

How general practice team composition and climate relate to quality, effectiveness and human resource costs: a mixed methods study in England

Version	Date	Amendments
1	22-08- 2018	Original version as submitted
2	14-08-2019	WP6: knowledge transfer to use Nominal Group Technique instead of RAND RAM method for consensus building. WP5b: vouchers to value of £50 will be given to practices for staff room refreshments, (rather than £50), as an incentive to staff to complete the survey

Links to HS&DR portfolio

This study relates to other research within the HS&DR portfolio and which has involved members of the current research team. It adopts a mixed methods approach that is closely comparable to HS&DR 15/144, 'Exploring the relationship between care home staffing and quality of care', which is led by Spilsbury, and also involves Gage and Jordan. Other ongoing linked HS&DR studies are: 13/157 on measuring GP productivity; 14/96, on the role of GPs in care homes (involving Gage, Spilsbury); 14/196 GP recruitment and retention (Campbell is PI, with Chilvers, Richards). Linked completed HS&DR studies involving co-investigators include: Integration and continuity of primary care [1] (Peckham); Physicians assistants in primary care [2] (Gage, Lusignan); Interprofessional community working [3] (Gage).

Background and Rationale

Introduction

The British National Health Service (NHS) is a primary care led system with general practitioners (GPs) being the first point of contact for citizens with non-emergency health care needs. GPs have traditionally worked in practices, led by partners (or a sole partner), employing a team of staff (nurses, care assistants, receptionists, managers) and liaising with other community services. They coordinate care for local people who register with their practice. The sector is currently facing financial and other pressures that threaten the patient experience. Increases in the number of older people, more lifestyle-related conditions, rising expectations and transfer of some tasks previously undertaken in hospitals to primary care have added significantly to the general practice workload. Simultaneously, recruitment and retention problems have reduced the number of GPs per capita [4], and shortages of primary and community nurses have exacerbated staffing problems [5-8]. The number of qualifying doctors choosing general practice has gradually declined over the last decade [9], whilst increasing numbers of GPs have left practice, with many opting to work abroad [10,11].

Concerns about recruitment and retention have coincided with a period of rapid change in the organisation of general practice. Over time, practices have become larger and incorporated a wider range of staff. In September 2016, the BMA reported 7,613 GP practices in England, a decline of 8% since 2006 [12,13]. Recently, new organisational forms (e.g. 'super-practices', federations, and integrated models of primary and community-based care), and different ownership and contractual models (e.g. Alternative Provider Medical Services) of general practice have developed. In this challenging and changing situation, research is required to produce evidence that will enable primary care commissioners and GP practice managers to make resource allocation decisions that will ensure the workforce is effectively and efficiently deployed, and high quality care is maintained [14,15]. Whilst it is clear that practices are becoming increasingly multi-disciplinary, with a wider range of staff involved in direct patient care representing more varied roles, identifying the optimal mix of professionals is complex [16-18]. Historically workforce planning has been uni-disciplinary, but promotion of workforce flexibilities for care delivery relies on a range of disciplines and requires a different approach to workforce planning.

Workforce composition

Workforce is the largest single component of healthcare expenditure and the size and composition of the workforce affects performance and outcomes for patients [19]. The ability of health care systems to provide safe, high-quality, effective, and patient-centred services depends on sufficient, well-motivated, and appropriately skilled personnel operating within service delivery models that optimise their performance [20]. Problems have been highlighted by the Health Foundation regarding national workforce policy in the English NHS concluding that “*Workforce is a relatively neglected area of policy which is often pursued as an afterthought, with important clinical, operational and financial impacts on the front line*” [21]. However, a number of recent policy proposals (e.g. the NHS Five Year Forward View [22], and the GP Forward View [5]) have specifically addressed general practice workforce issues. Moreover, developments driven locally by general practices, Clinical Commissioning Groups and community health service providers have led to changes in the practice organisation and structure [23]. In addition, there have been a number of national reviews of the primary care workforce which have had an influence on policy and practice [7,24,25].

Evidence explaining why this research is needed now

Aside from calling for increased investment and extended use of technology, recent workforce challenges in general practice have been approached in two ways: different ways of working (e.g. skill mix changes, task shifting, role substitution), and organisational changes [5,6,26,27]. As a result, extended use of mid-level practitioners (advanced nurses, paramedics, pharmacists, physiotherapists) and the introduction of new roles (physician’s associates) is becoming more widespread. New collaborative forms of general practice and integrated models involving hospital-based specialists are also emerging [27] (‘super practices’, networks and federations; and polyclinics and multispecialty providers, respectively).

Different ways of working

The Five Year Forward View [22] promoted the development of new models of care and highlighted that “*Greater use of skill mix will be key to releasing capacity. Wider members of the practice-based team will play an increasing role in providing day-to-day coordination and delivery of care. ...which would require equipping them with the skills and flexibilities to deliver the new models of care, including the development of transitional roles.*” (p7, 30). Four approaches to skill mix changing have been identified: diversification, specialisation, horizontal substitution and vertical substitution [28], but there is little evidence on the effect of such changes on outcomes, productivity, quality of care and costs [22,29-31].

There is some evidence for extending the use of mid-level professionals (advanced nurses, pharmacists, physiotherapists) and introducing new roles (e.g. physicians’ associates), indicating that this may offer potential for reducing costs [2]. However, redefining boundaries has been shown to meet resistance within teams [32,33]. Existing reviews of skill-mix in primary care have focused mainly on role substitution, particularly between physicians and nurses. A review of reviews by Marchand and Peckham for the Dept. of Health found no other strategies were reported (paper in preparation). Overall findings are that clinical outcomes associated with substitution from physician-led to nurse-led care are comparable [34-36]. While nurse-led care increases patient satisfaction and is associated with longer consultations, rates of referrals, prescribing and investigations are similar. This is consistent with the fact that both physicians and nurses follow the same guidelines. A review of evidence on GP recruitment and retention, showed organisational changes were not explored [37]. Moreover, the number of studies that examine the impact of specific roles in relation to skill-mix and patient care is limited. Much of the available evidence is not specifically focused on primary care and does not extend scrutiny beyond physicians and nurses; thus wider task shifting and role substitution is not evaluated [38-40]. The focus of studies on particular staff types or roles is constraining because it fails to adopt the ‘whole team’ approach necessary to address systemic implications [41-43].

New models of general practice

New collaborative forms of general practice (as highlighted above) involve both a wider range of professional and non-professional roles as well as hospital-based specialists [27]. Roles in primary care are expanding from the traditional clinical and administrative base to include, for example, welfare advice, allied health professionals, volunteers and community and voluntary organisations [44-46]. Little is known about how these developments impact on the practice or patient care. Existing research suggests that context matters in the development of primary care models and that there is no one way to develop a model to meet the needs of patients and providers across all contexts [47,48]. Integrated models of care are not supported by robust research evidence and aspects that are important for success are not clarified. Due to complex role relationships, integration requires greater reciprocal interdependence among professionals and other staff,

patients and families. This necessitates a high level of coordination and collaboration. A recent review of integration in primary and community care concluded that, within each organisational model, key micro-level team composition and functioning factors are most important; fundamentally, there is a need for evidence on what promotes successful team working in primary care [49].

Team climate and staff outcomes

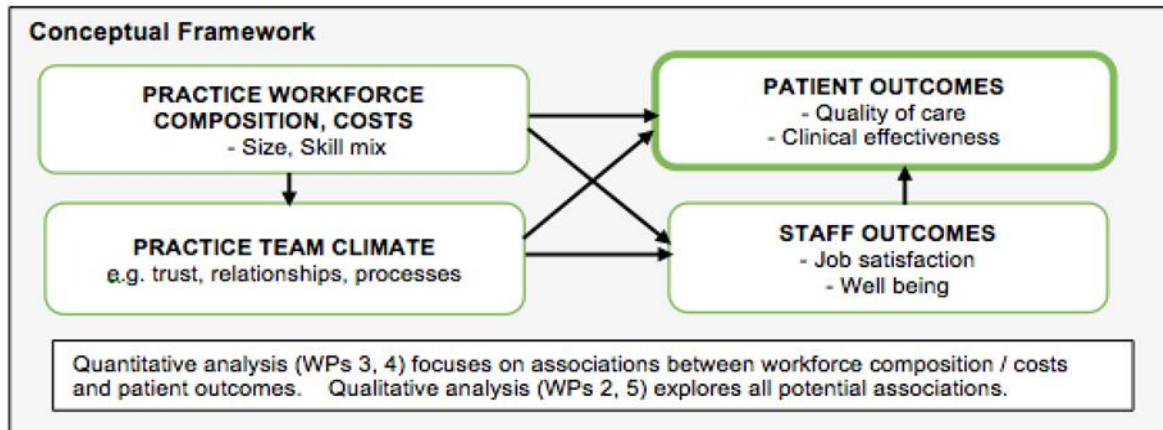
Increased management of common chronic conditions within general practice demonstrates the need for multidisciplinary teams to share responsibility [50]. Although team climate, defined as '*a team's shared perceptions of organisational policies, practices and procedures*' [51], has been associated with a range of factors (including relational aspects of team working, team composition, processes and innovation), evidence on whether team climate is related to quality of care is equivocal [52,53]. There is limited understanding of the effect of organisational factors within a practice and a need for further research has been identified [54]. An extensive literature supports the effectiveness of multidisciplinary teams, and there is consensus that strong leadership, shared goals and good communication improve functioning [55]. Additionally, studies have variously shown single disciplinary [56] and interdisciplinary [57,58] teams as being more effective. However, from different models of GP-community team collaboration in England (case management, integration, networks), there is no clear evidence that any format is preferable overall [3] or that co-location is important [1,59].

It is also essential to remember that quality of care is affected by the performance of individuals and not only related to team functioning [60]. In this context, the workforce crisis has increased the pressure on general practice to such an extent that concerns have been raised about the mental and physical health of the workforce. The sustainability of the workload [61] and its effect on patient care is in question [62]. High levels of physical exhaustion have been recorded amongst GPs [61], accompanied by a low sense of personal accomplishment [63]. As staff shortages in general practice extend to the nursing and allied professions, concerns also exist about the possibility of nurse burnout having an impact [64]. Team climate influences job satisfaction and can contribute to burnout [65] and, in turn, influence the effectiveness of the entire health system [66]. Yet, currently, the impact of job satisfaction and burnout on quality of care is unclear [67-69]. Job satisfaction is a complex concept arising from both intrinsic and extrinsic factors: intrinsic recognition, responsibility and the nature of the work itself alongside extrinsic working conditions and remuneration. Ultimately, job satisfaction, team climate and workforce wellbeing are linked [69].

This background of relatively novel and evolving situations signposts an urgent need for comprehensive research designed to explore and evaluate the multiple, yet quite specific, aspects that contribute to the changing landscape of GP primary care. Peeling back the layers of interaction to explore processes at team and individual levels is essential for generating powerful evidence with strong internal validity in order to achieve robust generalizable results. Additionally, pinpointing quality of healthcare, the patient experience and costs are essential for keeping practice implications and recommendations in clear focus.

Conceptual framework

The proposed research is built around a framework which encompasses the above considerations: practice workforce composition, team climate, patient and staff outcomes (see Figure). Whilst existing research tends to focus on individual aspects, our work will explore the practice environment from several perspectives and through a series of work packages.



Aims and Objectives

The overall aim is to explore how team composition and climate affect quality of care, clinical outcomes (effectiveness) and human resource costs in England, in order to inform practice management and commissioning decisions. The workforce configurations in general practices are highly variable and there is a lack of evidence about what skill mixes and staff deployments generate the best outcomes for patients and savings for health care economies. In addition, evidence on how the micro-level team climate (trust, relationships, processes, etc) relates to quality is not strong. This study will address these gaps.

The **objectives** (each mapped to a work package, WP) are to:

1. Provide a descriptive overview of general practice: policy context; delivery models; practice level variability in skill mix and human resource costs (WP1)
2. Review available evidence on how skill mix and team climate affect quality of care, clinical effectiveness, staff wellbeing and job satisfaction (WP2)
3. Conduct practice level modelling of associations between skill mix and quality of care and explore implications for role substitution and costs (WP3)
4. Conduct patient level modelling of associations between skill mix and clinical effectiveness and implications for costs (WP4)
5. Examine, in depth, how team working affects quality of care and effectiveness through focus groups with service users, a staff survey in a sample of GP practices and case studies in 12 varied practices (WP5)
6. Engage with GP primary care practitioners, commissioners and service users to develop implementation recommendations (WP6)
7. Actively disseminate findings widely (WP7)

Research Plan /methods

Study design

The aims and objectives will be addressed through a complex, concurrent, parallel, multistage, mixed methods design, with embedded survey and intensive case study [70]. Mixed methods are powerful for investigating complex processes in health care, providing insights into the multifaceted phenomena related to quality, access and delivery [70]. They draw on the advantages of both quantitative and qualitative approaches [71] to enable a comprehensive understanding of multilevel processes and systems such as those involved in primary care [72,73].

The project comprises seven linked work packages (WPs), as shown in the flow chart (uploaded separately). Each WP maps to a study objective. The WPs will be delivered sequentially with quantitative and qualitative enquiry occurring concurrently, and integration at several levels [70].

The quantitative work (WPs 1 (part), 3, and 4; objectives 1, 2, 3, 4) will use existing large data sets to explore associations between GP workforce and practice characteristics and indicators of performance (quality and clinical outcomes / effectiveness), providing evidence on magnitude of effect that is generalizable.

The qualitative work (WPs 1 (part), 2 and 5a,b,c; objectives 1, 2, 5, 6, 7) will include: a) focus groups of patients and carers to explore what the GP team composition means to them; b) a survey of the team members in a representative sample of GP practices to assess team climate and individual wellbeing and job satisfaction and explore associations with skill mix and practice performance; c) in-depth case study analysis of team working and individual experiences in a small number of diverse practices in order to understand how trust, relationships and processes contribute to quality. Findings from the case studies will inform the interpretation of quantitative results [70] by providing possible explanations for observed phenomena in the local context [71].

Integrating quantitative and qualitative approaches, using methods of connecting, building and merging [70], will enhance the internal validity of the research [74,75]. Connections will be achieved through aligned sampling for the in-depth case study analysis and the survey of GP practices (i.e. embedded / nested studies); building will involve drawing on findings from early WPs to inform the design of successive work; merging will involve a coherent process of 'narrative weaving' of quantitative and qualitative findings. Individual WPs will be reported separately and the central themes (GP team composition, climate, quality and effectiveness of care, costs) will be assessed for consistency ('fit'), and interpreted for the overall final report, knowledge transfer (WP6) and dissemination (WP7) processes.

Advisory Groups: Two reference panels (representing service users and professional groups in GP primary care), and a Study Steering Committee will be convened at the start of the project to provide ongoing advice and support to the research team. The composition and roles of the *Service Users Panel (SUP)* and *Study Steering Committee (SSC)* are explained in the PPI and Management sections below.

The *Professionals and Commissioners Panel (PCP)* will comprise nine members, recruited from across England, with representation from urban and rural areas. Invitations to participate will be distributed through existing networks (including RCGP). A balance will be maintained between GPs (partners or in other senior / decision making positions), other professional groups in GP primary care and NHS commissioners, and there will be an emphasis on ensuring that the Panel members are aware of the new service models, with a variety of experience of working in, or supporting, GP practices at the team, organisational, or policy level. Existing contacts with CCGs active in new service models will be used to target suitable individuals for participation.

The PCP will meet using an online (face-to-face) group meeting platform twice a year (a total of six meetings), to fit with key project milestones. The members will be asked to provide input on all aspects of the project, data collection materials, and the emerging findings from each WP. They will be informed early about the activities for knowledge transfer and wider dissemination of the findings, and this will be a standing item on their agenda. WP leaders will present at the first meeting as part of an induction process, and then attend at appropriate points in the project. The PCP will be convened by Chilvers (co-I), and a Chair will be agreed at the first meeting.

WP 1: Descriptive overview of general practice in England: policy context; delivery models; skill mix variability; human resource costs (addresses objective 1).

Leads: Peckham (tasks (i), (ii)), with Campbell, Marchand; Jordan (tasks (iii), (iv)), with Joy, Gage; months 1-6

The aim of WP1 is to analyse current policy and practice developments and workforce trends in English general practice in order to provide the overall context for the project and subsequent WPs. It is organised as four tasks: policy review; description of new and emerging models of general practice; construction of a database of all general practices in England ('Practices Database'); calculation of practice workforce costs. This preliminary work will inform the literature review (WP2) and case study site selection (WP5). The Practices Database will form the basis of the quantitative analysis (WP3,4). Subsets of practices will be analysed in more depth in WP5.

(i) Policy review and analysis

The task will involve a documentary review and analysis to provide an overview of trends in general practice activity, resourcing and workforce, and the accompanying policy response. The aim is to provide an understanding of the external contexts (professional practice guidelines, policy, patient demand, legal frameworks, financing, etc) that impact on practice organisation, decision making and workforce structure.

There have been a number of recent reviews and policy proposals related to the workforce in general practice, and WP1(i) will analyse the workforce trends and summarise and synthesise these policy papers.

Documents will be sourced through internet searches covering statutory bodies (e.g. Department of Health, NHS England, NHS Digital, NHS Confederation, National Association of Primary Care), and regulatory authorities such as the Care Quality Commission. Commissioning guidance from NICE, technical papers (e.g. from the Centre for Workforce Intelligence). Documents produced by professional organisations (e.g. BMA, RCGP) will also be examined. Members of the research team are involved nationally in NHS and GP policy boards and forums and have knowledge of policy, as well as established networks to facilitate this work.

Relevant policy documents relating to the GP workforce will be subject to a thematic analysis. A report will be produced that synthesises available data on expenditure and employment trends, policy initiatives and organisational changes (month 6), and updated throughout the project.

(ii) *New models of general practice*

To set the scene for the analysis of the effect of task shifting, skill mix changes and service redesign on quality of care, clinical outcomes and costs in subsequent WPs, new developments in general practice will be described and categorised. Information will in part be provided by the policy review (task (i) above), with the search enlarged to incorporate documentation on the new roles for mid level practitioners, non medical prescribing and physicians associates from the relevant professional associations (Nursing and Midwifery Council, Royal College of Nursing, Chartered Society of Physiotherapists, Royal Pharmaceutical Society, UK Association of Physicians Associates, etc). In addition, recent and current research on new organisational developments will be accessed, much of which is involving members of the research team, including:

- The Department of Health funded evaluation of the new models of care programme (Peckham is co-I) [76]
- Evaluations of local multi-speciality providers (PI Peckham)
- Data from the NIHR study on GP federations led by Professor McDonald (Peckham is advisory group chair)
- Policy Research Unit in Commissioning and the Health Care System research for Dept. of Health (Peckham directs, involves Marchand), including the 9th GP Work Life survey, and work on scaling up primary care
- The National Association of Primary Care's Primary Care Home Programme [77]

Documents will be analysed thematically to develop variables that describe different workforce and inter and intra-practice configurations. These data will be used to construct a matrix that identifies key categories of workforce and organisational mix to inform the subsequent analysis of workforce models, outcomes and costs. Findings will be written up in a report (month 6), and updated throughout the project.

(iii) *Practices Database*

The purpose of this task is to construct a database in Microsoft Access that will include all practices in England. The BMA reported 7,613 general practices in England in September 2016 [12], and whilst this number is falling, it is expected that the database will include over 7000 practices. This Practices Database will form the basis for the subsequent modelling of associations between GP workforce features and indicators of quality of care (WP3) and clinical effectiveness (WP4). It will also be used in the analysis of the survey of practice staff in a sample of general practices (WP5b), and inform the selection and analysis of case study sites (WP5c). Data will be largely obtained from existing published sources and will comprise details on the workforce of all practices, and information on other practice characteristics. The analysis will be based on a cross section of data, and a pragmatic approach will be followed, allowing for use of the most recent data possible.

Workforce variables: Data on practice staffing will be sourced from NHS Digital Primary Care Workforce Minimum Dataset (wMDS). Practices are mandated to regularly self declare details of each member of their workforce through the Primary Care Web Tool (PCWT). The details recorded of each staff member include:

- Name, registration number, NI number, gender, date of birth, ethnicity, clinical field of interest (optional)
- Date joined / left (and reason), or transferred
- Staff group (n=4) each with several subgroup / roles (entered through drop down menu):
 1. GPs - senior partner/ partner/ salaried/ registrar/ junior etc.
 2. Nurse – practice/ advanced/ nurse practitioner/ district/ trainee etc.
 3. Direct patient care – dispenser/ health care assistant/ paramedic/ pharmacist/ phlebotomist/ physician's associate/ physiotherapist/ podiatrist/ counsellor/ occupational therapist/ nurse associate/ apprentices (varied) etc.

4. Administrative / non clinical - estates and ancillary/ manager/ secretary/ reception/ telephonist etc.
- Type of contract (fixed term, locum, bank, etc.), contracted and actual hours worked

The wMDS is administered by the 'Workforce Team' within NHS Digital. Data are extracted quarterly and subject to quality checks, and standardised reports containing practice staffing indicators are routinely available. The reports include practice code identifier, name, CCG and other location identifiers, and patient list size broken down by sex and age. Information on staffing includes the full time equivalence (FTE) of practice employees in the four staff groups (doctor, nurse, direct patient care, administrative / non clinical), and for each constituent role, and by type of contract, and vacancies (<http://content.digital.nhs.uk/wMDS>). A current limitation of wMDS is that volunteers fulfilling important roles in many practices (e.g. care navigators) are not reported. NHS Digital is aware of this and data collection may be extended to incorporate volunteers by the time the analysis is conducted in this project.

Data from the wMDS will be transferred to the Practices Database and variables to represent the size and skill mix of practices will be constructed. These are likely to include: total FTE of care staff per head of practice population (and weighted by age distribution of practice); ratio of care staff FTE to total practice FTE; ratio of GP FTE to other care staff FTE; proportion of staff that are part time (vs full time) or temporary (locum, bank etc); proportion of care staff FTE that are mid level practitioners / new roles (advanced nurses, physiotherapists, pharmacists, physicians' associates); staff turnover / retention (from numbers joining and leaving); vacancies.

Other characteristics of practices: Other variables describing practices will be added to the Database.

- List size, age, sex and ethnic distribution of the practice population, size of clinical registers, geographic location, rurality, and index of multiple deprivation (weighted summary of seven indicators – housing, income, employment/ health / disability, education / skills / training, crime, living environment) sourced from routine reports produced by the 'Primary Care domain team' within NHS Digital.
- Contract type (General Medical Services, Personal Medical Services, Alternative Provider Medical Services) which affects practice payments, and a breakdown of payment types will be obtained from NHS Digital Annual Payments Review.
- Type of practice (traditional vs. new model, and type of new model) according to the categorisation developed in WP1(ii). Information to populate this variable will be drawn from sources used in WP1(ii) and through enquiry of regional organisations, such as the primary care specialty teams of the 15 Clinical Research Networks, and the 44 STP offices. Where needed, practices will be contacted for information.

These variables will be incorporated in the modelling of quality and effectiveness in WPs 3 and 4 as potential confounders of the relationship between staffing / skill mix and quality and clinical outcomes (effectiveness). They will also be used to indicate the representativeness of samples of practices included in WP5b and WP5c.

Analysis: Missing data in the Practices Database will be addressed through the modelling- of-missingness approach encompassed by multiple imputation. Specifically, multiple imputation with chained equations using a minimum of 10 multiple imputed sets and predictive mean matching will be employed [78]. The variables in the Practices Database will be analysed descriptively using frequencies, measures of central tendency and variability. Cross tabulations will be produced to explore associations between the workforce variables derived from the wMDS, and other practice characteristics. The analysis will be conducted at regional and national level. The possibility of developing a typology of general practices, based on a factor analysis approach, as attempted in Switzerland [79], and its potential utility for the subsequent modelling will be explored. A report will be produced providing a descriptive account of general practice in England (month 6).

(iv) Practice workforce costs

Using the workforce data in the Practices Database, variation in practice workforce costs will be estimated using a top down approach with national unit costs [80] applied to the direct FTE cost of each staff role by practice. The process will result in a total staff cost per practice, and proportions of total cost for different staff groups will be calculated. Workforce costs for practices will be examined in relation to the total payments received (NHS Digital Annual Payments Review) and key practice features such as list size, demography, morbidity, deprivation and model type. Gains and savings to practices associated with different workforce and skill mix configurations will be explored. The results of the costs analysis will be added to the report on the national descriptive analysis of practices (WP1 (iii), month 6).

WP 2: Literature review of available evidence on the effect of skill mix, roles, team climate and job satisfaction on quality of care, clinical outcomes and costs in GP primary care (addresses objective 2)

Lead Peckham, with Marchand; months 1-6

The systematic review will examine evidence on the impact of GP team composition (e.g. task shifting, introduction of new roles, role substitution, interdisciplinary working) and climate on quality of care, clinical outcomes, staff wellbeing and job satisfaction. It will build on prior reviews of the workforce undertaken by Peckham and Marchand for Dept. of Health, NHS England and Health Education Kent, Surrey and Sussex [81].

The review will conform to the PRISM guidelines <http://www.prisma-statement.org/>, and be registered with PROSPERO (International Prospective Register of Systematic Reviews) <https://www.crd.york.ac.uk/PROSPERO>. A wide range of sources will be searched, including: MEDLINE, EMBASE, CINAHL, PsycInfo, TRIP Database, HMIC, Science and social science citation indices, databases held at the King's Fund; trials and work-in-progress resources (identified via the CRD findings trials and health related research web resource, HRA summaries); health economics databases (e.g. NHS EED). Bibliographies of retrieved papers will also be scanned to identify further references. The grey literature will also be accessed, including searches of DHSS-Data and BLDSC, SIGLE, TRIP database, the King's Fund database and King's Fund Library.

All controlled trials, before and after studies, cohort studies, cross sectional studies, case studies and good quality qualitative studies will be included. Studies will be assessed for quality using a grading system based on that used by the Centre for Reviews and Dissemination. Following the extensive review of skill mix in primary care published in 2004 [29], the search will only include articles published since 2002, and published in English from the UK and other countries with similar health system to the UK (e.g. Canada, Australia, Netherlands, New Zealand). A pilot search to identify relevant inclusion and exclusion criteria has been conducted and suggests that about 10,000 relevant references will be identified. It is likely that some additional searches will need to be undertaken to specifically search for some new roles to ensure a comprehensive review but it is not anticipated that a substantial number of additional relevant papers will be found.

Studies will be included that: are set in primary care; relate to workforce or professional, clinical support and administrative roles; cover skill-mix, team mix, task substitution, task shifting, task delegation, professional delegation, new or changed role, team or practice climate, staff wellbeing or burnout, job satisfaction; include evidence on outcomes: e.g. clinical (patient) outcomes, patient -reported outcomes (i.e. patient satisfaction), quality of care, staff outcomes (e.g. stress, wellbeing), resource use, costs. Studies set in secondary care or non GP led practice primary care settings will be excluded.

Two independent researchers will initially screen all titles and abstracts against inclusion /exclusion criteria to identify potentially relevant papers. Next, two independent researchers will screen the full versions of papers identified as possibly relevant. The Cochrane guideline for systematic reviews will be used to assess the quality and risk of bias. The quality assessment and systematic data extraction will use a form that will include the conventional Population, Interventions, Comparators, Outcomes and Study design (PICOS) headings and will incorporate the assessment of relevance, theory, integrity and sustainability of interventions. Since articles from social sciences are likely to be included (without randomised controlled or before and after methodologies), the quality and relevance of each article will be evaluated in terms of best practices in their specific field.

Methods for integrating quantitative and qualitative studies will be drawn upon in the analysis [82,83]. An integrative review enables a diverse range of quantitative and qualitative methodologies to be simultaneously synthesised [84]. Data will be categorised thematically and an iterative process of evaluation will be adopted to identify patterns, commonalities and emerging themes [83,84] for the outcomes of interest. A report mapping existing evidence will be produced with gaps in evidence identified (month 8).

WP 3: Practice level analysis modelling of associations between skill mix and quality of care, exploring implications for role substitution and costs (addresses objective 3)

Lead Joy, with Jordan, Gage; months 7-12

This WP will model the associations between the workforce characteristics of all GP practices in England (expected sample >7000), and indicators of quality of care, controlling for other practice characteristics which may confound the relationship. The aim is to explore how workforce and skill mix variation is associated with quality of care at practice level. The Practices Database compiled in WP1 will contain the data on workforce

features and other practice characteristics to which quality of care indicators will be added for the statistical modelling.

Measuring quality: Quality of care is a broad concept originally described by Donabedian (85) as having structure (e.g. patient/ provider ratios), process (e.g. proportion of people with diabetes receiving blood sugar tests) and outcome (e.g. risk adjusted avoidable mortality) dimensions. More recently the Institute of Medicine (IOM) has identified six domains: safety, effectiveness, patient centredness, timeliness, efficiency, equity [86]. The measures of quality to be used in the analysis will draw on up-to-date indicators routinely collected in the NHS [87]. Collectively they reflect several recognised dimensions of quality: a) clinical achievement, from the Quality and Outcomes Framework; b) IOM indicators encapsulated in the Care Quality Commission inspection ratings; c) patient experiences from the GP Patient Survey. (WP4 will focus on a specific measure of quality, namely clinical effectiveness using patient level outcomes.)

Data sources:

a) The *Quality and Outcomes Framework (QOF)* is the annual system that rewards practices through allocation of points for achieving quality standards [88]. It reflects practice achievement (across 77 clinical indicators for 19 different conditions) in: keeping registers of patients; assessing people on the registers (e.g. blood pressure measurement for people with hypertension); the proportions who meet defined clinical thresholds. The primary care domain team within NHS Digital produces an annual QOF report which is routinely available (<http://content.digital.nhs.uk/qof>). Completion of QOF is voluntary, but compliance is high (7,619 practices provided data in 2015/16).

The overall clinical summary score from QOF will be used in the analysis since this shows greater variability between practices than is seen in individual indicators. Standard methods will also be used [89] to construct a composite indicator that reflects public health impact. Following other researchers, weights will be assigned to indicators proportional to importance in terms of estimated number of lives saved (per 100,000 patients), rather than more traditional weights derived from, say, factor loadings [90,91]. For further analysis, we will draw upon the National Audit Office [92], which showed considerable variation, across four disease areas – coronary heart disease (CHD), stroke, hypertension and diabetes.

b) Ratings by the *Care Quality Commission (CQC)* (the independent regulator of health and social care in England) result from regular inspections of GP practices (4 point scale: outstanding, good, requires improvement, inadequate) (<http://www.cqc.org.uk/content/about-us>). Ratings reflect 5 questions, each involving several key lines of enquiry, to ensure consistency: is it safe (patients protected from abuse and avoidable harm); is it effective (care / treatment achieves good outcomes base on best evidence); is it caring (staff treat patients with kindness, dignity, respect); is it responsive to needs (organised to meet patient needs); is it well led (leadership, management, governance, support high quality care round individual needs; encourages learning and innovation; open and fair culture). CQC scores for practices are routinely available (to inform choice and as a quality incentive). CQC will facilitate data access for the research (letter of support uploaded).

c) Practice level patient experience indicators will be obtained from the *GP Patient Survey (GPPS)*, which is undertaken independently by IPSOS MORI on behalf of NHS England (<https://gp-patient.co.uk/about>). The GPPS covers many domains, including quality of the consultation, overall care, choice, care and concern. The findings on access, overall experience and out-of-hours services feed in to the NHS Outcomes Framework and the CCG Outcome Indicators (domain 4 on experience of care). (<https://www.england.nhs.uk/statistics/statistical-work-areas/gp-patient-survey/>). Campbell has eight years involvement in the GPPS [93,94] and will discuss indicators for use in the modelling with the Service User Group. Access is recognised as a key indicator and will be included in the analysis.

Analysis: Quality indicators will be merged with the Practices Database using practice identifiers. Care quality outcomes will be measured as functions of practice staffing whilst controlling for demographic and other characteristics of practices not directly related to staffing (Table 1) using appropriate statistical techniques. The underlying structure of these data is potentially clustered by GP within CCGs, and appropriate specification tests to account for this source of variation will be conducted. If required, the multilevel regression modelling will utilise a random effects variable for CCG [95]. Ordinal logistic regression will be used for the CQC score, and linear regression for other outcomes. The Practices Database is likely to contain highly correlated explanatory variables so model diagnostics will include tests on variance inflation factors. Variables will be transformed where necessary, although interpretability (how skill mix changes impact on quality indicators) will be a paramount consideration. All statistical analysis will be performed using R version 3.3.3 [96].

Table 1: Variables to be used in the practice level modelling of quality of care

Practice workforce variables	Practice Characteristics	Quality indicators
<ul style="list-style-type: none"> - Total FTE care staff per head of practice population - Ratio of care staff FTE to total practice FTE - Ratio of GP FTE to total practice FTE - Proportion of care staff FTE that are temporary (locum, bank)/ mid level (physician's associate, advanced nurse) - Staff turnover, vacancies 	<ul style="list-style-type: none"> - List size - Age/ sex distribution of practice population (e.g. % over 75) - Morbidity (clinical registers) - Region, urban / rural - Index of multiple deprivations - Contract type, practice payments - Type of practice (traditional /new) 	<ul style="list-style-type: none"> a) QOF clinical summary score b) CQC inspection rating c) GPPS patient experience indicators

Economic analysis: The objective of the analysis is to identify the contribution (productivity) of each staff group (GPs; nurses; other patient facing staff; other administrative) to establish if role substitutability or complementarity is present, when controlling for other confounding factors. A translog production function [97] (a generalisation of simple Cobb Douglass production function [98] approach) will be employed to accommodate cross products and allow estimation of output elasticities. This will further allow derivation of a translog cost-function, supporting estimation of the cost share associated with each staffing input [99]. The result of this analysis will be an indication of the rate of substitutability between staffing inputs to achieve a given level of output (quality), and the cost input shares associated with each type of resource. Alternative approaches to the estimation of productivity and efficiency are possible. However, the translog approach is well supported in this case by the available data, namely: information on the specific staffing inputs and prevailing prices, as described in WP1. In addition, independent data on total reimbursement (total costs) at a practice level are available (NHS Digital, Annual Payment Review). This covers all other practice costs and allows for costs other than staffing to be accommodated in the analysis to support this cost function approach. Covariates will be included in the model to control for confounding based on demography, socioeconomic status, deprivation, rurality and practice size, as recorded in the Practices database. Suitable diagnostic tests will be performed to ensure results from the model are meaningful.

Longitudinal analysis: Possibilities for longitudinal analysis will be explored as subsequent rounds of wMDS become available, and through updating the practice level information and the quality of care measures. Relationships will be modelled as cross sectional time series, as far as the data allow, and taking caution not to draw inferences from too distant past that may be non-stationary, especially as new primary care models emerge. Appropriate estimation methods will be explored to allow for lagged effects and suspected endogeneity in situations with small T and large N.

Results will be written up in a report (month 12) and used to inform the selection of case studies in WP5c, and to assess the representativeness of the samples of practices included in WP4 and WP5b.

WP 4: Patient level modelling of associations between skill mix and clinical effectiveness, exploring staff deployment and implications for costs (addresses objective 4)

Lead Joy, with Jordan, Gage; months 13-27

This WP will model the associations between the workforce characteristics of a sample of GP practices in England, and patient outcomes / indicators of clinical effectiveness, controlling for patient demographic and comorbidity status, and other practice characteristics which may confound the relationship. The aim is to explore how workforce and skill mix variation is associated with clinical outcomes at the patient level.

Data source: Data on patient outcomes will be obtained from the CALIBER programme (ClinicAI disease research using Linked Bespoke studies and Electronic health Records), based at the Farr Institute of Health Informatics Research, at UCL. Natalie Fitzpatrick, Farr Institute Data Scientist and Facilitator has agreed to collaborate with the research team for this WP (letter of support uploaded). The Farr Institute accesses patient level data from the Clinical Practice Research Datalink (CPRD), an ongoing primary care database of anonymised medical records covering over 700 practices in the UK (some 7% of the population) which has been shown to be broadly representative in terms of age, sex and ethnicity [100]

For WP4, data will be used from the subset of English practices that have consented to participate in the CPRD linkage scheme. This links patient records to trusted third party sources, including Hospital Episode Statistics, ONS mortality data, disease registries (e.g. cancer and MI), Index of Multiple Deprivation (IMD) and Townsend score. CPRD undertakes quality checks to identify research ready practices (continuous reporting) and patients (subject to minimum data requirements). It then performs the data linkage and extraction, and transfers the data

to the Farr Institute safe haven. CALIBER provides support to researchers for project set up, gaining Independent Scientific Advisory Committee (ISAC) approval, finalising data sharing agreements, data preparation, including consistency checks, data transfer and follow up as required. There are currently some 546 research ready practices in England for inclusion in the proposed analysis.

The reporting required to qualify for QOF payments has significantly improved the completeness of practice reporting [100]. Patient level data available from CALIBER include:

- Practice ID, region, last data collection date
- Patient ID, gender, month/ year of birth, marital status, prescription exemption status, diagnoses, capitation supplement (low medium high), socio-economic status based on post code (IMD and Townsend score), date registered and left practice
- Consultation / event: date, type, duration, diagnosis, staff ID and role,
- Referrals, immunizations, tests, therapies / prescription details

Outcome measures of clinical effectiveness: Emergency hospitalisations for ambulatory care sensitive conditions (ACSC) will be the measure of effectiveness used in the analysis. Hospitalisations for ACSCs present a significant burden upon healthcare systems and adjusted rates are used as markers for performance globally as well as in the NHS [101,102]. ACSCs have been described as those conditions where it is possible, to a large extent, to prevent acute exacerbations and reduce the need for hospitalizations through strong primary health care-based services delivery [98], and are indicators used within the NHS Outcomes Framework (<http://content.digital.nhs.uk/nhsf>). Whilst the levels of hospital admissions for select ACSC appear to be decreasing or stabilising over time, there remains wide variation in hospitalisation rates. In the context of this WP, ACSC are a suitable proxy for primary care clinical effectiveness, and individual conditions will be selected from the Kings Fund categorisation:

- Vaccine preventable: influenza and pneumonia
- Acute (dehydration and gastroenteritis, pyelonephritis, perforated or bleeding ulcer, cellulitis, pelvic inflammatory disease, ENT infections, dental conditions, convulsions/ epilepsy, gangrene)
- Chronic (asthma, congenital heart failure, diabetes complications, COPD, angina, iron deficiency anaemia, hypertension [101]:

Analysis: Patient level linked hospital and primary care pseudoanonymised data will be provided by CALIBER and merged with the Practices Database (n=546 practices for which linked data are available). A hierarchical modelling approach will be adopted to accommodate the data at two levels (patient outcomes and characteristics; practice level variables). Patient level data on emergency hospitalisations for ACSC will be measured as functions of the practice staffing resources, whilst controlling for geo-demographic and other characteristics of practices and patients that may affect outcomes (Table 2).

Clustering by practice will be addressed by an appropriate multilevel logistic regression model for the likelihood of admission. The primary analysis will test for cross-level interactions between practice characteristics and skill mix profile and emergency admission into secondary care. However, included in the CALIBER data are consultation data, including staff-type. Hence, the linked data structure has the potential to build indicators aggregated at patient-level, for example:

- a) proportion of consultations by staff-type in cross section period
- b) time between hospital admission and last consultation, and role of last staff member to see patient

Potential associations between admission ACS and such variables will also be explored.

All statistical analysis will be performed using R version 3.3.3 [96].

Table 2: Variables to be used in modelling clinical effectiveness

Practice workforce variables	Practice Characteristics	Patient characteristics	Patient outcomes
<ul style="list-style-type: none"> - Total FTE care staff per head of practice population - Ratio of care staff FTE to total practice FTE - Ratio of GP FTE to total practice FTE - Proportion of care staff FTE that are temporary (locum, bank)/ mid level (physician's associate, advanced nurse) - Staff turnover, vacancies 	<ul style="list-style-type: none"> - List size - Age/ sex distribution of practice population (e.g. % over 75) - Morbidity (clinical registers) - Region, urban / rural - Deprivation index - Contract type, practice payments - Type of practice (traditional /new) 	<ul style="list-style-type: none"> - Sex - Co-morbidities - Socio-economic status deprivation - Ethnicity 	<p>Clinical effectiveness: Emergency hospitalisations for Ambulatory Care Sensitive Conditions</p> <ul style="list-style-type: none"> - Vaccine preventable - Acute - Chronic

Economic analysis: The modelling will provide estimates of the association between input parameters such as staff levels and staff mix and health outcomes (emergency ACSC admissions). Where a significant relationship is found, the marginal or impact effect (depending on continuous or discrete explanatory variable) will be estimated. This will provide an indication, relative to the sample average practice, of how a change in staffing inputs may affect the likelihood of avoiding an emergency ACSC admission, and corresponding cost impacts will be estimated. Additional staffing input costs (or savings) will be obtained from validated sources [80] as reported in WP1, whilst standardised tariffs included in the linked data will allow for the savings from avoidable hospitalisations to be addressed. The analysis will provide an indication of the potential (costs) savings, on average, for a small change in the input parameters such as staffing, compared to the sample average practice. The analysis will distinguish between practices of different types with variation in marginal effects explored. The distribution of effects across the NHS will be considered, where possible, since at a practice level additional staffing costs may be incurred, whereas the NHS will save on treatment costs if health outcomes of patients are improved. Sensitivity analysis will be conducted to account for uncertainty in the estimates of marginal effects and for the unit costs associated with the treatment of health outcomes.

Longitudinal analysis: Data from CALIBER contains retrospective information on patient outcomes, such that there are reasonable possibilities for longitudinal analysis. Relationships will be modelled as cross sectional time series, as far as the data allow. Caution will be taken not to draw inferences from too distant past that may be non-stationary, especially as new primary care models emerge. Estimation methods will be explored which take account of the possibility of lagged effects and endogeneity within those data and specification tests performed to assess and allow for the presence of bias.

A report on WP 4 will be produced (month 27).

WP 5: In-depth qualitative analysis of general practice team composition and climate (addresses objectives 5)

Lead Peckham, with Marchand, Campbell, Spilsbury, Lusignan; months 7-27

This WP will primarily focus on qualitative methods to understand team working. It will assess how decisions about workforce composition and roles are made, and evaluate different workforce structures. Team climate will be explored in terms of impact on the delivery and quality of patient care, job satisfaction and the effective functioning of the practice team. Complementary methods will interrogate these areas from different perspectives: a) focus groups of service users; b) survey of team members in a sample of practices; c) in depth case studies of diverse practices. Data will be collected, analysed and reported separately, adhering to standards of quality and excellence for each method. Findings from each of these studies will be synthesised using a convergent parallel mixed methods design (d) [75] to provide a report that will inform the development of the implementation recommendations (WP6). This will be targeted at end users who make decisions about team composition and with the objective of promoting working conditions that enhance the delivery of effective and efficient services to patients.

a) Patient and carer focus groups

Patient and carer perspectives on the influence of general practice teams on the care they receive will be assessed through focus groups. Group discussions are the preferred method because they allow participants to explore and clarify their views on their care through group processes and in ways that would be less easily accessible in a one-to-one interview [103]. The discussions aim to elicit patient and carer insights into how skill mix, relationships, practice changes, and internal and external pressures on the service are experienced.

Eight focus groups will be convened. In discussion with our PPI representatives, four categories of GP users have been identified: (i) older people (aged over 65 years), (ii) adults in employment, (iii) parents with young children, and (iv) carers of adults. To consider geographical as well as population differences, two focus groups will be held for each category of service user, one covering the north of England (centred on Leeds) and the other in the south (Surrey/ Kent/ Medway). Distinguishing these four key categories of users, who may interact with their practices and practice staff in distinct ways, will provide a degree of homogeneity in the groups, which is important for establishing open and equal discussion [104]. Each focus group will include about 10 members, from a range of different types of practices (identified through the Practices Database constructed in WP1). The practice PPI group will be provided with full information about the study, and asked to nominate a volunteer to work with the research team to recruit participants.

The focus group topic guide will be informed by the review (WP2) and developed with the project's Service User Group. Topics will cover: participants' experiences of care in their practice; views about the roles of team members; how they work together; possible changes in team composition or practice organisation that might affect elements of quality (such as access, continuity of care, communication and effectiveness). Views will also be sought on how funds for general practice might be used to benefit patients and improve primary care services. Focus groups will be conducted in accessible premises where patient and carer groups already meet. In line with INVOLVE guidelines, participants will receive support to attend the focus group (travel, child care or care of other dependent relative if needed), and a shopping voucher gift of £20 per person.

Participants will provide informed consent, and be assigned a unique study number to maintain anonymity and confidentiality. For consistency, the same two researchers will conduct all eight focus groups. Discussions will be audio recorded (with participants' permission), transcribed and uploaded to NViVO for analysis.

Transcripts will be subjected to thematic analysis [105], process analysis (to explore the impact of group composition) [106] and constant comparative technique to evaluate both within and across group discussions. This provides a basis for understanding similarities and differences across the range of participants [107]. Focus group data will be reported and then synthesised with the other strands of WP5 (see 5d).

b) Survey of team members in a representative sample of general practices

We will explore associations among team climate, staff wellbeing, job satisfaction, workforce characteristics and practice performance indicators in the sample of 240 practices that are members of the Royal College of General Practitioners Research and Surveillance Centre (RCGP RSC). Lusignan (co-I) is Director of the RCGP RSC and holds the database of practices. The sample is largely representative of the national population [108].

The practices in the RCGP RSC sample will be identified in the complete Practices Database (WP1) through location identifiers, for the purposes of obtaining basic descriptive information, and to further test representativeness of the sample. Practice managers will be asked to facilitate distribution of the survey to all staff; a link to an online option will be available. The survey will be advertised to practices in the monthly RSC newsletter. Contact is maintained with practices through a liaison officer. Practices will be given £50 vouchers for staff room refreshments as a small 'thank you' if over 65% of practice staff return a completed questionnaire.

Survey responses will be pseudoanonymised for individual respondents but have practice ID attached. Items will include basic demographic factors (age, gender, role, time in practice) and four well validated instruments (some of which will also be used in the case studies, WP5c):

- The Warr Cook Wall [109] measure of job satisfaction, which has been found appropriate for clinical and non clinical staff in practice settings, and measures eight domains related to work attitudes, motivation and work involvement, and aspects of psychological wellbeing
- The abbreviated Maslach Burnout Inventory, a 9 item scale that measures the frequency (everyday to never) of emotional exhaustion, depersonalisation and personal accomplishment [110,111]
- The short form (14 item) Team climate Inventory which has been shown suitable for use in primary care, to provide an assessment of four domains of team climate (vision, participatory safety, task orientation, support for innovation) that influence effectiveness [51,112]
- The Healthcare Team Vitality Instrument a self-report 10 item tool which assesses team functioning through individuals' perceptions of environmental support structures, engagement and empowerment, patient care and team communication [113]

Analysis: Responses will be entered or downloaded into a secure database and descriptive statistics calculated using methods appropriate for each instrument. We will explore variation in instrument scores within and between practices, associations between instrument scores at practice level, and differences between practices in relation to their workforce composition and practice type. A report of the survey findings will be produced and then synthesised with the other strands of WP5 (see 5d).

c) Case studies in 12 general practices

Case studies (using mixed methods) will be employed to acquire an in-depth understanding of workforce composition, roles, skill-mix strategies and team climate and how these are associated with effectiveness of service delivery, patient experience and outcomes. A case study approach provides a mechanism for framing exploratory work within different contexts [115,115]. Specifically we will conduct a multiple case (embedded) design [114], using interviews, observation and survey methods to identify the structures and processes related

to workforce composition, roles, relationships and decision-making across a variety of practice organisational forms, taking account of local contexts, for their influence on quality and effectiveness. The aim is to provide new insights to enable managers to develop innovative approaches to addressing workforce issues in GP led primary care [116], with a focus on: how workforce decisions are made; how particular staff mixes have developed; how different roles contribute to practice work and patient care; what enables staff to work effectively together.

Selection of case study sites: To capture different contexts, a range of practice types will be sampled [117]. Using the Practices Database from WP1, practices will be purposefully identified according to: list size (small / large), patient age distribution, type of contract, deprivation, rurality, region, GP: patient ratios and performance (quality or effectiveness indicators from WP3, 4). The aim is to enlist 12 practices, (although we anticipate approaching more than 12 practices to achieve this sample): some cases will represent a more traditional skill-mix strategy (task substitution from doctor to nurse, role creation, e.g. physician assistant, nurse practitioner); the rest of the practices will represent new integrated models (e.g. multispecialty community provider). Information in the Practices Database will provide baseline descriptive information of each case study practice, including workforce structure and performance indicators.

Methods: Ethnographic methods (observations, interviews and surveys) are appropriate within case study design and for the objective of exploring individual and team work and the context in which care is delivered [118]. To understand what workforce composition, roles and relationships promote effective and efficient care, the 'receptive contexts for change' framework devised by Pettigrew et al. [119] will be used. This distinguishes between internal factors that influence decision-making (e.g. resources, organisational culture, effective relationships) and external contexts (e.g. quality and coherence of policy affecting general practice and workforce, local organisational and socio-demographic environment). Data will be collected on aspects related to skill mix and influences on team functioning and patient care. The Pettigrew et al framework provides sensitive concepts to guide data collection and novel sense-making of skill-mix in general practice. In addition, interactionist theory will be drawn upon to understand how individuals – professionals and their support staff - interact with each other to negotiate their role and function, and react to their environment at the organisational (meso) and policy (macro) level [120-122]. This will ground the findings within the social systems of general practice and service delivery.

Data collection will be conducted with staff employed by the practice and service users (patients and/ or informal caregivers) and will comprise:

- (i) *Surveys with practice staff*, - to provide background on the practice working environment, all practice staff will be asked to complete the short-form Team Climate Inventory (TCI) [112] and Healthcare Team Vitality Instrument [113], as used in the GP workforce survey (5b above).
- (ii) *Interviews with practice staff*, - between six and 12 team members per practice, dependent on size, diversity of professionals, roles, skill mix strategies, including clinical and non-clinical staff, and any allied health (e.g. physiotherapists, dieticians) or non-professional (community workers, lay advisers, volunteers) staff. Semi-structured interviews will include open and closed questions to gather rich data on experiences. The following areas will be covered:
 - work environment: decision-making processes, interprofessional dynamics, interaction, relationships and trust
 - wellbeing, using the abbreviated Maslach Burnout Inventory questions, as used in the larger workforce survey (5b above) [110, 111], followed by assessment through open questions about how this impacts on job satisfaction, the delivery of patient care, and feelings of workplace control
 - organisational behaviour: attitudes and behaviours towards the practice, colleagues, assistants, patients and the external environment more broadly.

Participants will be able to choose the location for the interview (some staff may prefer interviews to be conducted away from their place of work). Interviews will be audio recorded (with participants' permission) and transcribed for analysis.

- (iii) *Observations of practice meetings*, - to understand the organisation of practice work and patient case load. Observations offer the opportunity to gather data on everyday interactions that can be compared with participant interview data. At least two meetings will be observed in each practice (team / senior planning

meeting and, where possible, patient-case management meetings). Researchers will keep comprehensive field notes of meeting observations based on descriptions of events (rather than researcher interpretation).

(iv) A *patient survey* will be conducted in each case study site. The aim is to capture opinions from a broad range of patients about their experiences of interacting with the practice. All patients attending the practice for consultations with any team member over a one week period will be invited to complete the survey prior to leaving the practice. Patients will be informed about the survey when they book in and via notices around the practice, website and any newsletters. A member of the research team will be present to hand out the questionnaires. A secure postbox will be provided in the practice reception area for the return of completed forms direct to the researchers. The survey will be designed and piloted with input from the Service User Group. It will be brief but focussed, and in paper format, with a maximum of 20 closed questions on one side of A4. Items will cover: sex; age group; clinic session attended; type of staff member seen (GP, nurse, etc); selected items from the GP Patient Survey (GPPS) as a measure of quality, including access; perceptions of team functioning and effectiveness; views on new and extended roles and organisational reforms. Some items will be common to all practices and others modified to reflect specific contexts. The need for translation will be explored with individual practices. Campbell, who advises nationally on the GPPS, will support the questionnaire development. The GPPS aims for an average of 110 surveys per practice. It is expected that over the course of a week it will be possible at least to equal that number of responses, in even the smallest practices, resulting in a minimum sample of 2000 questionnaires.

Analysis of case study data: Each data collection method generates data that represents an embedded unit within each case study (practice). These units provide the means for comparisons both within and across case studies, taking into consideration the local context. Quantitative data (measures of team climate and vitality, patient survey) will be entered into SPSS and analysed using descriptive statistics, and t tests/ Anova to understand differences within and between cases. Health professional responses on climate and vitality will be aggregated and compared within and between cases. Interviews and observation notes will be subject to thematic analysis. Both intra and inter case themes will be identified, and similarities and differences explored with reflections on contexts. Quantitative and qualitative data will be synthesised to compare cases between practices. This will drill down into understanding of how team climate and vitality relate to practice structure, organisation, workforce features and working practices, and how patients perceive the quality and effectiveness of the service. A report of case study findings will be produced and then synthesised with the other strands of WP5 (see 5d).

(d) Analysis and synthesis of WP5

WP5 will use a range of methods (a – c above) to generate depth of understanding of teams within different contexts. We will collect and analyse data separately, adhering to standards of quality and excellence for each method and report each study. However, it is imperative that findings are synthesised for end users who make decisions about team composition and promoting working conditions to enhance the delivery of effective and efficient services to patients. To this end, findings from each study (a-c) will be synthesised using a convergent parallel mixed methods design [75]. A narrative synthesis will be framed using relevant theory (as referenced above) for in depth exploration, discussion and critique intended to test and challenge observed findings. Clarity and transparency will underpin the reporting (linked to data sources) to enable judgement of the quality of the inferences and conclusions. Group discussions involving all types of staff will be held in up to 12 practices that are not case study sites in order to test the validity of the findings. Meetings will be set up with proceedings recorded, transcribed and analysed.

WP 6: Knowledge Transfer; developing implementation recommendations for GP Practices and NHS Commissioners (addresses objective 6)

Lead Chilvers, with Richards, All; months 28-33

Design: In line with the knowledge mobilisation literature, evidence has to be produced that is comprehensible, and in relevant formats for potential users [123,124], as well as taking the context into consideration [125]. A Nominal Group Technique (NGT) will be used to synthesise findings from WPs 1 to 5 and elicit consensus among experts on implementation recommendations. The NGT method facilitates the generation of ideas in relation to problems, solutions, or both, and is based on the premise that accurate and reliable assessment is best achieved by consulting a panel of experts and accepting group consensus [126,127].

The NGT involves the following two stages. (a) Development sessions attended by the members of the research team, Service User Panel (SUP) and Professionals and Commissioners Panel (PCP) to establish key learning from the research and identify Knowledge Transfer Topics (KTTs); (b) Consensus-building workshops with commissioners, healthcare professionals in general practice and service-user representatives (experts) to consider the KTTs and develop recommendations and 'priority action points' that will support practice management and commissioning decisions related to the GP workforce composition and team functioning [126, 127]. These two main stages for WP6 are described below.

Stage 1: Summarising key findings into Knowledge Transfer Topics Two internal development sessions will be held, one in London and one in Leeds, attended by the leads from WPs 1 to 5 and representatives from the SUP and PCP (up to 15 participants), and coordinated by Chilvers. The focus will be on identifying broad KTTs from the research findings and creating summary resources to be presented and discussed at the consensus-building workshops. At the first meeting, findings from the previous WPs will be assessed. Members will be asked to consider the strength and quality of the evidence and to prioritise topics. The key learning from that meeting will be written up and taken to the second meeting to be finalised. At the meeting, 'trigger material' for the consensus workshops will be agreed. There will be the same membership for both development sessions.

Stage 2: Consensus building workshops Two workshops bringing together external experts will be formed to reach consensus [128] on how the research findings can be incorporated into GP practices to improve efficiency, quality of care or staff wellbeing. The NGT approach has already been used in general practice and implementation research [129,130]. It is a face-to-face iterative process that involves controlled feedback, structured interaction and a statistical group response [127]. The outcome will be recommended Priority Action Points to inform practice and commissioning.

The workshops will be held in London and Leeds and the same KTTs will be discussed in both workshops. There will be different membership in each workshop, reflecting various General Practice contexts, such as urban/rural or social deprivation (as guided by the research findings). Each workshop will include a mixed group of about 15 to 18 stakeholders (GPs, other primary care practitioner professionals, commissioners and service users), making 30 to 36 in total, to enable detailed discussions of different KTTs in smaller groups. Obtaining representation of different stakeholders will be important to ensure that all perspectives are included [127]; each group will contain a minimum of two of each of the stakeholders listed above. The groups will be run by Chilvers and Richards, who are experienced facilitators. Notes will be taken by two observers, including another member of the research team and a SUP representative

The workshops will start with an introduction to the NGT process and presentation of background information, evidence from the research and KTTs. Subgroups will then be formed to discuss specific KTTs. This process will start with silent generation of ideas through private consideration by group members. Individuals then present their ideas within each subgroup, followed by group discussion (moderated by a research team member) to generate an agreed list of ideas and a priority order. The subgroups convene to present their agreed priorities and identify common themes. The final step involves further discussion and voting to rank ideas to establish Priority Action Points.

Analysis: The workshops will discuss about three KTTs to derive a set of responses presented in a ranked order as Priority Action Points for each workshop (possibly including two or three Priority Action Points per KTT). There are several alternative voting processes (and rules) that can be followed, with implications for the final rankings [126]. The analysis plan will be agreed as part of the development sessions. Votes will be recorded for analysis in Excel and the results of different voting rules compared. As the workshops will be focussing on different general practice contexts, the Priority Action Points will not be combined across the two workshops but the research team will draw together commonalities and themes. The results will be fed back to both groups after the workshops, with areas for reflection highlighted, and further comments will be invited over a period of 1 month after the sessions [131,132].

Sampling and recruitment:

Two main processes will be followed for recruiting stakeholders to the NGT Workshops. The aim is to ensure that there is good geographical coverage and that different types of practices and a variety of socio-economic and ethnic areas are represented. Firstly, an open invitation (to commissioners, GPs, other professionals in General Practice and service users) will be publicised via the project website, social media and targeted communications. Secondly, partnerships (to support recruitment will be formed with national networks, such as

the Clinical Research Networks, the Primary Care Collaboratives, RCGP and other influential groups. It is also expected that snowballing technique will be used to supplement this process and increase participation rates, with members of the team and individuals who have participated in the research during the two-year period circulating invitations to their contacts. A recruitment incentive of £150 will be offered to each stakeholder taking part in the workshop, and participant travel expenses will be reimbursed.

Timelines: Discussions about the NGT consensus-building workshops (including a methodology/ introduction session for the research team, SUP and PCP) will take place at the end of the first year. The emerging findings for the development sessions will be considered alongside each WP in Year 2. The evidence summaries will be ready by month 28. The development sessions (two rounds) will take place over months 29 and 30, with the KTTs ready in month 31. The NGT workshops will be scheduled for month 32 and the report, with associated outputs to support knowledge transfer, will be finalised in month 33. Audio, visual and text summaries prepared as source materials will also be available for dissemination activities (WP7).

Service user and professional and commissioner involvement: The SUP and PCP will be consulted regarding the design and implementation of WP6. A dedicated meeting on NGT will be provided for both groups to support panel members' understanding of the method and to seek input from members. Panel representatives will join the development sessions (stage 1) to contribute to the selection of KTTs. Volunteers will be sought from the SUP and PCP to attend training in NGT facilitation and to participate as facilitators and / or a note takers in the NGT workshops. The stakeholders (commissioners, professionals and service users) who take part in the NGT consensus-building workshops will be independently recruited as described above.

WP 7: Wide dissemination of findings (addresses objective 7)

WP7, Lead Lusignan, with All; months 34-36

We plan an active dissemination strategy throughout the project (led by Lusignan) to ensure results are shared and have impact. Input will be provided by WP6 (Knowledge Transfer), the Service User Panel (SUP) and Study Steering Group (SSG).

We will produce outputs that meet the needs of six key audiences:

- A. Commissioners and NHS managers (e.g. Clinical Commissioning Groups, Sustainability and Transformation Plan areas, NHS England)
- B. GPs, GP consortia, and other primary care providers
- C. Patients and the public
- D. External statutory organisations (e.g. Dept. of Health, NHS Digital, National Institute for Care Excellence (NICE), Care Quality Commission, Health Education England)
- E. External non-statutory bodies: Royal College General Practitioners (RCGP), Royal College Nursing (RCN), British Medical Association and its Local Medical Committees; other groups dependent on skill mix e.g. Faculty of Physicians Associates (FPA), Royal College of Physicians
- F. Academia, especially primary care academia through RCGP, conferences and Society of Academic Primary Care (SAPC)

To ensure that the outputs inform practice and thereby maximise benefit to patients and the NHS, the dissemination strategy will use a knowledge management framework [133], creating information at macro (health system), meso (health region/ locality) and micro (individual provider/ practice) levels.

The knowledge translation literature indicates that new information is most effectively disseminated using multiple approaches and ideally face-to-face. In addition to maintaining a project website and giving written and online feedback to study participants, activities will include:

- Ten interactive workshops across England on implementation of good practice recommendations developed in WP6 (Audiences A, B, D & E)
- Patient/public guide (developed with input from the SUP)– to help patients and public appraise the pros and cons of skill mix in primary care; targeted at practices PPI group members; lay members of CCGs/STPs; national patient groups/charities (skill mix to deliver quality) (C)
- Press releases and policy briefings disseminated through links with key organisations (assisted by the ESG) (A,D, E & F)
- Social media (Linked in & Twitter) with associated infographics at key milestones (All)

- MOOC Webinar, video (Youtube), multimedia evidence summaries (All)
- Publications, including full NIHR report, articles for professional and academic journals, conference presentations (All)

Projected outputs

The research is addressing a strategically important issue. Shortages of GPs and other staff, in the face of increasing demand for primary care services and rising expectations, are jeopardising the patient experience. To address the workforce shortage, the research will generate evidence on how primary care team configuration and climate affect quality of care, clinical outcomes and costs. Evidence on this is scarce, and the proposed research will analyse new and existing datasets, and use qualitative methods, to produce findings to fill this gap.

Specifically, the findings will produce evidence about what skill mix configurations work best in primary care, and what opportunities exist for substitution of tasks between different health practitioners in order to reduce costs whilst maintaining or improving outcomes. This will enable GP partners, managers and commissioners to make staffing decisions that will ensure that the limited available human resources can be deployed in a way that maximises patient benefit. Identifying efficient workforce configurations will enable more patients to be treated effectively at the same or lower costs. This will benefit the population who are service users, through improved access to more timely care, and tax payers (funders of the NHS), because the NHS budget will be more efficiently allocated. Overall this will contribute to the smooth running of the NHS in the future, and its sustainability.

The research will also provide information on the relative efficiency of new models of primary care, and whether new staff roles, and new ways of using existing staff, are associated with improvements in patient outcomes or savings in costs. Findings will also indicate how team working and relationships relate to patient outcomes and experiences and staff wellbeing and job satisfaction, providing further guidance about how to foster productive team working environments.

Implementation recommendations: Findings from all aspects of the work will be brought together in a consensus forming process involving GPs, professionals, commissioners and service users in order to produce implementation recommendations that are relevant and workable throughout the NHS. These recommendations will inform short term staffing decisions and longer term training plans at practice, regional and national levels. They will be disseminated through multiple means including interactive workshops, policy briefings and presentations to the relevant audiences.

Plan of investigation and timetable

The study lasts 36 months. The timetable is shown in the flow chart and gantt chart (uploaded separately)

Project management will occur throughout, undertaken by the PI, assisted by a project manager. Months 1 – 2: first project management meeting (all co-investigators); membership of three project advisory groups (Service User Panel, Partners and Commissioners Panel, Study Steering Group) and meeting schedules confirmed.

Months 1 – 6, Completion of WPs 1, 2 (overview, systematic review). Findings will feed in to subsequent WPs (e.g. selecting case study sites in WP5).

Milestones, month 6: report on policy context, report on new models, completed Practices Database with workforce costs (WP1); report on mapping of evidence from the systematic review (WP2)

Months 7 – 12:

- WP3, practice level modelling, with report (milestone) month 12
- WP4, apply for Independent Scientific Advisory Committee approval for use of CALIBER data in year 2
- WP5, set up including: apply for ethical approvals (for focus groups, practices survey and 12 practice case studies); selection of study sites; identify possible practices for recruiting to focus groups

Months 13 – 27:

- WP4, patient level modelling, with report (milestone) month 27
- Qualitative data collection and analysis (WP5), i.e. focus groups, practices survey, case studies, each with separate reports (milestones) month 24; synthesis months 25-27; overall report (milestone) month 27

Months 28-33: WP6, development of implementation recommendations, (based on key messages from earlier WPs), through expert consensus building workshops; guidelines completed (milestone) month 33.

Months 34 – 36: Completion of final report; dissemination strategy (WP7)

Project management

The PI (Gage) will be responsible for the overall conduct of the research. She will be supported by a project manager (80%FTE) who will assist with the day to day running of the project (arranging meetings, completing ethical processes, coordinating WPs, budget, reporting). Each WP has a lead.

The research team (all co-applicants) will form a Project Management Group which will meet six times a year to review progress against milestones and plan upcoming tasks. Each WP will organise regular meetings attended by relevant team members, the PI and research manager. All meetings will be noted, with action points to be followed up at subsequent meetings, and will be face-to-face whenever possible. The research costs include an annual subscription for an online videoconferencing facility which will enable unlimited virtual meetings to take place between remote members of the project team, as needed. Team members already work with each other in various capacities and across other NIHR funded projects. A face-to-face team meeting took place to prepare this proposal.

A *Study Steering Committee* (SSC) will be convened to review progress and provide advice and support to the research team. It will meet twice per year, and will be attended by all members of the core research team (PI, project manager, co-applicants). The SSC will comprise about ten members, including: representatives of key statutory and professional bodies related to the general practice workforce (Health Education England, Royal College of General Practitioners, NHS Employers, BMA, NHS England, NHS Clinical Commissioners) and allied professionals (e.g. Royal College Nursing or Nursing and Midwifery Council, Chartered Society of Physiotherapists, Faculty of Physician's Associates); expert academic methodologists (mixed and qualitative methods, statistics, health economics); independent patient / public representative (e.g. from the Patient's Association). The Chair will be agreed prior to the first meeting.

Approval by ethics committees

Various data are being gathered within the project. Ethical approval will not be required for the systematic review, or the practice level analysis in WP3, since both draw on available secondary sources (literature and data).

For WP4, data will be used from the Clinical Practice Research Datalink (CPRD) scheme. CPRD operates under the auspices of the Medicines and Healthcare products Regulatory Agency (MHRA), and strict rules to ensure data security and anonymity. Access to this data will be contingent on Independent Scientific Advisory Committee (ISAC) approval and data sharing agreements, which we will obtain with support from CALIBER during the early months of the project.

NHS ethical approval will be required for the in depth qualitative enquiry in WP5. Participation in surveys (GP practice staff and patients) will be voluntary, and completion of questionnaires will be taken as consent. Service user focus groups, and interviews and observations involving practice staff, will only be conducted following informed consent from all involved. Interviews may be conducted off the practice premises, if volunteers prefer. Anonymity and confidentiality will be assured throughout.

The implementation recommendation consensus building process in WP6 draws largely on the existing knowledge of GPs, health professionals, commissioners and service users, combined with evidence from the published literature and the research. The work is thus unlikely to require full ethical review. However, written confirmation of this will be obtained from the Health Research Authority.

Plans for ethical review

We will begin the process of obtaining ethical reviews early in the first year to avoid delays in starting work on WP4 and WP5 in month 13. Time will be factored in for gaining site approvals (WP5) which have to be finalised once the main favourable ethical opinion has been obtained. CALIBER will support the team in the application for Independent Scientific Advisory Committee (ISAC) approval and data sharing agreements for

the linked patient level data for WP4. The research team will prepare the application to the Health Research Authority (HRA) for the review of WP5, working with the Service User Panel on the preparation of information for participants, focus group topics and patient questionnaire. We will also seek confirmation from HRA that ethical approval is not required for the WP6 expert consensus building of implementation recommendations.

University of Surrey procedures require applications to be scrutinized by the internal committee, prior to submitting for external review. Full University approval will be granted subsequent to successful completion of external approval processes.

Patient and Public Involvement

At the outset we approached PPI groups of two local general practices. Both chairs provided positive feedback on our draft proposal and highlighted the workforce problems facing GPs. One local practice was described as being 'in crisis' because of an inability to recruit GPs and a high level of demand, with the practice manager 'fire-fighting'. The other mentioned the expanded use of volunteers (GP connectors) in local practices, and emphasised the need for research to evaluate such developments to inform wider roll out. This respondent introduced us to Mr Phelim Brady, the Chairperson of the Guildford and Waverley CCG Patient Participation Group. With the endorsement of the CCG, Mr Brady agreed to be a co-applicant and contributed to discussions at the outline stage.

At the second stage, Mr Brady, introduced Mrs Lynda McDermott, and both joined research team meetings. Their views influenced decisions about organisation of the Service User Panel, and composition of the patient focus groups (WP5), particularly that focus groups should take place in the north and south, with separate groups for the main categories of GP users (older people, working age, parents, carers).

The Service Users Panel (SUP) will comprise 10 members recruited from different types of practices (traditional and new models, in varied socio-economic-ethnic areas in Kent and Surrey) and meet four times per year to provide the perspective of patients and the public on issues within the research. The SUP will be asked to assist with preparing information sheets for participants, focus group topics, patient survey questions, statements for the implementation guideline development process and dissemination materials for lay audiences. The SUP will receive training for their role and full information about the project at the first meeting. For subsequent meetings, the research team will provide a short written update on progress, and issues for discussion regarding the ongoing work. Work Package leaders will attend SUPs at appropriate points in the project to describe the work they are doing and seek advice from members. Individual members of the SUP will be invited to liaise with different WPs. Thereby, at least one SUP member will be integrated into both the development and delivery aspect of each WP throughout the project. For WP6, the knowledge transfer, two service user representatives will be trained in the Nominal Group Technique to support a role as equal partners in the research team. The SUP will be chaired by Mr Brady (co-I), supported by the PI and project manager. Members will be reimbursed for their attendance at SUP meetings, and contributing to WPs, for reasonable travel expenses and time commitments at INVOLVE rates.

Team expertise

The research will be delivered by a highly experienced multidisciplinary team. Each academic member has an extensive track record of delivering on externally funded research and publication in high quality journals. Several hold national policy advisory positions in the primary care domain.

The team includes:

- clinical academic GPs (Campbell, Lusignan) whose particular interests are in primary care quality and workforce, and informatics respectively
- experts in primary care organisation, effectiveness, workforce and human resources from health / social policy (Peckham), psychology (Marchand, Richards) and nursing (Spillsbury) perspectives, using qualitative and mixed methods
- technical specialists in big data and statistics (Joy), health economics (Jordan) and knowledge mobilisation for policy and planning in health systems and clinical engagement (Chilvers)
- representative of the NHS management and commissioning community (Fuller), a STP clinical lead / former CCG clinical chair and chief clinical officer, and practicing GP

- PPI representative (Brady), with experience of public sector management and local PPI work
- Gage (PI), is director of a portfolio of research within the Surrey Health Economics Centre, and has a track record of project management and health services research on workforce issues
- Collaborator (Fitzpatrick), Farr Institute of Health Informatics Data Scientist, for liaison over data access

Justification of support required

The majority of the **research costs** are allocated to staff (and associated indirect costs): Gage (PI), will oversee the project (15%); Joy, will lead WPs2,3 (20%); Jordan will be responsible for the national Practices Database (WP1) and lead the health economics in WPs2,3 (20%); Peckham (7%) and Marchand (50%) will oversee the systematic review (WP2) and primary research in practice case study sites (WP5), with input from Spilsbury (7%). The knowledge transfer processes (WP6) will be coordinated by Chilvers (20%) and Richards (7%). Lusignan (7%) will provide practice liaison (WP5) and lead on dissemination (WP7); Campbell (5%), an experienced researcher on quality and workforce in primary care will advise overall. Fuller (5%FTE) provides a commissioning perspective; Brady (5%FTE) will chair the SUP (PPI Advisory Group).

The team will be supported by a project manager (80%); research fellows for the statistical modelling (24 months), health economics (12 months), review and case studies (50%, 27 months; 40%, 24 months), focus groups (10%, 20 months), transcription (33%, 12 months), GP practice liaison for the workforce survey and dissemination (25%, 18 months); librarian for searches (1 month).

Non staff costs include expenses associated with: access to the CALIBER data for WP4; conducting focus groups (participant vouchers, room, refreshments, travel) and practice case studies (travel / accommodation at sites nationwide, payments to practices) for WP5; knowledge transfer processes (reimbursement to participants, facilities hire) in WP6; dissemination (conferences, open access publications, interactive workshops, visual materials) for WP7; research team communication (online teleconferencing, inter-site travel for face-to-face meetings); Professionals and Commissioners Panel (reimbursement to members, online platform charge); Service User Panel (reimburse members (INVOLVE rates), travel costs, refreshments, 12 meetings); Study Steering Committee (travel, subsistence, 6 meetings); Sundries (interlibrary loans, survey printing).

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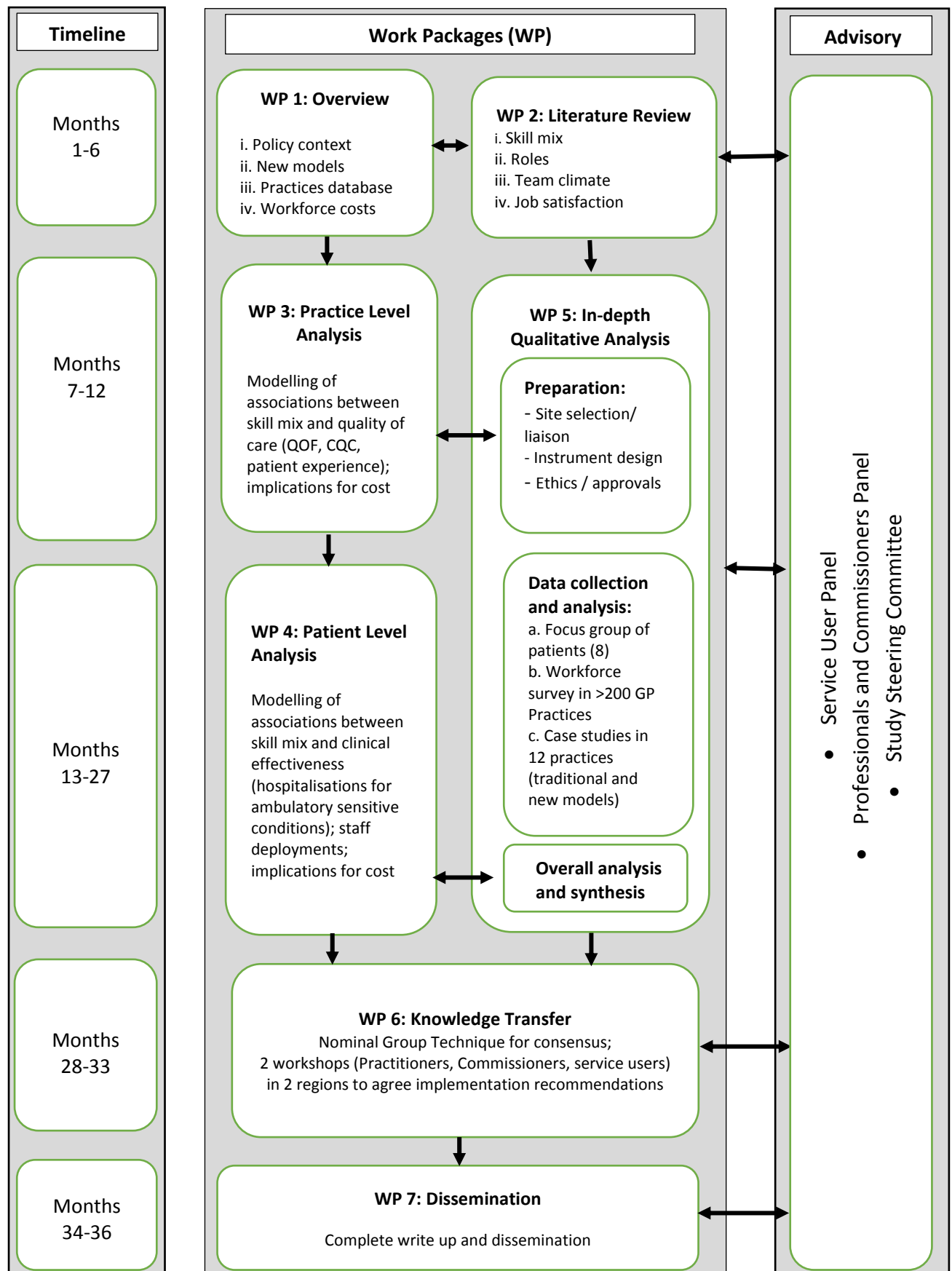
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FLOW CHART: How general practice team composition and climate relate to quality, effectiveness and human resource costs: a mixed methods study in England



Gantt chart of project activities, with milestones/ reports (M)

2018 - 19 – 20 - 2021	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
Set up, SUP, PCP, SSC members/ meetings*																																				
WP1(i) Policy context						M																														
WP1(ii) New models						M																														
WP1(iii) Practices Database						M																														
WP1(iv) Workforce costs						M																														
WP2 Systematic review						M																														
WP3 Practice level modelling												M																								
WP4 Apply ISAC approval									M																											
WP4 Patient level modelling																											M									
WP5a,b,c Ethical approvals; site selection												M																								
WP5a Focus groups conduct and analysis																							M													
WP5b Practices survey and analysis																							M													
WP5c 12 Practice case studies and analysis																							M													
WP5 Synthesis; 12 practice discussions																										M										
WP6 Preparation/ links WPs 1-5																																				
WP6 Knowledge transfer																																M				
WP7 Final report, writing up																																				M
WP7 Dissemination (ongoing, throughout)																																				
M: Milestones / Reports																																				
*Management	Research team (all co-investigators) will meet formally every 2 months (Project Management Group); WP meetings will take place as needed, monitored by PI and project manager Service User Panel (coordinated by Brady), meets 4 times per year, Practitioners and Commissioners Panel (coordinated by Chilvers), and Study Steering Committee (coordinated by PI, with independent Chair, to be appointed) will each meet twice a year, scheduled around key points in the project.																																			