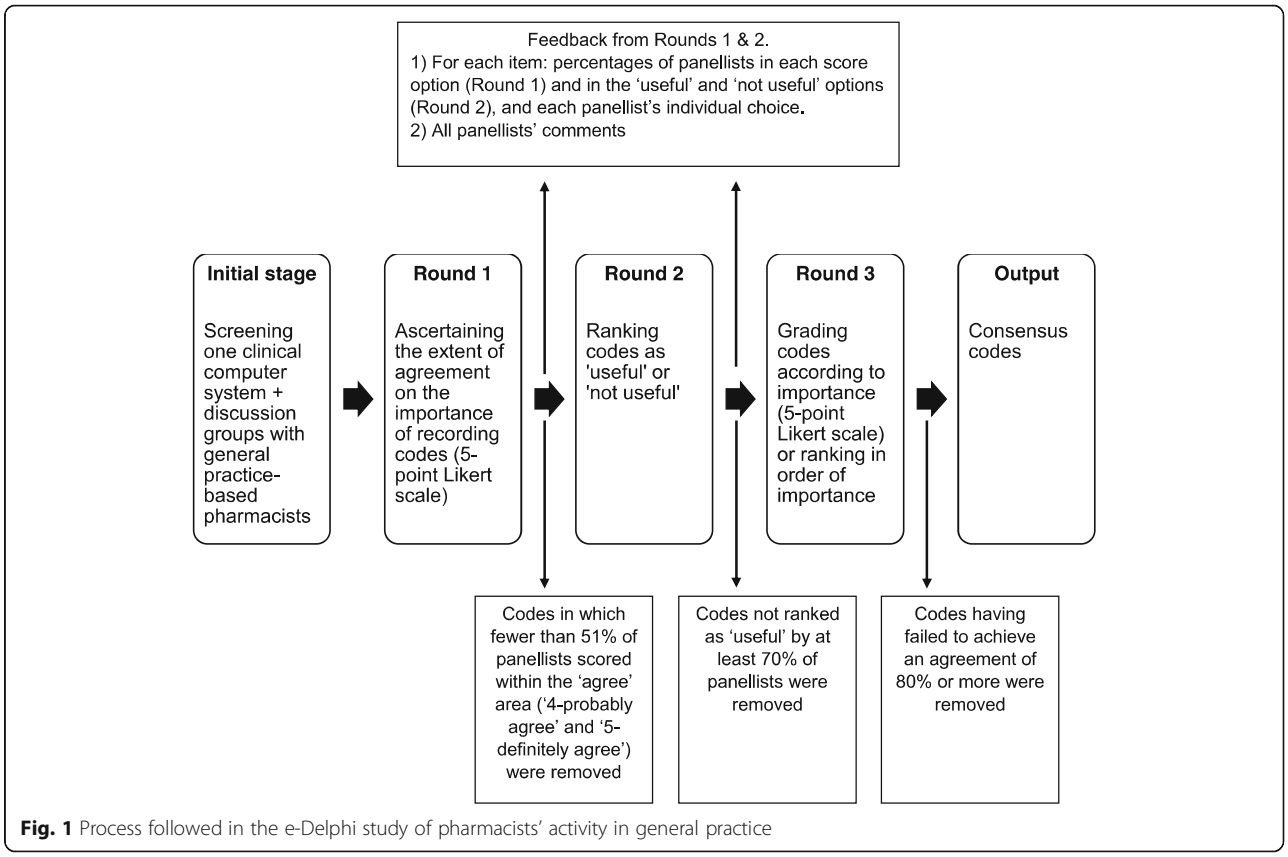

Fig. 1 Process followed in the e-Delphi study of pharmacists' activity in general practice

into potential categories. Each category was highlighted with a different shading on the Word® document. Categories were eventually collapsed into themes with associated sub-themes. Themes were then refined and named collectively by the whole research team.

Results

Panellists

Responses were received from 21 individual panellists: 12 in Round 1, 18 in Round 2 and 16 in Round 3 (nine panellists followed through from Round 1 to 3). All panellists were employed in general practice and involved in capturing pharmacy services. Table 2 presents the demographics of the panellists, aggregated for reasons of anonymity.

Panellists reported a wide scope of practice, such as: various face-to-face consultation clinics including medication reviews, elements of diagnostics and performing regular home and care home visits, medication prescribing and monitoring duties including high risk drugs (e.g. immunosuppressants, lithium, warfarin) and overseeing the repeat prescription service; managing the discharge/clinical letter workflow and medicines reconciliations; education duties (e.g. training medical students or registrar GPs); consultancy work with healthcare professionals (e.g. medication queries) and leading multidisciplinary clinical meetings at a practice or broader level; audits and service reviews; telephone consultations with patients for advice on minor ailments and triage; and supporting the running of Patient Participation Groups. Pharmacy technicians, under the supervision of pharmacists, were involved in most of the above activities except for authorising prescriptions.

Qualitative data

Commentaries were sorted into three main themes: challenges and facilitators; level of detail; and activities

Table 2 Demographics of the e-Delphi expert panel

	Years of practice as healthcare professional	Years of practice within the general practice environment	Region of practice
Pharmacists (19)	5 to 31 years	1 to 23 years	Essex, Greater Manchester, London, Midlands, South Wales
Pharmacy technicians (2)	> 10 years	< 5 years	London

related to funding. These themes gave a better understanding of the reasons behind the selection of certain codes as the most important options and allowed extrapolation to relevant recommendations.

Challenges and facilitators

The panellists discussed several factors that might act as challenges or facilitators in the process of recording activities.

With regards to challenges, there was a fear that activity coding might complicate a pharmacist's working day (i.e. an extra daily task) and generate additional time-requirements.

> *The use of codes is time consuming. For me, coding would add complexity to [my] working day.* (Round 1, Panellist 1)

Some panellists claimed that the greater the available options (e.g. codes differentiating activities to a larger degree), the more laborious the process of coding would become.

> *Coding should not be too onerous as it gets difficult to maintain that high level of reporting.* (Round 2, Panellist 9)

It was also reported that entering a code might occasionally act as a distractor from focusing on the patient during consultations.

> *Having codes to use may mean concentrating to complete templates rather than actually delving into patients' needs and care plans.* (Round 1, Panellist 12)

Memorising codes was another reported challenge.

> *Hard to see how all these codes will be used in the GP practice setting as pharmacists would have to remember them.* (Round 1, Panellist 5)

There were concerns that codes are likely to be used irregularly amongst different pharmacists and/or practices hence complicating any subsequent data collection.

> *The data extracted might be limited due to an irregular use of codes.* (Round 1, Panellist 1)

Panellists also mentioned that some codes referred to tasks not frequently carried out by general practice-based pharmacists. Examples included synchronising repeat medications, believed to mainly be a task for administrators, and reviewing community pharmacists' Medicine Use Reviews (MURs), infrequently undertaken by general practice-based pharmacists. A MUR is a service offered by community pharmacists in the UK and involves adherence-focused reviews with patients on certain medicine groups.

Concerning facilitators, it was suggested that a national activity coding template would ease the process of coding. All options would be in the same place and therefore easily accessible.

> *It would be extremely useful to develop a national template with all codes on for easy access.* (Round 1, Panellist 4)

There was, however, a fear that a national template might not entirely account for local needs that individual practices and/or pharmacists might experience.

> *Is there such a thing as one size fits all with regards to a template or should we create an a la carte menu for people to pick from?* (Round 1, Panellist 12)

The need to create clear definitions for all codes was also highlighted.

> *All codes need to be clearly defined.* (Round 1, Panellist 3)

Level of detail

The amount of detail the codes should include was frequently commented upon and conflicting opinions were present.

For example, there was discussion about medication review codes and whether or not these should:

- Be more specifically attributed to the person carrying out the review (e.g. pharmacist, GP).

> *It's useful to know as quick glance at the code whether GP or pharmacist did the medication review.* (Round 3, Panellist 7)

> *The details of the clinician on a code are only relevant for auditing. For everyday practice, the system will identify the user as the type of clinician.* (Round 2, Panellist 11)

- Define the exact disease area (e.g. asthma, depression etc.) for which the review was conducted.

> *Some disease-specific medication review codes are helpful especially if pharmacists are working in the earlier part of their employment as independent*

prescribers and sticking to their scope of practice. (Round 2, Panellist 9)

A general medication review code encompasses all conditions. If wanted to, you can see what condition-medication you are reviewing from notes (and can be searched on the electronic systems) without need to code specifically. (Round 2, Panellist 8)

- Indicate the level of the review (i.e. presence or absence of the patient during a review).

Information is limited without the patient [being] present [at a medication review], so it's good to code the patient's presence or absence. (Round 3, Panellist 8)

Reviewing medication even without the patient adds some value so segregating it [patient's presence] out of the [general] medication review code is of limited value. (Round 2, Panellist 9)

Activities related to funding

Panellists emphasised the importance of primarily coding activities associated with the availability of funding streams for general practices. They provided characteristic examples of funding-related activities such as the monitoring of high-risk drugs which was viewed as a part of commissioned 'out-of-hospital services' (i.e. healthcare services offered by UK non-hospital providers, such as general practices, that attract NHS funding). In addition, medication reviews for patients with certain conditions, such as asthma and diabetes, were believed to qualify for Quality and Outcomes Framework (QOF) funding. QOF is a program for English, Welsh and Northern Irish general practices that incentivises clinical excellence.

We have a huge array of things to do daily and much of it relates to practice funding so have to be secure in doing this. This [e-Delphi] study needs to search against codes already in use for the purposes of QOF/ 'out-of-hospital services' etc. to get more accurate data. (Round 1, Panellist 1)

Codes already used in practice for purposes of getting funding are useful. (Round 3, Panellist 4)

Activity codes

Of the 81 codes in Round 1, 59 codes made it through to Round 2 (58 from Round 1 and one added following panellists' comments) and 34 codes made it through to Round 3 (33 from Round 2 and one added following panellists' comments). Additional file 1 presents percentage agreement for each code in all rounds. Final consensus (in Round 3) was reached on ten codes (see Table 3). Table 4 presents the Round 3 codes that failed to achieve final consensus. In addition, there was no clear hierarchy in ranking for the importance of any of the following Round 3 codes which were subsequently discarded: 'able to manage medication'; 'drug compliance good'; 'unable to manage medication'; 'difficulty managing medication'; 'uses medication administration system'; and 'needs assistance with medication regimen adherence'.

Discussion

Of the ten codes for which consensus was reached, eight relate to activities and two to patient outcomes. The selected patient outcome codes refer to the presence of side effects and to the satisfactory understanding of medications. Panellists did not provide reasons for why they viewed these two patient outcome codes as important, however, this might be because these codes are seen as standard checks for a pharmacist to ensure the patient's adherence to medication.

The eight chosen activity codes refer to only three distinct activities: medication review, monitoring of high-risk drugs and medicines reconciliation. In contrast, general practice-based pharmacists across the Dudley Clinical Commissioning Group (i.e. a UK clinically-led body, part of the NHS, in charge of designing and commissioning healthcare services for the local area) were found to code at least 20 different activities ranging from direct patient care tasks to duties related to education, quality assurance, repeat prescribing and waste management [33]. Activity codes in Dudley, however, were determined exclusively by the service lead without taking account of any validation by pharmacists or any external expert input, which our study has done.

The activities favoured for coding are mainly funding-related tasks: medication reviews (especially for conditions

Table 3 Codes for which final consensus (agreement ≥80%) was reached

• Medication review done
• Medication review done by pharmacist
• Asthma medication review
• Chronic Obstructive Pulmonary Disease (COPD) medication review
• Diabetes medication review
• Depression medication review
• High-risk drug monitoring
• Medicines reconciliation post-discharge with notes
• Has shown side effects from medication
• Patient understands why taking all medication

Table 4 Codes in Round 3 that failed to achieve final consensus (categorised by percentage agreement*)

Agreement 70–80%	• Antipsychotic medication review • Polypharmacy medication review • Medication changed • New medication added • Medicines reconciliation performed
Agreement 60–70%	• Medicines adherence checked • Advice about drug treatment • Advice about side effects of drug treatment • Medication review without patient • Anticoagulation medication review • Drug changed to cost effective alternative • Medication stopped • Medication stopped-side effect • Medication error
Agreement 50–60%	• No drug side effect reported • Synchronisation of repeat medication • Contact with the local community pharmacy • Medicine Use Review (MUR) done by community pharmacist

*Percentage agreement indicates how many panellists identified a code as 'Very Important' and 'Important'

viewed by panellists as the top priorities in QOF: asthma, COPD, diabetes and depression) along with the monitoring of high-risk drugs which was viewed by panellists as a priority in 'out-of-hospital services'. The fact that one of the national KPIs accounts for the ability to meet QOF targets might have arguably influenced panellists' choice of codes. These results support the finding that there is increasing engagement of UK general practice-based pharmacists with incentive programs related to funding acquisition for their employer practices [34]. Panellists, however, provided no comments on why they chose medicines reconciliation (not viewed as funding-related) as an activity to code.

As shown in Additional file 1, the majority of codes that made it through to Round 3 had also good percentage agreement in Rounds 2 and 1. Some codes, however, with high percentage agreement in Round 2 did not get final consensus in Round 3. For instance, the 'no drug side effect reported' code did not maintain high percentage agreement in contrast to its opposite 'has shown side effects from medication' code. This could have been because it is more important for pharmacists to record the presence rather than the absence of side effects, for example, to alert the rest of the general practice-based team. Codes describing the patient's ability to manage medications were also discarded in Round 3, perhaps because they were not deemed as direct measures of a pharmacist's activity (these codes describe patient behaviours). It is also worth noting that panellists finally selected a medicines reconciliation code pointing out the availability of patient notes rather than the generic 'medicines reconciliation performed'. This choice makes sense, terminology-wise, because medicines reconciliation cannot properly be done without access to patient notes [35]. Panellists rejected codes describing medication reviews for anticoagulants and antipsychotics, despite the fact that one of the KPIs requires general practice-based pharmacists to reduce antipsychotic prescribing. These codes were possibly excluded because patients on antipsychotics or anticoagulants would be under hospital or specialist care.

General practice-based pharmacists were against having to deal with a large number of codes because they would be onerous, provide more detail than necessary and be less likely to have universal uptake. A few, higher-order codes were preferred instead. For instance, panellists did not select codes describing specific actions taken during a medication review (such as altering medication, ascertaining adherence and offering advice about treatment), most likely because these could be covered and implied under the higher-order 'medication review done' code. Probably for the same reason of avoiding large numbers of codes, panellists excluded codes indicating the level of a review and codes believed to describe rare tasks for general practice-based pharmacists such as synchronising repeat medications and reviewing community pharmacists' MURs. Although communication with community pharmacists was recognised during the initial focus groups as an important element of general practice-based pharmacist's role [23], panellists did not consider it important enough to code how often it happens. The 'contact with local community pharmacy' code was rejected potentially because interactions between general practice-based and community pharmacists are extremely frequent [34] and using codes would have made coding quite time consuming.

To dispel fears about the negative impact that the use of codes could have on day-to-day workflow, additional simplification of the activity coding process could be beneficial. For example, an Australian public hospital employed barcode technology to facilitate capture of pharmacists' activities [36]. Technology can ease reference to codes and accelerate their entry into clinical computer systems thus making activity coding a smoother process for general practice-based pharmacists.

Implications

This study has shown consensus on a number of activity (and patient outcome) codes. Clear definitions of codes along with policies on their use need to be created (e.g. explanations of terminology, instances or prerequisites for entering each code) to encourage an unvarying application of codes and hence facilitate any subsequent data collection.

Strengths and limitations

This is the first study that has followed an acknowledged consensus method to determine general practice-based pharmacists' preferences concerning activity coding. As

the Delphi method requires, the panel used in the current study included some of the key experts on the topic who have been following the evolution of UK general practice-based pharmacists' roles for many years. Consequently, findings reflect real needs/requirements concerning capturing pharmacists' impact in general practice and, additionally, account for diverse levels of experience (people relatively new in general practice were also represented in the study) as well as different geographical areas of practice. The study explored the views of the whole pharmacy team in general practice including pharmacy technicians who are increasingly contributing to general practice-based activities [37].

As it was an entirely UK-based study, findings might not be generalisable to other countries due to possible differences between healthcare systems. Individual elements, however, will still be useful wherever attempts are being made to implement and justify general practice-based pharmacists' services. For example, aspects of the findings might be useful to Australia, Canada and New Zealand which all have formal programs for integrating and testing pharmacists' services in general practice [38–40]. The original list of activity codes was mainly based on only one clinical computer system and there might be additional codes present on other systems. Panellists, however, had the chance throughout the Delphi study (and in the initial focus groups before the actual Delphi rounds) to suggest any other activities of importance to capture. Therefore, it is anticipated that the study has identified the important activities for recording general practice-based pharmacists' impact regardless of the clinical computer system used.

Conclusions

This study followed a formal consensus technique to offer insight into needs and preferences of general practice-based pharmacists with regards to activity coding. Final consensus was reached for ten codes with a notable preference for codes required for obtaining general practice funding. These findings will be useful for general practice-based pharmacists wanting to align their activity coding practices with options widely recognised as useful. These findings will also inform policy that attempts to shape activity coding for general practice-based pharmacists by considering pharmacists' actual needs and preferences.

Additional files

Additional file 1: Codes in all rounds of the e-Delphi study and percentage agreement on each one. Description of data: This additional file consists of a table that presents all codes that were present in the e-Delphi's rounds, including percentage agreement that each code received in each round. (DOCX 17 kb)

Additional file 2: Round 1 questionnaire. Description of data: This additional file consists of the questionnaire used for Round 1 of the e-Delphi study. (PDF 294 kb)

Additional file 3: Round 2 questionnaire. Description of data: This additional file consists of the questionnaire used for Round 2 of the e-Delphi study. (PDF 104 kb)

Additional file 4: Round 3 questionnaire. Description of data: This additional file consists of the questionnaire used for Round 3 of the e-Delphi study. (PDF 99 kb)

Abbreviations

COPD: Chronic Obstructive Pulmonary Disease; GP: General Practitioner; KPI: Key Performance Indicator; MUR: Medicine Use Review; NHS: National Health Service; QOF: Quality and Outcomes Framework; STARPU: Specific Therapeutic Group Age-sex weightings Related Prescribing Units

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Availability of data and material

The datasets generated and analysed during the current study are not publicly available because that would compromise participants' anonymity. Reasonable requests for information, however, can be made to the corresponding author.

Authors' contributions

GDK, KR and NP contributed to the study concept and design, analysis of data and writing of the manuscript. GS was involved in the recruitment of participants. All authors have approved the manuscript.

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Ethics approval and consent to participate

The study received ethical approval from the University of Reading Research Ethics Committee (study number: 17/21) and the Health Research Authority (Integrated Research Application System Project ID: 228337). The completion of the questionnaire implied consent and involvement in further rounds of the e-Delphi was deemed as ongoing consent. No additional written consent was collected.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

CHAPTER 6. COMMUNITY PHARMACY TEAMS' EXPERIENCES OF GENERAL PRACTICE-BASED PHARMACISTS: AN EXPLORATORY QUALITATIVE STUDY

This chapter is the paper from the study which reports on community pharmacy team experiences of general practice-based pharmacists, as published in BMC Health Services Research (Karampatakis, G.D., Patel, N., Stretch, G., Ryan, K., 2020. Community pharmacy teams' experiences of general practice-based pharmacists: an exploratory qualitative study. BMC Health Serv. Res. 20(1), 431.). Comments from general practice-based pharmacists, during the focus group study, about the importance of building relationships with community pharmacy staff influenced my decision to explore what actually the other side (i.e. community pharmacy staff) think about their colleagues in general practice. In addition, anecdotal rumours about opposition from community pharmacy staff to the integration of pharmacists into general practice further intensified the need for this study. With this interview study, therefore, I set out to understand what does and what does not work for community pharmacy staff with regards to pharmacist presence in general practice, thereby informing policy and practice on what needs to be done to ensure mutual collaboration between pharmacies and practices. Through this study, I answered the third objective of my PhD, which set out to understand how community pharmacy teams experience and view the presence of pharmacists in general practice.

Author contributions are presented in the relevant section of the paper. Briefly, I contributed to the idea for and design of the study, and undertook data analysis and interpretation. Data collection (i.e. individual interviews with community pharmacy staff) was carried out by final year, MPharm project students who were appropriately trained in interview methods. I also wrote the manuscript, which was then annotated and approved by all authors.

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RESEARCH ARTICLE Open Access

Community pharmacy teams' experiences of general practice-based pharmacists: an exploratory qualitative study

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Abstract

Background: In England, since 2015, there has been a formal drive to integrate pharmacists into general practice as a new healthcare service. Research efforts have offered insights into how general practice-based professionals and patients view the service, however, they took no account of community pharmacy teams' opinions. There have been anecdotal statements about opposition from community pharmacies to the service, due to fears of losing business. The aim of the current study was to identify the experiences and perceptions of community pharmacy teams regarding pharmacists' presence in general practice.

Methods: The National Health Service Choices website was used to identify community pharmacies within a radius of two miles from eight West London general practices. The search resulted in 104 community pharmacies which were all contacted via telephone. Pharmacy staff who verbally expressed their interest to participate were then provided with the study's documents. Qualitative, face-to-face, semi-structured interviews were conducted inside the pharmacy from which each participant was recruited. Interviews lasted 30 to 45 min and were audio-recorded. Audio-recordings were transcribed verbatim and transcripts analysed thematically.

Results: Forty-eight community pharmacy staff participated. Four themes were discerned: awareness ("I knew that [pharmacists] have already been implemented [in general practice] but I haven't really followed it … where does the pharmacist role come?"); interactions ("I'm just so pleased that there's a pharmacist professional in the general practice … because we speak the same language!"); patient care ("if I was a patient knowing that there is a general practitioner and a pharmacist [in general practice], I would … think 'nothing can go wrong at the moment'"); and funding challenges ("if general practices take on the extra responsibility of stop smoking or flu vaccination campaigns … financially, this would affect this pharmacy").

Conclusions: The current study revealed the perceived impact of general practice-based pharmacists on community pharmacies would be improved communication between pharmacies and practices. Findings will inform policy so that any future framing of pharmacists' presence in general practice considers the needs of community pharmacies.

Keywords: Community pharmacy, England, General practice, Experiences, Qualitative study

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Background

England is experiencing pressures in the delivery of primary healthcare due to an ageing population with multiple co-morbidities and significant difficulties in recruiting and retaining general practitioners (GPs) [1, 2]. To address these pressures and make effective use of the workforce (including a projected excess of recently qualified pharmacists by 2040 [3]), a national, two-phased scheme for integrating pharmacists into general practice was launched in 2015 by the National Health Service (NHS) England [4, 5]. The scheme introduced over 1000 pharmacists into general practice [6]. In early 2019, the NHS Long Term Plan [7] encouraged general practices to work together in Primary Care Networks (PCNs). PCNs are organisations covering 30–60,000 patients with the remit to connect community-based healthcare services with each other as well as with the hospital, social and voluntary sectors. As part of a new contract between general practices and NHS England, PCNs will be funded £1.8 billion to hire an additional 20,000 primary care staff within the next 5 years including large numbers of general practice-based pharmacists [8]. General practice-based pharmacists in England carry out a wide spectrum of activities, the majority of which focus on providing expertise around medication use [9–12]. Characteristic examples of activities are face-to-face patient clinics for managing long-term conditions and/or acute care and/or medication reviews, including elements of physical assessments; drug monitoring including dealing with high-risk drugs and ordering laboratory or other clinical tests; lifestyle advice, for example, weight management, diet and smoking cessation; telephone consultations with patients for triage and common ailments such as management of pain; medicines reconciliations; prescribing, if qualified to do so; managing the repeat prescription service; and advising general practice-based staff on medication-related queries.

Internationally, several countries have formally attempted to integrate pharmacists into general practice. For example, several programmes have been introduced in different parts of Australia, all of which have been small-scale [13–16]. In Canada, large-scale programmes of implementing pharmacists' services into general practice have taken place in Ontario and Quebec [17, 18] whereas smaller efforts have been also made in Newfoundland and Labrador [19]. In the USA, efforts of introducing general practice-based pharmacists have involved a small number of pharmacists/practices and have been restricted to a very certain geographical location [20–24]. However, there are a few instances of wider programmes such as the 'Collaboration Among Pharmacists and Physicians to Improve Outcomes Now' which ran across 13 states [25]. In New Zealand, governmental programmes implemented 31 general practice-based pharmacists nationwide by 2017 [26]. In Netherlands, a relatively recent initiative introduced ten general practice-based pharmacists [27].

Although some pharmacists in England have occasionally worked in general practice in the past [28, 29], this is the first time that the role has been formally implemented and tested at a national level [30]. As a result, very little is known about the impact of pharmacists in general practice. A preliminary evaluation of the first phase of the English scheme reported benefits for GPs (including increased capacity and a more focused workload), patients (including longer appointments with the same person) and pharmacists (including increased role satisfaction) [31]. The evaluation, however, did not account for the perceptions of community pharmacy staff. Staff in community pharmacies mainly consists of pharmacists, including pre-registration pharmacists, and pharmacy technicians.

Community pharmacies are independent contractors of NHS England and are integral to the care of patients. There are currently about 11,600 community pharmacies across England [32]. Many of these pharmacies operate long hours, hence providing patient care at times when other healthcare services are unavailable and/or serve small, deprived communities where access to healthcare is hard.

As part of their contract, community pharmacies provide three tiers of services, namely 'essential', 'advanced' and 'locally commissioned' [33–35]. All these services are carried out by pharmacists. The 'essential' services are required from all community pharmacies whereas the 'advanced' and 'locally commissioned' services are provided on an optional basis. The 'essential' services include dispensing duties, liaising with other healthcare settings when needed (in particular general practices), disposal of medical waste and referral of patients to the appropriate healthcare professional. 'Advanced' services refer to tasks such as the adherence-focused medicine use reviews (MURs), to be phased out by the end of 2020; the new medicine service (NMS); flu vaccinations; and providing emergency medication supplies to patients. Community pharmacies receive payment for offering 'advanced' services and as such employers expect pharmacists to meet certain targets for their provision. 'Locally commissioned' services include minor ailment, smoking cessation, lifestyle advice and vascular risk assessment services. Pharmacy technicians, under the supervision of a pharmacist, provide various services in community pharmacies, for example, processing prescriptions, preparing and dispensing medications, ordering items and managing stocks, liaising with staff in other healthcare settings and advising patients on their medications as well as on minor ailments and smoking cessation [36, 37].

There are existing interactions between community pharmacies and general practices, mainly around prescriptions [38, 39]. However, the increase in number of pharmacists in general practice and the roles they can undertake (for example, medication reviews) has anecdotally caused some opposition and resistance from community pharmacy teams to the integration of pharmacists into general practice. These rumours are based on fears of losing business due to role clashes, for example, general practice-based pharmacists' medication reviews replacing MURs and the NMS [40, 41]. A few, mostly international studies examining collaboration between community pharmacies and general practice focused on the views of general practice-based pharmacists and other staff, rather than on the opinions of community pharmacy teams [42–46]. Therefore, there is a gap in the literature examining the impact of general practice-based pharmacists on community pharmacies.

The aim of the current study was to explore community pharmacy teams' experiences and perceptions of the presence of pharmacists in general practice in England.

Methods

Study design

To pursue an in-depth exploration of experiences, a qualitative study design was selected. Individual interviews, rather than focus groups, were selected as participants might not have felt comfortable to discuss their honest views in front of other co-participants, especially if there were areas of disappointment/frustration. All interviews were conducted between October and December 2017.

Setting

Participants were recruited from community pharmacies within the geographical area of one West London GP Federation (a cohort of practices working together as a collective entity) which constituted a 'pharmacists in general practice' site. At the time of data collection, eight Federation practices participated in the scheme, employing seven pharmacists and serving approximately 72,000 patients. This Federation was targeted as a recruitment point due to working connections with the research team's organisation.

Participants and recruitment

Potential participants included community pharmacists (either regular or locum), pre-registration pharmacists and pharmacy technicians. Pharmacy technicians were included because they are an important part of community pharmacy teams with expanding roles and responsibilities that support pharmacists in their roles [47, 48]. The NHS Choices website was searched to identify all community pharmacies within a two-mile radius of the postcodes of the eight practices. This identified 104 pharmacies (61 independent, 24 small chain, 13 large chain and six supermarket pharmacies). Names, addresses and phone numbers for the pharmacies were retrieved. Ten interviewers (final year pharmacy students trained to undertake interviews) were paired and each pair was randomly assigned 20 or 21 pharmacies. Each pharmacy was contacted by telephone and the responsible pharmacist introduced to the study and asked if they, or a member of their staff, were willing to participate. People who expressed their willingness to participate were provided, by e-mail or post, with information about the study including details on the research team and interviewers. After a week, invitees were again contacted by telephone to schedule an interview.

Data collection

Participation in the interviews was voluntary. Regular debriefings between the research team (GDK, KR, NP and GS) and the interviewers were held throughout the data collection period. GDK is a doctoral research student, KR is a Professor of Social Pharmacy, NP is an Associate Professor in Pharmacy and GS is a lead general practice-based pharmacist. All interviews were face-to-face, semi-structured, audio-recorded and conducted within the pharmacies in a quiet place of mutual convenience. An interview schedule, composed of open-ended questions and prompts, was used (see Table 1). Each interview terminated when the participant did not

Table 1 Interview schedule

Thank you for taking the time to contribute to our research project.

1. What are your roles and responsibilities within this pharmacy?
   - Your role, age, years of service
   - Skills and training
   - Day-to-day working life
2. Please tell us about your perceptions of pharmacists working in general practice.
   - Positives/negatives
   - Perceived impact on your own roles, responsibilities
   - Actual experiences or hearsay (where from?)
3. Please tell us about your experiences, if any, of the pharmacists in general practice scheme
   - Relationships – with GPs, pharmacy team members
   - Positive/negatives - examples
   - Impact on own roles, responsibilities
4. Overall view of the GP-pharmacist partnership on your work/services provided
   - Feelings
   - Thoughts about how your work has changed
   - What changes would you like to see made to the scheme?

have anything else to share. Interviews lasted 30 to 45 min.

Data analysis

Audio-recordings were transcribed verbatim by the interviewers. Transcripts were inductively coded [49] using NVivo 11 and analysed thematically by GDK as described by Braun and Clark (familiarisation with data; coding; searching for themes; reviewing themes; defining and naming themes; and developing the report) [50]. Coding was verified by the rest of the research team before developing categories. Categories were re-assessed and collapsed into potential themes with associated sub-themes. Themes were then refined and named collectively by the research team. Participants' feedback on transcripts or findings was not sought.

Results

Demographics

Table 2 provides an overview of the participants' demographics. Forty-eight community pharmacy staff participated in the study. Of these, most were pharmacists with a wide range of time spent in community pharmacy. The majority of participants worked for independent pharmacies.

Themes

Four overarching themes were discerned in the data: awareness; interactions; patient care; and funding challenges. Figure 1 illustrates the four themes with all associated sub-themes.

Awareness

Participants' awareness of pharmacists in general practice varied. Some were completely ignorant of their presence or thought that a general practice-based pharmacist meant a pharmacy situated within the practice.

> *To be honest, I don't know anything about the scheme [of integrating pharmacists into general practice] so I'm not able to speak about it.* (Pharmacist 25)

The majority of participants, though, were aware of pharmacists' presence in general practice but uncertain about details such as employment models, roles and responsibilities.

> *I knew that [pharmacists] have already been implemented [in general practice] but I haven't really followed it … where does the pharmacist role come? For example, I don't know if they see the patient [together] with the GP or if they have their own room or like clinic or whatever where they can see patients.* (Pharmacist 28)

Participants attributed their limited awareness of the topic to a lack of formal publicity about the scheme. They reported, for example, that general practices had not informed community pharmacies about the integration of a pharmacist or the specific roles this pharmacist would undertake.

> *General practices never told community pharmacy teams that there's going to be a pharmacist integrated into them. It's just when we see a prescription that has a name and pharmacist prescriber [that we understand there is a pharmacist in a practice]. And then, there was one incident where the pharmacist [in general practice] actually phoned [us] for some information and that was the first time we knew that the practice had a pharmacist.* (Pharmacist 10)

Participants also reported receiving no information on the scheme from NHS England or pharmacy professional bodies, including upcoming rounds of recruitment, number of posts, job security matters or the longevity of the role. They said they were opportunistically updated on the topic via self-research, such as reading online documents including job applications, or through friends or family working in general practice.

> *There is not a lot of information about pharmacists in general practice out there. No General Pharmaceutical Council (GPhC) [the responsible body for regulating the pharmacy profession in England, Scotland and Wales] e-mails, nothing whatsoever. I think that if GPhC wants this [pharmacists' integration into general practice] to go through, they have to advertise it more. We have so little update from them!* (Pharmacy technician 8)

Participants highlighted the importance of being made aware of the presence of a pharmacist in a general practice so that they had some time to adjust and avoid awkwardness.

Table 2 Demographics of participants

	Total number interviewed	Years of experience in community pharmacy
Pharmacists	32	4 months to 44 years
Pre-registration pharmacists	8	2 to 5 months
Pharmacy technicians	8	1 to 30 years

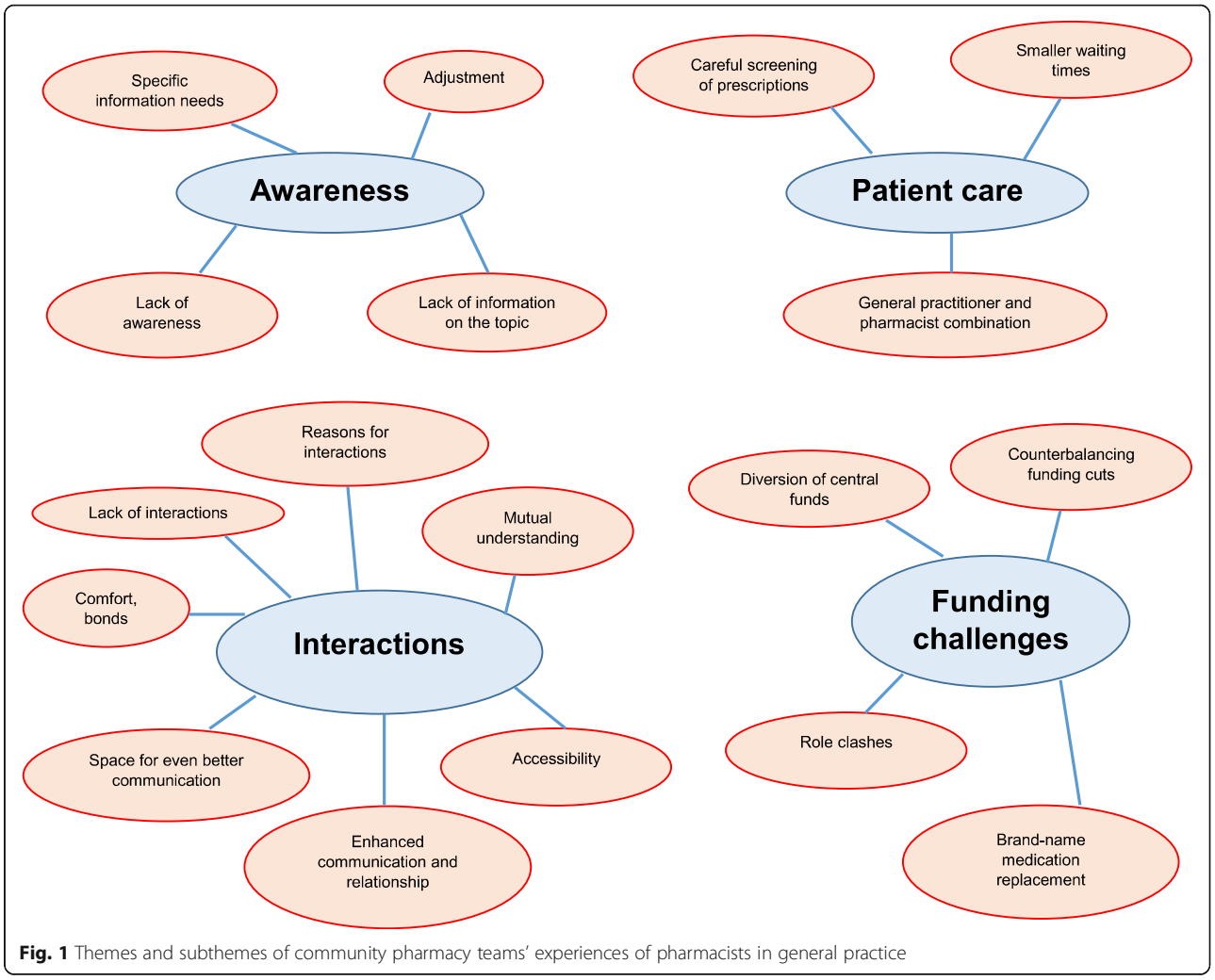

Fig. 1 Themes and subthemes of community pharmacy teams' experiences of pharmacists in general practice

It's like 'are we being told off'? But ultimately you'd just have to think that if it's to do with patient care and streamlining everything and making things quicker, as long as we're told that there's a pharmacist now employed [in a general practice] to do this and this. (Pharmacist 2)

Community pharmacy teams had specific information needs including the time scales for recruiting general practice-based pharmacists; the practices involved; the precise targets that a practice aims to achieve with the integration of a pharmacist; the benefits for the surrounding community pharmacies; and the times during which pharmacists are available in a practice, especially for pharmacists covering multiple practices.

Interactions

There were a few participants without any sort of interaction with a general practice-based pharmacist.

I know that some of our prescriptions come from a pharmacist prescriber in general practice. But I have never personally spoken to that person. (Pharmacist 31)

Queries and/or problems on prescriptions issued by general practices were the main reasons for interactions, usually over the telephone, between community pharmacy teams and general practice-based pharmacists. These queries included missing items on a repeat prescription, need for dose amendments and need for an alternative prescription if a product was out of stock.

[Community pharmacies] do dosette boxes [for storing scheduled doses for a patient's medications to aid adherence]. When there has to be changes in the dosette boxes, we speak to the general practice-based pharmacist. So, that's the main interaction we have: any prescription they [general practice-based pharmacists] issue, if there's a query in that prescription

like a dose amendment then we speak to them. (Pharmacist 1)

Participants emphasised their satisfaction about being able to speak to another pharmacist on the telephone when engaging with general practices. Community pharmacists, including pre-registration pharmacists, felt more comfortable and at ease speaking to another pharmacist than speaking to a GP. They attributed this feeling to intra-professional bonds that make interactions with somebody at the same level and with similar training easier.

When I call [doctors] there is a bit of clash and I just feel if I speak to a pharmacist [in general practice] it's so much easier. There is always that awkwardness between doctors and pharmacist. For example, I was once on the phone with a doctor and he said 'I have no time for this'. I would not say that to somebody. (Pharmacist 21)

Fellow pharmacists were thought to fully understand the business side of community pharmacy and its implications, as opposed to receptionists or GPs who have historically dealt with queries from community pharmacy teams.

It's great that I can pick up the phone and speak to a pharmacy member of [general practice] staff who understands what I mean by dosette or why I need a prescription. For example, you have ordered ten items for a repeat and [general practice] issue nine. Receptionists will say 'I will do it tomorrow or the day after, it's not urgent'. They don't realize it's popped in the dosette and it needs to go at the same time. Receptionists sometimes don't get these basic things because to them that's foreign stuff. But in the world of pharmacy that's just minor. (Pharmacist 20)

I'm just so pleased that there's a pharmacist professional in the general practice. I'm so happy about it because we speak the same language! GPs are so remotely unaware of many things [in community pharmacy]. (Pharmacist 3)

Participants also highlighted that it is easier to contact a pharmacist in general practice than a GP. Quick access resulted in resolution of queries and timely issue of prescriptions. The presence, therefore, of pharmacists in general practice was believed to reduce workload stress on community pharmacy teams by streamlining the dispensing process and avoiding multiple phone calls to practices.

I feel the pharmacist [in general practice] is more accessible than a doctor, because obviously doctors are very busy. For example, if I want to query a patient's dose [on a prescription issued by the practice] it's very easy to get through to a pharmacist. Because by the time we contact and get to a doctor and the receptionist is like 'The doctor is busy, I don't know when they can call you, it can be today, it can be tomorrow'. But with the pharmacist it is 'Okay, let's do this right now'. I get a quick reply, so it's very good. (Pharmacy technician 3)

Conversely, a few participants reported occasional difficulties in accessing the pharmacist in general practice, citing the absence of a direct line and variable availability. Moreover, said one participant, high workload pressures led general practice-based pharmacists to refuse to deal with more than one query at a time.

Participants thought pharmacists' presence in general practice has resulted in enhanced communication and better relationships between community pharmacies and general practices. For instance, practices with an integrated pharmacist were thought to more readily consider reports from community pharmacies, for example, investigating identified cases of hypnotics' overuse. In addition, they thought that GPs, who employed a pharmacist, were more likely to ask community pharmacists for guidance on prescribing.

There can be a real communication gap between surgeries and [community] pharmacies. This gap closes down having [a pharmacist] be part [of] that setting. And then the general practices that have a clinical pharmacist on site, they're always very welcoming and always more willing to help and communicate with a pharmacist that's calling out from the community because they appreciate [the pharmacist's] role. (Pharmacist 5)

One participant, however, mentioned that practices covered by the same pharmacist refused to handle prescription requests at times when pharmacists were not physically present in the practice. Participants also noted that there is still room for improved communication between community pharmacies and general practices. For instance, participants emphasised the importance of establishing face-to-face interactions and familiarity with general practice staff as a springboard for closer working relationships and mutual support.

I think the working relationships will improve a lot more if community pharmacy teams could actually face-to-face meet these people [general practice-based staff], with whom we speak on the phone. For

example, they could tell us what their problems are and we can see if we can make any changes to make their lives easier. And we can tell them what our problems are and they can help sort them out. At the end of the day you have one neutral person, the patient. (Pharmacist 19)

Patient care

Participants thought that the integration of pharmacists into general practice has led to improved satisfaction and better quality of care for patients. For example, faster processing of prescriptions meant shorter waiting times and enhanced safety, especially patients' ability to receive antibiotics and emergency medicines quickly.

Participants were confident that general practice-based pharmacists clinically screen all prescriptions before they are signed and forwarded to community pharmacies. They were not confident that screening happened when receptionists and GPs processed prescriptions. Careful screening was believed to identify prescription problems, such as incorrect doses, obsolete items and unsynchronised repeat medication. Screening could also identify unsatisfactory adherence, potential interactions and adverse effects that otherwise might have been missed.

General practice-based pharmacists pick up more than what the GP would, for example … if we request a prescription [from the practice], the receptionist puts the prescriptions down and then the doctor just rush-signs them whereas a pharmacist on site takes more time looking at things and realising that patients are actually overusing or underusing [medicines]. (Pharmacy technician 2)

GPs' skills in diagnostics combined with pharmacists' expertise in medications was perceived to be an ideal approach to patient care.

If I was a patient knowing that there is a GP and a pharmacist [in general practice], I would kind of automatically think 'Nothing can go wrong at the moment, two professions combining together that must be the correct thing for me'. (Pre-registration pharmacist 6)

Funding challenges

There were concerns that pharmacists' integration into general practice was associated with cuts in the funding of community pharmacies. Participants thought, without corroborating evidence, that there had been a diversion of central funds from community pharmacies to general practices to support the new role.

I know that there definitely have been cuts because I know some pharmacies have been closed down. So that is definitely true, but, where policymakers have actually put the money obviously no one knows. But because this is a new role, it makes sense that they're just kind of pushing funding all in there. (Pharmacist 12)

There were also fears that certain services traditionally carried out in community pharmacies could potentially be provided by general practice-based pharmacists, thereby negatively affecting the profitability of community pharmacies. Examples included MURs and other patient-facing services.

If, for example, general practices take on the extra responsibility of stop smoking or flu vaccination campaigns, then it is possible that some of the patients who would have normally come to my pharmacy will go to the practice for it. General practices have the capacity now to do these additional services because of an extra pharmacist. Financially, this would affect this pharmacy. If a general practice has done a smoking cessation service, they would get the registration fee, they would get the quit [compensation] and yet I would be providing the medication. So, all I get would be the cost of medication and nothing else. (Pharmacist 26)

Finally, the widespread use of generic medications because of the presence of general practice-based pharmacists meant reduced income for community pharmacies due to lower reimbursements.

I have personally seen a drop in our remuneration and it pinches you. This is because general practice-based pharmacists try and put more generics everywhere, if they can, because a lot of the drugs initially were all branded and now it's basically as many generics. So, it's less income [for us] because obviously the brands are a lot more expensive and increase our turnover overall. (Pharmacist 24)

To counterbalance funding reductions, participants claimed that they would have to increase over-the-counter medication sales, and pursue additional qualifications (for example, clinical diplomas) to increase the range of services they could offer.

Discussion

Findings indicate a lack of awareness amongst community pharmacy teams of various aspects of general practice-based pharmacy services. Conversely, improved communication has resulted in more timely and safer

patient care. The financial viability of community pharmacy, however, is still a concern. Despite these few concerns, the majority of participating community pharmacy staff did not oppose to the scheme and were supportive of pharmacists' integration into general practice.

The findings can be interpreted using the 'structuration model of collaboration' developed by D'Amour and colleagues [51]. This theoretical framework analyses intra- and inter-professional collaboration in healthcare. It consists of four dimensions, two of which (internalisation; shared goals and vision) examine relationships between professionals and two (governance; formalisation) that examine organisational aspects influencing collaboration.

If we take the dimensions that examine relationships between professionals, in the current study these would refer to the relationships between community pharmacy teams (participants) and general practice-based pharmacists. These two cohorts of people will be our collaborating parts of interest, which in the 'structuration model of collaboration' are described as the 'actors' in collaboration. To begin with internalisation (composed of trust and acquaintanceship), in our study, was obtained by intra-professional bonds between 'actors' and confidence that general practice-based pharmacists functioned as a safety net on prescriptions. Participants' sense of 'having one of them in general practice' was the element that bridged gaps between organisations (practices and pharmacies). Barriers to internalisation were participants' insufficient knowledge of roles and absence of face-to-face acquaintanceship between 'actors'. Participants conceptualised the dimension of shared goals and vision by quoting the benefit of the patient as the reason for both 'actors' to tighten relationships. It is unclear, however, whether or not 'actors' had the chance to explicitly communicate this goal since most mutual interactions were brief, non-face-to-face discussions on prescription matters. Potential failure of both 'actors' to focus on the interests of the patient could activate allegiances to personal interests (such as participants' keenness to defend their existing funding status) that could preclude mutual understanding.

Regarding organisational dimensions, formalisation (entailing how the clinical care is structured) was indicated in the way general practice-based pharmacists were easily accessible, often via direct telephone lines, which facilitated communication between 'actors'. The dimension of governance (leadership functions promoting collaboration) was illustrated in participants' eagerness to take the lead and secure relationships. Both organisational dimensions, however, were hindered by scarce official initiatives. For example, practices did not divulge pharmacists' integration which surprised participants who had limited time to adjust (including getting used to ways of offsetting income reductions). Some participants even ignored the presence of the other 'actor' making collaboration impossible. Additionally, lack of information from professional bodies hindered participants' understanding of the full benefits of the scheme and generated suspicions about role clashes.

Internationally, there are mixed views on collaboration between community pharmacies and general practice-based pharmacists. Studies in Canada and Australia have reported good relationships and mutual support [44, 45]. Other Australian studies, in contrast, have described community pharmacists' reluctance to collaborate or skepticism that pharmacists' integration might disrupt existing relationships between practices and pharmacies [42, 43]. In England, one study revealed significant tensions between community and general practice-based pharmacists stemming from professional hierarchy and competing, business-related interests [46]. Our findings, however, are predominated by positive experiences and contradict experimentally found or anecdotal frictions. A potential reason for the difference between our findings and those of the other English study is that their participants included general practice-based pharmacists not part of the scheme. Our community pharmacy-based participants had to deal with pharmacists in the scheme who might have been more willing and ready to collaborate with colleagues from community due to their training that includes mandatory sessions on how to build relationships with community pharmacies [52]. Indeed, a national survey of all pharmacists integrated into general practice in the first phase of the scheme highlighted increasing liaison with community pharmacies [9].

Implications

The study has several implications. There is a need to:

- Appropriately educate community pharmacy teams (for example, via shadowing opportunities) about general practice-based pharmacists' scope of practice and establish formal, regular meetings between community pharmacy and general practice staff.
- Update community pharmacy teams, in a timely and detailed manner, about any future framing of pharmacists' presence in general practice (such as expansion of presence or modifications in roles).
- Record the number of interactions with community pharmacies amongst the impact measures for general practice-based pharmacists.

- Establish direct telephone lines or bleepers for pharmacists covering multiple general practices.

Strengths and limitations

To our knowledge, this is the first study investigating community pharmacy teams' experiences of general practice-based pharmacists. The qualitative design allowed for an in-depth and thorough understanding of participants' views. The study captured the experiences of the whole team in community pharmacies as participants included pharmacists, pharmacy technicians and pre-registration pharmacists. Findings account for various levels of working experience in community pharmacy as well as different pharmacy types. Although findings primarily apply to the UK, individual elements will also inform international efforts to integrate pharmacists into general practice such as those in Australia, Canada, New Zealand, Netherlands and the USA.

A limitation of the study is that participants were solely recruited from one area. There might therefore have been additional views of community pharmacy teams in other areas, arising from different general practice-based pharmacists' employment models and roles. The inclusion, however, of a large number of participants ensured identification of a wide range of experiences. The findings are, therefore, not generalisable but many insights might be transferable to other similar settings. Although the presence of multiple interviewers might translate to some differences in the way interviews were conducted, the use of a common interview schedule provided standardisation in the depth and breadth of topics covered. Researchers followed a reflexive approach throughout data analysis and interpretation by ignoring any personal experiences. Some unavoidable personal assumptions during data categorisation might, however, still exist.

Conclusions

The current study revealed the potential impact of general practice-based pharmacists on community pharmacies. No significant perceived opposition, from community pharmacy teams, to the scheme was found. Beside benefiting patients and GPs, which was the main driver behind the scheme, pharmacists' integration into general practice has the potential to streamline the workload of community pharmacy teams and enhance their relationships with practices by enabling communication at a pharmacist-to-pharmacist level. This is an important outcome in light of the recently announced initiatives to better link general practice services with the rest of community healthcare services in the UK. Findings will therefore inform delivery of the NHS Long Term Plan, so that any framing of pharmacists' presence in general practice includes the needs of community pharmacies. Results will also assist any international policy that is setting out to integrate pharmacists into general practice on how to better integrate care through communication between general practice-based pharmacists and community pharmacies.

Abbreviations

GP: General Practitioner; GPhC: General Pharmaceutical Council; MUR: Medicine Use Review; NHS: National Health Service; NMS: New Medicine Service; PCN: Primary Care Network

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Authors' contributions

GDK, KR, NP and GS contributed to the study concept and design, data analysis and interpretation and writing of the manuscript. Students listed in the 'Acknowledgments' section collected the data as part of their final year project. All authors read and approved the final manuscript.

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Availability of data and materials

The datasets generated and analysed during the current study are not publicly available because that would compromise participants' anonymity and the researchers are still publishing findings. Datasets, however, are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

The study was submitted to and approved by the Research Ethics Committee of the School of Chemistry, Food and Pharmacy at the University of Reading (study number: 18/17). Informed, written consent was obtained from all individual participants included in the study.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Publisher's Note

CHAPTER 7. PATIENTS' EXPERIENCES OF PHARMACISTS IN GENERAL PRACTICE: AN EXPLORATORY QUALITATIVE STUDY

This chapter is the paper from the study which reports on patient experiences of general practice-based pharmacists, in the version accepted for publication in BMC Family Practice (Karampatakis, G.D., Patel, N., Stretch, G., Ryan, K., 2021. Patients' experiences of pharmacists in general practice: an exploratory qualitative study. BMC Fam. Pract. In press). Patients are amongst the most important stakeholders, as they are one of the cohorts most influenced by pharmacist integration into general practices. The fact that general practice-based pharmacist numbers kept increasing, with constantly changing employment models and responsibilities, further stimulated my interest to perform a study with patients and add to knowledge derived by previous research efforts. With this interview study, I set out to understand what works and what does not work with pharmacist presence in general practice for patients, with the ultimate goal to inform policy and practitioners on actions to be taken to improve pharmacist services. With this study, therefore, I answered the fourth and last objective of my research project. This objective aimed to elicit patient experiences of general practice-based pharmacists.

Author contributions are presented in the relevant section of the paper. Briefly, I contributed to the concept and design of the study, undertook data collection (i.e. I carried out all interviews with patients) and analysis and interpretation of data. I also wrote the manuscript, which was then annotated and approved by all authors.

Patients' experiences of pharmacists in general practice: an exploratory qualitative study

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Abstract

Background: Since 2015, pharmacists have been integrating into English general practices and more recently into primary care networks. General practice-based pharmacists provide a range of patient-facing services, such as medication reviews, management of long-term conditions and minor ailments, prescribing duties and answering queries over the telephone. Literature reports patients' satisfaction with general practice-based pharmacists' services, however, previous research captured only limited experiences. The aim of the current study was to pursue an extensive exploration of patients' experiences of pharmacists in general practice.

Methods: General practice-based pharmacists, working in practices in West London, Surrey and Berkshire, handed invitation packs to patients seen during consultations. Patients that wanted to take part in the study were invited to undertake a qualitative, in-depth, face-to-face, semi-structured interview within the practice with which each patient was registered. Interviews lasted from 15 minutes to more than one hour and were audio-recorded. Recruitment continued until data saturation. Audio-recordings were transcribed verbatim and transcripts analysed thematically.

Results: Twenty participants were interviewed. Four themes were discerned: awareness ("I had been coming to this practice for 24 years and I didn't know that there was a pharmacist"); accessibility ("People ring for a GP [general practitioner] appointment … it's Monday and they [receptionist] tells you 'We can slot you in on Friday' … with a pharmacist on board, they can [instantly] look at you"); interactions ("I've always had a really good interaction with them [pharmacists] and they listen and they take on board what I'm trying to say"); and feedback ("It's easier [to collect

feedback instantly] because I could have forgotten half of what they [pharmacists] have told me in an hour or so's time").

Conclusions: Findings indicate that pharmacists' integration into general practices could improve accessibility to, and the quality of, care received. The findings will assist policy development to provide general practice-based pharmacists' services as per patients' needs.

Keywords: pharmacists; general practice; England; patients; experiences; qualitative research.

Background

English general practices have been facing ongoing workload pressures stemming from an ageing population and reductions in the general practitioner (GP) workforce [1]. As a result, patients have been experiencing decreased access to primary care services, which has subsequently led to high levels of dissatisfaction [2-4]. To tackle these problems, and in parallel exploit the increasing numbers of qualified pharmacists [5, 6], there has been a wide drive to integrate pharmacists into general practices. Efforts to integrate pharmacists began with a two-phased scheme between 2015 and 2019, supported by the National Health Service (NHS), that introduced approximately 1,000 general practice-based pharmacists in England [7]. In early 2019, the NHS Long Term Plan was announced that urged general practices to form Primary Care Networks (PCNs) [8]. PCNs are collaborative entities linking primary care services with hospital, social care and voluntary sector organisations and covering populations between 30,000-50,000 people [9]. PCNs are expected to hire about 26,000 additional staff by 2023/24, including large numbers of pharmacists, with employment costs fully reimbursed by NHS England [10]. Each of

the approximately 1,260 PCNs is expected to have at least one pharmacist by 2020 [11]. The projection is that by 2023/24, a typical PCN will have about five pharmacists, raising the total number of general practice-based pharmacists across England to about 7,000 [12, 13]. A typical practice serving 10,000 patients is anticipated to have a pro-rata coverage by a pharmacist for 12 hours per week [12].

Official statistics from NHS England show that in September 2020 there were 1,582 full-time equivalent general practice-based pharmacists in England compared to 1,249 in September 2019, which translates to an increase of 26.7% [14]. Despite the increase in the total number of general practice-based pharmacists, approximately 50% of the general practices in England did not have a pharmacist in early 2020 [15]. In addition, only half of the PCNs recruited a pharmacist in 2019 [16]. By the end of June 2020, 24% of the PCNs were still to claim funds from NHS England to hire a pharmacist [17]. The proposed reasons as to why a significant proportion of PCNs have not recruited a pharmacist included insufficient numbers of appropriately qualified pharmacists for the posts, low pay grades that discourage pharmacists from taking posts in PCNs, uncertainty of PCNs on how to effectively use the skills of a pharmacist and the recent pandemic [15, 17, 18]. As a result, there are claims that the expected targets with regards to general practice-based pharmacists' numbers might be impossible to be achieved [15].

Common roles of English general practice-based pharmacists include face-to-face clinics with patients for structured medication reviews and long-term condition management; telephone consultations for minor ailments and triage; prescribing duties, for those qualified; and supporting staff in medication-related queries and meeting targets of incentive programmes [19-21].

Several countries have attempted to implement general practice-based pharmacists' services, including Australia [22], Canada [23], USA [24], New Zealand [25] and the Netherlands [26]. In the UK, having pharmacists in general practice is not an entirely new concept [27, 28]. This is the first time, however, that the role is being implemented to a large extent and so needs to be formally tested [29]. Little is known about how the presence of pharmacists in general practice impacts the wider healthcare system, including patients and healthcare professionals, and there have been ongoing calls for a thorough exploration of the role [30-32].

Existing literature, both nationally [33-39] and internationally [40-45], has offered some insights into patients' views of general practice-based pharmacists. Some of these studies elicited opinions before patients had any contact with a general practice-based pharmacist [44, 45]. Of the studies referring to views post contact with a pharmacist [33-43], most described the contentment of patients with pharmacists' presence in general practice as well as intentions to recommend pharmacists' services.

Previous research efforts in England, however, were conducted some years ago and were limited to specific geographical regions, hence unlikely to have accounted for the whole range of employment models and roles of general practice-based pharmacists. Additionally, the waves of pharmacists still being integrated into English general practices might translate to varying patients' experiences as a result of increasing exposure to pharmacists' services as well as to diverse skillsets of pharmacists. The aim of the current study was to pursue an exploratory approach and explore patients' experiences of general practice-based pharmacists in three different locations in England and therefore contribute to a more universal mapping of experiences. In particular, the current study set out to answer the following

research question: What are the patients' experiences and views of pharmacists working in general practice?

Methods

Study design

A realistic qualitative interview design was chosen to allow for an in-depth exploration of experiences, using interpretive thematic analysis.

Setting

Participants were recruited from large general practices located in West London, Surrey and Berkshire, targeted as recruitment points due to working connections with the research team's organisation. The West London practice, with a list of approximately 16,000 registered patients, has participated in the 'pharmacists in general practice' scheme since inception. This practice was composed of two sites and, at the time of the study, had 12 GPs, four nurses and three pharmacists. Pharmacists (in total) served approximately 170 patients per week, both through face-to-face and telephone sessions. Practices in Surrey and Berkshire were not part of the initial scheme but at the time of data collection they also employed pharmacists. The practice in Surrey was composed of a single site, had 16,000 patients registered and 13 GPs, two trainee GPs, five nurses and one pharmacist. The pharmacist dealt with approximately 100 patients on a weekly basis (both face-to-face and over the telephone). The practice in Berkshire consisted of two sites, had 14,000 registered patients and employed nine GPs, two nurses and two pharmacists. Pharmacists there served approximately 60 patients per week in total, both via face-to-face and telephone appointments.

Recruitment

A purposive sampling approach was followed to recruit people who have visited a pharmacist in general practice. General practice-based pharmacists, working in the above-mentioned practices, handed invitation packs to eligible patients they met during consultations. Patients were eligible if they were aged 16 years or over, English speakers and able to consent for themselves as determined by the recruiting pharmacist. Invitation packs contained the study's invitation letter; information sheet, providing details of the study and research team; consent form; reply form; and a business reply envelope. The study's documents asked potential participants to directly contact a member of the research team (GDK), either via email or by filling in the reply form and posting it within the pre-paid envelope. GDK is a doctoral research student with experience in qualitative research. Once interest for participation was expressed, GDK contacted potential participants and a mutually convenient time for the interview was arranged. No other reminders were sent. Recruitment continued until data saturation. The research team interpreted data saturation as the point in data collection at which no new information was discernable, also known as 'informational redundancy' [46-48]. When this point was reached, four more interviews were conducted before recruitment ceased.

Data collection

Recruitment and data collection took place between December 2018 and February 2020. Involvement in the study was voluntary and without monetary incentives. Audio-recorded interviews were conducted by GDK in private meeting or consultation spaces within the general practice with which each participant was registered. Just before each interview, mutual introductions took place to establish rapport and any questions that participants had were answered. In addition, the confidentiality of the interviews was highlighted by emphasising that discussions

could not be overheard by general practice-based pharmacists, that findings would only be discussed between the research team without any disclosure to pharmacists and that any data to be used in research outputs would be anonymised. All interviews were face-to-face and semi-structured. An interview schedule, consisting of some open-ended questions and prompts, was used. The interview schedule was developed exclusively for this study and can be found as an additional file (see Additional file 1). Interviews terminated only when participants did not have anything else to add. Interviews lasted from 15 minutes to more than one hour. Demographic information was collected at the time of interview.

Data analysis

Audio-recordings were transcribed verbatim half by GDK and half by a professional transcribing agency, a sub-set of the latter was checked for accuracy by GDK. Transcripts were analysed thematically by following the steps of Braun and Clark (data familiarisation, data coding, identifying themes, re-examining themes, defining and naming themes and synthesising the report) [49]. Data was inductively [50] coded by GDK with the aid of NVivo 11 software, and a single code was ascribed to every different idea. Coding was verified by the whole research team via debriefing meetings in which thorough discussions took place. Data under the same code was collated together and sorted into categories, which were then re-examined and collapsed into possible themes with associated subthemes. The research team collectively assessed, refined and named the themes, again during debriefing meetings. Participants' feedback on transcripts or findings was not sought.

Results

Twenty participants were interviewed in total. There was an equal proportion of male to female participants. All had some contact with a general practice-based pharmacist. Participants were from different age-groups but all were aged 40 years or older. Most were from a white British and other white backgrounds. Table 1 provides an overview of participants' demographics.

Table 1. Demographics of participants

	Age-group (years)	**Number of visits to the pharmacist in general practice***	**Ethnicity**	**Location from where participants were recruited**
Patients (n=20)	40-49 (n=2) 50-59 (n=5) 60-69 (n=5) 70-80 (n=6) 80+ (n=2)	1 to 12 times	White British (n=13) White Irish (n=3) Other White (n=2) Arab (n=1) Other Asian (n=1)	West London (n=7) Surrey (n=9) Berkshire (n=4)

*This does not include contact over the telephone.

Themes

Four predominant themes were discerned in the data: awareness; accessibility; interactions; and feedback. Figure 1 provides an overview of the themes and associated sub-themes.

[Insert Figure 1]

Theme 1: Awareness

Most participants claimed that patients were largely ignorant of the presence of pharmacists in general practice due to a perceived absence of relevant information material. They all realised by chance the existence of general practice-based pharmacists, just before or only at the time of consultation.

> *I had been coming to this practice for 24 years and I didn't know that there was a pharmacist here. It's possibly not my fault, they don't advertise, promote, they don't explain enough … I got a text [message] saying "make an appointment with the pharmacist"… [I was thinking] "What are they talking about"? "Where"?* (Participant 5)

There was also uncertainty, and often confusion, about the roles of general practice-based pharmacists and whether or not contact would be ongoing.

> *I still don't know why a patient would want to see a pharmacist in the general practice. I can't get my head around that. 'Cause if I want to ask the pharmacist something I go into the actual pharmacy. I'm not aware of the full extent of what they do.* (Participant 10)

Nearly all participants emphasised the need to promote the presence of pharmacists in general practice, to raise patients' awareness and therefore encourage the uptake of pharmacists' services. Numerous methods of promotion were proposed, such as television advertisements; messages on practice websites, social media accounts, waiting room screens and noticeboards, including introducing the pharmacist amongst the healthcare team photographs; posters and leaflets; and establishing visible consultation spaces for pharmacists.

Word of mouth was largely seen as an effective way to promote services, including through outreach activities and referrals.

> *I have three housemates registered in this practice and I can spread it by mouth, "You know that there's a pharmacist that attended to me today, they helped me a lot by giving me information".* (Participant 13)

> *If a GP feels "well, this particular problem would be better decided by a pharmacist" [then they should] refer. But that doesn't seem to happen very often.* (Participant 20)

Apart from the existence of general practice-based pharmacists, additional information needs of patients included the specific services offered by pharmacists; reasons to contact pharmacists; what is outside the pharmacist's remit; and the potential benefits of seeing the pharmacist.

Theme 2: Accessibility

General practice-based pharmacists were perceived, by several participants, to be readily available to take patients' queries over the telephone, in contrast to GPs who were much more difficult to contact.

> *The receptionist says "Oh yes, the [pharmacist is] in today. I'll just ask them to chat to you", and it's done within a day. Or the reception will say, "They're not in today but they'll be in tomorrow and I'll get them to call you".* (Participant 15)

Similarly, some participants claimed that there was far less waiting time with pharmacists' appointments, both with scheduling an appointment and in the waiting room. There were some suggestions that seeing the pharmacist should become the first stage when an appointment at the practice is required.

> *People ring for a GP appointment and they can be at death's door … [and] it's Monday and they [receptionist] tells you "We can slot you in on Friday". With a pharmacist on board, they can [see] you and if it's something more serious they would speak to the doctor. It's a faster system … you could have an 11 o'clock appointment for a GP and you won't be seen until 12-12.30. With the pharmacist, it may run over five minutes, it may be ten minutes but no more than that.* (Participant 1)

A few participants, however, reported occasional difficulties in getting appointments with pharmacists covering multiple practices, due to reduced availability and/or uncertainty about the exact days pharmacists were present in a specific practice. Likewise, one participant was frustrated not to directly be put through to the pharmacist, as phone calls were often returned at inconvenient times. Another one complained about pharmacists sometimes cancelling their appointments last moment. Some participants called for larger numbers of pharmacists, weekend sessions, appointments on the same day as GP appointments and availability of drop-in clinics.

Some participants mentioned that contact with the pharmacist should always be offered as a choice to the patient, in triage and online booking systems.

> *[Seeing] the pharmacist should be an equal opportunity [to the GP], a choice for patients. Even if you went through a telephone screening… [also] to have an online booking system which would incorporate the pharmacist.*
> (Participant 3)

Theme 3: Interactions

The vast majority of participants emphasised the high quality of the interactions they had with general practice-based pharmacists. They reported that their consultation with a pharmacist was a two-way interactive process. Pharmacists were believed to treat patients as equal fellow-speakers, rather than passive recipients of instructions, and to welcome patients' thoughts and questions.

> *I have colitis [and] I have a suspicion that it is triggered by sugar. I tried to have a discussion with the doctor but they didn't want to discuss it, they just said, "There is no research on that at all". At my last meeting with the pharmacist here, I mentioned it to them. They had a really useful discussion with me about it. And I came away feeling that I had been listened to. I felt that I had an informed and adult discussion. With the doctor, often they treat you like children "the doctor knows best, this is what you're gonna [do]".* (Participant 2)

The perceived absence of hierarchies and judgemental approaches by nearly all participants made them feel at ease with pharmacists and established mutual familiarity and relationships.

> *Well sometimes when you come to the doctor, I am always conscious of the time and I don't waffle. I don't just waste the doctor's time … So, there's a certain level of anxiety, stress ... I found that with the pharmacist there was a less judgemental attitude, they were very approachable, immediate, very easy to talk to.* (Participant 6)

> *The pharmacist, I've seen them once and I feel like I've known them for a long time. That's unusual ... I know the pharmacist's name. That's the difference.*

I've seen loads and loads of doctors here, more than once, and I don't know their names. (Participant 3)

Pharmacists, several participants claimed, visually connected with patients during consultations, which they took as an expression of being paid attention to.

They [pharmacist] looked me straight in the eye and I think sometimes if you're not looking at someone, you're probably wandering with your mind, whereas, they were concentrating on me. (Participant 12)

Many participants emphasised the caring attitude of pharmacists, which they attributed to fewer time-constraints compared to GPs.

They [pharmacists] are very dedicated in what they do, they're empathetic … the doctors, once the ten minutes are up, they stand up [and] you haven't even finished and you have to go. I hate that. I think that's dreadful. (Participant 8)

Several participants claimed that, as a result of longer appointment times, pharmacists were thorough in their approach, including concomitantly managing multiple co-ailments and developing structured care plans.

I had a new set of blood tests done which showed that my cholesterol levels had increased … They [pharmacist] went through my lifestyle, diet, exercise, where I live … They were thorough … [and] set a good plan to go forward, [to] have a review after three months and see how we go … I [also] had some twitching in my calf muscle, they weren't quite sure what it was, so they saw one of the GPs in the practice and chased it through with them. (Participant 7)

One participant, however, was afraid that pharmacists occasionally exceeded competency and requested more referrals to specialist care.

Pharmacists were reported, by several participants, to always review every single medication patients had, regardless of whether they related to the presenting complaint.

> *The [pharmacist] went through my list of other medications [as well] and dismissed the ones that I didn't really need to keep on my repeat because I wasn't having them … They said "Let's take them off because if you do need them in the future, they can be put back on again". No GP has ever said that to me before. So, you can see how older people just have this long list of medications that they may, if they don't realise, still be taking.* (Participant 17)

Nearly all participants emphasised the information/explanation that pharmacists provided, including the analytical way this was conveyed, which was seen to allow patients to fully understand their medication or condition and convince them to accept the pharmacist's advice.

> *The [pharmacist] has given me some reading material to take away with regards to possible injection [for my diabetes]. They showed me with a dummy pen how it would be administered. So, yeah, it was very informative. They took the time to actually explain [everything]… the book of information, they took the time to actually go through the pages, give a brief outline, how it may or may not influence me.* (Participant 14)

Conversely, a few participants stated that pharmacists should consider potential side effects of medications upfront (rather than trailing different medications) and explain everything about medications without having to be prompted. One participant

mentioned that pharmacists should also consider alternative therapies, such as natural substances and homeopathic remedies. Another participant was disappointed about pharmacists not recording condition-/medication-related history, hence having to re-provide these details in subsequent consultations.

All participants left consultations with pharmacists feeling confident, reassured and with peace of mind that their problems had been resolved.

> *My fear was that the medical people were going to keep pushing statins at me, regardless of my side effects. But they [pharmacist] said, "Look, we won't try any more". So, I was reassured by the fact that I'm not going to be pushed statins forever and I feel completely reassured that my interests are being properly looked after in terms of prescribing medication.* (Participant 11)

> *A lot of doctors made me feel quite a hypochondriac … with the pharmacist, you feel a sense of security after leaving them.* (Participant 1)

Theme 4: Feedback

Some participants doubted if patient feedback on general practice-based services was taken seriously into consideration.

> *Usually the feedback, the result of that doesn't go back to the people … Is that [feedback] making any difference, is that making any improvement? Did anybody read it? Has it been put in practice?* (Participant 4)

There was no consensus amongst participants on the preferred way to collect patient feedback on general practice-based pharmacists. Various means were proposed, such as face-to-face interviews; questionnaire forms, either as hard copies or online, including using tick-boxes or rating scales or human faces mirroring satisfaction

level; and politely reporting concerns directly to pharmacists. Most participants stated that the overall process of feedback provision should be quick, to encourage participation. As such, participants claimed, any feedback collection tool should be short in length.

The majority of participants also stated that feedback should be collected straight after consultations.

> *It's easier [to collect feedback instantly] because I could have forgotten half of what [the pharmacist] told me in an hour or so's time. I'd go "What did they say about my tablet"? … So, [it would be good] to get at me [for feedback] quickly afterwards, while I remember things.* (Participant 19)

> *The public wants [to give feedback] right at the time they are having the consultation … because if they give [a form] to you, then you go back to your office and you set it down and two or three days later you have more things piled up and you never send the feedback.* (Participant 5)

Discussion

Findings indicate that patients are unaware of pharmacists' presence in general practice and/or unclear when to contact pharmacists. When they do interact with general practice-based pharmacists, however, patients highly appreciate the quality of care they receive. Some ways to enhance the availability of pharmacists and collection of patient feedback were suggested.

The findings of the current study could best be interpreted in light of 'scientific realism', which views 'realities' in the contemporary world as meanings constructed by human minds [51, 52]. The key feature of 'scientific realism' is the element of explanation, which is illustrated in the slogan question of 'what it is within a

programme that works or does not work well, for whom and under what circumstances' [52, 53]. The correlation between 'scientific realism' and our findings lies in the fact that the current study identified strengths and limitations with pharmacists' presence in general practice, as viewed by patients, through an exploratory approach that sought to understand in-depth the reasons of why certain aspects with pharmacists in general practice work or do not work for patients.

More simply, elements with pharmacists' presence in general practice that 'work' for patients include pharmacists' availability, providing that pharmacists do not cover many practices and patients consciously seek pharmacists' care; and the high standard of interactions, which lead to positive emotions and a strong relationship between patients and pharmacists, and occur when there are no time-pressures during appointments. In contrast, the aspect with pharmacists in general practice that 'does not work' for patients is the existence of multiple information needs, due to the absence of relevant information, which limit the uptake of pharmacists' services.

Below, findings are related to pre-existing literature whilst also taking into account current 'social' circumstances which could affect patients' satisfaction with aspects of pharmacists' presence in general practice.

Comparison with existing literature and realistic discussion

The current study highlights the limited awareness of pharmacists in general practice amongst patients. Previous UK research has also reported unawareness due to absence of relevant communication from practices, including patients not realising that they had a consultation with a pharmacist, and confusion between community and general practice-based pharmacists' roles [34, 38]. Post publication of previous studies, our findings imply that there is still no clear direction (either at a central or

local level) to inform the wider public about general practice-based pharmacists' existence, what services they provide and how to access them.

Participants who consciously sought access to general practice-based pharmacists' services found pharmacists more accessible than GPs, something that has also been widely reported in literature [34, 36-38]. Our findings indicate that pharmacists' integration into general practices could fulfil the aim of offering patients smoother access to healthcare services and checks, however, the achievement of this goal is largely hindered by patients' unawareness of the presence of in-house pharmacists in practices. Moreover, a few of our participants reported difficulties in accessing pharmacists covering multiple practices, a phenomenon also noticed by patients in Australia [42]. Open-ended questions remain about accessibility to pharmacists in the future. Firstly, because pharmacists in PCNs are expected to work across multiple practices [12, 21] and secondly, because as awareness improves and demand increases, consultation times are likely to decrease. In addition, increasing numbers of remote consultations over the telephone (following the coronavirus pandemic) [54] might restrict pharmacists' ability to respond to patients' queries.

Our findings around the long duration and thoroughness of pharmacists' consultations repeat those of previous studies [33-42]. The novelty of our study, however, is that it also offers insight into the dynamics of interactions between patients and general practice-based pharmacists. These dynamics can be discussed using King and Hoppe's '6-function model' [55], which is a consensus-derived framework using six key functions to understand 'good approach' in patient-practitioner encounters (see Table 2 for an overview of the model).

Table 2. Overview of the '6-function model', analysing 'good approach' in patient-practitioner interactions

Function of interaction	Brief description
Fostering the relationship	Refers to establishing rapport and connection between practitioner and patient.
Gathering information	Refers to collecting as much information as possible from the patient to understand their needs from the encounter.
Providing information	Refers to offering information to the patient to facilitate understanding.
Decision making	Refers to enabling patients' deliberation and decision making, including developing action plans.
Enabling disease- and treatment-related behaviour	Refers to fostering self-management of the patient.
Responding to emotions	Refers to showing empathy and assisting patients in developing positive emotions.

In our case, the function of 'fostering relationships' was achieved by suppressing hierarchies/judgements and maintaining eye contact that established a welcoming environment for patients and generated mutual bonds. The function of 'gathering information' was illustrated by pharmacists' keenness to "listen to the patient" and constant effort to collect details on condition or lifestyle or medications, thereby avoiding unwarranted conclusions and leaving patients feeling that they had been heard. 'Providing information' was mirrored in the detailed explanations, including using graphic and/or descriptive means. 'Decision making' was indicated by the absence of pressure on the patient to follow certain treatments and the development of structured care plans. 'Enabling disease- and treatment-related behaviour' was obvious in the better understanding of medications patients developed post contact

with the pharmacist. The ‘responding to emotions’ function was obvious in the caring attitude and reassurance offered by pharmacists, and the opportunity for patients to speak freely and express their concerns. Therefore, all key functions of patient-centric communication were witnessed in our findings. The absence of time constraints contributed to the ability of pharmacists to interact at this high level during consultations. It is unclear through our findings, however, whether any skillset of pharmacists (different from those of GP’s) also had some role to play.

Last but not least, our study offered insight into patients’ preferences with regards to feedback collection. To help action these insights, the patients could themselves be involved in determining what type of feedback is required, how it is collected and information disseminated. There is ample literature describing involvement of patients at various stages in research, such as in designing research priorities, questions, methods, protocols and study documentation as well as in data collection, analysis, interpretation and dissemination [56-60]. Patient and public involvement (PPI) often links with positive outcomes, such as practical improvements in healthcare services (ranging from informational material for patients to changes in the delivery of services and the behaviours of healthcare staff), increased participation rates in studies and additional layers of understanding of research data [56, 58, 61-64]. Despite the described benefits, PPI attempts in research are not extremely common in the general practice setting due to limited resources and fears of complicating projects [65]. However, patient participation groups (PPGs) in general practices are an easy way of accessing PPI and could be actively involved in designing and implementing a patient-friendly feedback mechanism on general practice-based pharmacists’ services. Our findings could act as a starting point to involve PPGs in feedback collection.

Strengths and limitations

The qualitative design used in the current study allowed for an in-depth understanding of patients' experiences. The study was carried out at general practice settings diverse in terms of location and integration of pharmacists, hence the experiences captured are reflective of some different models of employing pharmacists in general practice and varied exposure of patients to pharmacists. Despite the limitations of ethnicity and age in the sample (see below), sufficient data saturation was achieved to offer findings a conceptual depth. We are confident, therefore, that findings synthesise a wide (if not the whole) range of potential experiences of patients at the specific recruitment points. Findings primarily apply to the UK reality, however, individual elements will still be useful for international attempts to integrate pharmacists into general practices.

We did not set out to include a representative sample of the population in terms of age, ethnicity and region of domicile. Participants were recruited only from three practices in the south of England. As a result, findings might not be fully generalisable but can provide insights that could be extrapolated to other similar settings. Moreover, participants who volunteered for interviews mainly included white and older people, hence findings do not offer a good representation of younger age-groups and black and ethnic minorities who may have different experiences. It could be that older patients are most likely to face polypharmacy and other medication-related problems and so use pharmacists' services, hence why younger patients were missing from our sample. The fact that interviews were carried out inside general practices might have introduced some biases in the responses of participants, due to a potential fear that pharmacists would learn about participants' views. We believe, however, that the mutual trust established between the

interviewer and participants and the reassurance about the confidentiality of the study encouraged the expression of honest views, hence making it very unlikely that findings would have significantly differed if interviews were carried out outside general practices. Although the research team followed a reflexive approach by ignoring personal experiences and collectively analysing data, because they are all pharmacists, some unavoidable instances of personal assumptions during data categorisation might still exist.

Implications

The specific implications of the current study are that there is a need to:

- Appropriately educate patients and the public about general practice-based pharmacists, including roles and responsibilities.
- Ensure pharmacists are present in the practice for an adequate amount of time each week, ideally on a daily basis, and explicitly communicate rotas to patients by also establishing an effective triage system to prevent exhaustion of pharmacists' resources.
- Secure the prerequisites for efficient interactions with patients, for example, adequate appointment lengths.
- Design a formal, quick and attractive feedback mechanism for patients.

Future studies should employ maximum variation sampling to include experiences of patients from different ethnicities, ages, educational levels and regions of domicile in the UK. Future studies should also include developing additional measures to more thoroughly explore the added value pharmacists bring in general practice settings and co-designing pharmacists' services with the public, including developing

interventions to satisfy information needs with regards to pharmacists in general practice.

Conclusions

The current study indicates that pharmacists' integration into general practice has the potential to enhance the timely access to, and quality of, services in primary care. Practitioners, including pharmacists themselves, can use our findings to enhance their own practice by improving patient-centred interactions during consultations. More importantly, findings will inform delivery of the NHS Long Term Plan on how to make best use, from a patient perspective, of general practice-based pharmacists and will also assist practices when attempting to promote the benefits of having a pharmacist. Results will also guide international policy about integrating pharmacists into general practices, including how to design and evaluate patient-centric services.

List of abbreviations

GP: General Practitioner

NHS: National Health Service

PCN: Primary Care Network

PPG: Patient Participation Group

PPI: Patient and Public Involvement

Declarations

Ethics approval and consent to participate

The study was submitted to and approved by a NHS Research Ethics Committee, in particular the Yorkshire & The Humber - Leeds West Research Ethics Committee, and the Health Research Authority (Research Ethics Committee's reference number: 18/YH/0347, Integrated Research Application System Project ID: 241663). Informed, written consent was obtained from all individual participants who were interviewed.

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated and analysed during the current study are not publicly available because that would compromise participants' anonymity and the researchers are still publishing findings. Datasets, however, are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

GDK, NP, GS and KR contributed to the idea and design of the study, data analysis and interpretation and synthesising the manuscript. Interviews were conducted by

GDK. GS, along with the general practice-based pharmacists listed in the 'Acknowledgements' section, recruited the participants. All authors read and approved the final manuscript.

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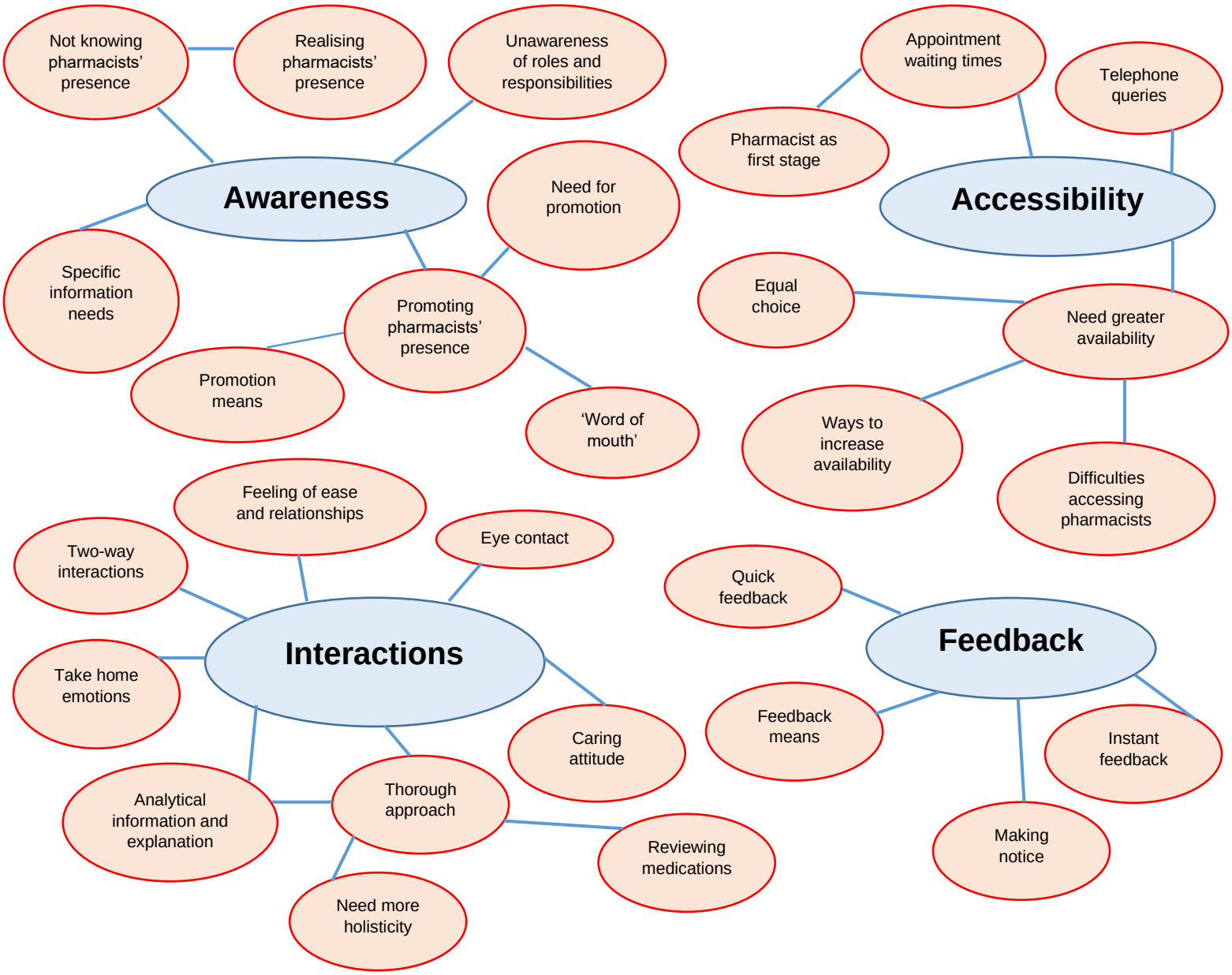
Figure 1. Themes and subthemes of patients' experiences of pharmacists in general practice.

Additional file 1

Format: Microsoft Word document (.docx).

Title of data: Interview schedule

Description of data: This additional file consists of a table that presents the interview schedule developed and used in this study.


Not knowing pharmacists' presence
Realising pharmacists' presence
Unawareness of roles and responsibilities
Awareness
Specific information needs
Need for promotion
Promoting pharmacists' presence
Promotion means
'Word of mouth'
Appointment waiting times
Telephone queries
Pharmacist as first stage
Accessibility
Equal choice
Need greater availability
Ways to increase availability
Difficulties accessing pharmacists
Feeling of ease and relationships
Eye contact
Two-way interactions
Interactions
Take home emotions
Caring attitude
Analytical information and explanation
Thorough approach
Reviewing medications
Need more holisticity
Quick feedback
Feedback
Feedback means
Instant feedback
Making notice

Additional file 1. Interview schedule

Intro (setting the stage)	Questions	Closing
• Introduce myself • Explain the aim of the study • Explain the process (highlight confidentiality) • Answer questions the participants might have • Ask participants to sign the Consent Form • Collect demographics • Explain that the word 'service' means consultation, or other means of contact, with a pharmacist in the surgery • Switch on the recorder (after gaining permission) – start the interview	• Tell me about your experiences of consulting the pharmacist in the general practice Prompts: a) What did you like about the service? b) What you didn't like about the service? c) What can be improved with the service? How? d) What additional expectations/needs do you have from the service? e) What other preferences do you have in the way the service is offered (e.g. access to the service)? • How do you think pharmacists in general practice could be better accepted by patients? Prompts: a) What do you know about patients' awareness of the service? b) How should the service be best promoted to patients? • Tell me about how would you prefer to give feedback on the service? Probes: • Please give me an example of that. • Please tell me a bit more about that. • Please be a bit more specific about that. • What do you mean by that?	• Ask participants if they have anything else to add (then stop recording) • Inform them how they can reach the research team if they have more questions • Thank them – let them know how helpful they have been

CHAPTER 8. DISCUSSION AND CONCLUSIONS

8.1. Summary of findings

My research revealed numerous problems pharmacists face when attempting to identify their impact in general practice, mainly arising from the inappropriateness of the national KPIs present at the time of my research in explicitly demonstrating the benefits of pharmacist integration into general practices. A number of activities were identified as important to systematically record within the framework of capturing pharmacist impact in general practice. My findings also indicate that community pharmacy staff and patients are largely unaware of pharmacist presence in general practice and/or uncertain about their roles and responsibilities. When they do liaise with general practice-based pharmacists, however, community pharmacy teams see a potential for streamlined workloads and enhanced relationships with nearby practices. Likewise, when patients seek access to pharmacists in general practice, they find it easier to get an appointment (either for face-to-face or telephone contact) with a pharmacist than with a GP. In terms of their actual consultation with general practice-based pharmacists, patients perceive receiving high quality care characterised by efficient and holistic interactions with them.

8.2. Mechanisms, contexts and outcomes

General practice-based pharmacists, community pharmacy teams and patients are the main stakeholder groups whose experiences were explored in my research. An account of GP, general practice-based manager and pharmacy technician views was also taken, however, these stakeholder groups were asked to comment on what works or does not work for pharmacists rather than for themselves. This discussion follows the main premise of realism, by describing what ‘works’ and what does ‘not

work' with pharmacist presence in general practice, for whom and under what circumstances (as evidenced in my research findings). Table 11 provides an overview of the configurations of mechanisms, contexts and outcomes, developed to best explain my research findings.

Table 11. Mechanisms, contexts and outcomes, developed to best make sense of research findings

	What works well	What does not work well
General practice-based pharmacists	• Quantifying activities at local level (M) + Systematic recording, appropriate codes (C) = Impact identification (O) • Funding-related codes (M) + Smooth recording process (C) = Acceptance by general practice-based pharmacists (O) • Building relationships with different teams (M) + Willingness from the other side (C) = Unifying patient care, enhancing scope of services (O)	• KPI inappropriateness (M) + Practices adhering to KPIs (C) = Disappointment and frustration with KPIs (O) • Inability to show difference on KPIs (M) + Practices adhering to KPIs (C) = Fears and suspicions about being measured (O) • Lack of patient awareness, wrong triage (M) + positive views not recorded (C) = Resistance expressed in patient surveys (O)
Community pharmacy teams	• 'Pharmacist-to-pharmacist' communication (M) + Awareness, easy accessibility (C) = Links with practices, smooth workload (O)	• Income reductions (M) + Lack of awareness, misconceptions (C) = Opposition to pharmacists in general practice (O)
Patients	• Pharmacists readily available (M) + Awareness, not multiple practice coverage (C) = Quick access to practices (O) • Two-way, patient-centric interactions (M) + Absence of time pressures (C) = Relationships, positive emotions (O)	• Multiple uncertainties and information needs (M) + Lack of relevant information (C) = Inability to effectively uptake pharmacist services (O)

M: Mechanism; C: Context; O: Outcome

Consideration of Table 11 shows that there are several elements to working in general practice that do 'not work' for the pharmacists themselves. For example, pharmacist disappointment and frustration with the KPI system are a result of the available measures not being fit for purpose in specifically targeting pharmacist work and capturing the depth and breadth as well as the quality of services. The continuous inability of pharmacists to show a positive difference in KPIs generated fears of being measured and suspicions that there is something more sinister behind

the existence of KPIs, for example, comparisons between individual pharmacists. A prerequisite, however, for the activation of these negative attitudes is that practices actually adhere to the national KPIs, which is not always the case as studies have shown that many practices have disengaged from national KPIs and use a plethora of alternative measures (Hampson and Ruane, 2019; Mann et al., 2018). In addition, pharmacists confront resistance and dissatisfaction in patient surveys, following inefficient triage (i.e. the referral to pharmacists of patients with needs unable to be satisfied by pharmacist skills) and inappropriate patient expectations of pharmacists. Adverse patient stances predominate when there are no mechanisms to ensure widespread collection of feedback to capture the whole spectrum of patient opinions and to record views expressed informally (e.g. via ‘thank you’ notes).

On the other hand, aspects of general practice that do ‘work’ for pharmacists include quantifying pharmacist activities at a practice level, which can effectively indicate impact by implying diminishing GP involvement in various tasks within the practice. A requirement, however, for activity quantification to successfully occur is that pharmacists systematically record their activities, which in turn necessitates the availability of appropriate activity codes. Activity codes describing funding-related tasks are those which are most likely welcomed by pharmacists, providing that the recording process in not laborious and/or distractive from patient care. Providing there is mutual willingness for collaboration, pharmacists appreciate the opportunity to act as a common point of reference and link various teams, thereby unifying patient care and enhancing the scope of external services (such as the MURs and waste management services offered by community pharmacists).

Communication at ‘a pharmacist-to-pharmacist’ level, characterised by mutual understanding and bonds, is the element of pharmacist presence in general practice

appreciated most by community pharmacy staff. As a result of these high level interactions with general practice-based pharmacists, community pharmacy teams experience a streamlined workload due to faster processing of prescriptions and stronger relationships with practices from a feeling of ‘having one of them’ at the other end. Necessary conditions for this communication are that community pharmacies are aware of the existence of in-house pharmacists in practices and are able to easily contact them. This requires general practice-based pharmacists to be available to respond to queries from community pharmacies via the existence of direct telephone lines. Occasionally, community pharmacies oppose the idea of having pharmacists in general practice from fear of losing business. These fears are triggered when staff in community pharmacies are surprised by the presence of pharmacists in general practice and/or fail to understand the benefits for their daily work.

General practice-based pharmacists are ‘more available’ than GPs, a feature that translates to shorter waiting times for patients when access to professional help is required. Necessary prerequisites, however, include patients seeking access to pharmacist services, which in turn entails awareness of pharmacist presence in practices and of how to arrange contact with them. Prerequisites also include pharmacists not covering a large number of practices, which inherently reduces their availability to patients. During consultations with pharmacists, patients experience two-way interactions guided by the principles of patient-centric communication and free of hierarchies and barriers. As a result, patients develop close relationships with pharmacists and express positive emotions, both at the time of consultation and later. According to patients, a facilitator that enables pharmacists to interact at this high level are longer appointment times (compared to overburdened GPs).

Subsequently, the absence of time pressures could be deemed as the catalytic context in which these effective interactions between pharmacists and patients occur. Effective uptake of pharmacist services in general practice, however, is mitigated by the various information needs of patients, including uncertainties about pharmacist roles and remit. Insufficient awareness obviously occurs when and where there is absence of relevant material to inform and update patients on the topic of in-house pharmacists in practices.

8.3. Realist discussion

As with any programme in society, the landscape of pharmacist presence in UK general practices has consistently been changing since inception of the initial scheme. For example, the monetary amounts invested, the way in which expenses for integrating pharmacists are funded and the numbers, employment models and duties for general practice-based pharmacists are all characteristics that have been in constant flux. In addition, the recent coronavirus pandemic has hugely influenced priorities in healthcare at all levels and delivery of healthcare services. Subsequently, elements of pharmacist presence in general practice, disfavoured by certain stakeholders at the time of my data collection, might have progressively transformed to areas of satisfaction, and vice versa. Although hard to attribute the exact social circumstances at any given time, an attempt will be made below to articulate some of the current factors that might influence the outcomes of pharmacist presence in general practice as presented above.

General practice-based pharmacists were dissatisfied with the use of KPIs. Following the introduction of PCNs, however, there have been updates in the measures for capturing the impact of healthcare services in PCNs. Mainly generic,

non-pharmacist specific measures have been proposed, focusing on structured medication reviews, enhanced health in nursing homes and cancer detection (NHS England, 2020b, 2019d). Some of the proposed measures are similar to the ones at the time of my research (e.g. ‘number of medication review processes undertaken’ or ‘prescribing rate of anti-microbial medication’) whereas others are entirely new (e.g. ‘number and proportion of people living in a nursing home who receive a delirium risk assessment’ or ‘the quality of shared decision making conversations’). Moreover, as illustrated in my literature review, there is inconsistency in how pharmacist impact is identified between different practices across the UK. Subsequently, there are undoubtedly digressions from the initial set of KPIs, which could well have suppressed pharmacist disappointment and resistance in places. Questions remain around the effectiveness of measures used by different practices, especially since a recently published study (not included in my literature review) found that pharmacist skills are often underutilised and/or poorly understood by their employer practices (Duncan et al., 2020). Additional questions remain around how any measurements carried out locally could be aggregated and appraised at a national level. Ideas could be drawn from Ireland where a very recent study centrally collated various data (such as pharmacist-recorded amount and type of medication changes and cost-related data, along with health-related outcomes reported by patients) to evaluate a small-scale pilot of integrating pharmacists into general practices (Cardwell et al., 2020). Although harder to obtain, due to the magnitude of efforts and diversity in models, it is not impossible to accumulate nationwide data on the impact of general practice-based pharmacists in the UK.

A basic problem with the national KPIs, used at the time of my research, was their inability to target pharmacist work. Identifying the specific pharmacist contributions is

an ongoing and persistent challenge, bearing in mind that boundaries between healthcare professions are becoming increasingly blurred following the NHS intention to establish ‘skill-mix’ in primary care (Kamara and Moulds, 2020; Nelson, 2019). The difficulty in identifying specific pharmacist contributions in multidisciplinary environments has been reiterated in the literature (Mossialos et al., 2013). Intra-professional boundaries between pharmacists in different sectors are also disappearing due to consistent efforts to expand pharmacist roles, which have further been intensified following the coronavirus pandemic. Characteristic examples include schemes to expand the clinical responsibilities of community pharmacists, via extensive referrals from A&E and general practices (Warner, 2019; Wickware, 2019c); re-registering with the General Pharmaceutical Council (i.e. the regulator for pharmacy profession in England, Scotland and Wales) 6,000 pharmacists and pharmacy technicians, who had voluntarily opted out of the register within the last three years, to support the national response to the pandemic (General Pharmaceutical Council, 2020); transforming community pharmacies into hubs for triage and self-care promotion (to minimise access to secondary care), including enabling annotation of electronic clinical records as well as supply of controlled drugs and issuing of repeat prescriptions without a prescriber’s input (Hymas, 2020; Slawther, 2020a, 2020b); and a drive to use pharmacists from across all sectors (such as CCG, general practice-based and specialist hospital pharmacists) as urgent care providers in nursing homes, a setting largely influenced by the pandemic (Burns, 2020; NHS Specialist Pharmacy Service, 2020). It is therefore obvious that pharmacist roles tend to become intertwined with those of other pharmacists, with no monopolies in tasks, as pharmacists from diverse settings are being brought to work side by side and share roles and responsibilities. As a result, the invention of ways to

separate the impact of pharmacists from that of other professionals within the general practice setting, as proposed in Chapter 4, still stands. Lack of clarity, however, remains as to whether and how the impact of general practice-based pharmacists could be teased out from that of other pharmacists. Identifying the impact of pharmacy as a profession, rather than differentiating between settings, is a potential approach to follow from now on.

Mainly funding-related pharmacist tasks were favoured for recording to demonstrate impact. A potential reason for the preference for funding-related activity codes is that their use by default attracts income for practices, thereby demonstrating pharmacist impact right away. As expenses in the general practice setting still outweigh earnings and despite the increases in investments over the last few years (British Medical Association, 2020), attitudes towards the usefulness of funding-related codes in showing pharmacist impact are unlikely to change. In contrast, preliminary suggestions (in my focus group study) about recording general practice-based pharmacist interactions with community pharmacies as well as activities relating to medicinal waste, MURs and nursing home presence were later contradicted in the e-Delphi study, as factors complicating the recording process (for various reasons reported in Chapter 5). The suggested activity coding scheme for healthcare professionals in PCNs, however, includes codes related to nursing home input, for example, fall risk assessments for residents. Moreover, as already mentioned, the recent pandemic increased the pharmacist role in nursing homes, hence recording general practice-based pharmacist impact in this setting is now even more relevant. It is worth also noting that medication reviews, which were amongst the activities for which consensus was reached in my e-Delphi study, are also included in the proposed activity codes in PCNs. Interestingly, monitoring of high-risk drugs and

medicines reconciliations, also amongst the consensus codes in my e-Delphi, are not part of the recommended activity coding scheme in PCNs.

Simply quantifying the activities of healthcare professionals does not necessarily mirror the quality of the performed tasks, unless these activities have been found to translate into positive health-outcomes (Donabedian, 1988). Capturing the quality of healthcare services is not a simple matter, as quality is multidimensional and requires a plethora of appropriate measures (Mainz, 2003). Quality in healthcare is associated with desired health-related outcomes and care consistent with latest professional knowledge (Institute of Medicine (US) Committee on Quality of Health Care in America, 2001). It is important, therefore, not just to measure numbers of general practice-based pharmacist activities but also invent ways to identify the quality of the tasks performed.

An important pharmacist contribution to the general practice setting is the connection between different teams, providing there is willingness from both sides. Community pharmacy teams, as indicated in my findings, favour collaboration with general practice-based pharmacists. Another recent study, not part of my literature review, similarly reported that Northern Irish community pharmacy teams are collaborating with pharmacy colleagues in general practice and eager to further tighten their mutual relationships (Barry et al., 2020). Barry et al., however, also described community pharmacy team confusion about their own responsibilities versus those of general practice-based pharmacists and some fears about income reduction, hence further necessitating the relevant education of community pharmacy teams about pharmacist presence in general practice (as pointed out in Chapter 6). Apart from community pharmacy staff, the readiness of other teams (e.g. occupational therapists and physiotherapists, paramedics, dieticians, smoking cessation services,

district nurses etc.) to liaise with general practice-based pharmacists is unclear, as this was outside the scope of my research project.

General practice-based pharmacists have to confront the lack of awareness amongst patients, something that hampers effective integration into general practice and uptake of their services. Patient unawareness of the presence of pharmacists in general practice and their roles has been reiterated in the literature (Mann et al., 2018; Ryan et al., 2018). My study with patients also confirmed limited awareness, which was further stressed in a recent paper not included in my literature review (Savickas et al., 2020). General practice-based pharmacists also face difficulties in receiving representative patient feedback. Patients, in my last study, were still unclear as to how to provide feedback on pharmacist services. As this study with patients was chronologically a few years away from my first study with general practice-based pharmacists, it is obvious that the lack of patient awareness and universal feedback collection are persistent and ongoing problems. As a result, claims about raising patient awareness of general practice-based pharmacists and refining a formal feedback mechanism on pharmacist services (as outlined in Chapters 4 and 7, respectively) are still highly valid.

One highlighted element of pharmacist presence in general practice is that they are easily accessible to community pharmacy teams and patients. There are several factors, however, that could negatively influence accessibility to general practice-based pharmacists. First, the coronavirus pandemic has led to consultations mainly being offered digitally to minimise instances where patients have to physically attend the practice (Baird, 2020). Professionals in general practice are therefore currently overwhelmed with telephone and video calls as well as emails (Practice Business, 2020). This demand could reduce general practice-based pharmacist availability to

respond to queries from community pharmacies and patients over the telephone, as well as patient ability to get appointments with pharmacists in person. Second, since the introduction of PCNs, pharmacists tend to serve multiple general practices, something that inevitably translates to less time for physical presence at individual practices. Coverage of multiple practices, moreover, was very recently found to be associated with increases in pharmacist workloads (Savickas et al., 2020). Workloads might increase further in the future as a result of increasing demand, assuming a progressively rising awareness of general practice-based pharmacist presence and services amongst community pharmacy staff and patients. Fewer hours in a practice, combined with higher workloads, are additional limiting factors in pharmacist availability. Therefore, suggestions about maintaining accessibility to general practice-based pharmacists, as presented in Chapters 6 and 7, are more topical than ever.

Prospective increases in demand and workloads could shorten the duration of general practice-based pharmacist appointments. The impact on patient-centric interactions and subsequent satisfaction, which were also the case with general practice-based pharmacist consultations in Ireland recently (James et al., 2020), is unclear. In addition, it is unclear whether or not high quality interactions occur via a computer screen, which appears to be the main means of contact between patients and general practice-based pharmacists at the moment. Measures that will capture the contributions of general practice-based pharmacists to the pandemic and account for alterations that the pandemic has brought to tasks (e.g. increases in remote contact with patients) are also worth considering.

8.4. Implications

My research project has various implications for policy, practice and research. A few important points, which will complement and summarise what has already been presented in Chapters 4, 5, 6 and 7, will be highlighted below.

8.4.1. Implications for policy

Despite the various investments and schemes to build the healthcare workforce in the last decade, in 2019, the NHS was found to be short-staffed by approximately 100,000 professionals across the health and care sectors (NHS Providers, 2019). In primary care, especially, there is an ongoing shortage of GPs, at least 9,000 in late 2019 (Bostock, 2019). The projection is that the shortage of GPs will not end soon and using non-medical professionals is the only way to tackle workforce gaps (Campbell, 2019). Numbers of general practice-based pharmacists and their roles can only increase in the future. For realists, as already mentioned, the success or failure of any social programme is directly dependent on uptake and satisfaction amongst its people. All my findings are based on the experiences of stakeholders. They can therefore inform development of policy to frame the expanding presence of pharmacists in general practices according to needs and expectations of stakeholders, thereby facilitating the maintenance of areas of success and rectification of areas of failure.

In particular, my findings indicate that there is a need to:

- Adopt measures that will capture the depth and breadth, as well as the quality, of pharmacist services in general practice and ultimately across the whole PCN structure.

- Ensure that measures are tailored to pharmacist work, to separate the impact of pharmacists from that of other professions, and also up-to-date with modifications and evolution in pharmacist tasks.
- Prioritise activities associated with funding for general practices, such as medication reviews and monitoring of high-risk drugs, in case uniformity in activity recording is desired/sought.
- Develop a formal, patient feedback mechanism for general practice-based services that will ensure a widespread identification of views.
- Design an organised strategy to raise the awareness of patients and community pharmacy staff, including details of any initiative to expand pharmacist presence in general practice; roles and responsibilities; reasons for and benefits of contacting general practice-based pharmacists; and work rotas of pharmacists in each practice.
- Maintain easy accessibility to pharmacists in general practice for community pharmacy teams and patients, mainly by ensuring the availability of pharmacists in individual practices for adequate amounts of time.
- Guarantee adequate length for appointments with general practice-based pharmacists to foster patient-centric approaches.

8.4.2. Implications for practice

The biggest contribution of my findings to practice is that they act as a paradigm for pharmacists, and other clinicians too, on how to enhance their own practice during consultations. At a time when patient expectations of NHS services are consistently rising (Duffy, 2018), employing patient-centric approaches is of vital importance. My research project will also enlighten pharmacists and other professionals about how to improve their inter-professional collaborations and relationships, hence gradually

meeting NHS expectations about multidisciplinary care in PCNs. Last but not least, findings will guide general practice-based pharmacists and other pharmacists in PCNs on what are the likely problems with identifying their impact, how to overcome them and how to align their activity recording processes with activities widely deemed as integral parts of the pharmacist role.

8.4.3. Implications for research

Future studies should focus on refining and/or expanding the number of configurations of mechanisms, contexts and outcomes associated with pharmacist presence in general practice, by using larger cohorts of stakeholders. Pursuing additional data, especially in the fluctuating social context, will result in greater insights as to why certain elements with pharmacist presence in general practice work or do not work, hence offering an even better understanding of the integration of pharmacists into this setting. For example, additional research could be done to determine:

- Whether general practice-based pharmacist dissatisfaction with impact identification measures is a universal phenomenon.
- What measures exactly are being used in each practice.
- Whether and how some measures at individual practices could be tested and applied at a national level.
- How working relationships between different sectors in PCNs are developing, for example, between practices and pharmacies.
- Whether and how accessibility to general practice-based pharmacists is maintained.

- Whether demand has had any effect on the quality of interactions during consultations.

In addition, co-designing general practice-based pharmacist services with stakeholders is another area for future research, including developing and improving impact identification measures; designing materials to satisfy information needs of the various stakeholders; and designing interventions to enhance accessibility to and quality of pharmacist services. Last but not least, it is important to obtain some quantifiable, independent measures (e.g. improvements in clinical parameters for long-term conditions, such as BP for hypertension patients, HbA1c for diabetics, pulmonary function tests for asthmatic patients; time-savings for GPs; and cost savings or income attraction for practices), which in combination with qualitative data will more thoroughly map pharmacist impact in general practice.

8.5. Strengths and limitations

I have captured the experiences of multiple stakeholder groups who examined strengths and limitations of pharmacist presence in general practice from different angles and perspectives. As a result, my findings are inclusive of many different dimensions of general practice-based pharmacist impact on the healthcare system. The multi-method design used means that my research followed what Greene described as ‘meaningful engagement with and dialogue between different lenses’ (Greene, 2002). Findings are therefore based on rich data offering an in-depth understanding of stakeholder experiences. Specifically, the focus group study allowed for a discussion of the specific impact measurement problems that people in the general practice-based pharmacist role actually face, including the specific implications of the problems. The e-Delphi study enabled the formation of

measurable consensus on the activities of importance to record, following many mixed opinions on the subject. Individual interviews, in turn, enabled a thorough exploration of patient and community pharmacy staff experiences, including areas of dissatisfaction and frustration. Whenever possible to achieve, data saturation was pursued and determined the end of the study, hence ensuring that the whole range of possible experiences in the particular study's setting was identified. Where saturation was not possible or applicable, exploration terminated when data obtained was insightful enough to support 'the building' of the evidence of impact (to speak in 'realistic' terms). Thematic analysis, which was used to process the qualitative data, offered the ability to follow a well-structured approach to data handling, summarise a large dataset and produce an organised and clear report that accounted for both prevalent viewpoints as well as non-prevalent or unanticipated insights and nuances in data. Thematic analysis also enabled me to present my findings in a simple way, understandable by different audiences, as well as to make my findings vibrant by including illustrative quotations. The number of stakeholder groups involved was determined based on what was practical and realistic for me to do within tight timelines. My findings are reflective of the actual impact of pharmacists in general practice due to their explorative nature and their account of subjective experiences, since causality (i.e. why something happened) and subjectivity are the main inherent features of 'impact' in healthcare (Ellis, 2015; Harding, 2014).

Bearing in mind the magnitude of pharmacist expansion in general practice across the UK, my research project was restricted to limited geographical locations. Therefore, there could be additional experiences and views arising from the inconsistency in general practice-based pharmacist models in terms of employment, roles/responsibilities and patient exposure to general practice-based pharmacist

services. Subsequently, findings will not be fully generalisable but many elements will be applicable to a range of similar settings. There were no senior commissioning stakeholders amongst my participants, which might mean that some valuable viewpoints regarding the identification of pharmacist impact were not captured. The presence, however, of a large number of general practice-based pharmacists with varied levels of experience (some were even established in general practice far before the introduction of the scheme) ensured that findings are credible in representing the actual challenges, facilitators and preferences concerning identification of pharmacist impact in general practice. The presence of multiple student interviewers in the study with community pharmacy staff might arguably generate concerns relating to different interview techniques (i.e. doubts about the degree to which different areas, upon which the reported findings were based, were explored by different interviewers) and so their overall quality. The various measures taken (inclusive of training-see section 3.3.3.3. for details), however, maximised standardisation between interviews and minimised the chances for inappropriate interview techniques that could have negatively affected the quality of the collected data. Moreover, the fact that transcripts from the interviews with community pharmacy staff were analysed by myself, rather than the undergraduate students, further ensured standardisation in the way data was understood, interpreted and reported. Despite its benefits (see above), thematic analysis has the drawback that it has an inherent subjective feature (i.e. the development of categories and themes has undoubtedly the researcher's 'mark'), hence meaning that another researcher could have developed alternative categorisations in data. The consistent attempts for reflexivity, however, by concentrating on the data, ignoring personal experiences and working collaboratively with the rest of the research team (see also section 3.5.1.2.)

minimised the possibility that any inter-researcher variability in categorisations would have offered contradicting insights and conclusions. As it happens with any programme in society, the whole landscape of pharmacist presence in general practice is constantly changing, hence some elements of my findings might no longer be fully valid. All my research actually offers is a snapshot of pharmacist presence in general practice at a given time. Elements of this snapshot, however, could be appropriately employed as a means of realisation of future efforts to integrate and expand pharmacist presence in general practice. My research was solely based in the UK (i.e. international patients and experts that could have brought additional insights into the topic of pharmacists in general practice were not included), hence findings primarily applying to the UK reality. Individual elements of my findings, however, can still be extrapolated to international efforts to integrate pharmacists into general practices.

8.6. Conclusions

My research project adds another ‘stone’ to the ‘building’ of evidence for the impact of pharmacists in general practices. My project revealed many elements of pharmacist presence in general practice, including the specific problems with impact identification, what activities are important to systematically capture and the experiences of community pharmacy teams and patients. My findings indicate that by integrating pharmacists into general practices, it is possible for the NHS to establish effective collaborations between different settings in healthcare, establish a smoother workload for pressurised community pharmacies, enhance patient accessibility to primary care services and enable patient-centric approaches in primacy care. Questions, however, remain around how to effectively identify the impact and the quality of the various services offered by general practice-based

pharmacists, as national measures so far have not been fit for purpose. Continuing success with pharmacist presence in general practice is contingent on the various social circumstances and should not be taken for granted. The advent of an international pandemic has reinforced the need for multidisciplinary healthcare teams and research-based improvements to the organisation and delivery of healthcare services, which need to be highly adaptable to rapidly changing needs. Efforts should therefore be made to maintain the conditions that trigger strengths with pharmacist presence in general practice. My findings will inform delivery of the NHS Long Term Plan, especially on how to foster relationships between general practice-based staff and remote teams, how to make best use of pharmacists in PCNs including from a patient perspective and how to promote the benefits of pharmacist services to maximise their uptake. Likewise, findings will assist pharmacists in their efforts to successfully integrate into primary care teams and enhance their day-to-day practice to meet expectations of their employers and the public. Internationally, elements of findings will be also useful and guide establishment and evaluation of pharmacist presence in general practices.

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DATA AVAILABILITY STATEMENT

As per ethics applications, raw datasets from the first three studies (i.e. transcripts from the focus groups with general practice-based staff, panellist responses in the e-Delphi rounds, and transcripts from the interviews with community pharmacy teams) will be retained for five years and then deleted. As also indicated in Chapters 4, 5, 6 and 7, these datasets from the first three studies are available from the authors on reasonable request. Raw data from the last study with patients (i.e. transcripts from the patient interviews) has been uploaded to the University of Reading Research Data Archive and can be accessed via http://dx.doi.org/10.17864/1947.297.

APPENDICES.

Appendix 1. Ethics application documents for the focus group study

School of Chemistry, Food and Pharmacy
Research Ethics Committee

Application Form for Internal Approval

SECTION 1: APPLICATION DETAILS

1.1

Project Title: Developing Key Performance Indicators (KPIs) for pharmacists in general practice.

Date of Submission: 09/11/2016 Proposed start date: 01/12/2016 Proposed End Date: 01/06/2017

1.2

Principal Investigator: Professor Kath Ryan

Office room number: 1.05D Internal telephone:

Email address: Alternative contact telephone:
(Please note that an undergraduate or postgraduate student cannot be a named principal investigator for research ethics purposes. The supervisor must be declared as Principal Investigator)

Other applicants

Name: Dr Nilesh Patel Staff/~~Student~~ (delete) Institution/Department: Reading School of Pharmacy. Email:

Name: Dr Wing Man Lau Staff/~~Student~~ (delete) Institution/Department: Reading School of Pharmacy. Email:

Name: Georgios Dimitrios Karampatakis ~~Staff~~/Student (delete) Institution/Department: Reading School of Pharmacy. Email:

….

1.3

Project Submission Declaration

I confirm that to the best of my knowledge I have made known all information relevant to the SCFP Research Ethics Committee and I undertake to inform the Committee of any such information which subsequently becomes available whether before or after the research has begun.

I understand that it is a legal requirement that both staff and students undergo Criminal Records Checks when in a position of trust (i.e. when working with children or vulnerable adults).

I confirm that a list of the names and addresses of the subjects in this project will be compiled and that this,

together with a copy of the Consent Form, will be retained within the School for a minimum of five years after the date that the project is completed.

Signed…… (Principal Investigator) Date:……

… (Student) Date: ……

…… (Other named investigators) Date:……

…… (Other named investigators) Date:……

1.4

SCFP (Internal Approval) Ethics Committee Applications

Projects expected to require review by the SCFP Ethics Committee must be reviewed by a member of the School research ethics committee and the Head of School before submission.

Signed…… (Chair/Deputy Chair of School Committee) Date:……

Signed…… (Head of Department) Date:……

Signed…… (SCFP Ethics Administrator) Date:……

SECTION 2: PROJECT DETAILS

2.1

Please provide a summary of the project in **non-specialist terms** that could be understood by **non-scientist members of the public**, which includes a description of the scientific background to the study (existing knowledge), the scientific questions the project will address and a justification of these. Please note that the description must be sufficient for the committee to take a reasonable view on the likely scientific rigour and value of the project

The concept of having pharmacists employed within general practices is being explored in some countries of the developed world in order to improve patient safety and reduce burden on general practitioners (GPs) (Tan et al., 2014). In the UK, NHS England along with Health Education England, the Royal College of General Practitioners and the British Medical Association's GP Committee are working in close collaboration with the Royal Pharmaceutical Society on a four year pilot to test the role of clinical pharmacists working across numerous sites. At present the pilot covers 698 general practices supporting over 7 million patients within England (Snow-Miller, 2015). Having a clinical pharmacist in GP practices means that GPs can focus their skills where they are most needed, for example on diagnosing and treating patients with complex conditions. Determination of the success of the pilot will depend on how it is evaluated. The pilot is expected to be evaluated using national and local Key Performance Indicators (KPIs) so that success and learning is identified and reported. National KPIs have already been set up (Snow-Miller, 2015). However, as yet NHS England has not put forward a formal evaluation strategy; thus this study aims to determine for two pilot sites in West London (Ealing and Hammersmith) which KPIs are important to measure and what the activities to measure for each KPI should be. Evaluation of the pilot project is important as this will inform whether there will be a nationwide expansion of integrating pharmacists within GP practices in the future. After the KPIs have been determined, pharmacists' activities followed under each KPI and the specific coding to be used for each activity will be defined.

References:

- Snow-Miller R. (2015) Clinical Pharmacists in General Practice Pilot. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/07/clinical-pharmacists-gp-pilot.pdf (accessed 10.13.16).
- Tan EC, Stewart K, Elliott RA, George J. (2014) Pharmacist consultations in general practice clinics: the Pharmacists in Practice Study (PIPS). Res. Soc. Adm. Pharm. 10(4): 623–32.

(*This box may be expanded as required – **Word Limit Maximum 250***)

2.2

Procedure

Please describe concisely what the study will involve for your participants and the procedures and methodology to be undertaken (*you may expand this box as required*).

A qualitative semi-structured focus group approach will be followed to obtain people's opinions and perceptions about the KPIs. Pharmacists and GPs directly involved in the pilot sites (Ealing and Hammersmith) will be recruited as participants. The study will be divided into two parts over a two hour period:

During the first part of the study, which will last approximately 1 hour, a Power-point presentation will be given by the researcher (Karampatakis). It will remind the participants why the evaluation of the pilot is important, what the KPIs at national level are and why it is important to decide what the local KPIs will be. In addition, this session will outline the importance of reaching an agreement regarding the activities that will be monitored and how these will be coded to aid data collection (this data collection will be part of a separate study). The researcher will explain the nature of his role, build rapport with participants and highlight the fact that his work will not monitor their individual work activities but aid them in recording data, a requirement of the pilot project. The researcher will actually collect all data for them (during the pre-mentioned separate study). Participants will have the opportunity to ask any questions and put forward ideas for discussion before participating in the focus group itself.

The second part of the session will be a focus group or two, depending on the number of participants, to enable them to freely express their own ideas for discussion by the group. Focus group will be conducted by Karampatakis. If two groups are needed, the second one will be conducted by one of the researcher's supervisors (Patel), and the two groups will be conducted concomitantly in different rooms. Participants will be asked to sign a consent form prior to the focus group. When signing the consent form, each participant will be allocated a unique participation number by the researcher. The researcher will talk as little as possible during the focus group, simply adding prompts to keep the discussion on topic. The focus group will last approximately one hour and be audio recorded. The main purpose of the focus group will be to obtain consensus on which KPIs to use for the two particular pilot sites investigated. Although the main researcher does not have previous experience in conducting focus groups, he undertook appropriate training at the University of Reading from staff experienced in focus group techniques.

The findings from the focus group will then lead on to a Delphi study which will enable agreement of activities and their respective coding. A separate ethics application will be made for the Delphi study in due course.

(Note: All questionnaires or interviews should be appended to this application)

2.3

Where will the project take place?

The focus group will take place in an independent venue away from the GP surgeries. The location of this venue is yet to be decided and confirmed.

2.4

Funding

Is the research supported by funding from a research council or other *external* sources (e.g. charities, business)? Yes

If Yes, please give details:

The research is supported by a University of Reading Postgraduate Studentship which is half sponsored by the Ealing GP Federation. Although the Federation is directly interested in the research, it will not have any sway over the results at any stage.

Please note that *all* projects (except those considered as low risk, which would be the decision of the School's internal review committee and require Head of Department approval) require approval from the University Research Ethics Committee.

2.5

Ethical Issues

Could this research lead to any risk of harm or distress to the researcher, participant or immediate others? Please explain why this is necessary and how any risk will be managed.

Participants will need to devote around two hours of their active working time to participate in this session. No monetary incentive will be provided. All possible precautions will be taken to limit the impact on participants' work. For this reason a mutually convenient day and time for participants will be arranged. Participation will be voluntary and every attempt will be made not to exceed the time-limit of two hours for the whole session. Consent for the seminar will be implied by attendance. Written consent will be obtained before voluntary participation in the focus group. All information obtained via the focus group will be anonymised and kept secure on password protected computers and in locked filing cabinets at the University of Reading. To maximise the researcher's safety and ensure that the objectives of the focus group are met, at least one of the supervisors will be present throughout the session, and step in if necessary. A debriefing with the supervisors will follow the focus group.

(*this box may be expanded as required*)

2.6

Deception

Will the research involve any element of intentional deception at any stage (i.e. providing false or misleading information about the study, or omitting information)?

No

2.7

Payment

Will you be paying your participants for their involvement in the study?

No

2.8

Data protection and confidentiality

What steps will be taken to ensure participant confidentiality? How will the data be stored?

Confidentiality and privacy will be ensured for all participants. No personal information will be collected and the data will be only used for scientific and educational purposes. Participants will be asked for their permission to record the focus group. The researcher will use a digital audio-recorder. Each participant in the focus group will be allocated a unique number, upon providing written consent. Any names that participants potentially mention

during discussions will be anonymized when the focus group is transcribed and the research written up. All voice recordings obtained during the focus group will be stored on the researcher's University password protected computer. After transcription is completed, all voice recordings will be deleted. Transcripts will be stored on a University shared drive accessible only by the researcher and supervisors. All hard copies of the transcripts will be stored in a locked filling cabinet at the University of Reading.

2.9

Consent

Please describe the process by which participants will be informed about the nature of the study and the process by which you will obtain consent

An e-mail will be sent to all participants by Stretch (lead pharmacist of the Ealing pilot site) describing the aim of the study and inviting participation. The email will have attached the invitation letter, participant information sheet and the consent form. The participants will have at least 24 hours to decide whether they want to participate in the focus group or not. Potential participants will be able to ask questions, by e-mailing Stretch or the researcher (Karampatakis) before agreeing to participate. Attendance at the seminar session will imply consent for that. The researcher will verbally explain the study again prior to the focus group to ensure that the participants understand everything that they are consenting to and that all questions have been answered. In addition, the researcher will explain to the participants their rights not to answer any questions that cause distress or to withdraw from the study at any time without giving a reason. The respective parts of the transcript, mentioned by participants who withdraw, will be destroyed and not used in the research. Written consent will be obtained before the beginning of the focus group and stored alongside the transcripts in a locked filing cabinet at the University of Reading.

2.10

Genotyping

Are you intending to genotype the participants? Which genotypes will be determined?

No

SECTION 3: PARTICIPANT DETAILS

3.1

Sample Size

How many participants do you plan to recruit? Please provide a suitable power calculation demonstrating how the sample size has been arrived at or a suitable justification explaining why this is not possible/appropriate for the study.

This study will invite participation from all pharmacists and relevant GPs working in the general practice surgeries that are part of the two pilot sites (Ealing and Hammersmith). Overall, it is expected that up to 12 pilot site pharmacists and 3 GPs collaborating in the pilot will participate in the study. From the participants recruited we would obtain a broad range of possible viewpoints to build the list of potentially suitable KPIs.

3.2

Will the research involve children or vulnerable adults (e.g. adults with mental health problems or neurological conditions)?

No

3.3

Will your research involve children under the age of 18 years? **No**

Will your research involve children under the age of 5 years? **No**

3.4

Will your research involve NHS patients, Clients of Social Services or will GP or NHS databases be used for recruitment purposes?

No

3.5

Recruitment

Please describe the recruitment process and append all advertising and letters of recruitment.

This study will invite participation from all pharmacists and relevant GPs working in the general practice surgeries that are part of the two pilot sites (Ealing and Hammersmith). An e-mail will be sent to all participants by Stretch (lead pharmacist of the Ealing pilot site) describing the aim of the study and inviting participation in the seminar and focus group. The email will have attached the invitation letter, participant information sheet and the consent form. The participants will have at least 24 hours to decide whether they want to participate in the study or not. For those participants who do not come back to Stretch or to Karampatakis, a follow-up, reminding e-mail will be sent, once, by Stretch. The researcher will verbally explain the study again prior to the focus group to ensure that the participants understand everything that they are consenting to and that all questions have been answered. In addition, the researcher will explain to the participants their rights not to answer any questions that cause distress or to withdraw from the study at any time without giving a reason. Information collected from participants who withdraw will be destroyed and not used in the research. Written consent will be obtained before the beginning of the focus group and stored alongside the transcripts in a locked filing cabinet at the University of Reading.

University of Reading

Professor Kath Ryan
Professor of Social Pharmacy
Reading School of Pharmacy
Whiteknights
Reading, RG6 6AP

Reading School of Pharmacy
Whiteknights, PO Box 226
Reading , RG6 6AP, UK
phone
fax

Invitation letter

1st December 2016

Dear Sir/Madam

Re: "Developing Key Performance Indicators (KPIs) for pharmacists in general practice"

I am writing to ask if you would be willing to participate in a focus group aiming to define the KPIs for the Ealing and Hammersmith pharmacists in general practice pilot sites. This will then enable general consensus over how the pilot sites should be evaluated and reported to NHS England. The study will be divided into two parts; part one will remind participants about KPIs and provide further information about the purpose of the focus group, which will be part two. The main purpose of the focus group will be to gather a consensus on which KPIs to use for the pilot sites. The whole event is anticipated to last no more than 2 hours.

This study has been approved by the School of Pharmacy Research Ethics Committee. The attached Participant Information Sheet contains further detail to help you to decide whether or not you wish to take part. Details will be provided by email about the exact day, time and venue for the study in due course.

If you would like to take part in our study, please contact Graham Stretch:
or George Karampatakis: so that we can arrange attendance for the focus group.

Should you require any further information regarding the project, please do not hesitate to contact me

Thank you very much for your time.

Yours sincerely,

Kath Ryan

Professor of Social Pharmacy
Reading School of Pharmacy

Project team:
Supervisors: Kath Ryan, Nilesh Patel, Wing Man Lau, Graham Stretch
Student: George Karampatakis

University of Reading

Participant Information Sheet

Study Title: Developing Key Performance Indicators (KPIs) for pharmacists in general practice

We would like to invite you to participate in this study and thank you in advance for taking the time to read this leaflet. Before you decide to take part, we would like to offer you more information about the study.

Background

The pharmacists in GP practices pilot is expected to be evaluated using national and local Key Performance Indicators (KPIs) so that success and learning is identified and reported. National KPIs have already been set up, but as yet NHS England has not put forward a formal evaluation strategy.

What is the purpose of the study?

This study aims to determine for two pilot sites in West London (Ealing and Hammersmith) which KPIs are important to measure and what the measures for each KPI should be. After the KPIs have been determined, pharmacists' activities that will be followed under each KPI and the specific coding to be used for each activity will be defined. These steps will enable the measurement of what the outcomes of pharmacists' activities are and audit them against the agreed KPIs.

Project Design

The study will involve a briefing session with pharmacists and GPs involved with the two pilot sites. The briefing session will remind the participants why the evaluation of the pilot is important, what the KPIs at national level are, and why it is important to decide what the local KPIs will be. In addition, the session will outline the importance of reaching an agreement regarding the activities that will be monitored and the respective coding for them. The session will then be followed by a focus group to gather possible KPIs that could be used as targets for these two particular pilot sites. These sessions will be conducted by a PhD student from the University of Reading. There are no right or wrong answers to any of the discussions. The information gained from the focus group will be analysed according to the topics you raise and will ultimately help us understand what KPIs are important and how to evaluate them.

Who is organising and funding the study?

The University of Reading is the main organiser. The study is funded by a University of Reading Postgraduate Studentship which is half sponsored by the Ealing GP Federation.

Why have I been invited?

You have been invited because you are either working as a pharmacist or GP within the Ealing and Hammersmith pilot sites.

University of Reading

Do I have to take part?

There is no obligation to participate. If you would like to participate in this project, please contact Graham Stretch or George Karampatakis so that we can arrange attendance for the focus group.

Graham Stretch:
George Karampatakis:

What will happen if I take part?

Once you have confirmed your interest, a time and place will be arranged for attendance of the focus group. There will be a briefing session followed by the focus group, which will last in total 2 hours. Before commencing the focus group you will be asked to sign a consent form. In doing so, you will be confirming that you understand the information in this leaflet and that you have agreed to take part. The focus group will be based around the topic of KPIs. You may refuse to answer any questions you do not want to answer. With your permission, we would like to voice record and transcribe your contribution to help us carry out a full analysis of the information we collect. You can withdraw from the study, and have your data destroyed, without consequence, at any time prior to data analysis by phoning one of the supervisors listed below.

What are the possible risks of taking part?

Potential risks and discomforts associated with this project are minimal. The focus group has been designed to avoid raising any personal or sensitive issues. You may refuse to answer any question if at any point you feel uncomfortable, without any consequence to you. In the unlikely event that topics arise that might cause you distress, you are free to terminate your participation without giving a reason and without any consequence. Just inform George Karampatakis, either face-to-face during the focus group or by e-mailing afterwards.

What are the possible benefits of taking part?

It is unlikely that you will gain personal benefit from taking part in this study, however, you might find that reflection on certain topics is useful to your professional practice. The results of the study should help to identify KPIs and their respective activities to measure outcomes of pharmacists' activities.

Will my taking part be kept confidential?

Yes, all information will be anonymous, confidential and used solely for this study. With your permission, the focus group will be audio recorded on a voice recorder and transcribed into a Word document. Voice recordings will be stored on the PhD student's University password protected computer. After transcription is completed, all voice recordings will be deleted. No names or any other details that might identify you will be included in the transcripts. Transcripts will be stored on a University shared drive accessible only by the PhD student and project supervisors. As per the University of Reading procedures all hard copies of the transcripts along with the consent forms will be stored in locked filling cabinets at the University of Reading and will be accessible only by the PhD student and the project supervisors. The transcripts and consent forms will be stored for 5 years and then destroyed. Although the consent forms will require you to give your

name, it will not be associated with any information that you provide as a coding system will be used to maintain anonymity.

What will happen to the results of the study?

The information acquired will contribute towards the PhD student's thesis and provide them with research training and help them to understand the experiences of key stakeholders involved with the pharmacists working in GP practice pilot. The information regarding KPIs will also inform the pilot sites about what and how to evaluate the services provided in preparation for requests made by NHS England. The information you give will remain confidential and you will not be identifiable from any reports. Findings may also be presented at conferences and published in peer reviewed journals for research and educational purposes.

What happens if something goes wrong?

In the event that you are not comfortable with the conduction of the study please feel free to contact either the study supervisor or the Quality Assurance in Research group at the University of Reading (see email addresses below).

Who has reviewed the study?

This project has been reviewed by the School of Pharmacy Research Ethics Committee and has been given a favourable opinion for conduct.

Contact details for further questions

Principle Researcher: Professor Kath Ryan
Professor of Social Pharmacy
Reading School of Pharmacy
Whiteknights
Reading, RG6 6AP

Project supervisors: Dr Nilesh Patel Dr Wing Man Lau

In the event of a complaint

Please e-mail the University of Reading's Quality Assurance in Research at

Thank you for your help.

University of Reading

Professor Kath Ryan

School of Chemistry, Food & Nutritional Sciences and Pharmacy

Whiteknights
PO Box 266, Reading RG6 6AP, UK

phone
fax

Consent Form

Developing Key Performance Indicators (KPIs) for pharmacists in general practice

Please initial boxes

1. I have read and had explained to me by **George Karampatakis** the accompanying Information Sheet, version 3 and dated 1/12/2016, relating to the project on: **Developing KPIs for pharmacists in general practice**. ☐
2. I have had explained to me the purposes of the project and what will be required of me, and any questions I have had have been answered to my satisfaction. I agree to the arrangements described in the Information Sheet in so far as they relate to my participation. ☐
3. I understand that participation is entirely voluntary and that I have the right to withdraw from the project any time, without my employment or legal rights being affected. ☐
4. I agree to the focus group being audio recorded. ☐
5. I have received a copy of this Consent Form and of the accompanying Information Sheet. ☐
6. I understand that all my details will be kept confidential and my name will not appear on any reports or documents. ☐

This application has been reviewed by the School of Pharmacy Research Ethics Committee and has been given a favourable ethical opinion for conduct.

Participant details

Name of Participant: _____

Signature: _____ Date: _____

Witnessed by

Name of researcher taking consent: _____

Signature: _____ Date: _____

Participation Number: ……..

Ethics Approval STUDY Number - 37/16

Parastou Donyai >
Wed 21/12/2016 11:55
To: Kath Ryan >; Nilesh Patel >; Wing Man Lau >; Georgios Dimitrios Karampatakis >
Cc: Barbara Parr >

Dear Kath, Nilesh, Wing and Georgios

I am pleased to inform you that Professor Becky Green has given a favourable opinion for conduct for your study 'Developing Key Performance Indicators (KPIs) for pharmacists in general practice' via the in-School exceptions route. This email constitutes your permission to proceed with the studies as described in your application. The following study number has been assigned to your study and you should quote this number in any correspondence you undertake about your studies.

STUDY Number - 37/16

If you feel that you need to make changes to the way your studies are run, please let us know at the earliest opportunity and we can advise you of whether a formal amendment to your proposal is required or not.

I wish you the best of luck with the projects and finish by reminding you of the need for safe custody of project data at all times (a service that Barbara Parr, copied in, can provide if you require it).
Kind regards
Parastou

Dr Parastou Donyai PhD, BPharm (Hons), BSc (Hons) Psych (Open), PGDPRM (Open), PGCertPsychTher Pharmacist, MRPharmS, FHEA, MBPsS
Associate Professor of Social and Cognitive Pharmacy
Director of Pharmacy Practice, Reading School of Pharmacy
(0118 378 4704 | | University of Reading, Room1.02, Food Biosciences Building,
PO Box 226, Whiteknights, Reading, Berkshire RG6 6AP

Appendix 2. Ethics application documents for the e-Delphi study

University of Reading

School of Chemistry, Food and Pharmacy
Research Ethics Committee

Application Form for UREC Applications

SECTION 1: APPLICATION DETAILS

1.1

Project Title: What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment – an e-Delphi study

Date of Submission: 03/03/2017 Proposed start date: 13/4/2017 Proposed End Date: 15/5/2017

1.2

Principal Investigator: Professor Kath Ryan

Office room number: 1.05D Internal telephone:

Email address: Alternative contact telephone:
(Please note that an undergraduate or postgraduate student cannot be a named principal investigator for research ethics purposes. The supervisor must be declared as Principal Investigator)

Other applicants

Name: Dr Nilesh Patel Staff/~~Student~~ (delete) Institution/Department: Reading School of Pharmacy. Email:

Name: Dr Wing Man Lau Staff/~~Student~~ (delete) Institution/Department: Reading School of Pharmacy. Email:

Name: Georgios Dimitrios Karampatakis ~~Staff~~/Student (delete) Institution/Department: Reading School of Pharmacy. Email:

….

1.3

Project Submission Declaration

I confirm that to the best of my knowledge I have made known all information relevant to the SCFP Research Ethics Committee and I undertake to inform the Committee of any such information which subsequently becomes available whether before or after the research has begun.

I understand that it is a legal requirement that both staff and students undergo Criminal Records Checks when in a position of trust (i.e. when working with children or vulnerable adults).

I confirm that a list of the names and addresses of the subjects in this project will be compiled and that this, together with a copy of the Consent Form, will be retained within the School for a minimum of five years after the date that the project is completed.

Signed…… (Principal Investigator) Date:……

…… (Student) Date:…….

…… (Other named investigators) Date:……

…… (Other named investigators) Date:……

1.4

University Research Ethics Committee Applications

Projects expected to require review by the University Research Ethics Committee must be reviewed by a member of the School research ethics committee and the Head of School before submission.

Signed…… (Chair/Deputy Chair of School Committee) Date:……

Signed…… (Head of Department) Date:……

Signed…… (SCFP Ethics Administrator) Date:……

University of Reading

SECTION 2: PROJECT DETAILS

2.1

Please provide a summary of the project in **non-specialist terms** that could be understood by **non-scientist members of the public**, which includes a description of the scientific background to the study (existing knowledge), the scientific questions the project will address and a justification of these. Please note that the description must be sufficient for the committee to take a reasonable view on the likely scientific rigour and value of the project

The concept of pharmacists employed within general practices is being explored in some countries to improve patient safety and reduce burden on general practitioners (GPs)[1]. In the UK, NHS England along with Health Education England, the Royal College of General Practitioners and the British Medical Association's GP Committee are working in collaboration with the Royal Pharmaceutical Society on a four year pilot to test the role of clinical pharmacists working across numerous sites. The pilot currently covers 698 practices supporting over seven million patients[2].

The pilot is expected to be evaluated using Key Performance Indicators (KPIs) so that success and learning is identified and reported. However, how this is done has not been fully agreed (i.e. what activities to record). This study aims to determine what activities (codes) that identify pharmacist involvement should be recorded, by the pharmacy team, on the electronic systems of the pilot sites so that pharmacist input can then be measured. To achieve this, the opinion of experts on the topic, from two pilot sites in West London (Ealing - Hammersmith/Fulham) along with nationally active experts, will be explored.

Initial agreement around activities was obtained by conducting focus groups with pharmacists, GPs and practice managers, for which ethical approval was provided by a School of Chemistry, Food and Pharmacy Internal Review. The next phase of the research aims to reach consensus on what activities need to be recorded. The information acquired is anticipated to assist the pilot sites in evaluating the services provided in preparation for requests made by NHS England.

(254 words).

References:

1. Tan EC, Stewart K, Elliott RA, George J. (2014) Pharmacist consultations in general practice clinics: the Pharmacists in Practice Study (PIPS). Res. Soc. Adm. Pharm. 10(4): 623–32.
2. Snow-Miller R. (2015) Clinical Pharmacists in General Practice Pilot. https://www.england.nhs.uk/commissioning/wp-content/uploads/sites/12/2015/07/clinical-pharmacists-gp-pilot.pdf (accessed 13.10.16).

(*This box may be expanded as required – **Word Limit Maximum 250***)

2.2

Procedure

Please describe concisely what the study will involve for your participants and the procedures and methodology to be undertaken (*you may expand this box as required*).

To achieve agreement (consensus) around what activities are important, an e-Delphi study is planned. The whole pharmacy team (=pharmacists and pharmacy technicians) of the two pilot sites along with experts on the topic from the Centre for Pharmacy Postgraduate Education (CPPE) and the Primary Care Pharmacy Association (PCPA), will be invited to participate. The experts will be identified by the project team from their public profiles and be invited by e-mail to participate. The design and the content of the first questionnaire will be based on the results of the qualitative focus groups which were previously conducted. The extensive and free discussion during the focus groups allowed a deep understanding of people's perceptions, providing useful material for the development of the first questionnaire for the e-Delphi study. It is anticipated that two to three rounds will be needed for our study. Each e-Delphi round will be based on the results of the previous round. In each round the expert panellists will be asked to rank each proposed activity by using a 5-point Likert scale: '1' for "definitely disagree" and '5' for "definitely agree". Apart from giving a mark to each activity, panellists will be asked to briefly explain their choice of score. The online questionnaire will be designed, each time, by the PhD student George Karampatakis with the use of the Bristol Online Survey (BOS) tool.

During the first round of the study, a link to the questionnaire along with a unique username, password and "token" (more details for the "token" can be found in section 2.8) will be e-mailed individually to each of the potential participants. By following the link and by using the unique username, password and "token", participants will have the ability to access the survey. This first e-mail will also have attached an invitation letter and the Participant Information Sheet. The activities that were identified during the focus groups as "useful" will mostly form the basis of the questionnaire, together with others identified by the project team. In the subsequent rounds, the link to the modified questionnaire along with a new username, password and "token" (more details for the "token" can be found in section 2.8) will be again individually e-mailed to each participant. In addition, the total score for each activity of the previous round along with the participant's own score (to be sent individually) and all comments given by the participants, will be provided. Participants will be asked to review their score until agreement is reached. Agreement will be implied if an activity receives a score of 80% or more. People who did not participate in the first round will still be eligible to participate in subsequent rounds.

Potential questions for the first questionnaire of the study are appended to this application. It is worthwhile mentioning that these questions will be piloted on a convenience sample of experts to allow refinement of the questionnaire before it is sent to participants.

(Note: All questionnaires or interviews should be appended to this application)

2.3

Where will the project take place?

Since it will be an online e-Delphi study, the completion of the questionnaire can be done wherever each participant wishes, providing there is available connection to the web.

2.4

Funding

Is the research supported by funding from a research council or other *external* sources (e.g. charities, business)? **Yes**

If Yes, please give details:

The research is supported by a University of Reading Postgraduate Studentship which is half sponsored by the Ealing GP Federation. Although the Federation is directly interested in the research, it will not have sway over the results at any stage.

Please note that *all* projects (except those considered as low risk, which would be the decision of the School's internal review committee and require Head of Department approval) require approval from the University Research Ethics Committee.

2.5

Ethical Issues

Could this research lead to any risk of harm or distress to the researcher, participant or immediate others? Please explain why this is necessary and how any risk will be managed.

Risks to participants associated with this study are minimal. Participation will be voluntary. No monetary incentive will be provided at any stage. All possible precautions will be taken to limit the impact on participants' work. It is anticipated that participants will need to devote approximately ten to fifteen minutes of their time to complete the respective questionnaire for each study round. To increase participants' convenience, the study will be an e-Delphi rather than a traditional paper-based Delphi. This means that participants can complete the relevant questionnaire remotely and whenever they wish[1]. In addition, online research is characterised by time and cost savings for participants[2]. There is no plan/intention for unlimited rounds in the study, as this exhausts participants and reduces their enthusiasm[3]. Participants' confidentiality and privacy is another sensitive issue. There are only three different groups of people being invited for participation (the pharmacy teams of the Ealing and Hammersmith/Fulham pilot sites along with nationally active experts). Therefore, there is a possibility that some of the participants will know each other (especially inside the local teams of the two pre-mentioned pilot sites). As a result, great care will be taken to protect participants' identity and guarantee that their views will not be made known by the researchers to their co-participants (details on confidentiality can be found in section 2.8).

References:

1. Donohoe, H., Stellefson, M., Tennant, B., 2012. Advantages and Limitations of the e-Delphi Technique. Am. J. Health Educ. 43(1): 38–46.
2. Mann, C., Stewart, F., 2000. Internet communication and qualitative research: a handbook for researching online. SAGE Publications, London.
3. Iqbal, S., Pipon-Young, L., 2009. The Delphi method. The Psychologist 22(7): 598–601.

(*this box may be expanded as required*)

2.6

Deception

Will the research involve any element of intentional deception at any stage (i.e. providing false or misleading information about the study, or omitting information)? **No**

2.7

Payment

Will you be paying your participants for their involvement in the study? **No**

2.8

Data protection and confidentiality

What steps will be taken to ensure participant confidentiality? How will the data be stored?

Confidentiality and privacy will be ensured for all participants. The use of the BOS tool guarantees that participants cannot be identified by their hand-writing, which might be the case for paper questionnaires. To further maintain confidentiality, in every round of the study a unique "token" (=participation code) will be individually e-mailed to each participant (as described in section 2.2). The first question of the questionnaire in every round will be: "enter your token". The list of participation codes, along with the unique usernames and passwords, will be stored only on the secure, password protected BOS platform and nowhere else other than the emails exchanged between participants and Karampatakis. The list of "tokens", passwords and usernames will be accessible ONLY to Karampatakis. Consequently, ONLY the PhD student (Karampatakis) will be aware of the identity of the participants who filled in the questionnaire. This is necessary so that Karampatakis has the ability to send reminder e-mails only to those participants who did not complete the survey by the deadline (rather than sending a reminder e-mail to the whole group). It will also enable the individual notification to each participant of their own score for each question of the previous round. Thus, participants will have the opportunity to compare their own results against the overall score. In order to make clear the expertise of the recruited panel in the subsequent publications some demographic data is necessary to be collected. Participants will be asked to state their overall years of practice as professionals, their years of practice and current role within the general practice environment or the pilot in general, as well as the region in which they currently practise. The correlation between demographic data and participation codes will be again known ONLY to Karampatakis. Data analysis and information made public or included in research outputs only will use aggregate results. In any dissemination of the survey data, all identifying information from individual responses to this survey will be censored. Great care will be taken to either pool/aggregate or coarsely categorize potential identifying information, e.g. participants' years of practice will only be reported as a range. No other sensitive information will be collected. All data collected will be only used for scientific and educational purposes. The completed online questionnaires will be accessible only to Karampatakis, and, after being separated from the "token", to his supervisors.

2.9

Consent

Please describe the process by which participants will be informed about the nature of the study and the process by which you will obtain consent

Participants will be invited to take part in the study via email (see section 3.5 – recruitment). Once participants have indicated their willingness to take part in the study by emailing Karampatakis (e-mail details to be provided in the Participant Information Sheet and the invitation letter), a subsequent email will be sent, which will include the link to the first questionnaire, the username, the password, the "token", along with another copy of the invitation letter and the Participant Information Sheet. In addition to this, participants will always have the ability to ask any questions they have about the study. This will be possible at any point, either before or after completing the questionnaire, by simply e-mailing Karampatakis. Participants will be given, in each study round, a time-period of two weeks to decide if they wish to complete the questionnaire. The completion of the questionnaire will imply continuing consent. No written consent will be required. Participants will maintain the right not to answer any questions that cause them distress, though this would be unlikely. They will also have the right to withdraw from the study at any point, by just informing Karampatakis, without giving any reason and without any kind of detriment in their work. Karampatakis will not reveal to anyone the identity of any persons who potentially withdraw from the study. In the event of a withdrawal, the respective questionnaire will be destroyed and data collected from any withdrawn persons will not be used in the research.

Please note that a copy of consent forms and information letters for all participants must be appended to this application.

2.10

Genotyping

Are you intending to genotype the participants? Which genotypes will be determined? **No**

University of Reading

SECTION 3: PARTICIPANT DETAILS

3.1

Sample Size

How many participants do you plan to recruit? Please provide a suitable power calculation demonstrating how the sample size has been arrived at or a suitable justification explaining why this is not possible/appropriate for the study.

The expert panel to be recruited will consist of all pharmacists and pharmacy technicians working across the two pilot sites (Hammersmith/Fulham and Ealing), which is largely composed of the participants involved in the focus groups. They are considered experts as it is entirely about their daily work within GP practices and they are directly involved in coding pharmacists' activities. To expand the expert panel and achieve a broader consensus, reflecting different opinions from across England, people with expertise on the topic from the CPPE and PCPA committees will also be invited to participate. These are deemed experts as they are nationally engaged on these committees and they have been designated a senior role in the pilot. Invitation e-mails will be sent to approximately 50 people but it is anticipated that around 30, overall, will be involved. From the recruited panel we aim to obtain a general consensus so that a list of pharmacists' activities, widely deemed to be essential, is built.

3.2

Will the research involve children or vulnerable adults (e.g. adults with mental health problems or neurological conditions)? **No**

3.3

Will your research involve children under the age of 18 years? **No**
Will your research involve children under the age of 5 years? **No**

3.4

Will your research involve NHS patients, Clients of Social Services or will GP or NHS databases be used for recruitment purposes? **No**

3.5

Recruitment

Please describe the recruitment process and append all advertising and letters of recruitment.

All communication with the participants (sending of the links to the questionnaires, previous scores etc.) will be carried out via e-mail. Regarding the pharmacy teams of the Ealing and Hammersmith/Fulham pilot sites, Stretch (lead pharmacist of the Ealing pilot site) will e-mail all members, on behalf of Karampatakis, to invite them to take part in the study. This e-mail will have attached the invitation letter and the Participant Information Sheet and a direction to contact Karampatakis directly if they want to participate. The experts from the CPPE and PCPA committees will be identified by the project team and also emailed to invite them to take part in the study. Their contact details are public knowledge. Once confirmatory emails have been received by Karampatakis, another email will be sent by Karampatakis, which will include the link to the first questionnaire, the password, the

username and the "token", along with another copy of the invitation letter and the Participant Information Sheet. Participants will be asked, in each study round, to complete the questionnaire within two weeks from the day it was sent. Completion of each questionnaire will imply consent. A reminder e-mail will be sent to all participants three days before the deadline for each questionnaire. For participants who do not reply by the deadline, a final e-mail will be sent the next day after the "due day", giving a new deadline of three more days for responding.

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
What pharmacists' activities in general practice should be recorded?v5

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◉ Yes ○ No

4b. Please confirm the reason(s) why the project does not require review by a REC within the UK Health Departments Research Ethics Service:

☐ Projects limited to the use of samples/data samples provided by a Research Tissue Bank (RTB) with generic ethical approval from a REC, in accordance with the conditions of approval.
☐ Projects limited to the use of data provided by a Research Database with generic ethical approval from a REC, in accordance with the conditions of approval.
☐ Research limited to use of previously collected, non-identifiable information
☐ Research limited to use of previously collected, non-identifiable tissue samples within terms of donor consent
☐ Research limited to use of acellular material
☑ Research limited to use of the premises or facilities of care organisations (no involvement of patients/service users as participants)
☑ Research limited to involvement of staff as participants (no involvement of patients/service users as participants)

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This study is part of a PhD. This is an e-Delphi study to be completed by pharmacists and pharmacy technicians working in general practice. It is anticipated that two to three rounds will be needed for the study. The student will be designing the questionnaire for each of the Delphi's round. The student will be also analyzing the results of each round.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research administering questionnaires/interviews for quantitative analysis or mixed methodology study

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
What pharmacists' activities in general practice should be recorded?v5

Please complete these details after you have booked the REC application for review.

REC Name:
non-REC study

REC Reference Number:
18/HRA/0111

Submission date:
22/05/2017

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment – an e-Delphi study

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mr	Georgios Dimitrios	Karampatakis
Address	Pharmacy Practice - Department of Pharmacy		
	University of Reading, PO BOX 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail			
Telephone			
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctor of Philosophy (PhD)

Name of educational establishment:
University of Reading

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Kath	Ryan
Address	Pharmacy Practice - Department of Pharmacy		
	University of Reading, PO BOX 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail			
Telephone			
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Nilesh	Patel
Address	Pharmacy Practice - Department of Pharmacy		
	University of Reading, PO BOX 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail	nilesh.patel@reading.ac.uk		
Telephone			
Fax			

Academic supervisor 3

	Title	Forename/Initials	Surname
	Dr	Wing - Man	Lau
Address	Pharmacy Practice - Department of Pharmacy		
	University of Reading, PO BOX 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail			
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr Georgios Dimitrios Karampatakis	☑ Professor Kath Ryan ☑ Dr Nilesh Patel

☑ Dr Wing - Man Lau

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (•) Student
- ( ) Academic supervisor
- ( ) Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Georgios Dimitrios	Karampatakis
Post	PhD student		
Qualifications	MSc in Clinical Pharmacy (2016) - University College London Ptychio in Pharmacy (2014) - Aristotle University of Thessaloniki		
ORCID ID	0000 0003 0623 8231		
Employer	University of Reading		
Work Address	Pharmacy Practice - Department of Pharmacy University of Reading, PO BOX 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Work E-mail			
* Personal E-mail			
Work Telephone			
* Personal Telephone/Mobile			
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Mike	Proven
Address	The University of Reading - Whiteknights House Whiteknights, PO Box 217 Reading		
Post Code	RG6 6AH		
E-mail			
Telephone			
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	N/A
Sponsor's/protocol number:	N/A
Protocol Version:	N/A
Protocol Date:	
Funder's reference number:	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number
N/A	N/A

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

What pharmacists' activities in general practice should be recorded?

In the UK, NHS England along with Health Education England, the Royal College of General Practitioners and the British Medical Association General Practitioners Committee are working in collaboration with the Royal Pharmaceutical Society on a four year pilot to test the role of clinical pharmacists working across numerous general practice sites. The pilot currently covers 698 practices and supports over seven million patients.
The pilot is expected to be evaluated using Key Performance Indicators (KPIs) so that success and learning is identified and reported. However, how this is done has not been fully agreed (i.e. what activities to record). This study aims to determine what activities that identify pharmacist involvement should be recorded, by the pharmacy team, on the electronic systems of the pilot sites so that pharmacist input can then be measured. The information acquired is anticipated to assist the pilot sites in evaluating the services provided in preparation for requests made by NHS England.
To achieve consensus around what activities are important, an e-Delphi study is planned. The whole pharmacy team of two pilot sites in West London along with experts on the topic identified from the Centre for Pharmacy Postgraduate Education and the Primary Care Pharmacy Association, will be invited to participate. It is anticipated that two to three rounds will be needed for the study. In each round the participants will be asked to rank each proposed activity on a 5-point Likert scale. Each round will be based on the results of the previous round. Agreement will be implied if an activity receives a score of 80% or more.
The research is supported by a University of Reading Postgraduate Studentship. The study is expected to last 12 months, although the Delphi will be completed within four months.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study*

and say how you have addressed them.

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Every part of this study was developed in close collaboration and discussion with the Chief Investigator's (CI) academic supervisors. An application was submitted to the University of Reading Research Ethics Committee which gave a favourable opinion of conduct. However, the University Committee has suggested HRA approval before the study can commence.
Risks to participants associated with this study are minimal. Participation will be voluntary. No monetary incentive will be provided at any stage. The study will entirely be around pharmacists' activities and will not include personal or sensitive topics that might cause distress to participants. All possible precautions will be taken to limit the impact on participants' work. It is anticipated that participants will need to devote approximately ten to fifteen minutes of their time to complete the respective questionnaire for each study round. To increase participants' convenience, the study will be an e-Delphi rather than a traditional paper-based Delphi. This means that participants can complete the relevant questionnaire remotely and whenever they wish. In addition, online research further encourages participation as it is characterised by time and cost savings for participants. There is no plan/intention for unlimited rounds in the study, as this exhausts participants and reduces their enthusiasm. It is anticipated that between two to three rounds only will be required for the study.
There are only three different groups of people being invited for participation (the pharmacy teams of two pilot sites in West London along with nationally active experts). Therefore, there is a possibility that some of the participants will know each other (especially inside the local teams of the two pilot sites). As a result, great care will be taken to protect participants' identity and guarantee that their views will not be made known by the researchers to their co-participants. To achieve this, "tokens" (=participation codes) will be used. A unique participation code will be allocated for each potential participant. The "tokens" will be only known to the CI. As a result, the CI will be the only person aware of participants' identity. The full process is explained in detail in the confidentiality sections of this application.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

To reach a wide consensus on what activities carried out by pharmacists in general practice should be recorded on the electronic systems of the practices they work in.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

N/A

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

The concept of pharmacists employed within general practices is being explored in some countries to improve patient safety and reduce burden on general practitioners (GPs). Australia and Canada are two examples of employing pharmacists in this setting. Research around this topic has been undertaken in these countries. The respective papers are mainly qualitative and focus on eliciting opinions of GPs, other members of practice staff, patients and the general public around pharmacist involvement in this environment. Although positive views exist in the literature, there were several doubts, especially from the GPs' side, around the purpose and the need for pharmacists in this setting. Therefore, it is important that pharmacists externalize and make obvious their activity and worth when pharmacy services are to be implemented in general practice. The published literature cannot be safely extended to all countries employing pharmacists in general practice as health systems, as well as work practices and cultures, might be significantly diversified amongst different nations.
In the UK, the idea of pharmacists employed within general practices is relatively new. UK pharmacists have occasionally been providing services in general practice in the past. However, it is only recently that NHS England decided to implement and test, in a formal way, having pharmacists working within general practices in England. To better achieve this, NHS England is closely working with Health Education England, the Royal College of GPs, the British Medical Association's GP Committee and the Royal Pharmaceutical Society on a four year pilot. The principal aim of the pilot is to test the role of clinical pharmacists working in general practices. It is estimated that the pilot currently supports over seven million patients in England.
It is anticipated that the pilot will be evaluated using Key Performance Indicators (KPIs) so that success and learning is identified and reported. However, how this is done has not been fully agreed (i.e. what activities are worthwhile recording). This study aims to determine what activities (codes), e.g. advising patients about drug treatment, that identify pharmacist involvement should be recorded by the pharmacy team on the electronic systems of the pilot sites. To achieve this, the study aims to reach a wide consensus on the most common and important pharmacists' activities. The study will explore the opinions of experts on the topic from two pilot sites in West London (Ealing and Hammersmith/Fulham). To widen the spectrum of opinions, thus achieving a more representative consensus, the study plans to recruit nationally active experts as well.
The information to be acquired is anticipated to assist the pilot sites in evaluating the services provided in preparation for requests made by NHS England. The value of the study is that it will offer insight into pharmacists' activities in general practice by helping to generate a global list of activities that can be recorded to show the extent and the value of pharmacy services.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

To achieve agreement (consensus) around what activities are important, an e-Delphi study is planned. The Delphi is a research method where a recruited panel of people, with expertise on a topic, are asked to give their opinion on specific statements. A research facilitator is then providing participants with an anonymized summary of all comments made over each statement. After that, participants are asked to review their answer in the light of other participants' comments. Consequently, the range of answers gradually shrinks and the "right" answer over each statement predominates. The Delphi was chosen as a method for the current study as it is deemed to be an excellent means for achieving consensus amongst experts (=panellists) on a topic that lacks evidence. The Delphi method has the ability to accumulate various opinions and perceptions and form an agreement around them.
The whole pharmacy team (=pharmacists and pharmacy technicians) of two pilot sites (Ealing and Hammersmith/Fulham) along with experts on the topic recruited using the Centre for Pharmacy Postgraduate Education (CPPE) and the Primary Care Pharmacy Association (PCPA), will be invited to participate. It is anticipated that two to three rounds will be needed for our study. Each e-Delphi round will be based on the results of the previous round. In each round the expert panellists will be asked to rank each proposed activity, e.g. diabetes medication review, by using a 5-point Likert scale: '1' for "definitely disagree" and '5' for "definitely agree". The 5-point Likert scale is a very common way of ranking statements. Apart from giving a mark to each activity, panellists will be asked to briefly explain their choice of score. The online questionnaire will be designed, each time, by the Chief Investigator with the use of the Bristol Online Survey (BOS) tool.
During the first round of the study, a link to the questionnaire along with a unique username, password and "token" will be e-mailed individually to each of the potential participants. By following the link and by using the unique username, password and "token", participants will have the ability to access the survey. This first e-mail will also have attached an invitation letter and the Participant Information Sheet. In the subsequent rounds, the link to the modified questionnaire along with a new username, password and "token" will be again individually e-mailed to each participant. In addition, the total score for each activity of the previous round along with the participant's own score (to be sent individually) and

all comments given by the participants, will be provided. Participants will be asked to review their score again until agreement is reached. Agreement will be implied if an activity receives a score of 80% or more. People who did not participate in the first round will still be eligible to participate in subsequent rounds.
Potential questions for the first questionnaire of the study are appended to this application. It is worthwhile mentioning that these questions will be piloted on a convenience sample of experts to allow refinement of the questionnaire before it is sent to participants.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- ☐ Design of the research
- ☐ Management of the research
- ☐ Undertaking the research
- ☐ Analysis of results
- ☐ Dissemination of findings
- ☑ None of the above

Give details of involvement, or if none please justify the absence of involvement.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☐ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☐ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth

☐ Respiratory
☐ Skin
☐ Stroke

Gender:	Male and female participants
Lower age limit:	Years
Upper age limit:	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

*Pharmacists or pharmacy technicians working across two West London pilot sites (Ealing - Hammersmith/Fulham).
*Experts identified via the Centre for Pharmacy Postgraduate Education (CPPE) and the Primary Care Pharmacy Association (PCPA) who hold a senior role in the national pilot.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

*Pharmacists or pharmacy technicians from other pilot sites or from sites that are not part of the pilot.
*People from the CPPE or PCPA committees who do not have any involvement with the pilot or only have a junior role in the national pilot.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Questionnaire as part of the e-Delphi study	2-3	No	10-15 minutes	The Chief Investigator is carrying out the study. Since it will be an online e-Delphi study, the completion of the questionnaire can be done wherever each participant wishes, providing there is available connection to the web. Completion of the questionnaire will imply consent. Participants will need to devote between 10-15 minutes to complete the questionnaire for each study round.

A21. How long do you expect each participant to be in the study in total?

It is anticipated that the questionnaires for the e-Delphi's rounds will be completed by participants in four months. Therefore, participants will be active in this study for four months. However, for carrying out the final analysis and drawing conclusions from the findings, up to 12 months approximately will be needed. Consequently, 12 months overall may be needed until participants become fully informed about the final list of activities agreed upon.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Potential risks and discomforts associated with this project are minimal. The e-Delphi study has been designed to avoid raising any personal or sensitive issues. In the unlikely event that a question causes distress to any of the

participants, they will have the option either to skip that particular question or to terminate their participation without giving a reason and without any consequence. Participants will need to devote between 10-15 minutes to complete the questionnaire for each study round. To limit the impact on participants' time, the study is an e-Delphi. Thus, it will be carried out online. Therefore, participants can complete the questionnaire whenever they wish, and not necessarily during their active working time, and from wherever they wish as long as they have connection to the web.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

The potential benefit for participants is that they can express their own opinion on what activities they do are useful to record which will then aid any future evaluation by NHS England of the pilot sites they are working in. The results of the study should then inform policy makers and their employers on the value of continuing promoting or funding pharmacists working in/with GP practices.

A26. What are the potential risks for the researchers themselves? *(if any)*

There is not any significant risk for the researchers. The only potential risk is the unlikely event that none of the potential participants is interested in participating in the study.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Regarding the pharmacy teams of the Ealing and Hammersmith/Fulham pilot sites, a lead pharmacist of the Ealing pilot site (who will also act as the local Investigator for this site) will e-mail all members, on behalf of the Chief Investigator (Karampatakis), to invite them to take part in the study. This e-mail will have attached the invitation letter and the Participant Information Sheet and a direction to contact the Chief Investigator directly if they want to participate.
The experts to be recruited using the Centre for Pharmacy Postgraduate Education (CPPE) and the Primary Care Pharmacy Association (PCPA) will be identified by the project team. Their contact details are public knowledge. They will be directly emailed to invite them to take part in the study. Thus, participants from the Ealing and Hammersmith/Fulham pilot sites will be recruited through their NHS job pathway (pharmacists or pharmacy technicians in these two pilot sites). Participants identified via the CPPE and PCPA committees will be recruited through their membership in these committees and not through their NHS or any other job role as pharmacy staff. The reason is that only their CPPE or PCPA contact details are public knowledge.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

All potential participants will be initially approached by e-mail. The participants from the two West London pilot sites (Ealing and Hammersmith/Fulham) will be initially e-mailed, on behalf of the Chief Investigator, by the lead pharmacist in the Ealing site. This is necessary as the Chief Investigator does not have access himself to the contact e-mails of these pharmacy teams. The potential participants to be identified via the Centre for Pharmacy Postgraduate Education and the Primary Care Pharmacy Association will be directly e-mailed by the Chief Investigator as their contact details are public knowledge.

A30-1. Will you obtain informed consent from or on behalf of research participants?

○ Yes ◉ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

If you are not obtaining consent, please explain why not.

The completion of the questionnaire will imply consent and participation in further rounds of the e-Delphi will be taken as continuing consent. No extra written consent will be required.

Please enclose a copy of the information sheet(s) and consent form(s).

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☑ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☑ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☐ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☐ University computers

☐ Private company computers

☐ Laptop computers

Further details:
The study will be an e-Delphi and, therefore, will be entirely carried out over the e-mail using work or public e-mail addresses. The only personal data to be collected will be some demographic data. These will be collected through the questionnaires of the e-Delphi. Demographic data are necessary to make clear the expertise of the recruited panel in the subsequent publications. In detail, participants will be asked to state their overall years of practice as professionals, their years of practice and current role within the general practice environment or the pilot in general, as well as the region in which they currently practise. The correlation between demographic data and participation codes will be known ONLY to the Chief Investigator. The only personal data to be transferred via e-mail will be the unique usernames, passwords and participation codes. These will only be written down on the e-mails exchanged between the Chief Investigator and the participants and nowhere else. No demographic or other personal data will be transferred by e-mail. Direct quotes from the participants' comments in the e-Delphi might be published but they will be entirely anonymized.

A37. Please describe the physical security arrangements for storage of personal data during the study?

All demographic data along with the unique usernames, passwords and "tokens" will be stored only on the secure, password protected Bristol Online Survey (BOS) platform. All questionnaires will be on an electronic format and no hard copies will be collected. Completed questionnaires, along with demographic data will be stored only on the BOS platform for 5 years (as per the university of Reading procedures). The completed online questionnaires will be accessible only to the Chief Investigator, and, after being separated from the "token", to his supervisors. It is worthwhile adding that all e-mails by the Chief Investigator to participants will be sent on password protected University of Reading computers.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Anonymized participation with the use of "tokens"

Confidentiality and privacy will be ensured for all participants. The use of the Bristol Online Survey (BOS) tool guarantees that participants cannot be identified by their hand-writing, which might be the case for paper questionnaires. To further maintain confidentiality, in every round of the study a unique "token" (=participation code) will be individually e-mailed to each participant. The first question of the questionnaire in every round will be: "enter your token". The list of participation codes, along with the unique usernames and passwords, will be stored only on the secure, password protected BOS platform and nowhere else other than the emails exchanged between participants and the Chief Investigator (Karampatakis). The list of "tokens", passwords and usernames will be accessible ONLY to the Chief Investigator. Consequently, ONLY the Chief Investigator will be aware of the identity of the participants who filled in the questionnaire. This is necessary so that the Chief Investigator has the ability to send reminder e-mails only to those participants who did not complete the survey by the deadline (rather than sending a reminder e-mail to the whole group). It will also enable the individual notification to each participant of their own score for each question of the previous round. Thus, participants will have the opportunity to compare their own results against the overall score. In order to make clear the expertise of the recruited panel in the subsequent publications some demographic data is necessary to be collected. Participants will be asked to state their overall years of practice as professionals, their years of practice and current role within the general practice environment or the pilot in general, as well as the region in which they currently practise. The correlation between demographic data and participation codes will be again known ONLY to the Chief Investigator. Data analysis and information made public or included in research outputs will use only aggregated results. In any dissemination of the survey data, all identifying information from individual responses to this survey will be censored. Great care will be taken to either pool/aggregate or coarsely categorize potential identifying information, e.g. participants' years of practice will only be reported as a range. No other sensitive information will be collected. All data collected will be only used for scientific and educational purposes. The completed online questionnaires will be accessible only to the Chief Investigator, and, after being separated from the "token", to his supervisors.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

Completed online questionnaires and demographic data will be accessible to the Chief Investigator and, after removing the "token", to his academic supervisors (Ryan, Patel, Lau).

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data of each study round, which will all be anonymized without being able to link them with any participant, will be analyzed by the Chief Investigator. The analysis will be carried out with the use of either SPSS or Microsoft Excel on the Chief Investigator's university, password protected, computer. The analysis part will just involve the calculation of the agreement percentages over each question.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Mr	Georgios Dimitrios	Karampatakis
Post	PhD student		
Qualifications	MSc in Clinical Pharmacy (2016) - University College London Ptychio in Pharmacy (2014) - Aristotle University of Thessaloniki		
Work Address	Pharmacy Practice - Department of Pharmacy University of Reading, PO BOX 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Work Email			
Work Telephone			
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ◉ Over 3 years

If longer than 12 months, please justify:
It is a University of Reading policy that data are stored for five years. Personal data in the current study will only be anonymized demographic data (overall years of practice as professionals, years of practice and current role within the general practice environment or the pilot in general, as well as the region in which participants currently practise).

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

Research data (i.e. completed questionnaires) will be stored only on the secure, password protected Bristol Online Survey (BOS) platform. They will be accessed only by the Chief Investigator (Karampatakis) and his academic

supervisors (Kath Ryan, Nilesh Patel, Wing-Man Lau).

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
A suitable register does not exist.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website

☐ Other publication

☐ Submission to regulatory authorities

☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifying demographic data will be used. However, anonymized demographic data will be either pooled/aggregated or coarsely categorized, e.g. participants' years of practice will only be reported as a range.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
It is important that participants are aware of the results so they can start recording the agreed upon activities. Therefore, a debrief/feedback session with participants will be carried out or, alternatively, an e-mail with an executive summary and the list of activities agreed upon will be sent to all participants.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed?*Tick as appropriate:*

☐ Independent external review

☐ Review within a company

☐ Review within a multi−centre research group

☑ Review within the Chief Investigator's institution or host organisation

☐ Review within the research team

☐ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The Chief Investigator completed an ethics application for the University of Reading Research Ethics Committee which gave a favourable opinion of conduct.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed?*Tick as appropriate:*

☐ Review by independent statistician commissioned by funder or sponsor

☐ Other review by independent statistician

☐ Review by company statistician

☐ Review by a statistician within the Chief Investigator's institution

☐ Review by a statistician within the research team or multi−centre group

☐ Review by educational supervisor

☐ Other review by individual with relevant statistical expertise

☑ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Professor	Kath	Ryan
Department	Pharmacy Practice - Department of Pharmacy		
Institution	University of Reading		
Work Address	Pharmacy Practice - Department of Pharmacy University of Reading, PO BOX 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Telephone			
Fax			
Mobile			
E-mail			

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

An agreement over the activities (codes) that need to be recorded at each "pharmacist on GP practice" pilot site.

A58. What are the secondary outcome measures?*(if any)*

N/A.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	30
Total international sample size (including UK):	0
Total in European Economic Area:	0

Further details:
The expert panel to be recruited will consist of all pharmacists and pharmacy technicians working across the two pilot sites (Hammersmith/Fulham and Ealing). They are considered experts as the study is entirely about their daily work within GP practices and they will be directly involved in coding pharmacists' activities. To expand the expert panel and achieve a broader consensus, reflecting different opinions from across England, people with expertise on the topic identified via the CPPE (=Centre for Pharmacy Postgraduate Education) and PCPA (=Primary Care Pharmacy Association) committees will also be invited to participate. These are deemed experts as they are nationally engaged on these committees and they have been designated a senior role in the pilot. Invitation e-mails will be sent to approximately 50 people but it is anticipated that around 30, overall, will be involved. From the recruited panel we aim to obtain a general consensus so that a list of pharmacists' activities, widely deemed to be essential, is built.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The expert panel to be recruited will consist of all pharmacists and pharmacy technicians working across two pilot sites in West London (Hammersmith/Fulham and Ealing). To expand the expert panel and achieve a broader consensus, reflecting different opinions from across England, people with expertise on the topic identified via the CPPE (=Centre for Pharmacy Postgraduate Education) and PCPA (=Primary Care Pharmacy Association) committees

will also be invited to participate. Invitation e-mails will be sent to approximately 50 people but it is anticipated that around 30, overall, will be involved. A formal sample size calculation was not used.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Determining percentage agreement for each proposed activity does not require any advanced statistical tool. Microsoft Excel or SPSS will be used to input the data and then calculate percentage agreement. Reasons given for scores provided, and any comments compiled, will be analyzed thematically, using Microsoft Word, for reporting to the participants.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Professor	Kath	Ryan
Post	Professor of Social Pharmacy		
Qualifications	PhD (1998) - University of Otago Bachelor's Degree in Pharmacy (1974) - University of Otago		
Employer	University of Reading		
Work Address	Pharmacy Practice - Department of Pharmacy University of Reading, PO BOX 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Telephone			
Fax			
Mobile			
Work Email	k.m.ryan@reading.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Nilesh	Patel
Post	Lecturer in Pharmacy Practice		
Qualifications	PhD (1999) - Kings College London BPharm (1994) - Kings College London PGCAP in Teaching and Learning (2006) - Kings College London		
Employer	University of Reading		
Work Address	Pharmacy Practice - Department of Pharmacy University of Reading, PO BOX 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Telephone			
Fax			
Mobile			
Work Email			

	Title	Forename/Initials	Surname
	Dr	Wing-Man	Lau
Post	Lecturer in Pharmacy Practice		
Qualifications	PhD in Drug delivery and Pharmaceutics (2008) - Cardiff University Master of Pharmacy (2004) - King's College London PGC in Academic Practice (2012) - University of Reading		
Employer	University of Reading		
Work Address	Pharmacy Practice - Department of Pharmacy University of Reading, PO BOX 224 Whiteknights		
Post Code	RG6 6AP		
Telephone			
Fax			
Mobile			
Work Email			

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of Reading
Given name	Mike
Family name	Proven
Address	Whiteknights House, Whiteknights, PO Box 217
Town/city	Reading
Post code	RG6 6AH
Country	UNITED KINGDOM
Telephone	
Fax	
E-mail	

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☑ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☐ No application for external funding will be made

What type of research project is this?

○ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

◉ Other

Other – please state:
Part of a PhD project (funded by the by a University of Reading Postgraduate Studentship)

Please give details of funding applications.

Organisation	PHARMACY CARE SOLUTIONS LIMITED
Address	Acorn House 33 Churchfield Road
	Acton
	London
Post Code	W3 6AY
Telephone	
Fax	
Mobile	
Email	grahamstretch@nhs.net

Funding Application Status: ◉ Secured ○ In progress

Amount: £10,000 per year

Duration
Years: 3
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
N/A

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Sylvia	Westrup
Organisation	Ealing CCG		
Address	NWL Primary Care, Mint Wing		
	St. Mary's Hospital		
	London		
Post Code	W2 1NY		
Work Email	lnw.primarycare@nihr.ac.uk		
Telephone			
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/07/2017
Planned end date: 01/07/2018
Total duration:
Years: 1 Months: 0 Days: 1

A71-1. Is this study?

○ Single centre
◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study 107

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☐ NHS organisations in England	
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☑ GP practices in England	107
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	107

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◉ Yes ○ No

A73-2. If yes, will any of these organisations be NHS organisations?

○ Yes ◉ No

If yes, details should be given in Part C.

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The University of Reading has its own independent Research Ethics Committee (UREC) to which all research proposals must be submitted. Before submission to UREC all projects undergo departmental internal review. This study was submitted, as per the standard procedures, to the UREC which gave a favorable opinion of conduct. However, UREC suggested that HRA approval takes place before undertaking the study. The University of Reading Quality Assurance in Research Committee is responsible for managing the conduct of the research. Therefore, any complaints or problems with the conduct of the study can be directly reported by the participants to this University Committee or to the academic supervisors (contact details are provided in the Participant Information Sheet).

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The sponsor of this research is the University of Reading.
The University has in place Professional indemnity insurance and Public liability insurance for potential legal liability of the University. These provide cover for legal liabilities (i.e. there has to be 'legal fault' on the part of the University) for damage to people's property or injury to their person. The relevant documents are attached.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The sponsor of this research is the University of Reading.
The University has in place Professional indemnity insurance and Public liability insurance for potential legal liability of the University. These provide cover for legal liabilities (i.e. there has to be 'legal fault' on the part of the University) for damage to people's property or injury to their person. University employees and students acting or working on behalf of the University are covered. The relevant documents are attached.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◯ Yes ◉ No ◯ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS site ○ Non-NHS site		Forename	Graham
			Middle name	
			Family name	Stretch
	Country: England		Email	
			Qualification (MD...)	• PhD in Pharmacy (1997) - University of Manchester • BSc Hons Pharmacy (1993) - University of Liverpool
	Organisation name	NIHR CRN: North West London		
	Address		Country	UNITED KINGDOM
	Post Code	NULL		
IN3	◉ NHS site ○ Non-NHS site		Forename	John
			Middle name	
			Family name	Adams
	Country: England		Email	
			Qualification (MD...)	MPharm (2008) – University of Manchester
	Organisation name	NIHR CRN: North West London	Country	UNITED KINGDOM
	Address			
	Post Code	NULL		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◯ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◉ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☐ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Mr Georgios Dimitrios Karampatakis on 11/07/2017 15:49.

Job Title/Post:	PhD student
Organisation:	University of Reading
Email:	

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Dr Mike Proven on 11/07/2017 16:02.

Job Title/Post:	Coordinator for Quality Assurance in Research
Organisation:	University of Reading
Email:	

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Wing Man Lau on 13/07/2017 16:33.

Job Title/Post:	Lecturer in Pharmacy Practice
Organisation:	University of Reading
Email:	

Academic supervisor 2

This section was signed electronically by Dr Nilesh Patel on 11/07/2017 16:22.

Job Title/Post:	Lecturer in Pharmacy Practice
Organisation:	University of Reading
Email:	

Academic supervisor 3

This section was signed electronically by Professor Kath Ryan on 12/07/2017 12:39.

Job Title/Post:	Professor of Social Pharmacy
Organisation:	University of Reading
Email:	

DRAFT

Reading School of Pharmacy

Whiteknights, PO Box 226
Reading, RG6 6AP, UK

phone
fax

Project team

- George Karampatakis (Chief Investigator - PhD student):
- Professor Kath Ryan: or
- Dr Nilesh Patel: or
- Dr Wing Man Lau: or

Invitation letter

01/ 09 / 2017

Dear Sir/Madam

Re: What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment – an e-Delphi study

I am writing to ask for your participation in an e-Delphi study. Please refer to the attached Participant Information Sheet which contains further detail about the study and will help you decide whether or not you wish to take part. If you wish to take part, you will need to e-mail me ( ) so that I can send you the relevant details.

The aim of the study is to reach a broad consensus amongst experts on what activities (codes), that identify pharmacist involvement in the general practice environment, should be recorded on the electronic systems of the pilot sites. This will then allow the investigation of the outcomes of pharmacist input into general practice.

We would really appreciate your honest views so that the data are robust.

Should you require any further information regarding the project, please do not hesitate to contact me ( ).

Thank you very much for your time.

Yours sincerely,

George Karampatakis

PhD student
Reading School of Pharmacy

Reading School of Pharmacy

Whiteknights, PO Box 226
Reading, RG6 6AP, UK

phone
fax

Project team

- George Karampatakis (Chief Investigator - PhD student):
- Professor Kath Ryan: or
- Dr. Nilesh Patel: or
- Dr. Wing Man Lau: or

Participant Information Sheet

Study Title: What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment – an e-Delphi study

We would like to invite you to participate in a research study. Before you decide to take part, we would like to offer you detailed information about this study.

Background

In the UK, NHS England along with Health Education England, the Royal College of General Practitioners and the British Medical Association's GP Committee are working in close collaboration with the Royal Pharmaceutical Society on a four year pilot to test the role of clinical pharmacists working across numerous sites. At present the pilot covers 698 general practices supporting over seven million patients in England. The pilot is expected to be evaluated using national and local Key Performance Indicators (KPIs) so that success and learning is identified and reported. However, how the input of pharmacists is measured has not been fully agreed (i.e. what pharmacists' activities should be recorded).

What is the purpose of the study?

This study aims to determine what activities (codes) that identify pharmacist involvement in the general practice environment should be recorded, by the pharmacy teams, on the electronic systems of the pilot sites. Identification of appropriate activities will enable the investigation of pharmacists' impact.

Project Design

This study will be carried out using the e-Delphi method. This is a commonly used method to achieve consensus amongst experts on a topic that lacks evidence. To further increase your convenience, this e-Delphi study will be conducted online and it is anticipated you will be asked to take part in two to three distinct rounds, depending on the agreement scores. In each round you will be asked to complete an online questionnaire, grading each pharmacist activity on a scale of 1 to 5. The majority of activities are SystmOne codes, together with some others identified by the project team. For each code/activity, you will

have the opportunity to write a short comment about why you gave a specific score, if you wish. In the subsequent round(s), you will receive the total score for each activity of the previous round and relevant comments provided by the participants. You will also be individually e-mailed your own score for each activity. You will then be asked to again score the activities (codes), in a modified questionnaire, until agreement amongst the participating experts is reached. Consensus is defined by the project team as getting 80% or greater agreement on an activity to be recorded. The participants in the study will be pharmacists/pharmacy technicians employed in pilot sites along with experts identified via national committees, such as the Centre for Pharmacy Postgraduate Education (CPPE) or the Primary Care Pharmacy Association (PCPA), who are directly involved in the pilot. By the end of this project, we will hopefully have a narrowed-down list of activities (codes) deemed to be essential for recording pharmacist input within general practice. This list will be based on a broad consensus amongst people, from across England, with expertise on the topic of pharmacists working in general practices in England. With this list, the Chief Investigator (CI) will be able to investigate, at a later stage, outcomes of pharmacists' activities and audit them against the KPIs.

Who is organising and funding the study?

The study is funded by a University of Reading Postgraduate Studentship.

Why have I been invited?

You have been invited because you are either working as a pharmacist/pharmacy technician in pilot sites or you have a senior role in the pilot. Consequently, you are deemed an expert on the subject of pharmacists' activities in general practice.

Do I have to take part?

There is no obligation to participate. If you would like to participate in this project, please fill in the questionnaire that will be e-mailed to you, for each study round.

What will happen if I take part?

To take part in the study, please e-mail the CI ( ). You will then be receiving another e-mail from the CI with a link to the respective questionnaire along with a unique username, password and "token" (=participation code). You will have to click on the link and follow the instructions provided. For each study round, you will receive a different link, username, password and "token" to enter. The questionnaire for each round can be completed only once. The completion of the questionnaire will imply that you understand the information in this leaflet and that you have agreed to take part. No separate written consent will be required. You can withdraw from the study at any time, without consequence, by informing the CI ( ). In the event of a withdrawal, the questionnaire from the round in which you withdrew will be destroyed, however, your data from previous rounds will still be used in the research. The identity of all participants will be known ONLY to the CI and will not be revealed to anyone else.

What are the possible risks of taking part?

Potential risks and discomforts associated with this project are minimal. The e-Delphi study has been designed to avoid raising any personal or sensitive issues. You may refuse to answer any question if at any point you feel uncomfortable, without any consequence to you. In the unlikely event that topics arise that might cause you distress, you are free to terminate your participation without giving a reason and without any consequence.

What are the possible benefits of taking part?

The potential benefit of participating is that you can express your own opinion on what data are useful to be captured by general practice pharmacy teams, thus, to aid any future evaluation by NHS England of the national pilot. The results of the study should also help to identify important activities to measure outcomes of pharmacists' input in the general practice environment.

Will my taking part be kept confidential?

Yes, all information will remain confidential and used solely for this study. All questionnaires will be designed using the Bristol Online Survey (BOS) tool, thus, all questionnaires will be in an electronic format. This guarantees that you cannot be identified by your hand-writing. To further maintain confidentiality, in each study round you will be e-mailed, along with the username and the password, a unique "token" (=participation code). You will be asked to enter this "token" as the first question on the survey itself. The "token" will be different for each study round. This will enable the CI to be alerted whether you have completed the questionnaire or not so that he can send you a reminder e-mail, if necessary. It will also allow your individual notification around your own score for each question of the previous round, giving you the opportunity to compare your own results against the overall score. Please note that the username, password and the token details will all be stored only on the secure, password protected BOS platform and nowhere else other than the emails exchanged between you and the CI. Usernames, passwords and "tokens" will be stored until each study round finishes (i.e. approximately for 20 days). The list with the usernames, passwords and "tokens" will be accessible ONLY by the CI. Consequently, only the CI, and no one else, will be aware of the identity of the person filling in the questionnaire. Your email addresses will be maintained on the CI's University, password protected e-mail memory. As soon as you received the final list of the activities agreed upon (and all respective conclusions) your e-mail address along with any e-mails exchanged between you and the CI will be deleted (i.e. your e-mail addresses will be kept for approximately 12 months). All e-mails by the CI will be sent through his University, password protected e-mail account. To make clear the expertise of our participants in any subsequent publications (see the section entitled "What will happen to the results of the study?" below), some demographic data will be collected. You will be asked to state your overall years of practice as a professional, your years of practice and current role within the general practice environment or the pilot in general, as well as the region where you practise. The correlation between demographic data and token details will be known ONLY to the CI. Data analysis and information made public or included in research outputs will use only aggregated results. In any dissemination of the survey data, all identifying information from individual responses to this survey will be censored. Great care will be taken to either aggregate or coarsely categorize potential identifying information, e.g. participants' years of experience will only be reported as a range. The completed online questionnaires (along with the demographic data collected) will be stored only on the

BOS platform for five years (as per the University of Reading data time-storage requirements). The password protected BOS platform guarantees that the questionnaires will be accessible (for five years) only to the CI, and, after being separated from the "token", to his supervisors (Kath Ryan, Nilesh Patel, Wing Man Lau). After the time-period of five years has passed, all online questionnaire copies will be destroyed by deleting the whole Delphi study from the BOS platform. No hard copies of questionnaires will be created or maintained, at any stage. In each Delphi round, the CI will use the completed questionnaires to calculate the percentages of agreement over each activity and, thus, preparing the questionnaire for the next round.

What will happen to the results of the study?

The information acquired will contribute towards the PhD thesis of the CI. It will also inform the pilot sites about what and how to evaluate the services provided in preparation for requests made by NHS England. The information you give will remain confidential and you will not be individually identifiable from any reports. Findings may also be presented at conferences and published in peer reviewed journals for research and educational purposes.

What happens if something goes wrong?

In the event that something goes wrong with your participation in the study please feel free to contact either one of the study supervisors or the Quality Assurance in Research group at the University of Reading (see email address below).

Who has reviewed the study?

This project has been reviewed by the University of Reading Research Ethics Committee and has been given a favourable opinion for conduct. The study has also received Health Research Authority (HRA) approval (Integrated Research Application System Project ID: 228337).

In the event of a complaint

Please e-mail the University of Reading's Quality Assurance in Research at qar@reading.ac.uk

Thank you for your help.

What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment - an e-Delphi study (Round 1)

Page 1: Welcome

Dear Sir/Madam

Welcome to this questionnaire about pharmacists' activities in general practice. We want to know which ones you think are the most important to record. This will then allow the measurement of the impact of pharmacists working in the general practice environment.

The questionnaire is built from existing activity/outcome codes from a variety of sources which means that, at this stage, there is a lot of repetition and overlap. The aim, with your help, is to reduce the number of coded activities/outcomes and identify a few that will be essential for accurately capturing your impact in general practice without recording being burdensome.

This is the first round of a Delphi study, which is anticipated to run over 2-3 rounds. Consensus is defined as getting 80% or greater agreement on an activity/outcome to be recorded.

The questionnaire can be saved part way through (by clicking on the "Finish later" option which can be found at the bottom of each page) and returned to later. It will take approximately 10-15 minutes to complete. The questionnaire is part of the research for my PhD in Pharmacy at the University of Reading.

Many thanks in advance for your time.

Yours sincerely,

George Karampatakis

Chief Investigator - PhD student

Reading School of Pharmacy

Supervisors: Prof. Kath Ryan, Dr. Nilesh Patel

Page 2: Data protection

Please note that data collected in this questionnaire will be stored only on the secure, password protected Bristol Online Survey (BOS) platform.

The completed online questionnaires will be accessible only to me (George Karampatakis), and, after being separated from the “token”, to my supervisors (Kath Ryan, Nilesh Patel).

Data analysis and information made public or included in research outputs will use aggregated results. In any dissemination of the survey data, all identifying information from individual responses to this survey will be removed. Great care will be taken to either aggregate or coarsely categorize potential identifying information, e.g. participants’ years of experience will only be reported as a range. No other sensitive information will be collected.

Cookies and personal data stored by your Web browser are not used in this survey.

Page 3: How to complete this questionnaire

This questionnaire has two parts. The main part focusses on the activities/outcomes to be recorded (page 5). The final part (page 7) asks for some brief professional information about you.

In the main part we ask your opinion using rating scales. Please select the grade that best represents your opinion. Please read each question carefully and answer all the questions to the best of your ability. For each question you will also have the opportunity to write a short comment, if you wish, about why you gave a specific grade. For any general comments there is a "General comments" section right after the main questionnaire (page 6).

There are no right or wrong responses. We are just interested in your personal point of view and would really appreciate your honest views so that the data are robust. You can now proceed to the main questionnaire section.

Page 4: Token

1. Please enter your "token" (e-mailed to you by George Karampatakis) ✱ *Required*

Page 5: Questions

To what extent do you agree that the following codes (questions 2-82) are important to record?

2. Able to use medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

2.a. Brief explanation of your score (optional)

3. Able to manage medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

3.a. Brief explanation of your score (optional)

4. Unable to manage medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

4.a. Brief explanation of your score (optional)

5. Difficulty managing medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

5.a. Brief explanation of your score (optional)

6. Uses medication administration system (e.g. dosette box)

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

6.a. Brief explanation of your score (optional)

7. Patient understands why taking all medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

7.a. Brief explanation of your score (optional)

8. No drug side effect reported

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

8.a. Brief explanation of your score (optional)

9. Has shown side effects from medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

9.a. Brief explanation of your score (optional)

10. Drug side effect - acceptable to patient

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

10.a. Brief explanation of your score (optional)

11. Advice about side effects of drug treatment

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

11.a. Brief explanation of your score (optional)

12. On four or more medications

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

12.a. Brief explanation of your score (optional)

13. Medication satisfactory

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

13.a. Brief explanation of your score (optional)

14. Drug compliance checked

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

14.a. Brief explanation of your score (optional)

15. Medicines adherence checked

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

15.a. Brief explanation of your score (optional)

16. Drug compliance good

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

16.a. Brief explanation of your score (optional)

17. Needs assistance with medication regimen adherence

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

17.a. Brief explanation of your score (optional)

18. Needs assistance with medication concordance

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

18.a. Brief explanation of your score (optional)

19. Advice about drug treatment

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

19.a. Brief explanation of your score (optional)

20. Patient medication advice

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

20.a. Brief explanation of your score (optional)

21. Advice to continue with drug treatment

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

21.a. Brief explanation of your score (optional)

22. Medication discussed with pharmacist

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

22.a. Brief explanation of your score (optional)

23. Seen by pharmacist

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

23.a. Brief explanation of your score (optional)

24. Medication review done

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

24.a. Brief explanation of your score (optional)

25. Medication review done by pharmacist

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

25.a. Brief explanation of your score (optional)

26. Medication review done by pharmacy technician

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

26.a. Brief explanation of your score (optional)

27. Medication review done by medicines management pharmacist

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

27.a. Brief explanation of your score (optional)

28. Medication review with patient

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

28.a. Brief explanation of your score (optional)

29. Medication review without patient

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

29.a. Brief explanation of your score (optional)

30. Medication review of medical notes

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

30.a. Brief explanation of your score (optional)

31. Respiratory disease medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

31.a. Brief explanation of your score (optional)

32. Asthma medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

32.a. Brief explanation of your score (optional)

33. COPD medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

33.a. Brief explanation of your score (optional)

34. Cardiac medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

34.a. Brief explanation of your score (optional)

35. Coronary heart disease medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

35.a. Brief explanation of your score (optional)

36. Anticoagulant medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

36.a. Brief explanation of your score (optional)

37. Diabetes medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

37.a. Brief explanation of your score (optional)

38. Diabetic medicine

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

38.a. Brief explanation of your score (optional)

39. Hypertension six month review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

39.a. Brief explanation of your score (optional)

40. Antipsychotic medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

40.a. Brief explanation of your score (optional)

41. Depression medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

41.a. Brief explanation of your score (optional)

42. Epilepsy medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

42.a. Brief explanation of your score (optional)

43. Dementia medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

43.a. Brief explanation of your score (optional)

44. Bisphosphonate medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

44.a. Brief explanation of your score (optional)

45. Osteoporosis medication compliance review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

45.a. Brief explanation of your score (optional)

46. Polypharmacy medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

46.a. Brief explanation of your score (optional)

47. Other medication review

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

47.a. Brief explanation of your score (optional)

48. Medicine list reviewed for inefficient use/unwanted medicines

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

48.a. Brief explanation of your score (optional)

49. Efficacy of all medication checked

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

49.a. Brief explanation of your score (optional)

50. Indication for each drug checked

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

50.a. Brief explanation of your score (optional)

51. Repeat medication check

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

51.a. Brief explanation of your score (optional)

52. Repeat prescription reviewed by pharmacist

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

52.a. Brief explanation of your score (optional)

53. Synchronisation of repeat medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

53.a. Brief explanation of your score (optional)

54. Medication error

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

54.a. Brief explanation of your score (optional)

55. Advice to GP to change patient medication

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

55.a. Brief explanation of your score (optional)

56. Answer to GP medication-related query

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

56.a. Brief explanation of your score (optional)

57. Medication counselling

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

57.a. Brief explanation of your score (optional)

58. Medication monitoring

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

58.a. Brief explanation of your score (optional)

59. High-risk drug monitoring performed (e.g. blood levels of lithium, phenytoin)

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

59.a. Brief explanation of your score (optional)

60. Any other kind of drug monitoring performed (e.g. blood pressure for ACE-inhibitors, liver function tests for statins)

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

60.a. Brief explanation of your score (optional)

61. Blood pressure monitoring

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

61.a. Brief explanation of your score (optional)

62. Hypertension monitoring check done

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

62.a. Brief explanation of your score (optional)

63. Adjustment of a patient's medication inside the framework of drug monitoring

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

63.a. Brief explanation of your score (optional)

64. Medicines reconciliation performed

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

64.a. Brief explanation of your score (optional)

65. Medicines reconciliation post-discharge with patient

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

65.a. Brief explanation of your score (optional)

66. Medicines reconciliation post-discharge with notes

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

66.a. Brief explanation of your score (optional)

67. Medication on discharge letter

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

67.a. Brief explanation of your score (optional)

68. Medicines reconciliation on admission to a nursing home

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

68.a. Brief explanation of your score (optional)

69. Medication changed

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

69.a. Brief explanation of your score (optional)

70. Cost alternative medication switch

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

70.a. Brief explanation of your score (optional)

71. New medication added

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

71.a. Brief explanation of your score (optional)

72. Medication increased

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

72.a. Brief explanation of your score (optional)

73. Medication decreased

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

73.a. Brief explanation of your score (optional)

74. Medication stopped - side effect

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

74.a. Brief explanation of your score (optional)

75. Drug therapy discontinued

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

75.a. Brief explanation of your score (optional)

76. Stop an unnecessary request for an antibiotic (e.g. for rescue packs)

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

76.a. Brief explanation of your score (optional)

77. Medication optimisation

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

77.a. Brief explanation of your score (optional)

78. Medication management plan in situ

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

78.a. Brief explanation of your score (optional)

79. Clinical check on a patient

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

79.a. Brief explanation of your score (optional)

80. Contact with the local community pharmacy

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

80.a. Brief explanation of your score (optional)

81. Medicine use review (MUR) done by community pharmacist

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

81.a. Brief explanation of your score (optional)

82. Review of a MUR sent by the community pharmacy to the clinical pharmacist in the general practice

Please don't select more than 1 answer(s) per row.

	1 (definitely disagree)	2 (probably disagree)	3 (neither agree nor disagree)	4 (probably agree)	5 (definitely agree)
Score	☐	☐	☐	☐	☐

82.a. Brief explanation of your score (optional)

Page 6: General comments

83. Please provide any general comments/ideas/thoughts you have

Page 7: Demographics

84. Please state your overall years of practice as a health professional ✱ *Required*

85. Please state your years of practice within the general practice environment ✱ *Required*

86. Please state your current role(s) within the general practice environment ✱ *Required*

87. Please state the region of England where you practise ✱ *Required*

Page 8: Thank you

Dear Sir/Madam

I would like to sincerely thank you for completing the first round of the Delphi study.

Your participation will significantly contribute to demonstrating pharmacy input within general practices.

Once all the questionnaires have been collected and analysed, I will be contacting you again for the second round of the study.

In the meantime and in case you have any further questions/concerns, please do not hesitate to contact me)

Again many thanks for your time.

Yours sincerely,

George Karampatakis

Chief Investigator - PhD student

Reading School of Pharmacy

Supervisors: Prof. Kath Ryan, Dr. Nilesh Patel

What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment - an e-Delphi study (Round 2)

Page 1: Welcome

Dear Sir/Madam

Welcome to the second round of this e-Delphi study. With your help, our aim is to further reduce the number of coded activities or patient outcomes and identify those codes thought essential for capturing your impact in general practice. You can still take part in this round irrespective of whether you completed the first e-Delphi round.

The questionnaire can be saved part way through (by clicking on the "Finish later" option which can be found at the bottom of each page) and returned to later. The questionnaire will take approximately 5-10 minutes to complete.

Many thanks in advance for your time.

Yours sincerely

George Karampatakis

Reading School of Pharmacy

Supervisors: Prof. Kath Ryan, Dr. Nilesh Patel

Page 2: Data protection

Please note that data collected in this questionnaire will be stored only on the secure, password protected Bristol Online Survey (BOS) platform.

The completed online questionnaires will be accessible only to me (George Karampatakis), and, after being separated from the “token”, to my supervisors (Kath Ryan, Nilesh Patel).

Data analysis and information made public or included in research outputs will use aggregated results. In any dissemination of the survey data, all identifying information from individual responses to this survey will be removed. Great care will be taken to either aggregate or coarsely categorize potential identifying information, e.g. participants’ years of experience will only be reported as a range. No other sensitive information will be collected.

Cookies and personal data stored by your Web browser are not used in this survey.

Page 3: How to complete this questionnaire

This questionnaire has two parts. The main part focuses on the activities/outcomes to be recorded (page 5-13). The final part (page 15) asks for some brief professional information about you.

In the main part we ask you to rank certain codes as "useful" or "not useful". Please read each question carefully and answer all the questions to the best of your ability. For each question you will also have the opportunity to write a short comment, if you wish, about your choice(s). For any general comments there is a "General comments" section right after the main questionnaire (page 14).

There are no right or wrong responses. We are just interested in your personal point of view and would really appreciate your honest views so that the data is robust. You can now proceed to the main questionnaire section.

Page 4: Token

1. Please enter your "token" (e-mailed to you by George Karampatakis) ✱ *Required*

Page 5: Patient outcome codes

2. Please state whether each of the following options (related to patient's ability to understand and manage medications) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Able to use medication	☐	☐
Able to manage medication	☐	☐
Unable to manage medication	☐	☐
Difficulty managing medication	☐	☐
Uses medication administration system	☐	☐
Drug compliance good	☐	☐
Needs assistance with medication regimen adherence	☐	☐
Patient understands why taking all medication	☐	☐

2.a. Brief explanation of your choice(s) *Optional*

3. Please state whether each of the following options (related to side effect outcomes) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
No drug side effect reported	☐	☐
Has shown side effects from medication	☐	☐

3.a. Brief explanation of your choice(s) *Optional*

Page 6: Medication advice codes

4. Please state whether each of the following options (related to advice given) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Advice about side effects of drug treatment	☐	☐
Advice about drug treatment	☐	☐
Advice to continue with drug treatment	☐	☐
Medication discussed with pharmacist	☐	☐
Advice to GP to change patient medication	☐	☐
Medication counselling	☐	☐

4.a. Brief explanation of your choice(s) *Optional*

Page 7: Medication review codes

5. Please state whether each of the following options (related to who has conducted the review) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Medication review done	☐	☐
Mediation review done by pharmacist	☐	☐
Medication review done by pharmacy technician	☐	☐

5.a. Brief explanation of your choice(s) *Optional*

6. Please state whether each of the following options (related to the level of the review) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Medication review without patient	☐	☐
Medication review of medical notes	☐	☐

6.a. Brief explanation of your choice(s) *Optional*

7. Please state whether each of the following options (related to specific conditions) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Asthma medication review	☐	☐
COPD medication review	☐	☐
Cardiac medication review	☐	☐
Coronary heart disease medication review	☐	☐
Anticoagulation medication review	☐	☐
Diabetes medication review	☐	☐
Antipsychotic medication review	☐	☐
Depression medication review	☐	☐
Epilepsy medication review	☐	☐
Dementia medication review	☐	☐
Polypharmacy medication review	☐	☐

7.a. Brief explanation of your choice(s) *Optional*

8. Please state whether each of the following options (related to adherence ascertainment) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Drug compliance checked	☐	☐
Medicines adherence checked	☐	☐

8.a. Brief explanation of your choice(s) *Optional*

9. Please state whether each of the following options (related to other potential activities during medication reviews) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Indication for each drug checked	☐	☐
Medication changed	☐	☐
New medication added	☐	☐
Medication increased	☐	☐
Medication decreased	☐	☐
Medication stopped - side effect	☐	☐

9.a. Brief explanation of your choice(s) *Optional*

10. Please state whether each of the following options (related to repeat medications) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Repeat prescription reviewed by pharmacist	☐	☐
Synchronisation of repeat medication	☐	☐

10.a. Brief explanation of your choice(s) *Optional*

11. Please state whether each of the following options (related to medicinal waste/costs) is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Medicine list reviewed for inefficient use/unwanted medicines	☐	☐
Cost alternative medication switch	☐	☐
Drug changed to cost effective alternative	☐	☐

11.a. Brief explanation of your choice(s) *Optional*

Page 8: Monitoring codes

12. Please state whether each of the following options is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Medication monitoring	☐	☐
High-risk drug monitoring	☐	☐
Any other kind of drug monitoring	☐	☐
Blood pressure monitoring	☐	☐

12.a. Brief explanation of your choice(s) *Optional*

Page 9: Medicine reconciliation codes

13. Please state whether each of the following options is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Medicines reconciliation performed	☐	☐
Medicines reconciliation post-discharge with patient	☐	☐
Medicines reconciliation post-discharge with notes	☐	☐
Medicines reconciliation on admission to a nursing home	☐	☐

13.a. Brief explanation of your choice(s) *Optional*

Page 10: Code related to medication errors

14. Please state whether the following code is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Medication error	☐	☐

14.a. Brief explanation of your choice *Optional*

Page 11: Code related to antibiotics

15. Please state whether the following code is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Stop an unnecessary request for an antibiotic	☐	☐

15.a. Brief explanation of your choice *Optional*

Page 12: Codes related to interactions between practice-based and community pharmacists

16. Please state whether each of the following options is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Contact with the local community pharmacy	☐	☐
Medicine use review (MUR) done by community pharmacist	☐	☐
Review of a MUR sent by the community pharmacy to the clinical pharmacist in the general practice	☐	☐

16.a. Brief explanation of your choice(s) *Optional*

Page 13: Code related to contact with a practice-based pharmacist

17. Please state whether the following code is useful or not

Please don't select more than 1 answer(s) per row.

	Useful	Not useful
Seen by pharmacist	☐	☐

17.a. Brief explanation of your choice *Optional*

Page 14: General comments

18. Please provide any general comments/ideas/thoughts you have *Optional*

Page 15: Demographics

19. Please state your overall years of practice as a healthcare professional ✱
Required

20. Please state your years of practice within the general practice environment ✱
Required

21. Please state the region of England where you practise ✱ *Required*

22. Please state your current role(s) within the general practice environment ✱
Required

23. Please provide some examples of activities that you carry out in general practice on a regular basis ✱ *Required*

Page 16: Thank you

Dear Sir/Madam

I would like to sincerely thank you for completing the second round of the Delphi study.

Your participation will significantly contribute to demonstrating pharmacy input within general practices.

Once all the questionnaires have been collected and analysed, I will be contacting you again for the third (and last) round of the study.

In the meantime, and in case you have any further questions/concerns, please do not hesitate to contact me ( )

Again, many thanks for your time.

Yours sincerely,

George Karampatakis

Reading School of Pharmacy

Supervisors: Prof. Kath Ryan, Dr. Nilesh Patel

What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment - an e-Delphi study (Round 3)

Page 1: Welcome

Dear Sir/Madam

Welcome to the third (and FINAL) round of this e-Delphi study. With your help, our aim is to identify a few codes that will not duplicate each over and that will effectively capture your impact in general practice (without recording being burdensome).

This is a much shorter questionnaire (as compared to the previous rounds). It will take approximately 3 - 5 minutes to complete.

You can still take part in this round irrespective of whether you completed the previous e-Delphi round(s).

The questionnaire can be saved part way through (by clicking on the "Finish later" option which can be found at the bottom of each page) and returned to later.

Many thanks in advance for your time.

Yours sincerely

George Karampatakis

Reading School of Pharmacy

Supervisors: Prof. Kath Ryan, Dr. Nilesh Patel

Page 2: Data protection

Please note that data collected in this questionnaire will be stored only on the secure, password protected Bristol Online Survey (BOS) platform.

The completed online questionnaires will be accessible only to me (George Karampatakis), and, after being separated from the “token”, to my supervisors (Kath Ryan, Nilesh Patel).

Data analysis and information made public or included in research outputs will use aggregated results. In any dissemination of the survey data, all identifying information from individual responses to this survey will be removed. No other sensitive information will be collected.

Cookies and personal data stored by your Web browser are not used in this survey.

Page 3: How to complete this questionnaire

Before completing the questionnaire, it is very IMPORTANT that you read the feedback from the previous round (i.e. overall percentages and comments provided by participants) that has been e-mailed to you by George Karampatakis.

In the main part of the questionnaire (pages 5 - 13), we seek your opinion on 34 codes. All questions will ask you to grade codes according to their importance (except for one in which you will be asked to rank the options in order of importance). Please read each question carefully and answer all the questions to the best of your ability (especially those in which duplication exists - PLEASE identify those codes that BEST illustrate the proposed activity or outcome).

For each question you will also have the opportunity to write a short comment about your choice(s). For any general comments there is a "General comments" section right after the main questionnaire (page 14).

Please note that there are no right or wrong responses.

You can now proceed to the main questionnaire section.

Page 4: Token

1. Please enter your "token" (e-mailed to you by George Karampatakis) *

Required

Page 5: Codes related to patient's adherence and ability to manage medication

2. Please grade the following code according to its importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medicines adherence checked	☐	☐	☐	☐	☐

2.a. Brief explanation of your choice *Optional*

3. Please rank the following codes (patient outcomes) in order of importance, where 1 is most important and 6 is least important

Please don't select more than 1 answer(s) per row.

Please don't select more than 1 answer(s) in any single column.

	1	2	3	4	5	6
Able to manage medication	☐	☐	☐	☐	☐	☐
Drug compliance good	☐	☐	☐	☐	☐	☐
Unable to manage medication	☐	☐	☐	☐	☐	☐

Difficulty managing medication	☐	☐	☐	☐	☐	☐
Uses medication administration system	☐	☐	☐	☐	☐	☐
Needs assistance with medication regimen adherence	☐	☐	☐	☐	☐	☐

3.a. Brief explanation of your choice(s) *Optional*

Page 6: Codes related to side effect outcomes

4. Please grade the following codes according to their importance (N.B. consider if both are equally important or not)

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
No drug side effect reported	☐	☐	☐	☐	☐
Has shown side effects from medication	☐	☐	☐	☐	☐

4.a. Brief explanation of your choice(s) *Optional*

Page 7: Code related to patient's understanding of medication

5. Please grade the following code according to its importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Patient understands why taking all medication	☐	☐	☐	☐	☐

5.a. Brief explanation of your choice *Optional*

Page 8: Codes related to advice given

6. Please grade the following codes according to their importance (N.B. consider whether or not the first option encompasses everything)

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Advice about drug treatment	☐	☐	☐	☐	☐
Advice about side effects of drug treatment	☐	☐	☐	☐	☐

6.a. Brief explanation of your choice(s) *Optional*

Page 9: Medication review codes

7. Please grade the following code (related to the level of the review) according to its importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medication review without patient	☐	☐	☐	☐	☐

7.a. Brief explanation of your choice *Optional*

8. Please grade the following codes according to their importance (N.B. online systems can identify the type of clinician)

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medication review done	☐	☐	☐	☐	☐
Medication review done by pharmacist	☐	☐	☐	☐	☐

8.a. Brief explanation of your choice(s) *Optional*

9. Please grade the following codes according to their importance (N.B. consider whether or not this level of detail is necessary)

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Asthma medication review	☐	☐	☐	☐	☐
COPD medication review	☐	☐	☐	☐	☐
Anticoagulation medication review	☐	☐	☐	☐	☐
Diabetes medication review	☐	☐	☐	☐	☐
Antipsychotic medication review	☐	☐	☐	☐	☐
Depression medication review	☐	☐	☐	☐	☐
Polypharmacy medication review	☐	☐	☐	☐	☐

9.a. Brief explanation of your choice(s) *Optional*

10. Please grade the following codes (related to other potential activities during medication reviews) according to their importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medication changed	☐	☐	☐	☐	☐
New Medication added	☐	☐	☐	☐	☐
Synchronisation of repeat medication	☐	☐	☐	☐	☐
Drug changed to cost effective alternative	☐	☐	☐	☐	☐

10.a. Brief explanation of your choice(s) *Optional*

11. Please grade the following codes (related to stopping medications) according to their importance (N.B. consider whether or not the first option encompasses everything)

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medication stopped	☐	☐	☐	☐	☐
Medication stopped - side effect	☐	☐	☐	☐	☐

11.a. Brief explanation of your choice(s) *Optional*

Page 10: Monitoring code

12. Please grade the following code according to its importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
High-risk drug monitoring	☐	☐	☐	☐	☐

12.a. Brief explanation of your choice *Optional*

Page 11: Medicine reconciliation codes

13. Please grade the following codes according to their importance (N.B. consider whether or not the first option encompasses everything)

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medicines reconciliation performed	☐	☐	☐	☐	☐
Medicines reconciliation post-discharge with notes	☐	☐	☐	☐	☐

13.a. Brief explanation of your choice(s) *Optional*

Page 12: Code related to medication errors

14. Please grade the following code according to its importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Medication error	☐	☐	☐	☐	☐

14.a. Brief explanation of your choice *Optional*

Page 13: Codes related to interactions between practice-based and community pharmacists

15. Please grade the following codes according to their importance

Please don't select more than 1 answer(s) per row.

	Very Important	Important	Moderately Important	Slightly Important	Not at all
Contact with the local community pharmacy	☐	☐	☐	☐	☐
Medicine Use Review (MUR) done by community pharmacist	☐	☐	☐	☐	☐

15.a. Brief explanation of your choice(s) *Optional*

Page 14: General comments

16. Please provide any general comments/ideas/thoughts you have *Optional*

Page 15: Demographics

17. Please state the region of the UK where you currently practise ✱ *Required*

Page 16: Thank you

Dear Sir/Madam

I would like to sincerely thank you for completing the final round of the Delphi study.

Once all data is properly analysed, you will receive an e-mail containing a brief summary of the findings.

In the meantime, and in case you have any further questions/concerns, please do not hesitate to contact me ( )

Again, many thanks for your time.

Yours sincerely,

George Karampatakis

Reading School of Pharmacy

Supervisors: Prof. Kath Ryan, Dr. Nilesh Patel

University of Reading

Coordinator for Quality Assurance in Research
Dr Mike Proven, BSc(Hons), PhD

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Professor Kath Ryan
Professor of Social Pharmacy
School of Chemistry, Food and Pharmacy
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RG6 6AL

25 April 2017

Dear Kath

UREC 17/21: What pharmacists' activities (codes) should be recorded: working towards investigating pharmacist input in the general practice environment - an e-Delphi study. *Favourable opinion with conditions*

Thank you for the application (email dated 15 March 2017 from Barbara Parr and including attachments refers). On the basis of these documents I can confirm that the Chair is pleased to confirm a favourable ethical opinion subject to the following conditions:

(i) The Committee asked that the project should go ahead only once HRA (Health Research Authority) review has been completed satisfactorily with a favourable opinion received. The Committee would require sight of the confirmation letter once received from HRA.

I would be grateful for your response to these points in due course – ***and in any case before the practical work of the study commences.***

Separately (*and* ***not*** *as a condition of approval*), the Committee would like to ask you to consider the recent advice – from UREC and the University's Research Data Manager, and given via Heads of Schools – to include a statement in the Consent form that would facilitate the 'downstream' sharing of data. The advice was that the researcher should check that:

"The consent form asks the research participant for permission to preserve some or all of the data they provide over the long term, and to make the data available, in anonymised form if required, either openly or subject to appropriate safeguards, so that they can be consulted and re-used by others, in accordance with the University's Research Data Management Policy."

Please note that the Committee will monitor the progress of projects to which it has given favourable ethical opinion approximately one year after such agreement, and then on a regular basis until its completion.

Please also find attached Safety Note 59: Incident Reporting in Human Interventional Studies at the University of Reading, to be followed should there be an incident arising from the conduct of this research.

The University Board for Research and Innovation has also asked that recipients of favourable ethical opinions from UREC be reminded of the provisions of the University Code of Good Practice in Research. A copy is attached and further information may be obtained here:

http://www.reading.ac.uk/internal/res/QualityAssuranceInResearch/reas-RSqar.aspx

Yours sincerely

Dr M J Proven
Coordinator for Quality Assurance in Research (UREC Secretary)
cc: Dr John Wright (Chair); Barbara Parr (Research Secretary); Dr Laura Pass (Research Clinical Psychologist);

NHS
Health Research Authority

Mr Georgios Dimitrios Karampatakis
Pharmacy Practice - Department of Pharmacy
University of Reading, PO BOX 224
Whiteknights, Reading
RG6 6AP

Email: hra.approval@nhs.net

14 July 2017

Dear Mr Karampatakis

Letter of HRA Approval

Study title:	**What pharmacists' activities (codes) should be recorded? Working towards investigating pharmacist input into the general practice environment – an e-Delphi study**
IRAS project ID:	**228337**
Protocol number:	**N/A**
REC reference:	**18/HRA/0111**
Sponsor	**University of Reading**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The attached document *"After HRA Approval – guidance for sponsors and investigators"* gives detailed guidance on reporting expectations for studies with HRA Approval, including:

- Working with organisations hosting the research
- Registration of Research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics and is updated in the light of changes in reporting expectations or procedures.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **228337**. Please quote this on all correspondence.

IRAS project ID	228337

Yours sincerely

Joanna Ho
Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Mike Proven, Sponsor Representative, University of Reading*
Professor Kath Ryan, Academic Supervisor, University of Reading
Ms Sylvia Westrup , Lead NHS R&D Contact, Ealing CCG

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [University of Reading Public Liability]	N/A	13 June 2016
IRAS Application Form [IRAS_Form_13072017]		13 July 2017
IRAS Application Form XML file [IRAS_Form_13072017]		13 July 2017
IRAS Checklist XML [Checklist_13072017]		13 July 2017
Letter from funder [Funding Letter]		
Letter from funder [Funding Letter]		
Letters of invitation to participant [Invitation letter]	5 (five)	15 May 2017
Non-validated questionnaire [Questionnaire]	5 (five)	15 March 2017
Other [Statement of Activities]	1 (one)	18 May 2017
Other [Schedule of Events]	1 (one)	18 May 2017
Participant information sheet (PIS)	6	11 July 2017
Referee's report or other scientific critique report [University of Reading Research Ethics Committee report]	N/A	25 April 2017
Research protocol or project proposal [Study protocol]	2 (two)	13 May 2017
Summary CV for Chief Investigator (CI) [CV for CI]	N/A	18 May 2017
Summary CV for student [CV for CI (student)]	N/A	18 May 2017
Summary CV for supervisor (student research) [CV for supervisor 1 (Professor Kath Ryan)]	N/A	16 May 2017
Summary CV for supervisor (student research) [CV for supervisor 2 (Dr Nilesh Patel)]	N/A	16 May 2017
Summary CV for supervisor (student research) [CV for supervisor 3 (Dr Wing Man Lau)]	N/A	16 May 2017

IRAS project ID	228337

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Mike Proven
Tel: 0118 378 7119
Email:

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The Statement of Activities will act as an agreement of an NHS organisation to participate. No other agreement is expected.
4.2	Insurance/indemnity arrangements assessed	Yes	Sponsor indemnity is in place for the design and management of the study. NHS indemnity applies to the conduct of the study. Where applicable, independent contractors (e.g. General Practitioners)

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	Funding secured from Pharmacy Care Solutions Limited. No funding will be provided to participating NHS organisations as indicated in the Statement of Activities.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Not Applicable	This study did not require review by a REC as the research is limited to the involvement of staff as participants only.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.

This is a non-commercial multicentre study where all participating NHS organisations will be undertaking the same research activity, therefore there is only one site-type for this study.

The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website.

If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.

The HRA has determined that participating NHS organisations in England **are not expected to formally confirm their capacity and capability to host this research,** because the research will involve staff only as participants to take part in a series of online questionnaires.

- The HRA has informed the relevant research management offices that you intend to undertake the research at their organisation. However, you should still support and liaise with these organisations as necessary.
- Following issue of the Letter of HRA Approval the sponsor may commence the study at these organisations when it is ready to do so.
- The document "Collaborative working between sponsors and NHS organisations in England for HRA Approval studies, where no formal confirmation of capacity and capability is expected" provides further information for the sponsor and NHS organisations on working with NHS organisations in England where no formal confirmation of capacity and capability is expected, and the processes involved in adding new organisations. Further study specific details are provided the *Participating NHS Organisations* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections of this Appendix.

IRAS project ID	228337

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Local Collaborator should be in place for each participating NHS organisation. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Local staff at participating NHS organisations will be taking part in the study where contact will be made with the Chief Investigator via email only. Therefore no HR access arrangements are expected for this study.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 3. Ethics application documents for the study with community pharmacy teams

University of Reading

School of Chemistry, Food and Pharmacy
Research Ethics Committee

Application Form for Internal Approval

SECTION 1: APPLICATION DETAILS

1.1

Project Title: Perceptions and experiences of community pharmacy staff on pharmacists working in general practice.

Date of Submission: 30/8/17 Proposed start date: 25/9/17 Proposed End Date: 8/12/17

1.2

Principal Investigator: Dr Nilesh Patel

Office room number: HN 1.05A Internal telephone: 4639

Email address: nilesh.patel@reading.ac.uk Alternative contact telephone:
(Please note that an undergraduate or postgraduate student cannot be a named principal investigator for research ethics purposes. The supervisor must be declared as Principal Investigator)

Other applicants

Professor Kath Ryan

Name of student researchers: Tonderai Dhliwayo, Wing Vong, Farzad Rustame, Stuti Chauhan, Jayesh Bhatt, Ghanish Cheemontoo, Esha Darlami, Damini Patel, Asma Ali, Zarah Chaudhry.

Emails of project team: Kath Ryan); Tonderai Dhliwayo), Wing Vong), Farzad Rustame), Stuti Chauhan), Jayesh Bhatt), Ghanish Cheemontoo), Esha Darlami), Damini Patel), Asma Ali), Zarah Chaudhry), Graham Stretch

(advisor:)

….

1.3

Project Submission Declaration

I confirm that to the best of my knowledge I have made known all information relevant to the SCFP Research Ethics Committee and I undertake to inform the Committee of any such information which subsequently becomes available whether before or after the research has begun.

I understand that it is a legal requirement that both staff and students undergo Criminal Records Checks when in a position of trust (i.e. when working with children or vulnerable adults).

University of Reading

I confirm that a list of the names and addresses of the subjects in this project will be compiled and that this, together with a copy of the Consent Form, will be retained within the School for a minimum of five years after the date that the project is completed.

Signed (Principal Investigator) Date: 22/9/17

…… (Student) Date……

(Other named investigators) Date: 22/9/17

See below…… (Other named investigators) Date……

Tonderai Dhliwayo

Wing Vong

Farzad Rustame

Stuti Chauhan

Jayesh Bhatt

Ghanish Cheemontoo

Esha Darlami

Damini Patel

Asma Ali

Zarah Chaudhry

1.4

SCFP (Internal Approval) Ethics Committee Applications

Projects expected to require review by the SCFP Ethics Committee must be reviewed by a member of the School research ethics committee and the Head of School before submission.

Signed…… (Chair/Deputy Chair of School Committee) Date:……

Signed…… (Head of Department) Date:……

Signed…… (SCFP Ethics Administrator) Date:……

University of Reading

SECTION 2: PROJECT DETAILS

2.1

Please provide a summary of the project in **non-specialist terms** that could be understood by **non-scientist members of the public**, which includes a description of the scientific background to the study (existing knowledge), the scientific questions the project will address and a justification of these. Please note that the description must be sufficient for the committee to take a reasonable view on the likely scientific rigour and value of the project

Population growth in the UK means that there is an ever-increasing demand for general practitioners' (GP) services. Unfortunately, the increased demands in a climate where there is a shortage of GP's, has led to increased waiting times and general complaints about the lack of patient care. Pharmacists are practitioners at the forefront of healthcare with access to patients. They are equipped to provide patients with one-to-one support regarding the use of their medicines, which ensures that they get the best from them and so improve their health. Due to pharmacists' skills and valuable position within communities, the NHS has introduced a pilot scheme to employ pharmacists' services in selected general practices. However, the scheme has met with some resistance, with anecdotal reports of concern amongst community pharmacists, who having seen increased funding for the pharmacists in general practice pilot scheme, have perceived a reduction in funding for community pharmacy.

Currently, there is little evidence regarding the perceptions of community pharmacy staff (pharmacists, pre-registration pharmacists, pharmacy technicians and dispensers) in relation to the scheme or the potential for greater integration of their profession into general practice. This is of importance as community pharmacists are integral to the continuing care of patients, provide services to patients for which they are reimbursed and have existing relationships with general practices. In this project, we aim to explore community pharmacy staff perceptions and experiences of the pharmacists in general practice pilot scheme. Community pharmacies situated around general practices in Ealing where the scheme is operating will be interviewed. In-depth interviews will be conducted by final year pharmacy students in pairs. The findings will contribute to evidence-based knowledge and highlight new information with regards to the pharmacists in general practice pilot scheme.

(*This box may be expanded as required* – ***Word Limit Maximum 250***)

2.2

Procedure

Please describe concisely what the study will involve for your participants and the procedures and methodology to be undertaken (*you may expand this box as required*).

We will recruit community pharmacy staff (pharmacists, pre-registration pharmacists, pharmacy technicians and dispensers) within the Ealing, London area where there are general practices involved in the pharmacists in general practice pilot scheme. Eight general practices have been identified that fulfil this criterion. Semi-structured interviews will be undertaken to gauge perceptions and experiences of pharmacists employed in general practice and how, or if, this has impacted upon their own provision of services.

The project team consists of 10 undergraduate fourth year MPharm students (who will work in pairs), two supervisors (Ryan and Patel) and one advisor (Stretch).

Community pharmacy staff: Participants will be identified by searching the NHS Choices website (open and public access) for community pharmacies in the Ealing area using postcodes of the eight general practices and a radius of up to two miles to narrow the search. Names, addresses and phone numbers of the pharmacies will be retrieved from the list obtained through NHS Choices. The researcher pairs will assign themselves to a group of pharmacies. The pairs will phone each pharmacy to ask to speak to the responsible pharmacist who will be asked if they have the time to briefly talk about the study. If they don't have the time, and provided they are happy to do so, a convenient time will be arranged to call back. The pharmacist will be told about the study and asked if they will be willing to take part, or nominate an appropriate member of staff who would be willing to participate. We will be looking to recruit a pharmacist and/or other staff members (pre-registration student, pharmacy technician or dispenser), for participating community pharmacies If any identified member of staff verbally consents to taking part in the study an email address will be collected with their permission. All potential participants will then be emailed a covering letter, information sheet and consent form. If an email is not provided but they want to take part in the study, the potential participant will be posted the above documentation. Participants will be followed up one week later by a phone call, then three days after this before recruitment attempts will cease.

The researcher pairs will conduct individual depth, semi-structured, audio-recorded, qualitative interviews, lasting approximately 30-45 minutes with 10-12 participants (community pharmacists and/or other pharmacy staff members). The guiding interview schedule is appended. The interviews will be undertaken at a time and place convenient to the participants, recorded on audio recorders (with consent), and downloaded to password protected computers as soon as practicable after the interview, after which the recordings will be deleted from the audio recorder. If consent for audio recording is not received then the researchers will make notes of the interview. Full transcripts will be prepared by the researchers, after receiving training from the supervisors, on password-protected computers and stored on a project specific shared drive on a University of Reading secure server.

Participants will remain anonymous and any emails collected will not be disclosed. Consent forms will be given a code to be used on all further documents relating to the same participant, and then stored separately from all data in the principal investigator's locked filing cabinet at the University. Participant names or health information will not be collected during interviews. Age for all participants, brief role details, including years of practice, and type of pharmacy (independent, medium chain, or large chain) will be recorded, held in confidence, and reported in aggregate form to protect anonymity. The researchers will be trained by the supervisors to undertake thematic analysis, which will be the methodology used for analysing the interview data. Findings will be used to complete student research project reports and for research and educational purposes, such as teaching, conference presentations and publication in peer-reviewed scientific journals. Consent forms will be confidential and kept in locked storage for five years at the University of Reading, according to its data storage policy.

Note: All questionnaires or interviews should be appended to this application)

2.3

Where will the project take place?

This project will take place at the various community pharmacy premises located around general practices involved with the pharmacists in general practice pilot scheme. Eight general practices have been identified that fit these criteria within Ealing, London. Within a two-mile radius of each surgery there are a total of 104 community pharmacies.

- The Florence Road surgery, 26 Florence road, London, W5 3TX
- The Surgery, 14 Cuckoo Lane, London, W7 3EY
- The Argyle Surgery, 128 Argyle Rd, London, W13 8Er
- Grosvenor House Surgery, 147 Broadway, London, W13 9BE
- Elthorne park Surgery, 106 Elthorne Park Rd, London, W7 2JJ
- Cloister Road Surgery, 41-43 Cloister Rd, London, W3 0DF
- Bramley Road surgery, 2 Bramley Rd, London, W5 4SS
- Ealing Park Health Centre, 195A S Ealing Rd, London, W5 4RH

2.4

Funding

Is the research supported by funding from a research council or other *external* sources (e.g. charities, business)? **No**

If Yes, please give details:

Please note that *all* projects (except those considered as low risk, which would be the decision of the School's internal review committee and require Head of Department approval) require approval from the University Research Ethics Committee.

2.5

Ethical Issues

Could this research lead to any risk of harm or distress to the researcher, participant or immediate others? Please explain why this is necessary and how any risk will be managed.

Participation is entirely voluntary. Interviews will be largely guided by the participants themselves and they will choose what to disclose and what to keep private. There is a potential yet very small risk to participants. For example, some participants might start to feel a little uncomfortable whilst being interviewed. If follow-up or prompting questions seem inappropriate the researchers will respect the participant's choice not to answer and move onto the next topic. The safety of all participants will be addressed by reminding the researchers of their previous MPharm training in data protection and information governance, consent and confidentiality, raising and reporting concerns and communication

skills. These will be reinforced by the project supervisors as well as the researchers being given depth interview training. All participants have the right to withdraw at any time and have their data destroyed without any consequences. Non-participation will also be without consequence.

All interviews will take place with two researchers in the private consultation room of the pharmacy, or a quiet place of mutual convenience. Details of all supervisors will be given to participants on the information sheet, in case they want to raise any further questions, make a complaint or withdraw from the study.

Before the interviews take place, the researchers will notify the supervisors of the place, date and time of the interview and will need to report back (via telephone call) to the supervisor within 30 minutes of the expected completion of the interview to say that they are safe and have left the premises/interviewee. If they do not report in that time frame, the supervisors will call them. If no response the supervisors will wait 15 minutes and call again. If still no response, the supervisors will call the police.

No health information will be collected from participants, however any personal information acquired during the interviews, such as emails, qualifications and years of service, will be kept strictly confidential. Participants will not be expected or asked to disclose any personal or contact details that could identify them during the interview.

At the end of the first interview there will be a debriefing session for each pair with the supervisors. If the researcher has concerns or experiences any distress because of the interviews, guidance and support will be provided by the supervisors as appropriate.

(*this box may be expanded as required*)

2.6

Deception

Will the research involve any element of intentional deception at any stage (i.e. providing false or misleading information about the study, or omitting information)? **No**

[If so, this should be justified. You should also consider including debriefing materials for participants, which outline the nature and the justification of the deception used]

2.7

Payment

Will you be paying your participants for their involvement in the study? **No**

If yes, please specify and justify the amount paid

Note: excessive payment may be considered coercive and therefore unethical. Travel expenses need not to be declared.

2.8

Data protection and confidentiality

What steps will be taken to ensure participant confidentiality? How will the data be stored?

All the data collected during the study period will be used for research and educational purposes only and no personal information such as names or any health information will be collected. Interview sessions will be recorded using a digital audio recorder with the participants' permission, or notes taken during the interview if permission to audio record is not given. The audio recordings will be copied onto a secure password protected server after which they will be deleted from the recorder. Transcription of the recordings will be done on Word® document after participant de-identification, with each participant represented by a letter and a number, to ensure the confidentiality and anonymity of individual participants in the dissemination of findings from this research. Electronic copies of the transcripts will be stored on a secure password protected University of Reading server. Data will be analysed using thematic analysis of the transcriptions on Word®. Participant data, such as consent forms will remain confidential and be kept in locked storage in a supervisor's office for five years at the University of Reading, according to its data storage policy.

Participants will be asked for brief role details, age, qualifications and years of service, in addition to the type of pharmacy they work in, which will be held in confidence. Data analysis and information made public or included in research outputs will only use aggregated results. In any dissemination of the data, all identifying information from the interviews will be removed. Great care will be taken to either pool/aggregate or coarsely categorize potential identifying information, e.g. number of years working in pharmacy will only be reported as a range. No other sensitive information will be collected.

At the conclusion of the study, the audio recordings and confidential data will be deleted. All electronic data (recordings and transcripts) and hard copy (consent forms) will be held securely (on password-protected shared drive or supervisor's locked filing cabinet and locked office respectively) for five years, after which, it will be destroyed.

2.9

Consent

Please describe the process by which participants will be informed about the nature of the study and the process by which you will obtain consent

Participants will be given an invitation letter, consent form and a participant information sheet via email or by post. The participant information sheet will describe the aims of the project and what is required of the participants and how and where the interviews will take place. Involvement in the research is voluntary and people can decline to be involved without consequence. At the time of the interview researchers will explain the study to the participants and ask if they have any questions. Any questions will be answered and then the participants will be asked to complete the consent form. The completion and return of the consent form at the time of the interview will signify the participant's informed consent to be involved in the project.

Please note that a copy of consent forms and information letters for all participants must be appended to this application.

2.10

Genotyping

Are you intending to genotype the participants? Which genotypes will be determined? **No**

Please note that a copy of all information sheets on the implications of determining the specific genotype(s) to be undertaken must be appended to this application.

SECTION 3: PARTICIPANT DETAILS

3.1

Sample Size

How many participants do you plan to recruit? Please provide a suitable power calculation demonstrating how the sample size has been arrived at or a suitable justification explaining why this is not possible/appropriate for the study.

The aim is to recruit up to 10-12 people for each researcher pair for interview or as many as possible in the time available. This is based on the number of participants available for the study at the chosen locations, as well as time and resource constraints. Within a two-mile radius of the eight surgeries there are 104 community pharmacies, which will be equally split and assigned to each pair of researchers. With five researcher pairs, this will give approximately 50-60 participants in total.

3.2

Will the research involve children or vulnerable adults (e.g. adults with mental health problems or neurological conditions)? **No**

If yes, how will you ensure these participants fully understand the study and the nature of their involvement in it and freely consent to participate?

(Please append letters and, if relevant, consent forms, for parents, guardians or carers). Please note: information letters must be supplied for all participants wherever possible, including children. Written consent should be obtained from children wherever possible in addition to that required from parents.

3.3

Will your research involve children under the age of 18 years? **No**

Will your research involve children under the age of 5 years? **No**

3.4

Will your research involve NHS patients, Clients of Social Services or will GP or NHS databases be used for recruitment purposes?

NHS Choices will be used to identify the community pharmacies.

Please note that if your research involves NHS patients or Clients of Social Services your application will have to be reviewed by the University Research Ethics Committee and by an NHS research ethics committee.

3.5

Recruitment

Please describe the recruitment process and append all advertising and letters of recruitment.

A targeted sample of potential participants will be identified using the NHS Choices website. We will purposively select participants who are knowledgeable about the pilot and have local experience of it as well as those who know nothing about it to ensure as wide a range of perceptions and experiences as possible. The locations for recruiting these pharmacies is Ealing, London. Postcodes of eight general practices involved in the pharmacists in general practice pilot scheme, and a radius of up to two miles will be used to narrow the search and identify the pharmacies. Names, addresses and phone numbers of the pharmacies will be retrieved from the list obtained through NHS Choices and kept by the supervisors. From this list, the researcher pairs will assign themselves to a group of pharmacies, which will be recorded and noted by the supervisors. The pairs will phone each pharmacy to ask to speak to the responsible pharmacist who will be asked if they have the time to briefly talk about the study. The responsible pharmacist will be the person in charge of the premises at the time of contact. This could be a regular or a locum pharmacist. Both types of pharmacists would be of interest to our study. If the responsible pharmacist doesn't have the time, and provided they are happy to do so, a convenient time will be arranged to call back. The pharmacist will be told about the study and asked if they are willing to take part, or nominate an appropriate member of staff who would be willing to participate. We aim to recruit a pharmacist and/or other staff members (pre-registration student, pharmacy technician or dispenser) for participating community pharmacies. If any identified member of staff verbally consents to taking part in the study an email address will be collected with their permission. All potential participants will then be emailed a covering letter, information sheet and consent form. If an email is not provided but they want to take part in the study, the potential participant will be posted the above documentation. Participants will be followed up one week later by a phone call, then three days after this before recruitment attempts will cease.

University of Reading

Participant Letter of Invitation

Project title: Perceptions and experiences of community pharmacy staff of pharmacists working in general practice.

Dear Sir or Madam,

Thank you for indicating your interest in this study. Please accept this letter as a formal invitation to take part in this study about your perceptions and experiences of the pharmacists in general practice pilot scheme that has been set up by NHS England in association with the Royal Pharmaceutical Society and the Royal College of General Practitioners.

Before you decide if you would like to take part, it is important for you to understand why the project is being undertaken and what it will involve. Please take time to read the attached participation information sheet. If you wish to discuss the study further or have any other queries about the study, please feel free to contact Dr Nilesh Patel who is the principal investigator for this study (,

If you would like to participate in this study, please reply to this email or phone Dr Patel using the number above.

Yours sincerely,

Dr Nilesh Patel
Lecturer in Pharmacy Practice

Project team:
Supervisors: Kath Ryan, Nilesh Patel
Students: Tonderai Dhliwayo, Wing Vong, Farzad Rustame, Stuti Chauhan, Jayesh Bhatt, Ghanish Cheemontoo, Esha Darlami, Damini Patel, Asma Ali, Zarah Chaudhry

Supervisor: Dr Nilesh Patel

☎

Email:

University of Reading, Room 1.05a,

Harry Nursten Building,

PO Box 226, Whiteknights, Reading,

Berkshire. RG6 6AP

Reading School of Pharmacy

Harry Nursten Building

Whiteknights, PO Box 226

Reading RG6 6AP

UK

Project Title: Perceptions and experiences of community pharmacy staff of pharmacists working in general practice.

Invitation:
I would like to invite you to take part in an interview. Before you decide if you want to take part, I would like you to understand why this study is being carried out and what your participation would involve. If you need any clarification after reading this information sheet, I can call you and go through the information sheet with you to answer any questions you have. It should only take about 5 to 10 minutes to read this information sheet.

What is the purpose of the study?
The purpose of this study is to explore pharmacy staff perceptions about, and experiences of, having pharmacists working in general practice.

Why have you been invited?
You have been invited to take part in the study because you are a community pharmacist, pre-registration pharmacist, pharmacy technician or dispenser working in Ealing, which has general practices employing pharmacists to provide pharmacy services. We would like to find out your perceptions and experiences, if any, of having pharmacists working in general practice.

Do you have to take part?
Participation in any part of this study is entirely voluntary. It is up to you to decide if you wish to join the study. If wish to take part, please reply to the email invitation or alternatively contact Dr Nilesh Patel (contact details in the letter head) who is the principal investigator for this study.

What will happen if you take part?
You will be contacted by a final year undergraduate pharmacy student to arrange a suitable date and time for interview. At the time of the interview researchers will explain the study to you and ask if you have any questions. Your questions will be answered and then you will be asked to complete the consent form. The interview should last approximately 30-45 minutes. The interviews will be audio recorded with your permission and the data will be stored securely. The audio recordings will be destroyed once transcribed and all confidential information provided will be anonymised. Please note that you are also free to withdraw at any time during the study, without giving a reason or consequence.

University of Reading

What will you have to do?
Please read the information provided to you in this information sheet, and in the email invitation. If you are interested in the study, you will need to reply to the email invitation or alternatively contact Dr Nilesh Patel. On the day of the interview you will need to sign a consent form after which you will be asked by a pair of students about your perceptions and experiences, if any, of having pharmacists working in general practice.

What are the possible disadvantages and risks of taking part?
The study is designed with minimal potential risks to all participants. You have the right not to answer any questions that might make you feel uncomfortable. You are free to terminate your participation in the interview without giving any reason. Please inform the student pairs before or during the interview or contact Dr Patel. The contact details of Dr Patel are provided in the letter head and he will be available to talk to you if you require any additional support.

What are the possible benefits of taking part?
The study might not help you directly but the information you provide might create a better awareness of how the pharmacists in general practice pilot scheme is perceived by community pharmacy staff or affects the services they provide to patients.

What if there is a problem?
Any complaints about the way you have been dealt with during the study can be addressed by contacting Dr Patel as indicated in the letter head. Alternatively, you can contact Professor Kath Ryan (; or the University of Reading's Quality Assurance in Research at qar@reading.ac.uk.

Will my taking part in the study be kept confidential?
Confidentiality for all participants will be ensured and all data collected will be used for scientific research and educational purposes only. Interviews will be recorded with your permission using an audio recorder. The recordings will be downloaded onto a password-protected secure University of Reading server for transcription into a Word® document. Once this is completed, the digital recordings will be deleted from the recorder.

Consent forms will be stored in a locked cabinet in a secure office and will be accessible only by the principal investigator after the study is complete. All participants' identifiable details will be removed from the interview transcripts and all information anonymised using a letter and a number, to ensure the confidentiality and anonymity of individual participants in the dissemination of findings from this research. All electronic (recordings and transcripts) and hard copy (consent forms) data will be held securely for five years, after which, it will be destroyed.

What will happen if you don't carry on with the study?
If you do not wish to carry on with this study, you can withdraw at any time without giving a reason and without consequence or repercussions.

What will happen to the result of the study?
The results of this study will be used to complete student research project reports and for research and educational purposes, such as teaching, conference presentations and publication in peer-reviewed scientific journals. The details of all participants will be kept confidential and you will not be identifiable from any research paper or other publications. You may request a summary of the results if you want.

Who is organising and funding the research?
The study is being conducted with the University of Reading acting as the academic institution.

Who has reviewed the study?
This study has been reviewed by the School of Pharmacy, University of Reading. The approval number is xxxxxxx.

Contact details for further questions, or in the event of a complaint

Principal Researcher: Dr Nilesh Patel
Lecturer in Pharmacy Practice
Reading School of Pharmacy
Whiteknights
Reading, RG6 6AP

Project supervisor: Professor Kath Ryan).

Thank you for your help.

University of Reading

Dr Nilesh Patel
Department of Pharmacy

School of Chemistry, Food & Nutritional Sciences and Pharmacy

Whiteknights
PO Box 266, Reading RG6 6AP, UK
phone
fax

Perceptions and experiences of community pharmacy staff of pharmacists working in general practice.

Please initial boxes

1. I confirm that I have read and understand the Participant Information Sheet (version 4, dated 03/10/17) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason or repercussions. ☐

3. I understand that the researchers will maintain confidentiality and that any information I supply to the researchers will be kept confidential and used for research and educational purposes only. ☐

4. I have received a copy of this Consent Form (version 4, dated 03/10/17) and of the accompanying Participant Information Sheet (version 4, dated 03/10/17). ☐

5. I agree to take part in the above study, which has been subject to ethical review according to the procedures specified by the University of Reading Research Ethics Committee and has been allowed to proceed. ☐

6. I agree to the interview being recorded. ☐

7. I give permission for the researcher(s) to make written notes during the interview. ☐

Participant details

Name of Participant: _____

Signature: _____ Date: _____

Witnessed by

Name of researcher taking consent: _____

Signature: _____ Date: _____

From: Parastou Donyai <p.donyai@reading.ac.uk>
Sent: 03 October 2017 14:44
To:
Cc: Barbara Laura Parr (
Subject: re: Ethics Approval - Study Number 18/17
Importance: High

Dear Nilesh and Kath

I am pleased to inform you that Professor Becky Green has given a favourable opinion for conduct for your study '**Perceptions and experiences of community pharmacy staff on pharmacists working in general practice**' via the in-School exceptions route. This email constitutes your permission to proceed with the studies as described in your application. The following study number has been assigned to your study and you should quote this number in any correspondence you undertake about your studies.

STUDY Number - 18/17

If you feel that you need to make changes to the way your studies are run, please let us know at the earliest opportunity and we can advise you of whether a formal amendment to your proposal is required or not.

I wish you the best of luck with the projects and finish by reminding you of the need for safe custody of project data at all times (a service that Barbara Parr, copied in, can provide if you require it).

Kind regards

Parastou
Dr Parastou Donyai PhD, BPharm, BSc (Hons) Psych (Open), PGDPRM (Open), PGCertPsychTher
Pharmacist, MRPharmS, FHEA, MBPsS
Associate Professor of Social and Cognitive Pharmacy
Director of Pharmacy Practice, Reading School of Pharmacy

Ethics Representative, Pharmacy

* | University of Reading, Room 1.02, Harry Nursten Building,
PO Box 226, Whiteknights, Reading, Berkshire RG6 6AP

Appendix 4. Ethics application documents for the study with patients

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Patients' experiences of general practice-based pharmacists (v4)

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

(●) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
◯ Scotland
◯ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◯ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◯ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
This study is part of a PhD programme (Doctor of Philosophy). The PhD student will act as the Chief Investigator for the study which will include face-to-face interviews with patients. The Chief Investigator will be designing the interview schedule, carrying out the actual interviews, analyzing (in close cooperation with the rest of the research team) all interview data and producing a report and publication on the findings.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Patients' experiences of general practice-based pharmacists (v4)

Please complete these details after you have booked the REC application for review.

REC Name:
Yorkshire and the Humber-Leeds East

REC Reference Number:
18/yh/0347

Submission date:
02/08/2018

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Patients' experiences of general practice-based pharmacists in England: an exploratory qualitative study

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Mr	Georgios Dimitrios	Karampatakis
Address	Pharmacy Practice - School of Pharmacy		
	University of Reading, PO Box 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail			
Telephone			
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctor of Philosophy (PhD)

Name of educational establishment:
University of Reading

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Professor	Kath	Ryan
Address	Pharmacy Practice - School of Pharmacy		
	University of Reading, PO Box 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail			
Telephone			
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Nilesh	Patel
Address	Pharmacy Practice - School of Pharmacy		
	University of Reading, PO Box 224		
	Whiteknights, Reading		
Post Code	RG6 6AP		
E-mail			
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Mr Georgios Dimitrios Karampatakis	☑ Professor Kath Ryan ☑ Dr Nilesh Patel

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ◉ Student
- ○ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Mr	Georgios Dimitrios	Karampatakis
Post	PhD student		
Qualifications	MSc in Clinical Pharmacy (2016) - University College London MPharm (2014) - Aristotle University of Thessaloniki		
ORCID ID	0000 0003 0623 8231		
Employer	University of Reading		
Work Address	Pharmacy Practice - School of Pharmacy University of Reading, PO Box 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Work E-mail			
* Personal E-mail			
Work Telephone			
* Personal Telephone/Mobile			
Fax			

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Dr	Mike	Proven
Address	The University of Reading - Whiteknights House Whiteknights, PO Box 217 Reading		
Post Code	RG6 6AH		
E-mail			
Telephone			
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	N/A
Sponsor's/protocol number:	N/A
Protocol Version:	N/A
Protocol Date:	
Funder's reference number (enter the reference number or state not applicable):	N/A
Project website:	N/A

Additional reference number(s):

Ref.Number Description	Reference Number
N/A	N/A

Registration of research studies is encouraged wherever possible. You may be able to register your study through

your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

(●) Yes ( ) No

Please give brief details and reference numbers.
This study is a result of a previous e-Delphi study with general practice-based pharmacists for which Health Research Authority approval was successfully gained in July 2017 (IRAS project ID: 228337).

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

What are the experiences and the needs of patients concerning general practice-based pharmacists?

In England, there is a drive to integrate pharmacists into general practices through large national schemes. The integration began with a pilot project followed by a second phase of roll-out aiming to introduce one practice-based pharmacist per 30,000 population by 2020. The availability of practice-based pharmacists to this extent is a new service offered in UK primary care. In terms of evaluating the service's impact on the wider healthcare system, a set of ten national Key Performance Indicators (KPIs) has already been developed (eight numerical and two based on patient and GP experiences).
Patients' experiences have been historically deemed as one of the main domains that mirror the quality of a new healthcare service. Therefore, our purpose with this qualitative study is to directly work with patients and elicit their experiences with regards to general practice-based pharmacists including their service preferences, information needs, other expectations they may have from the service and their current satisfaction levels. The study will involve a series of individual, face-to-face, interviews with patients who have experienced practice-based pharmacists' services and who are registered with general practices part of the Ealing GP Federation in West London. All interviews will be carried out in meeting or consultation spaces inside the practice with which each patient is registered. Our aim is to understand patients' views in depth. We anticipate that our findings will inform national policy on how to shape the service to better meet patients' expectations and/or needs including introducing appropriate improvements in the way the service is offered or marketed to the patients.
The research is supported by a University of Reading Postgraduate Studentship. We anticipate that the overall project (data collection, analysis and written up) will take approximately 12 months.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Every part of this study was developed in close collaboration and discussion with the Chief Investigator's academic supervisors and in compliance with the University of Reading research policies.
Risks for the participants associated with this project are minimal. This project will consist of individual, face-to-face, interviews with patients. As our purpose is to understand participants' opinions in depth, we selected a purely qualitative design for this study rather than carrying out a survey-based approach which does not necessarily capture experiences. We selected the approach of individual interviews (rather than focus groups) to encourage participants to fully express their honest opinions on the service (participants are often uncomfortable to express their views in front of other co-participants during group discussions).

Recruitment will be de done by general practice-based pharmacists at the time of their consultations with patients. Contribution to the recruitment process (for general practice-based pharmacists in Ealing) and participation in the study (for patients) will be voluntary and no monetary incentives will be provided. This will ensure that no coercion or pressure on participants during recruitment is possible. Participants will be receiving info sheets fully describing the study and will also have the option to ask for further clarifications during, before or after the interview. All participants will be adults and competent to provide consent for participation (competency will be determined by a qualified healthcare professional, the practice-based pharmacist, during recruitment). Written consent will be obtained before participation in the interview (including permission to audio-record the interview and provision of contact details should participants desire to be informed of the findings).
The whole research team has undertaken appropriate training in qualitative research methods and conducted one-to-one interviews in the past. Therefore, we believe that the interviewing process will be successful and participants' views will be explored in depth. Debriefing sessions of the whole research team will be carried out regularly to discuss and solve any potential problems with data collection. The interviewer (i.e. the Chief Investigator) will avoid discussions, during the interview, on any topics potentially sensitive for the participants. Should participants feel uncomfortable, however, they will have the right to refrain from parts of the discussion or to terminate their participation at any time without giving a reason and without any detriment. In the event of a withdrawal prior to data analysis, participants will be able to have their data destroyed (if withdrawal occurs during or after data analysis, however, data will still be used in the research). Participants will be asked to devote approximately 90 minutes of their time (the actual interviewing time will approximately be 60 minutes but up to 90 minutes may be needed for introductions, answering questions, signing of consent forms, demographic data collection etc.). Therefore, all possible precautions will be followed to limit the impact on participants' work/commitments (interviews will be held within the practice with which each patient is registered and at a convenient time for the participants and every attempt will be taken not to exceed the above-mentioned time limits). Confidentiality and privacy will be ensured for all participants and participants will not be individually identifiable from any research outputs (see relevant sections). All interviews will be carried out inside private rooms (e.g. meeting or consultation spaces) so that participants feel comfortable to freely express their honest views about pharmacists' services.
There are no significant risks for the researchers.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

What are patients' experiences and needs with regards to pharmacists' services provided within general practices in England (including service awareness, preferences and needs, information needs, expectations from the service, satisfaction levels, areas for improvement)?

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to*

a lay person.

N/A

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

It has recently been found that, in England, there is a shortage of approximately 8000 general practitioners (GPs) and an oversupply of pharmacists with excess numbers estimated to be between 11,000 and 19,000 within the next 20 years. To address the needs in the healthcare workforce, therefore, National Health Service (NHS) England along with Health Education England, the Royal College of General Practitioners, the British Medical Association's General Practitioners Committee and the Royal Pharmaceutical Society co-support and sponsor large national schemes to co-locate pharmacists within the general practice environment (as equal members of the primary care teams). This drive to integrate pharmacists into general practice began with a national pilot (announced in July 2015) which resulted in more than 490 new pharmacists' posts across 90 sites in England (this translates to approximately 698 practices). Following the pilot, a second phase of introducing pharmacists into general practice started (in April 2016) with the ultimate goal to allocate one pharmacist per 30,000 people by 2020. Large monetary investments have been provided to support these 'pharmacists in general practice' (PGP) schemes (over £140 million so far). Although UK pharmacists have occasionally provided services in general practice in the past, this is the first time that NHS England has tried in a formal way to implement and test the role of pharmacists in this setting. The availability of a general practice-based pharmacist to this extent, therefore, is a new service offered in UK primary care.
In terms of evaluating the impact of the service on patients, GPs and the overall healthcare system, a set of national Key Performance Indicators (KPIs) has been developed. At the moment, ten of the KPIs are based on numerical components (e.g. increase in total number of medication reviews) and two on patient and GP experiences. The experiences and the views of patients are always perceived to form a core measure of the success of a new healthcare service and an excellent indicator of what improvements and/or changes need to be implemented so that the provided service meets the needs of its users. Although one of the national measures for practice-based pharmacists' services accounts for patients' experiences, no explicit agreement on what way their views are best elicited has been announced as yet. At present, a variety of surveys are employed by different practices across the nation (e.g. "friends and family test"). Surveys and tick-box exercises, however, often fail to capture experiences of a service. Therefore, our purpose with this study is to develop a deep understanding of patients' attitudes towards general practice-based pharmacists (in particular what needs and/or expectations they have and how general practices and practice-based pharmacists could contribute) and explore patients' preferred ways of providing their feedback and incorporating the new service into their culture (previous work undertaken by us in 2015 found that patients, to a large degree, are unaware about practice-based pharmacists' capabilities and/or skills). We anticipate that our findings will be useful for national policymakers and service providers, particularly on what actions need to be taken so that the service (and its evaluation and/or marketing) is shaped according to patients' needs and preferences.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Our study will be of a qualitative design to explore in depth and fully understand participants' views. It will involve individual, semi-structured, face-to-face interviews with patients who have experienced general practice-based pharmacists' services and who are registered with practices that are part of the Ealing GP Federation in West London. We selected this West London GP Federation as a recruiting point because its practices have working connections with our organisation. We chose a qualitative design for the study versus a quantitative approach (e.g. questionnaire) to allow a more thorough understanding of experiences and a more immediate collection of data (questionnaires are sometimes associated with a low response rate which negatively affects the time-frameworks of a PhD). Individual interviews, rather than focus groups, were selected to encourage the expression of honest views (participants might not fully express their views in front of other co-participants during focus group discussions). We also anticipate that the semi-structured design will allow us to pick up any interesting points that arise in the discussion (an ability that would not be available if the format was strictly structured). Interviews will continue until data saturation (i.e. no new information is forthcoming), expected to be between 15 and 30 interviews.
Potential participants will be identified at the time of a consultation with a general practice-based pharmacist. The lead pharmacist in the Ealing GP Federation (local investigator) and his team (who consents to help with recruitment) will hand out the study's invitation pack to the first (from the time approval is gained) 50 patients they meet on their consultations who fulfil our inclusion criteria. The invitation pack will include an Invitation Letter, Participant Information Sheet, Consent Form and a Reply Form with a pre-paid, University of Reading, return envelope. Participants will be therefore fully informed about the study through the invitation pack and will also have the option for further clarifications by directly contacting the research team (see relevant section). Potential participants will be asked (through the Participant Information Sheet and Invitation Letter) to contact the Chief Investigator (CI) if they wish to be involved (either via e-mail or by filling in and posting, within the return envelope, the Reply Form). Once interest for participation is confirmed, the CI will contact participants to schedule the interview. The CI will conduct all interviews in private

meeting or consultation spaces within the general practice with which each patient is registered. Just before each interview, the CI will introduce himself, thoroughly explain to participants the process and answer any questions they may have. Participants will be then asked to sign the Consent Form. After that, some demographic data (age-group, gender, number of visits to a general practice-based pharmacist) will be collected by the CI by filling in a relevant form (appended to this application) followed by the actual interview. Each interview itself will approximately last 60 minutes but up to 90 minutes may be needed for the full process (introductions, answering questions, signing consent forms, collecting demographic data etc.). During the interview, the CI will use a flexible schedule (appended to this application) containing open-ended questions to begin the discussion and will then talk as little as possible simply adding prompts to keep the discussion on topic, explore comments in greater depth and encourage reflection on opinions. This is to ensure that participants are able to raise experiences and issues of importance to them in their own order and using their own language. All interviews will be audio-recorded after gaining participants' permission (if any of the participants is unhappy to be audio-recorded, then detailed notes will be kept instead). The audio records will be transcribed verbatim by the CI or by a professional transcriptionist (depending on the availability of funds) and transcripts will be analysed thematically. We expect that the scheduling and conduction of the interviews to take up to four months. Post the interviews, six more months will be needed until the data is fully analysed, interpreted and written up.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
We have already conducted some workshops and a coffee meeting with members of the Ealing GP Federation Patient Participation Group and we have identified a few key topics that patients deemed as 'important' to be further explored. These topics will be included in the discussion during the interviews. Therefore, patients had 'a say' in the design of the interviews and particularly in the topics to be covered. We will be also using representatives of the Ealing GP Federation Patient Participation Group to circulate the findings of this study.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection

- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☐ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit:	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Only people who fulfil all of the following criteria will be included in the study. Potential participants should:
*Be adults over 18 years
*Be English speakers
*Have had contact with a general practice-based pharmacist
*Be registered with practices that are part of the Ealing GP Federation
*Be competent to provide consent for themselves (as determined by a qualified healthcare professional - the general practice-based pharmacist)

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

*Patients without contact with a general practice-based pharmacist
*People not registered with practices in the Ealing GP Federation
*People unable to provide consent for themselves (e.g. those with severe mental difficulties)
*Non-English speakers (people unable to adequately express themselves in the English language)
*People less than 18 years old

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4

Participation in an one-to-one, face-to-face, semi-structured, qualitative interview	1	No	Up to 90 minutes	The Chief Investigator will conduct all interviews. All interviews will take place in private consultation or meeting spaces in the general practice with which each patient is registered. The actual interviewing time is expected to take up to 60 minutes approximately. The whole process, however, will take up to 90 minutes approximately (introductions, answering questions, seeking consent by asking participants to sign the Consent Form, collecting demographic data etc.).

A21. How long do you expect each participant to be in the study in total?

*The study process will last up to 90 minutes approximately (about 60 minutes for the interview and 30 minutes for introductions, answering questions, seeking consent, collecting demographic data). As a result, 90 minutes is the approximate duration for which each participant will be active in the study.
*Data collection, analysis and write up, however, may take up to 12 months and thus it might take that long until our participants become aware of the findings.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Potential risks and discomforts associated with this study are minimal. Participants will have to come back to the general practice if they want to attend the interview (and pay themselves for their travel expenses to come over) and devote about 90 minutes of their time for the actual study process (interview along with the introductions, collection of demographics, consent seeking etc.). To limit the impact on participants' various commitments (e.g. work), a mutually convenient day/time will be arranged for the interview and every attempt will be made not to exceed the time limit of up to 90 minutes for the whole process unless the participant wishes to keep talking. We will avoid raising during the interview any personal or sensitive issues. In the unlikely event that a participant feels distressed, they will have the option either to refrain from that part of the discussion or to terminate their participation without giving a reason and without any consequence. A friendly environment will be created for all participants. Interviews will be carried out in private spaces so participants feel comfortable to express any sort of views they have on the service. In case participants are not comfortable having their voice audio-recorded, they will have the right to ask the interviewer to keep detailed notes instead. No sensitive personal information (e.g. health details) will be collected.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

A24. What is the potential for benefit to research participants?

The potential benefit is that participants can have 'a say' on what actions/improvements need to be considered by national policymakers and service providers so that the 'clinical pharmacists in general practice' service better accounts for their preferences and/or needs.

A26. What are the potential risks for the researchers themselves? *(if any)*

There are no significant risks for the researchers except for the unlikely event in which we are unable to have enough participants to achieve data saturation. The interviews will be carried out inside a professional environment (general practice) and during working hours. The rest of the research team will also be aware of the place where data collection is taking place.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The lead pharmacist in the Ealing GP Federation (who will act as the local investigator) and his pharmacy team (who have consented to help with recruitment) will carry out the recruitment process. The local investigator and his team will hand out the study's invitation packs to the first (from the time ethical approval is gained) 50 patients they meet on their consultations who fulfil our inclusion criteria. The study's invitation pack will include an Invitation Letter, Participant Information Sheet, Consent Form, a Reply Form and a University of Reading reply paid envelope. Potential participants will be asked to contact the Chief Investigator (CI) if they want to be involved in the study either via e-mail (the Invitation Letter and Participant Information Sheet will contain the CI's professional e-mail address) or by filling in the Reply Form and posting it inside the pre-paid envelope. The Reply Form (appended to this application) will be asking participants to provide a contact telephone number so that the CI can then reach them to schedule the interview. Contribution to the recruitment process (for general practice-based pharmacists) and participation in the study (for participants) will be entirely voluntary and no monetary incentives will be provided. This will ensure that no pressure or coercion on potential participants by the local investigator and his team is possible.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
No screening of medical records will be done for verifying the fulfilment of inclusion criteria (fulfilment will be determined by the local investigator and his team during the conversation they have with patients at the time of a consultation).

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Potential interviewees will be first approached by the local investigator and those members of his team who are willing to get involved in the recruitment process. No pressure or coercion will be applied to potential participants.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

No vulnerable groups (e.g. people with severe cognitive difficulties unable to provide consent) will be included in the study. The local investigator and his team, who are all qualified healthcare professionals capable of judging competency, will exclude vulnerable people and minors (i.e. they will not be given invitation packs).
All potential participants will receive the Invitation Letter (appended to this application) and the Participant Information Sheet (appended to this application). Both these documents (part of the invitation pack) will be explaining the study in detail. Just before each interview, the Chief Investigator (CI) will verbally explain the study process and answer any questions participants have. Before or after the interview day, participants will have the ability to contact the research team (either via e-mail or phone call – the professional e-mails and phone numbers of the whole research team will be provided on the Participant Information Sheet) to clarify any extra queries they might have.
All participants will be asked by the interviewer (i.e. the CI) to provide written consent just before the interview (i.e. to sign the Consent Form which is appended to this application) including consent to audio-record the interview. The Consent Form will be also asking participants to provide a valid e-mail or postal address if they are interested to be

informed of the results of the study.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will have as long as they like to decide whether or not to take part in the study, until we stop recruiting.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

Since our study is purely qualitative, the purpose is to understand people's views in depth which cannot be done if participants lack reasonably adequate English language skills (i.e. ability to understand the questions and adequately express their views). Moreover, this is a PhD project so there is no monetary allocation for hiring interpreters or translators and there is only a limited time in which to complete the study. Therefore, as per our inclusion/exclusion criteria, non-English speakers will be excluded from the study.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

○ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

○ The participant would continue to be included in the study.

○ Not applicable – informed consent will not be sought from any participants in this research.

◉ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

This study does not involve any intrusive procedures or collection of any sensitive personal data. Therefore, we won't be monitoring capacity. Participation in the study will be once only and we will not have any other interactions with participants following the interview. Participants, however, will have the full right to withdraw from the project and have their data withdrawn prior to analysis (after that point we would be unable to remove data originating from a specific participant).

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [x] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [ ] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [ ] NHS computers
  - [ ] Social Care Service computers
  - [ ] Home or other personal computers
  - [x] University computers
  - [ ] Private company computers
  - [ ] Laptop computers

Further details:
There will be some exchange of e-mails (or phone calls) between the Chief Investigator and (potential) participants to arrange the interview and send a report of the findings, if requested (to send the report, post may also be used). Inevitably, some of the participants' e-mail or postal addresses or phone numbers will be personal. No demographic or other sensitive personal data, however, will be transferred by e-mail or post. All e-mails will be sent from the Chief Investigator's University of Reading e-mail address and similarly the CI's professional postal address will be used for any letters to be sent.
Direct quotes from the participants' interviews will be published but they will be entirely anonymized. Any names mentioned by participants during interviews will be removed from the transcripts and a coding system will be used to report quotes in publications, for example, Participant 1, 2, 3 etc.
Audio-recorders will be used during interviews (participants' consent to record their voice will first be obtained – if anybody refuses then detailed notes will be kept instead).
No sensitive personal information (e.g. health data) will be collected. The only personal data to be recorded will involve some demographic data (age-group, gender, number of visits to the general practice-based pharmacist). The collection of demographic data will be done though paper forms (to be filled in by the Chief Investigator just before the interview). Consent Forms will contain participants' names, but will not be associated with any other information provided, and will be stored separately. In summary, hard copies from the study will include demographic data forms, Consent Forms, any Reply Forms and any notes obtained during interviews from participants unhappy to have their voice audio-recorded (exact storage arrangements are described in the sections below). Electronic documents from the study will include audio-recordings and transcripts (again exact storage arrangements are described in the sections below).

A37. Please describe the physical security arrangements for storage of personal data during the study?

Consent Forms will contain participants' names and signatures and will be stored separately inside locked filling cabinets, created for research data storing purposes, within a locked office at the University of Reading. Demographic data forms will be coded (a unique participation code will be allocated for each participant at the time of collecting demographic data) and will be stored separately from the Consent Forms inside locked filling cabinets at the University of Reading. Any Reply Forms will be destroyed, by shredding and disposal as confidential waste, as soon as the respective interview is conducted (until their disposal, they will be stored inside locked filling cabinets).
Audio-recordings will be made on digital recorders and transferred to a University password-protected computer and shared drive as soon as possible after each interview, after which the recorder will be cleared.

Electronic copies of transcripts will be stored on a University password protected computer and shared drive after removing any potentially identifiable names. Each participant will be coded (the same participation code used for each demographic form will be also used for each transcript). Any notes obtained from participants unhappy to be audio-recorded will be stored inside locked filling cabinets.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

'Pseudonymisation of data'

After transcription, any potentially identifiable names will be removed from the transcripts. Each participant will be coded (e.g. Participant 1, 2, 3 etc.) and the same participation code will be used both for the transcripts and demographic data forms. The association between participation codes and names will be contained on a Word document which will be stored on the Chief Investigator's University of Reading, password-protected computer.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The Chief Investigator, Kath Ryan and Nilesh Patel will be the only researchers to have access to electronic documents or hard copies of data. Only the Chief Investigator will have access to the Word document containing the association between names and participation codes.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

All data will be qualitative. Audio-recordings will be transcribed verbatim either by the Chief Investigator or a professional transcriptionist (depending on availability of funds). Transcripts will be analysed thematically, collectively by the Chief Investigator and the rest of the research team (Kath Ryan and Nilesh Patel). The analysis will be done at the University of Reading using password-protected computers. Transcripts from the interviews will be coded and entered into NVivo 11 software for analysis.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Mr	Georgios Dimitrios	Karampatakis
Post	PhD student		
Qualifications	MSc in Clinical Pharmacy (2016) - University College London MPharm (2014) - Aristotle University of Thessaloniki		
Work Address	Pharmacy Practice - School of Pharmacy University of Reading, PO Box 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Work Email			
Work Telephone			
Fax			

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ○ 6 – 12 months
- ◉ 12 months – 3 years
- ○ Over 3 years

If longer than 12 months, please justify:
Personal data will need to be accessed until data is published and appropriately disseminated. From the time the study commences, up to 12 months may approximately be needed to write up data and produce a publication ready for submission to a scientific journal (depending on the journal, it might take more than 12 months from the time submitted to being accepted for publication).

A44. For how long will you store research data generated by the study?

Years: 5
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended.*Say where data will be stored, who will have access and the arrangements to ensure security.*

After data is published and participants fully informed of the results, the Word document containing the link between names and participation codes will be deleted. Audio-recordings will also be deleted. Consent Forms, forms containing demographic data and any notes (obtained from participants unhappy to be audio-recorded) will be destroyed by shredding and disposal as confidential data. Any participants' contact details will be destroyed (e.g. any e-mail addresses used for communication with participants will be removed from the Chief Investigator's professional e-mail address memory and phone numbers deleted). The (anonymous) transcripts will then be stored on the University of Reading repositories.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
A suitable register does not exist.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☐ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

Participants will not be individually identifiable from any research outputs. Any potentially identifiable names will be removed from the transcripts and a coding system (e.g. Participant 1, 2, 3 etc.) will be used to report direct participants' quotes. Demographic data to be reported will be aggregated and presented as ranges.

A53. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
We will send a lay report, summarizing the study's findings, to those participants who have consented to be informed (and have provided us with a valid e-mail or postal address for this reason). To inform the wider public, a publication will be done to an open access journal. We will also circulate the publication to the representatives of the Ealing GP Federation Patient Participation Group so that findings are further disseminated.

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☐ Review within the Chief Investigator's institution or host organisation
- ☐ Review within the research team
- ☑ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The study is part of the Chief Investigator's doctoral research. The research has been reviewed by the Chief Investigator's academic supervisors. It was developed in close collaboration between the Chief Investigator and academic supervisors and as per the University of Reading research policies.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 30
Total international sample size (including UK):
Total in European Economic Area:

Further details:
The exact number of interviews to be conducted will depend on when data saturation is achieved. The anticipation, however, is that 15 to 30 participants may be needed to achieve data saturation.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The project is qualitative thus quality and not quantity is the main priority. Therefore, a formal sample size calculation was not used. The exact sample size will depend on when data saturation (i.e. no more novel ideas or concepts emerging from the interviews) is achieved. Literature suggests that 15 to 30 participants may be needed to achieve data saturation.

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

All audio-recordings from the interviews will be transcribed verbatim by the Chief Investigator or a professional transcriptionist (depending on availability of funds). Transcripts will be analysed thematically collectively by the Chief Investigator and the rest of the research team (Kath Ryan and Nilesh Patel). No theoretical framework will be applied as our purpose with the project is to practically inform national policy, rather than interpret perceptions or examine any behavioural changes. An inductive approach will be followed. The six phases of thematic analysis as described in the method of Braun and Clarke will be applied (familiarization, coding, theme searching, theme reviewing, theme defining and naming, producing the report). Thematic analysis is chosen as it is an intuitive interpretive process, allows for categories to be discerned directly from the data and enables the formation of trustworthy conclusions accounting for the whole range of individual participant experiences. Coding of the transcripts will be done by using NVivo 11 software to facilitate the process. Coding and themes will be verified and refined collectively by the whole research team. No participants' checking on the results will be done.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Professor	Kath	Ryan
Post	Professor of Social Pharmacy		
Qualifications	PhD (1998) - University of Otago BPharm (1974) - University of Otago		
Employer	University of Reading		
Work Address	Pharmacy Practice - School of Pharmacy University of Reading, PO Box 224 Whitekinights, Reading		
Post Code	RG6 6AP		
Telephone			
Fax			
Mobile			
Work Email			

	Title	Forename/Initials	Surname
	Dr	Nilesh	Patel
Post	Lecturer in Pharmacy Practice		
Qualifications	PhD (1999) - Kings College London BPharm (1994) - Kings College London PGCAP in Teaching and Learning (2006) - Kings College London		
Employer	University of Reading		
Work Address	Pharmacy Practice - School of Pharmacy University of Reading, PO Box 224 Whiteknights, Reading		
Post Code	RG6 6AP		
Telephone			
Fax			
Mobile			
Work Email			

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)

Commercial status: Non-Commercial

○ Other

If Other, please specify:

Contact person

Name of organisation	University of Reading
Given name	Mike
Family name	Proven
Address	Whiteknights House, Whiteknights, PO Box 217
Town/city	Reading
Post code	RG6 6AH
Country	UNITED KINGDOM
Telephone	
Fax	
E-mail	

A65. Has external funding for the research been secured?

Please tick at least one check box.

☑ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☐ No application for external funding will be made

What type of research project is this?

○ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

◉ Other

Other – please state:
Part of a PhD project (funded by a University of Reading Postgraduate Studentship)

Please give details of funding applications.

Organisation	PHARMACY CARE SOLUTIONS LIMITED
Address	Acorn House 33 Churchfield road
	Acton
	London
Post Code	W3 6AY
Telephone	
Fax	
Mobile	
Email	

Funding Application Status: (•) Secured ( ) In progress

Amount: £10,000 per year

Duration
Years: 3
Months: 0

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
N/A

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Sylvia	Westrup
Organisation	Ealing CCG		
Address	NWL Primary Care, Mint Wing		
	St. Mary's Hospital		
	London		
Post Code	W2 1NY		
Work Email	lnw.primarycare@nihr.ac.uk		
Telephone			
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2018
Planned end date: 31/08/2019
Total duration:
Years: 0 Months: 11 Days: 31

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study 76

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☐ NHS organisations in England	
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☑ GP practices in England	76
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	

Total UK sites in study: 76

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The University of Reading Quality Assurance in Research Committee is responsible for managing the conduct of the research. Therefore, any complaints or problems with the conduct of the study can be directly reported by the participants to this University Committee or to the academic supervisors (contact details are provided in the Participant Information Sheet).
The organisation responsible for protection of personal information is the University of Reading (i.e. the Data Controller). Therefore, should participants have any queries or concerns regarding data protection and/or their rights, they can directly refer to the Data Protection Officer in the University of Reading (contact details are provided in the Participant Information Sheet).

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University of Reading has in place Professional indemnity insurance and Public liability insurance for potential legal liability of the University. These provide cover for legal liabilities (i.e. there has to be 'legal fault' on the part of the University) for damage to people's property or injury to their person. The relevant documents are attached.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

The University of Reading has in place Professional indemnity insurance and Public liability insurance for potential legal liability of the University. These provide cover for legal liabilities (i.e. there has to be 'legal fault' on the part of the University) for damage to people's property or injury to their person. University employees and students acting or working on behalf of the University are covered. The relevant documents are attached.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	(•) NHS/HSC Site ( ) Non-NHS/HSC Site		Forename	Graham
			Middle name	
			Family name	Stretch
			Email	
	Organisation name	NIHR CRN: North West London	Qualification (MD...)	• PhD in Pharmacy (1997) University of Manchester • BSc Hons Pharmacy (1993) -University of Liverpool
	Address		Country	UNITED KINGDOM
	Post Code	NULL		
	Country	ENGLAND		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- (●) Chief Investigator
- ( ) Sponsor
- ( ) Study co-ordinator
- ( ) Student
- ( ) Other – please give details
- ( ) None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Mr Georgios Dimitrios Karampatakis on 24/07/2018 12:31.

Job Title/Post:	PhD student
Organisation:	University of Reading
Email:	

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Dr Mike Proven on 25/07/2018 10:42.

Job Title/Post:	Coordinator for Quality Assurance in Research
Organisation:	University of Reading
Email:	

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Nilesh Patel on 24/07/2018 14:31.

Job Title/Post:	Lecturer in Pharmacy Practice
Organisation:	University of Reading
Email:	

Academic supervisor 2

This section was signed electronically by Professor Kath Ryan on 24/07/2018 21:51.

Job Title/Post:	Professor of Social Pharmacy
Organisation:	University of Reading
Email:	

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/ . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	Patients' experiences of general practice-based pharmacists in England: an exploratory qualitative study
IRAS Project ID:	241663
Sponsor Amendment Notification number:	18/YH/0347_#02M
Sponsor Amendment Notification date:	12Nov19
Details of Chief Investigator:	
Name [first name and surname]	Georgios Dimitrios Karampatakis
Address:	Pharmacy Practice - School of Pharmacy University of Reading, PO Box 224 Whiteknights, Reading
Postcode:	RG6 6AP
Contact telephone number:	
Email address:	
Details of Lead Sponsor:	
Name:	Dr Mike Proven (University of Reading)
Contact email address:	
Details of Lead Nation:	
Name of lead nation *delete as appropriate*	England
If England led is the study going through CSP? *delete as appropriate*	No
Name of lead R&D office:	R&D Office for Kent, Surrey and Sussex Clinical Research Network (Becky Dilley, , , address: Primary care Delivery Team, Bevendean House, University of Brighton, Falmer, Sussex BN1 9PH).

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

	R&D Office for Thames Valley and South Midlands Clinical Research Network (CRN: Thames Valley & South Midlands, studysupport.crnthamesvalley@nihr.ac.uk,).

Partner Organisations:
Health Research Authority, England NIHR Clinical Research Network, England
NHS Research Scotland NISCHR Permissions Co-ordinating Unit, Wales
HSC Research & Development, Public Health Agency, Northern Ireland

2. Summary of amendment(s)

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.
If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

No.	Brief description of amendment *(please enter each separate amendment in a new row)*	Amendment applies to *(delete/ list as appropriate)*		List relevant supporting document(s), including version numbers *(please ensure all referenced supporting documents are submitted with this form)*		R&D category of amendment *(category A, B, C)* *For office use only*
		Nation	**Sites**	**Document**	**Version**	
1	We would like to add more general practices into the study. So far, we have been collaborating with practices located in Ealing. However, recruitment of patients has been very slow. To increase recruitment rates, hence achieve data saturation in our qualitative interviews on patients' experiences of general practice-based pharmacists, we would like to add more general practices to the study. The study will continue to run as per our protocol. Recruitment will continue to be carried out by local general practice-based pharmacists linked with the research team. Pharmacists will hand invitation packs to eligible patients (as per criteria described in our original IRAS form) they meet in their consultation clinics inside the practices. Patients, interested in participating, will then directly get in touch with the research team. Interviews will also continue to be carried out by the Chief Investigator inside appropriate spaces in the practices with which each patient is registered.	England	Sites to be added in the study are general practices under the Thames Valley and South Midlands Clinical Research Network (practices across East Berkshire and Berkshire West Clinical Commissioning Groups) and under the Kent, Surrey and Sussex Clinical Research Network (practices across NHS East Surrey, NHS Guildford and Waverley, NHS North West	Localised Organisation Information Document (non-commercial project) Schedule of events	One (1) One (1)	

			Surrey, NHS Surrey Heath and NHS Surrey Downs Clinical Commissioning Groups). All practices to be added are listed in the Organisation Information Document.			
2	Slight modification in the Participant Information Sheet to remove any reference to specific sites. Under the 'Why have I been invited?' section we have removed any reference to a specific location. This section previously stated: You have been invited because…registered with a general practice in Ealing and you have had a consultation with a general practice-based pharmacist in the past. It now reads: **You have been invited because…registered with a general practice and you have had a consultation with a general practice-based pharmacist in the past.**	As above		Participant Information Sheet	Five (5)	
3						
4						
5						

[Add further rows as required]

3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator:

Print name: Georgios Dimitrios Karampatakis

Date: 01/11/2019

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative:

Print name Dr M J PROVEN

Post: Coordinator for Quality Assurance in Research

Organisation: University of Reading

Date: 12 November 2019

Reading School of Pharmacy

Whiteknights, PO Box 226
Reading, RG6 6AP, UK

phone
fax

Research team

- Georgios Karampatakis (Chief Investigator - PhD student):
- Professor Kath Ryan (academic supervisor): or
- Dr Nilesh Patel (academic supervisor): or

Invitation letter

19/07/2018

Dear Sir/Madam

Re: Patients' experiences of general practice-based pharmacists

I am writing to ask for your participation in an interview study. Please refer to the Participant Information Sheet (part of the study's invitation pack) which contains further detail and will help you decide whether or not you wish to take part.

If you wish to take part, you will need to contact me either via e-mail ( ) or by filling in the Reply Form and posting it within the pre-paid return envelope (both the Reply Form and the return envelope were part of the study's invitation pack).

Our aim with this study is to work directly with patients and identify their service preferences and needs with regards to general practice-based pharmacists (pharmacists within GP surgeries).

Should you require any further information regarding the study, please do not hesitate to contact any of the members of the research team (contact details on the top of this document).

Thank you very much for your time.

On behalf of the research team,

Georgios Karampatakis

Reading School of Pharmacy

Reading School of Pharmacy

Whiteknights, PO Box 226
Reading, RG6 6AP, UK

phone
fax

Research team

- Georgios Karampatakis (Chief Investigator - PhD student):
- Professor Kath Ryan (academic supervisor): or
- Dr Nilesh Patel (academic supervisor): or

Participant Information Sheet

Study title: Patients' experiences of general practice-based pharmacists

We would like to invite you to participate in a research study. Before you decide to take part, we would like to offer you detailed information about this study.

Background

In the UK, there is a drive to integrate pharmacists into general practice as a new healthcare service for patients. Evaluation of the service involves a number of national measures including the exploration of patients' views.

What is the purpose of the study?

The purpose of this study is to directly work with patients and find out their views and experiences of their encounter(s) with general practice-based pharmacists.

Project Design

To fully understand your opinions and thoughts, this study will involve a face-to-face, one-to-one interview. All interviews will be conducted by the Chief Investigator in a meeting or consultation room inside the general practice with which you are registered.

Who is organising and funding the study?

The study is sponsored by a University of Reading Postgraduate Studentship partially funded by Pharmacy Care Solutions Limited.

Why have I been invited?

You have been invited because you are over 16 years old, able to adequately express yourself in the English language, registered with a general practice and you have had a consultation with a general practice-based pharmacist in the past.

Do I have to take part?

There is no obligation to participate. It is entirely up to you.

What will happen if I take part?

If you are happy to be interviewed, please contact the Chief Investigator to confirm your willingness to take part. This can be done either by e-mailing or by filling in the Reply Form and posting it within the pre-paid envelope (both the Reply Form and pre-paid envelope were part of the pack that was handed to you by your general practice-based pharmacist). The Chief Investigator will then contact you to schedule the interview on a convenient day and time for you. We will require approximately 90 minutes of your time. Just before the interview, the Chief Investigator will verbally explain the study and you will have the opportunity to ask any questions you may have. You will be asked to sign a consent form. In doing so, you will be confirming that you understand the information in this leaflet and that you have agreed to take part (the Consent Form will also contain a section asking you to consent and provide us with a valid e-mail or postal address if you want to be informed of the findings). Then, the Chief Investigator will collect some demographic data (your age-group, gender, ethnicity and approximate number of visits to the general practice-based pharmacist) by filling in a relevant form. This data will be used to make explicit the range of participants we have interviewed in any subsequent research outputs. No other sensitive personal information will be collected. After that, the actual interview will follow in which you will have the ability to share with us your experiences of the service. With your permission, we would like to audio-record the interview so that the interviewer can focus on the discussion (rather than being distracted in trying to keep notes) and also to help us carry out a full analysis of the information we collect. In case you are unhappy to have your voice recorded you can ask the interviewer to keep detailed notes instead.

Please note that before or after the interview day, you can e-mail or phone any member of the research team should you require further clarification about the study (please see contact details on the top of this document).

What are the possible risks of taking part?

Potential risks and discomforts associated with this study are minimal. We will avoid raising any sensitive issues during the interview. You don't have to answer any questions that make you uncomfortable. You can withdraw from the study and have your data destroyed at any point prior to data analysis. You will just need to contact a member of the research team (see contact details on the top of this document). Similarly, should

you change your mind, you can ask us to remove your name from the register of participants interested in being informed of the results and destroy the contact details you have provided us (please contact a member of the research team).

What are the possible benefits of taking part?

The benefit of participating in this study is that you can freely express your own opinions and thoughts so that any future shaping of the service better takes into consideration patients' needs and/or preferences.

Will my taking part be kept confidential?

Yes, all information will remain confidential and be used solely for this study. Audio-recordings will be made on digital recorders and transferred to a University of Reading password protected computer and shared drive as soon as possible after the interview, after which the recorder will be cleared. Audio-recordings will be transcribed verbatim either by the Chief Investigator or a professional transcriptionist (depending on the availability of funds). Transcripts will be coded (i.e. a unique participation code will be allocated for each participant, for example, Participant 1, 2, 3 etc.) and any potentially identifiable names will be removed. Transcripts will be available exclusively on electronic copies which will be stored on a University of Reading password-protected computer and shared drive. The same participation code used for the transcripts will also be used for the forms containing demographic data. These will be stored inside locked filling cabinets in a locked office at the University of Reading. Consent Forms will be stored, separately from other hard copies, in University locked filling cabinets. Although the consent form will contain your name, it will not be associated with any information that you provide. Any Reply Forms you post to us will be destroyed as soon as the interview is conducted, by shredding and disposal as confidential waste (until that point, they will be stored inside locked filling cabinets). The association between names and participation codes will be written on a Word® document which will be stored on the Chief Investigator's University password-protected computer. The study data will be only accessed by the research team (the link between names and participation codes will be only accessible to the Chief Investigator).

As soon as data is published and participants (those who have consented) informed of the results, the electronic document containing the link between names and participation codes will be deleted. Forms containing demographic data and Consent Forms will be destroyed by shredding and disposal as confidential waste. Audio-recordings will be deleted from University computer shared drive. The (anonymous) transcripts will then be stored on the University of Reading repositories. Any participants' contact details will be destroyed (e.g. e-mail addresses will be deleted from the Chief Investigator's e-mail memory and phone numbers will also be deleted).

What will happen to the results of the study?

The results of the study will contribute towards the PhD thesis of the Chief Investigator. They will also be used to inform national policy on what actions need to be done so that the services that general practice-based pharmacists' provide better meet patients' expectations and/or needs. Findings may also be presented at conferences and published in peer reviewed journals for research and educational purposes. You will not be individually identifiable from any reports as a coding system will be used to report direct quotations from the interviews and demographic data will only be presented as a range.

What happens if something goes wrong?

In the event that something goes wrong with your participation in the study please feel free to contact either one of the study supervisors (listed on the top of this document) or the Quality Assurance in Research group at the University of Reading (see email address below).

Who has reviewed the study?

This project has been reviewed by a NHS Research Ethics Committee and the Health Research Authority (Integrated Research Application System Project ID: 241663) and has been given a favourable opinion for conduct.

In the event of a complaint

Please e-mail the University of Reading's Quality Assurance in Research at qar@reading.ac.uk

THANK YOU FOR YOUR HELP.

Appendix: Privacy notice

The organisation responsible for protection of your personal information is the University of Reading (the Data Controller). Queries regarding data protection and your rights should be directed to the University Data Protection Officer at imps@reading.ac.uk, or in writing to: Information Management & Policy Services, University of Reading, Whiteknights, PO Box 217, Reading, RG6 6AH.

The University of Reading collects, analyses, uses, shares and retains personal data for the purposes of research in the public interest. Under data protection law we are required to inform you that this use of the personal data we may hold about you is on the lawful basis of being a public task in the public interest. If you withdraw from a research study, which processes your personal data, dependant on the stage of withdrawal, we may still rely on this lawful basis to continue using your data if your withdrawal would be of

significant detriment to the research study aims. We will always have in place appropriate safeguards to protect your personal data.

You have certain rights under data protection law which are:

- Withdraw your consent, for example if you opted in to be added to a participant register
- Access your personal data or ask for a copy
- Rectify inaccuracies in personal data that we hold about you
- Be forgotten, that is your details to be removed from systems that we use to process your personal data
- Restrict uses of your data
- Object to uses of your data, for example retention after you have withdrawn from a study

Some restrictions apply to the above rights where data is collected and used for research purposes.

You can find out more about your rights on the website of the Information Commissioners Office (ICO) at https://ico.org.uk

You also have a right to complain the ICO if you are unhappy with how your data has been handled. Please contact the University Data Protection Officer in the first instance.

Georgios Karampatakis
Chief Investigator

Reading School of Pharmacy
Whiteknights, PO Box 226
Reading, RG6 6AP, UK
phone
fax

Consent form

Please initial boxes

1. I have read and had explained to me by Georgios Karampatakis the accompanying Participant Information Sheet relating to the study with title: **'Patients' experiences of general practice-based pharmacists'**. ☐
2. I have had explained to me the purposes of the study and what will be required of me, and any questions I have had have been answered to my satisfaction. I agree to the arrangements described in the Participant Information Sheet in so far as they relate to my participation. ☐
3. I have had explained to me what information will be collected about me, what it will be used for, who it may be shared with, how it will be kept safe, and my rights in relation to my data. ☐
4. I understand that my participation is voluntary and that I have the right to withdraw from the study any time prior to data analysis, and that this will be without detriment. ☐
5. I understand that the data collected from me in this study will be preserved and made available in anonymised form, so that they can be consulted and re-used by others. ☐
6. I agree to the interview being audio-recorded. ☐
7. I have received a copy of this Consent Form and of the accompanying Participant Information Sheet. ☐

This study has been reviewed by a NHS Research Ethics Committee and the Health Research Authority (Integrated Research Application System Project ID: 241663) and has been given a favourable ethical opinion for conduct.

Participant details

Name of Participant: _____

Signature: _____ Date: _____

Interviewer details

Name of Interviewer: _____

Signature: _____ Date: _____

I would like to be informed of the study findings by having a report sent to me by the research team. Please tick ☐ (optional)
If you tick the box above, please provide us with a valid e-mail (preferred) or postal address:

……

……

Reading School of Pharmacy

Whiteknights, PO Box 226
Reading, RG6 6AP, UK

phone
fax

Research team

- Georgios Karampatakis (Chief Investigator - PhD student):
- Professor Kath Ryan (academic supervisor): k or
- Dr Nilesh Patel (academic supervisor): or

Reply Form

Dear research team,

I am willing to take part in the interview for the study **'Patients' experiences of general practice-based pharmacists'** and am happy be contacted by the Chief Investigator to schedule the day and the time for the interview.

Name: ……...

Contact details (please provide telephone number):

……

……...

Demographics Form

Study title: Patients' experiences of general practice-based pharmacists

Participation code …….

- Age group

  16-18, 18-30, 30-40, 40-50, 50-60, 60-70, 70-80, 80+

- Gender ……..

- Approx. number of visits to the pharmacist in the surgery…….....

- Ethnicity…….

Yorkshire & The Humber - Leeds West Research Ethics Committee
NHSBT Newcastle Blood Donor Centre
Holland Drive
Newcastle upon Tyne
NE2 4NQ

Telephone:

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

04 September 2018

Mr Georgios Dimitrios Karampatakis
Pharmacy Practice - School of Pharmacy
University of Reading, PO Box 224
Whiteknights, Reading
RG6 6AP

Dear Mr Karampatakis

Study title:	**Patients' experiences of general practice-based pharmacists in England: an exploratory qualitative study**
REC reference:	**18/YH/0347**
IRAS project ID:	**241663**

Thank you for your letter of 22nd August, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact please contact hra.studyregistration@nhs.net outlining the reasons for your request.

Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management

permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Confirmation]		22 August 2018
Interview schedules or topic guides for participants [Interview topic guide]	4 (four)	19 July 2018
Interview schedules or topic guides for participants [Demographics Form]	3 (three)	22 August 2018
IRAS Application Form [IRAS_Form_02082018]		02 August 2018
Letter from sponsor [Sponsor Confirmation]		25 July 2018
Letters of invitation to participant [Invitation Letter]	4 (four)	19 July 2018
Letters of invitation to participant [Reply Form]	3 (three)	22 August 2018
Other [Response to the comments by the NHS REC and the HRA]	1 (one)	22 August 2018
Participant consent form [Consent Form]	5 (five)	22 August 2018
Participant information sheet (PIS) [Participant Information Sheet]	5 (five)	22 August 2018
Research protocol or project proposal [Protocol]	5 (five)	22 August 2018
Summary CV for Chief Investigator (CI) [CV for CI]		13 July 2018
Summary CV for student [CV for CI (student)]		13 July 2018
Summary CV for supervisor (student research) [CV for academic supervisor (Professor Kath Ryan)]		13 July 2018
Summary CV for supervisor (student research) [CV for academic supervisor (Dr Nilesh Patel)]		13 July 2018

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

<u>Reporting requirements</u>

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

Feedback

You are invited to give your view of the service that you have received from the Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

We are pleased to welcome researchers and R & D staff at our RES Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

18/YH/0347	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp

Dr Rhona Bratt
Chair

Email: nrescommittee.yorkandhumber-leedswest@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Dr Mike Proven*

Ms Sylvia Westrup, Ealing CCG

Mr Georgios Dimitrios Karampatakis
Pharmacy Practice - School of Pharmacy
University of Reading, PO Box 224
Whiteknights, Reading
RG6 6AP

Email: hra.approval@nhs.net
Research-permissions@wales.nhs.uk

17 September 2018

Dear Mr Karampatakis

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Patients' experiences of general practice-based pharmacists in England: an exploratory qualitative study**
IRAS project ID:	**241663**
REC reference:	**18/YH/0347**
Sponsor	**University of Reading**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

How should I continue to work with participating NHS organisations in England and Wales?
You should now provide a copy of this letter to all participating NHS organisations in England and Wales, as well as any documentation that has been updated as a result of the assessment.

Participating NHS organisations in England and Wales **will not** be required to formally confirm capacity and capability before you may commence research activity at site. As such, you may commence the research at each organisation 35 days following sponsor provision to the site of the local information pack, so long as:

- You have contacted participating NHS organisations (see below for details)
- The NHS organisation has not provided a reason as to why they cannot participate
- The NHS organisation has not requested additional time to confirm.

You may start the research prior to the above deadline if the site positively confirms that the research may proceed.

If not already done so, you should now provide the local information pack for your study to your participating NHS organisations. A current list of R&D contacts is accessible at the NHS RD Forum website and these contacts MUST be used for this purpose. After entering your IRAS ID you will be

able to access a password protected document (password: **House45**). The password is updated on a monthly basis so please obtain the relevant contact information as soon as possible; please do not hesitate to contact me should you encounter any issues.

Commencing research activities at any NHS organisation before providing them with the full local information pack and allowing them the agreed duration to opt-out, or to request additional time (unless you have received from their R&D department notification that you may commence), is a breach of the terms of HRA and HCRW Approval. Further information is provided in the "*summary of assessment*" section towards the end of this document.

It is important that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details of the research management function for each organisation can be accessed here.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within the devolved administrations of Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) has been sent to the coordinating centre of each participating nation. You should work with the relevant national coordinating functions to ensure any nation specific checks are complete, and with each site so that they are able to give management permission for the study to begin.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

I am a participating NHS organisation in England or Wales. What should I do once I receive this letter?
You should work with the applicant and sponsor to complete any outstanding arrangements so you are able to confirm capacity and capability in line with the information provided in this letter.

IRAS project ID	241663

The sponsor contact for this application is as follows:

Name: Dr Mike Proven
Tel:
Email:

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **241663**. Please quote this on all correspondence.

Yours sincerely

Simon Connolly
Senior Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Mike Proven, University of Reading*
Ms Sylvia Westrup, Ealing CCG

IRAS project ID	241663

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance Confirmation]		22 August 2018
HRA Schedule of Events	1	05 September 2018
HRA Statement of Activities	1	05 September 2018
Interview schedules or topic guides for participants [Demographics Form]	3 (three)	22 August 2018
Interview schedules or topic guides for participants [Interview topic guide]	4 (four)	19 July 2018
IRAS Application Form [IRAS_Form_02082018]		02 August 2018
Letter from sponsor [Sponsor Confirmation]		25 July 2018
Letters of invitation to participant [Reply Form]	3 (three)	22 August 2018
Letters of invitation to participant [Invitation Letter]	4 (four)	19 July 2018
Other [Response to the comments by the NHS REC and the HRA]	1 (one)	22 August 2018
Participant consent form [Consent Form]	5 (five)	22 August 2018
Participant information sheet (PIS) [Participant Information Sheet]	5 (five)	22 August 2018
Research protocol or project proposal [Protocol]	5 (five)	22 August 2018
Summary CV for Chief Investigator (CI) [CV for CI]		13 July 2018
Summary CV for student [CV for CI (student)]		13 July 2018
Summary CV for supervisor (student research) [CV for academic supervisor (Dr Nilesh Patel)]		13 July 2018
Summary CV for supervisor (student research) [CV for academic supervisor (Professor Kath Ryan)]		13 July 2018

IRAS project ID	241663

Summary of assessment

The following information provides assurance to you, the sponsor and the NHS in England and Wales that the study, as assessed for HRA and HCRW Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England and Wales to assist in assessing, arranging and confirming capacity and capability.

Assessment criteria

Section	Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	Statement of activities and schedule of events provided. Although formal confirmation of capacity and capability is not expected of all or some organisations participating in this study, and such organisations would therefore be assumed to have confirmed their capacity and capability should they not respond to the contrary, we would ask that these organisations pro-actively engage with the sponsor in order to confirm at as early a date as possible. Confirmation in such cases should be by email to the CI and Sponsor confirming participation based on the relevant Statement of Activities and information within this letter.
4.2	Insurance/indemnity arrangements assessed	Yes	No comments
4.3	Financial arrangements assessed	Yes	Student study. No funding available from sponsor to NHS organisations.

Section	Assessment Criteria	Compliant with Standards	Comments
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England and Wales

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
Patients attending at participating NHS organisations will be given information packs for the study. Researcher will then conduct the interviews, which may be within GP practices. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England and Wales in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. Where applicable, the local LCRN contact should also be copied into this correspondence. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England and Wales which are not provided in IRAS or on the HRA or HCRW websites, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net, or HCRW at Research-permissions@wales.nhs.uk. We will work with these organisations to achieve a consistent approach to information provision.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and Wales, and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A local collaborator will be required where the researcher requires access arrangements to NHS care facilities. GCP training is not a generic training expectation, in line with the HRA/HCRW/MHRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
A letter of access will be required where the researcher requires access arrangements to NHS care facilities. Appropriate occupational health and DBS checks will need to be confirmed.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.