Title: Investigating the contribution of physician associates (PAs) to secondary care in England: a mixed methods study

Summary

This study aims to investigate the contribution and impact of including physician associates (PAs formerly known as physician assistants) to medical teams on the organisation and delivery of patient care in hospitals in England. Increasing numbers of hospitals in England are employing PAs in a widening range of medical and surgical specialties. Demand for PAs from hospitals is outstripping the supply of PAs graduating from UK Universities. In response, the Minister of Health announced in August 2014 the doubling of NHS funded training places and there is anticipated to be 500 PAs graduating a year by 2018. The Royal College of Physicians is establishing a Faculty for PAs under its governance. Student PAs have a first degree, usually in a biomedical science, and are trained at a post graduate level in the medical model to assess, investigate, diagnose and commence or change treatment under supervision of a doctor within their agreed scope of practice. While they have a 50 year history in the United States they are new or unknown to most British health care settings. There are currently nearly 300 PAs, mostly UK trained, employed in medical teams in hospitals. We know little about how PAs are deployed in different teams, what activities they undertake, what difference their involvement makes to patient pathways, costs and service delivery systems. Likewise little is known about the patient perspective on the involvement of this new type of professional in their medical team. This mixed methods study proposes to investigate these questions in order to better inform the public, managers, clinicians and commissioners. Four interlinked research work-streams are proposed. Work stream I investigates the extent of the employment, deployment and role of PAs in hospital medical teams using two electronic surveys; one to medical directors of NHS acute Trusts and the other to PAs through their professional organisation. Work stream 2 investigates evidence of impact and factors supporting or inhibiting the adoption of PAs through a systematic review and policy review. Work stream 3 undertakes a more detailed investigation in between four and twelve hospitals each employing between 4 and 20 PAs in different specialties. These case studies include a) interviews with patients, managers, team and service members, b) analysis of routine management data and reports, c) observation of PAs at work and PA diaries of their activities, and d) a comparative retrospective analysis of patient outcomes and costs between consultations with PAs and doctors in the emergency department. The final work stream is a synthesis of evidence from the other work streams, which is then presented in emerging findings workshops with invitees from the research participants, the patient and public forum and other advisors to the study. Throughout the

study, papers will be submitted for publication in professional and lay journals and a final report will be submitted to the funding body.

1. Background and Rationale

Physician associates (PAs), previously known as physician assistants , are a new and rapidly growing ,occupational group to the United Kingdom (UK) National Health Service (NHS) with the first significant numbers of UK trained PAs graduating in 2009 [1]. PAs are an occupational group whose employment in medical teams in secondary care is being advocated by bodies such as the Royal College of Physicians (RCP) [2,3] , the College of Emergency Medicine [4] and the Department of Health commissioned Centre for Workforce Intelligence [5]. The growth in their employment is supported by the doubling of training places to over 200 per annum, as announced by Jeremy Hunt the Minister for Health in August 2014, and the increasing number of Universities offering PA courses [6]. Although the response from The Patients Association and the British Medical Association to the announcement by Jeremy Hunt was mixed, expressing caution and concern [7], the expansion of PAs in the UK is supported by NHS workforce policy and the medical Royal Colleges. Health Education England (HEE), the body responsible for the planning and education of the NHS workforce in England, included PAs in its workforce plans for the first time in 2013 and created a national PA development group [8]. The medical director of HEE has publically spoken of the need for 5,000 PAs in the NHS and there is an expectation that by 2018 there will 500 PAs graduating a year in England [9]. In Scotland, the inclusion of PAs in NHS workforce planning was agreed in 2012 and PA training was subsequently commissioned by the NHS in Aberdeen University [10]. The Council of the Royal College of Physicians (London) agreed in March 2014 to establish a Faculty of Physician Associates in collaboration with the UK Association of Physician Associates (UKAPA) to support and develop the role [11]. The Faculty shadow board also involves the other relevant Royal Colleges (Royal College of Surgeons, College of Emergency Medicine, and Royal College of General Practice). At least thirty hospital Trusts are early adopters of PAs in their medical staffing [1, 12] with demand now outstripping the supply of UK trained PAs to the extent that some hospital Trusts are recruiting PAs direct from the United States (USA, personal communication with medical directors). Despite this growth of interest and policy impetus, there is very little published evidence as to their contribution and impact. PAs substitute for doctors within different services in hospitals, yet little is known about how their employment affects patient care, effectiveness and costs.

This is a follow on study to an investigation of the contribution of PAs in general practice in England [13]. That study reported that “physician assistants were found to be acceptable,

safe, effective and efficient in complementing the work of GPs. …….Further research is required as to the contribution PAs could make in other services". p10. Hospitals are very different from general practice in organisation as well as type of treatment and care currently delivered to patients. The evidence we established in the general practice setting cannot automatically be applied to a hospital setting. Hence for the need for this study in the hospital setting where the current and planned growth of employment of PAs is occurring [1, 8,12]

We turn now to provide more detailed information on PAs, PAs in the UK setting and the evidence to date of their contribution in hospital settings.

1.1. Physician Associates (previously known as physician assistants)

Physician associates (PAs) are trained in a medical model to work in all settings and undertake physical examinations, investigations, diagnosis, treatment, and prescribe within their scope of practice as agreed with their supervising doctor [14, 15]. They have a fifty year history in the USA [16] with currently about 85,000 employed in health services and of these an estimated 40% in hospital settings [17]. The PA role is growing in other countries including India, Canada, the Netherlands [18], New Zealand and Australia [19, 20].

Reviews of mainly American studies have found patients to be very satisfied with PA care, and that PAs can provide equivalent and safe care for the case mix of patients they attend [21, 22, 23, 24]. The two systematic reviews (one general [23] and one specific to primary care [24]) noted that the quality of most studies was weak to moderate and there was limited evidence on resource utilisation, costs and cost effectiveness. More recently published small American studies of PAs in hospital settings provide new positive evidence as to the contribution PAs make to patient outcomes and resource use in a trauma–orthopaedic setting [25] and in low and high acuity emergency department settings [26,27]. One study has also reported that the indirect impact of employing PAs in a general surgical residency programme was to reduce the resident doctor workload, increase the doctors' ability to attend their training activities, and improve results in their American Board of Surgery in Training Examination [28]. A study has recently commenced to examine the substitution of medical doctors with PAs in hospitals in the Netherlands [29].

There is very limited published evidence about the PA contribution in secondary care in the UK. A 2006 evaluation of a Department of Health supported pilot project of PAs in England only included two PAs in hospitals [30] who worked in Emergency Departments and noted that they could make a range of contributions working at clinical assistant level [31]. The

evaluation in Scotland of a similarly supported pilot project included 11 USA trained PAs working in emergency medicine, intermediate care and orthopaedics [32]. It reported that the PAs were well received by patients, were working safely, and at the level of a trainee doctor (in some instances almost specialist trainees). The advantages of their employment were noted to be: increased consultant productivity, increased continuity in the consultant team and positive impact on patient throughput. There were, however, issues with PAs' lack of authority to prescribe medicines and order radiographs (both consequences of lack of a statutory regulation) and also assuring appropriate medical supervision when there were shortages of medical staff. A recent study of the introduction of PAs into one English paediatric intensive care unit described positive impact on patient care, continuity and running of the unit and that initial, predictable, implementation problems were soon resolved [33]. A survey, conducted in England in 2012, of doctors supervising PAs in primary and secondary care were reported to consider the PA as a flexible member of their team, well received by patients, making a positive contribution to patient outcomes and efficiency. The issue of lack of regulation was seen as the major problem which also resulted in increased requirement for time from the supervising doctor [34].

In the UK the positive evaluations of American-trained PAs in pilot projects in primary and secondary settings in 2005 (England, [30, 31] and 2009 (Scotland, [32] led to nationally agreed competency and curriculum statements [14,15] and post-graduate programmes in a growing number of Universities. PAs are not currently regulated by the state, although application has been made for regulation and is supported by HEE [9] and the Royal College of Physicians. The lack of state regulation means, amongst other issues, that PAs cannot prescribe. PAs at present maintain a voluntary register and undertake re-validation every six years [15].

There has been a growth in PA employment in UK hospital settings [35, 36]. In 2012 Ross reported over 200 PAs were employed in 20 hospitals and within 15 medical and surgical specialities [1]. Two years later in spring 2014 unpublished evidence on the UKAPA website [7] shows these numbers have increased by at least 50 and that PAs are employed in more than 30 hospitals. In 2013 they were reported to be in 20 adult and paediatric specialities including psychiatry, geriatrics, paediatric intensive care, infectious diseases, cardiology, neurosurgery and genitourinary medicine [7]. .In 2012 the greatest numbers of PAs were employed in emergency medicine and medical specialities such as respiratory medicine [1].

2. Evidence explaining why this research is needed now

There is an urgent need to provide information for managers and clinical leaders as to the impact and contribution PAs make to patient experience and outcomes, and to the working and costs of service delivery in different speciality teams within hospitals settings. There is a policy impetus in the UK to support the growth of the supply of PAs in response to Hospital Trusts, as employers, creating the demand for PAs to work in their medical teams [8, 9]. Key drivers of the policy and employer initiatives have been the pressures on the medical workforce , particularly in emergency medicine [4], but more widely linked to the implementation of the European Union Working Time Directive, which controls junior doctors' working hours [2,3,5,37,38,39]. PAs are seen as one type of mid-level practitioner that could help address these problems in the immediate, medium and long term without recruiting from another already pressured workforce, such as nursing [5,9] . PAs are an innovation in the UK and as such, our national survey for our first study showed that NHS managers, senior clinicians and commissioners were seeking hard evidence to inform their decision making as to the benefits or otherwise of including PAs in medical teams [13]. Those patients and patient organisations we interviewed also wanted evidence that this professional group was safe and did not result in some patients receiving an inferior service or unnecessary double handling i.e. being seen by one professional prior to repeating the consultation with a doctor [13].

While the rapid spread and growth of PAs in different hospital settings suggests the role is seen as advantageous by early adopters, managerial and consultant speakers and attendees at a recent HEE supported national conference on physician assistants were seeking more robust evidence [42]. There is currently little evidence as to acceptability, effectiveness and costs of PAs in different types of hospital medical teams available for the public, patients or health service leaders. This study seeks to address that evidence gap.

3. Aims and objectives

This study aims to investigate the contribution of physician associates (PAs), formerly known as physician assistants, to the delivery of patient care in hospital services in England.
The research questions addressed are:

1. What is the extent of the adoption and deployment of PAs employed in hospital medical services?
2. What factors support or inhibit the inclusion of PAs as part of hospital medical teams at the macro, meso and micro level of the English health care system?

3. What is the impact of including PAs in hospital medical teams on the patients' experience and outcomes?
4. What is the impact of including PAs in hospital medical teams on the organisation of services, working practices and training of other professionals, relationships between professionals and the service costs?

4. Research methods

This investigation adopts the same theoretical framing and methods used by the research team in the original study of PAs in primary care [13]. As an applied health service research study, an evaluative framework for judging health services developed by Donabedian [41] and expounded in the UK setting by Maxwell [42] is used. This examines the contribution that PAs, as new types of personnel, make to the effectiveness, appropriateness, equity (fairness), efficiency, acceptability and costs of secondary health care [41,42]. The investigation will also consider the interactions within and between the macro, meso and micro levels of the health care system in supporting or inhibiting the adoption of PAs as an innovation [43]. It will also be cognisant of theories concerning substitution and supplementation in task shifting from one group of professionals to another [44, 45] and the potential for contest between professional groups [46].

We will undertake an investigation in four work-streams:

1) Investigating the extent of adoption, deployment and role of PAs in hospital medical teams through two national electronic surveys; one to medical directors of acute trusts and one to PAs (addresses research question 1,2 at the macro and meso level of the health care system) ,
2) Investigating evidence of the impact of PAs and factors supporting or inhibiting the adoption of PAs at the macro and meso level of the system through a review of published evidence for the specialities found most commonly reported as employing PAs in the national surveys (work stream 1) and updating the published policy review from the prior study[13] (addresses research questions 1,3,4),
3) Investigation through case studies of between four and twelve hospitals, each employing between 4-20 (or more if the numbers have increased by the time the study starts) PAs, of the impact, contribution and consequences of PAs in the medical teams. This includes interviews with patients, managers, team and service members; analysis of routine organisational and management data and reports and observation of PAs at work. It also includes a comparison of patient outcomes and service costs in Emergency Departments by PAs and junior doctors where these two

professional groups are deployed interchangeably (addresses research questions 1,2,3,4),

4) A synthesis of evidence from the three work-streams. This will be presented and tested at two emerging findings workshops with invitees from the research participants, the patient and public forum and other advisors to the study (addresses the overarching study aim) .

The overall timescale will be 24 months.

4.1. Work-stream 1: Investigating the extent of adoption, deployment and role of PAs in hospital medical teams

Two electronic, descriptive self-report surveys [47] will map and describe the employment and deployment PAs in secondary care services in England (addressing research questions 1 and 2).

The first electronic survey will be to medical directors of all acute NHS Trusts (n=162), identified through publicly available information on Trust websites. Invitation emails to participate will be sent and reminders two weeks later. Using SurveyMonkey (Survey Monkey, Paulo Alto,CA USA) data will be sought on whether PAs are employed or not and if so in which specialties. Information on the reasons for employing PAs will also be sought. Respondents will be invited to provide free text views as to factors supporting or hindering the employment of PAs and share any unpublished local reports or data. The invitation email will also have a respond function, separate to the survey, so that medical directors can request updates and information on the study.

The second electronic self-report survey [47] will be to all PAs via UKAPA and the PA course directors who maintain contact with their alumni (personal communications). The survey will be an adapted version of the one used in our previous study in primary care [13] to which we had an estimated 65% response rate using the same approach to PAs. The survey will seek data not just on the speciality they are employed in but the detail of their deployment and context. It will seek data on the service setting, types and volumes of activities, the working hours, shift patterns, together with contextual team, staffing configurations and service/speciality information. It will include working week schedules to complete. Contextual information will also be sought on the size and type of hospital as well as the experience and background of the PA. We will ask them UKAPA and course directors to send a reminder 2 weeks later. By way of acknowledging and encouraging involvement, PAs

completing the survey will be invited to participate by returning a separate email in a draw for a £40 voucher.

Descriptive analysis of the data from both surveys will be undertaken using SPSS (IBM Corp. Released 2013. IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp.). Free text elements will be analysed thematically [48]. The analysis will provide information on the extent of employment, deployment and role of PAs in hospital medical teams (research question 1) as well as information on factors supporting or inhibiting the adoption of the role in medical teams (research question 2). It will also inform work stream 3, the case studies. Respondents will be invited to email the research team separately for a summary report of the findings and /or invitation to events in work-stream 4. A report will be written and two draft publications will be submitted to journals.

4.2. Work stream 2 Investigating evidence of impact and factors supporting or inhibiting the adoption of PAs in the literature and policy

A systematic review [49,50] will be undertaken to update the literature as currently known to the research team and was the process undertaken in the previous study and published [24]. We will register the review with PROSPERO, the international prospective register of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/). The review will focus on the evidence of the impact on patients experience and outcomes (research question 3) , service organisation, working practices, costs and other professional groups (research question 4) for the medical specialities most frequently employing PAs in England as identified in work-stream 1. Based on our previous experience [24] we will limit the review to the last twenty years to ensure relative comparability to present day health care systems. Our method will follow the guidance for reviews of health care produced by the Centre for Reviews and Dissemination [49], incorporating both qualitative and quantitative evidence [51]. We will search for evidence across health care electronic databases including SCOPUS, MEDLINE, EMBASE and PsycINFO. Preliminary searching will begin with a strategy based on keyword / index (MESH) terms. In addition 'lateral searching' techniques will be used such as checking reference lists of relevant papers, and using the 'Cited by' option on WoS and Scopus, and the 'Related articles' option on PubMed and WoS, as recommended in searching for studies of complex interventions [52]. In addition, leading researchers and expert practitioners in the field will be contacted to help identify unpublished research. Abstracts and brief records from databases will be screened for relevance to the research questions and filed in a bibliographic management package. A common data extraction sheet will be developed for evidence relevant to the research questions such as patient

outcomes, patient experience, patient safety and differences in productivity and costs compared to other professionals (junior doctors, nurse practitioners). Each retrieved study will be assessed by two researchers independently. Quality assessment will be undertaken using our published method [24] which uses CASP (Critical Appraisal Skills Programme) tools [53] supplemented with questions posed by the British Medical Journal for peer reviewers [54]. The analysis and synthesis of evidence will address the questions of the impact on patients experience and outcomes (research question 3) , service organisation, working practices, costs and other professional groups (research question 4). It will also inform the cases studies in work-stream 3. A report will be written of this element and a publication submitted to a journal. While this work is planned early in the study, it is our experience that the team has to remain alert to any new publications and run the search again towards the end of the study period to ensure any newly published evidence is considered in the final report.

We will also update our policy review of PAs in health care systems as published in our final report [13] with particular focus on secondary care and the specialities where PAs are most frequently employed in England. This review will address the question of the factors supporting or inhibiting the adoption of PAs within the hospital setting at the macro and meso level (research question 1). It will include a focus on the regulatory environment affecting the adoption and deployment of PAs. We will employ documentary review methods [55] as in our previous study [13]. Searches will be performed to identify relevant polices and reports on health care workforce planning, education and development. These will be scrutinized for factors likely to inhibit or support PA employment in secondary care and the use of any empirical evidence within that. We will undertake searches by the following means: of key websites in the UK e.g. government health departments in each of the four countries, the Centre for Workforce Intelligence (CWfI), Health Education England and its local Boards, using keyword searches in internet search engines such as Google™, snowballing techniques of references and website links and contacting key authors. Material will be saved in a bibliographical database. The data extraction framework, including identified supporting and inhibiting factors, used in the previous primary care study will be adapted. A narrative synthesis will be undertaken and presented in the final report.

4.3. Work-stream 3: the comparative case studies

A comparative case study design [56] will be used to address all the research questions at the micro level of the health care system through investigation in between four and twelve case studies i.e. hospitals employing PAs. Similar methods have been used in other studies investigating new staff groups in NHS hospitals [57, 58]. The hospitals will be diverse in

geographical location, size (300- 1000 beds) and types (district general, tertiary and specialist centres). We have agreement in principle to participate from senior managers and medical directors in two large hospitals (providing secondary and tertiary care services) in the West Midlands and London which currently employ the largest numbers of PAs in England (10 and 15 at the time of writing). Chief executives and medical directors in three smaller district general hospitals in the West Midlands and the South of England, all employing at least 3 PAs, have also expressed willingness in principle to participate. Final decisions will be informed by the findings form the national survey (in work stream 1) and willingness to participate when the study actually commences. The case study design will use mixed research methods [56] to both describe and also as far as possible quantify the impact of PAs in the context of secondary care. We will hold start-up meetings in each case study site for all relevant staff and patient and public representatives to explain the study and invite participation. Each case study will include PAs working in a wide range of different types of specialities, although we anticipate that at least two of the hospitals will have PAs working in in emergency medicine (currently the most frequently reported employment speciality [1]). In overview each case study will include:

a) Interviews with senior managers (inducting operations directors and human resources), lead consultants, members of the health care teams (medical, nursing, support staff), PAs, and patients,

b) Collecting and analysing management information (data and reports) such as patient throughput, adverse events/serious untoward incidents, patient feedback, audit reports and expenditure on medical locums, and where possible comparing with similar periods before the employment of the PA,

c) Collecting and analysing data on the work of the PAs through diaries and observation,

d) Comparing patient outcomes and costs for the treatment of patients in the emergency departments (ED) by PAs and junior doctors , a setting where individual clinicians are allocated to conduct an assessment and propose a plan for the patient,

e) Comparing and contrasting case study sites and synthesising results against the research questions and overarching framework.

These are now described in more detail.

Data will be gathered and analysed through 5 activities.

a)Semi structured interviews with senior managers such as operations directors and human resource managers (3 per site), lead consultants (up to 5 per site), members of the health care teams (medical, nursing, support staff up to 15 per site), PAs (between 3 and 10 per site) and patients (up to 10 per site). Topic guides [59] appropriate to each group will be

developed in consultation with the advisory group, the study patient and public forum and the Patient Research Reference Group at University Hospitals Birmingham. The topic guides for patients will include questions about the patient experience and perceptions of the role as well as acceptability in the medical team (research questions 1,3) . For managers and senior clinicians, topic guides will include questions on factors inhibiting and supporting the adoption (research question 2) as well as impact on organisation, patient outcomes and costs (research questions 3, 4). The topic guides for professionals will include questions on deployment, acceptability and impact on working practices, role boundaries and patient experience (research question 1, 2, 3, 4). Each group will be invited to participate in different ways: senior staff by emails, other staff by usual hospital staff communication means. Patients will be approached to participate via the clinical team in the first instance. We will purposively recruit [59] a patient sample which is diverse in age, gender, ethnicity and the service they are within in the hospital. Interviews will be conducted primarily face-to-face but some may be by telephone for example patients who may prefer to be interviewed following discharge. Notes will be taken during the interview and, with permission; the conversation will be digitally recorded. These will be transcribed; the recordings will then be destroyed. All efforts will be made to anonymise the data. The transcriptions will be analysed in a qualitative analysis software programme NVIVO (QSR Doncaster, Australia), using the constant comparison method [60] by at least two researchers, independently and then compared.

b) Collecting and analysing routine data and reports.

Managers and clinicians interviewed in a) above, will be invited to share any relevant organisational documents, management data for all of the services employing PAs that could assist in answering the research questions concerning deployment (research question 1), patient outcomes (research question 3) and organisation and cost (research question 4). This may include some or all of: patient throughput and outcome data, adverse events/serious untoward incidents, patient feedback, audit reports and expenditure on medical locums. If data are available, we will compare indicators before and after PAs were employed in a particular service e.g. medical locum costs. We will also explore to what extent electronic patient level data is available which also records the type of professional involved in activities such as requesting investigations. This data will be descriptively analysed and if appropriate subject to tests of significance to explore differences in time periods or between providers. Analysis and interpretation of such quantitative data will particularly draw in the expertise of the statistics and health economics members of the research team.

c)Work diaries and observation of PAs.

We will invite all PAs in all of the specialities (likely to be in the region of 30) to complete work diaries over 7 day periods, up to three times over 12 months chosen to capture times of likely change in their work environment e.g. rotation times for junior doctors, increased rates of unplanned admission in winter. Invitation will be individually by email and also advertised as part of the start-up meetings in the cases study site (see section 5). These diaries will be adapted from those in our prior study of PAs in primary care in which the majority of PAs were able to complete these. Data from the national surveys in work stream 1 and advice from the PAs on the team and in the advisory group will be used in adapting the diaries. This will provide detailed information on the deployment and role of the PA (research question 1) such as shifts worked, types of activities with the patients, other responsibilities e.g. administration, teaching. Data will be entered onto a SPSS data base and analysed descriptively.

We will invite PAs to volunteer to be observed while they are working. This element of the study draws on the ethnographic tradition [61] and has been used in many health service research studies in the UK [62]. It will take the form of shadowing the PA for all or part of their shift hours, including shifts out of the 9-5 period and at weekends. We will request up to three periods of shadowing for each PA. For any PAs volunteering, agreement will also be sought from the lead consultant. The PAs will seek permission from any patients they are attending for the researcher to be present, in the same way as permission is ought for students to be present during clinical care and treatment. Likewise notices will be put up in the service area explaining the presence of a researcher with the PA. Notes of observations of the PAs activities will be made, with permission, at the time or shortly afterwards. These will be typed up and later entered into NVIVO software. They will be thematically analysed [50] addressing the four research questions but specifically provide data on impact on organisation of services, other team members working practices and team relationships.

d) Pragmatic retrospective assessment comparing of the outcomes and service costs for patients attended by PAs and junior doctors in the emergency department.

The ED is a setting where PAs are employed and may work in different sections (minor injuries and major injuries) alongside, and substituting for, junior doctors [1, 63]. Patients triaged by a clinical professional to these sections of the ED are assigned and initially assessed by a clinical professional (PA, doctor or in the case of the minor injuries section other professional e.g. emergency care practitioner). Consequently we can undertake a pragmatic comparison of the patient outcomes and service cost of consultations by different types of professional based on the methods and data from two English studies, which

compared minor injuries section consultations with nurse practitioners as the mid-level professional (in the absence of UK data for physician associates) to that with doctors [64,65]. Following the surveys and preliminary recruitment of case study hospitals in 2015 and 2016 it was found that additional ED sites (from the initially proposed four) may be required to undertake this element. While the initial proposal had only included a comparison in the minor injuries section it became apparent in trying to recruit the hospitals and PAs that by January 2017 PAs were rarely working in the ED at all as they were more frequently assigned to the acute medical assessment units. Where they were assigned to the ED it was to the major injuries section. *Method* Since commencing the study practical constraints have led to a switch to retrospective analysis of hospital databases from prospective data collection. With agreement of the lead clinician and staff, a designated time period in which the PAs have been working in the ED will be identified which will ensure the required sample size of records for patients seen by PAs... From the designated time period, data for patients attending the ED will be retrieved by NHS administrative staff, or NHS research nurse, if available, (but funded by this research study). Data extracted at this stage will include demographics, post code (to calculate deprivation) [69], triage score, treatment and investigations, prescriptions, diagnosis and outcome (destination), service use times and reconsultations within seven days, if these data are routinely available on the database. Trusts will remove all patient identifiers, replacing the NHS number with a pseudonymised code number, which will allow for re-consultations to be identified. The anonymised records will then be passed to the research team and entered onto an SPSS database. The research team will assign a case-mix classification to the record, adapted from the published one used in a previous study [13], using the ED triage scoring system to classify the presenting condition and other data to classify the complexity of the patient. A sample of anonymised patient records will be assessed by independent consultants in emergency medicine, blinded to the type of professional undertaking the patient consultation, for a judgement as to the clinical adequacy of care using the criteria in the Sakr et al study [64]. Two consultants we have approached in hospitals which do not employ PAs have indicated willingness to be reviewers. Tests of inter-rater reliability will be conducted [47].

Outcome measures:

It should be noted that this is a pragmatic study designed to provide information for clinicians, the public, service managers and commissioners on a wide range of measures of quality, satisfaction, impact, and cost. The primary outcome is specified in order to assist in calculating a sample size and is a proxy for patient safety and clinical effectiveness but the goal of this element of the study is to synthesize evidence emerging from all the outcomes,

along with the other work streams, and we therefore use the sample size calculation as a guide to avoid futility at either end of the scale.

Primary outcome:

- The primary outcome is of unplanned re-attendance within seven days for the same condition. Unplanned re-attendance by patients, seen in any section, within seven days for the same condition at the same department is one of the NHS clinical quality indicators for Accident and Emergency Departments in England [66].

Secondary outcomes:

- The clinical adequacy of care. This will be an expert clinical judgement as to the clinical adequacy of care (criteria including record of medical history ,examination of patient , requests for diagnostic tests , diagnosis , treatment decisions, referrals and planned follow up) provided by the PA or junior doctor at the initial consultation. This judgement is made by consultants in emergency medicine reviewing all ED records in the sample categorised by case mix group. Other studies of substitution by nurses practitioners for doctors in the ED have also used expert review of clinical adequacy as an outcome measure [64.65].
- Measures of consultation processes (taken from the clinical record) including length of consultation (time stamp), use of diagnostic tests and immediate outcomes of the consultation (including prescriptions, treatments, referrals and follow ups) and associated costs.

These secondary outcome measures have also been used in the two studies investigating the substitution of doctors by nurse practitioners in the minors section of the ED [64,65]

Sample size:

Anticipated rate of unplanned reconsultation: In the absence of UK data on PAs in the ED setting, we considered three sources of information, including two randomised controlled trials substituting nurse practitioners for doctors in the minors section of the ED [64,65] (as we did with our previous study in primary care [13]). Firstly, NHS ED clinical quality indicator data show that unplanned re-attendance at the *same* ED in England within seven days for patients seen in any section and by any professional is 7.4% of patients with individual EDs ranging from 2.4% to 21.7% in December 2014 [67]. Secondly, Sakr et al [64] reported an unplanned re-consultation rate, for the same condition within 28 days, of 8.6% (nurse practitioners) and 13.1% (doctors) and thirdly, Cooper et al [65] reported rates of 18.3% and 21.5% respectively. Clearly, the seven-day data at the same ED site will underestimate a 28-day outcome at any ED, urgent care or general practice site. Both studies were conducted in single ED sites and we do not know whether they are high or low on the

spectrum seen from the clinical quality indicator data. Taking this into account, we chose Cooper et al.'s [65] 18.3% as an anticipated base rate towards the higher end of the observed range.

Minimum clinically important difference: We took Sakr's Lancet published study [64] as having least risk of bias from the comparison and study design. Their sample size calculation was to detect a difference between groups of 2.5 vs. 5%. Although this proved an underestimate, we are also interested in finding a relative difference of 50%, though in a non-inferiority hypothesis, so we compare 18.3% to 27.4%. It should be noted that as this is a pragmatic study investigating a wide range of measures of impact and cost, we feel that estimating with confidence intervals [68] and understanding the differences between professions will be more informative for clinicians, service managers and commissioners than a binary hypothesis test on one of the outcomes. We anticipate 18.3% of patients will re-consult (unplanned) within 28 days for the same problem in any health service. We aim to test a non-inferiority hypothesis on this primary outcome measure, which states that PAs do not exceed 27.4% unplanned re-consultations, with 80% power at 5% significance. This requires 284 in each group (calculation from Stata v11.1 software). We will include an extra 20 to allow for adjustment for case mix [69]. Allowing for 33% non-response requires 456 patients in each group (seen by PAs vs. seen by doctors). This calculation is based on the limited evidence base which we outline below.

Analysis: Data will be entered into a patient level SPSS data base, including age, gender, post code (to assign an indicator of deprivation [69]), type of presenting complaint (as used in Sakr et al [64]), ED triage score, unplanned re-attendance within seven days for the same complaint and indicators of adequacy of the assessment and management of the index consultation. Analysis and presentation of these will involve summary measures of location (e.g. means /medians /proportions) and dispersion (standard deviations/percentiles) appropriate for the type and distribution of the individual variables. Descriptions of difference at the aggregate level will be made between those seen by PAs and junior doctors for all patient outcomes. A logistic regression [70] will also be carried out for the primary outcome i.e. the patient making an unplanned re-consultation at the ED for the same complaint within seven days if there is indication of confounding factors such as age or neighbourhood socio-economic deprivation.

Economic analysis An analysis of the comparative costs of using PAs and junior doctors in the ED will be conducted from an NHS perspective. The main variables of interest will be extracted from the anonymous patient records and will include: consultation length (time in

and time out in minutes); diagnostic tests ordered (blood tests , X-rays), treatments (e.g. prescriptions) , referrals made and follow on care recommended; and whether the PA or junior doctor sought advice from a senior colleague in ED during the consultation. Unplanned re-consultations will be obtained from the patient record after the index event. The case mix (i.e. types of presenting complaints) of PAs and junior doctors will be compared, in collaboration with the emergency medicine experts involved in the assessment of adequacy of care. If differences are observed, the comparison of the two professional groups will be conducted according to a categorisation of the complexity of the problems. Differences between PAs and junior doctors with respect to consultation lengths, and appropriate treatments, referrals and follow-up care will be explored. Statistically significant differences will be costed. The cost of differences in consultation times will be established pro rata from salaries, with on-costs. Salary and on-costs of junior doctors will be obtained from the respective national professional organisations. The costs of diagnostic test and referrals will be established from local financial managers. The findings will be presented in a cost-consequences framework that will indicate the difference in costs to the hospital of employing PAs and junior doctors for treating patients with minor illness and injuries in EDs, and how this affects patient satisfaction, the appropriateness of care and treatment costs.

e) Collective analysis of the case study data.

In the first instance we will synthesise findings at the individual case study level to address our research questions and within our overarching theoretical framework. These emerging results will be presented back to the individual hospitals and participants. We will then compare and contrast findings across the four case study sites [58]. We will present evidence addressing our four research questions, including issues of effectiveness, appropriateness, equity, acceptability and costs. Emerging findings will be presented in the workshops in work stream 4. A report and publications will be written for the case study work stream.

4.4. Work-stream 4: Synthesis of the three work-streams

The evidence from each of the three work-streams will be synthesised by the research team and brought to a wider consultative group of people who have participated in the study including the advisory group and public and patient involvement group. We will synthesise our findings from the different work streams to present evidence addressing our four research questions (Table 1) and within our overarching theoretical framework. This framework includes dimensions of effectiveness (including patient safety and cost), appropriateness, equity, acceptability.

Table 1: Research questions and data from work streams

Research question	Work stream providing data and analysis
1.What is the extent of the adoption and deployment of PAs employed in hospital medical services in England?	Work stream 1- national surveys Work stream 3 – case studies
2. What factors support or inhibit the inclusion of PAs as part of hospital medical teams at the macro, meso and micro level of the English health care system?	Work stream 1 – national survey to medical directors Work stream 2 – systematic and policy review Work stream 3 – case studies
3. What is the impact of including PAs in hospital medical teams on the patients' experience and outcomes?	Work stream 2 – systematic and policy reviews Work stream 3 – case studies
4. What is the impact of including PAs in hospital medical teams on the organisation of services, working practices and training of other professionals, relationships between professionals and the service costs?	Work stream 2 – systematic and policy reviews Work stream 3 – case studies

Emerging findings will be presented in a workshop of participants from work streams 1 and 3, repeated in London and Birmingham (West Midlands), to facilitate greater attendance form those involved in different parts of the country. Participants will be invited to question and help interpret the emerging findings. This will then inform the final report submitted to the funders. The use of such workshops was very successful in the prior funded study [12].

5. Ethics and governance

The work-streams raise different ethical and governance issues. Some general principles apply to all. Individual organisations will not be identified in any reports or papers that are published although keeping anonymity of organisations in the case study phase may be more difficult and will be discussed with the participants. Professional and patient participants will be volunteers and there will be no coercion to participate. Individual consent to participate will be sought from staff and patients. All informants will be assured of anonymity and confidentiality in the transcription, analysis and reporting of their interviews. Any direct quotations from interviews or observations used in the report will be non-attributable. Data will kept on password protected computers in locked University offices accessible only to the named researchers. Data will be stored and destroyed in line with the Data Protection Act

Different work-streams will require different processes of ethical review and associated research governance permissions. The team are very experienced in all of these but do not underestimate the capacity for these multiple systems at local levels to inexplicably and unpredictably create delays. We will apply for the study inclusion in the NIHR UKCRN portfolio which will allow access to the NIHR Coordinated System for gaining NHS Permission (CSP). The study patient and public representative (PPI) forum and University

Hospitals Birmingham (UHB) patient research reference forum will be involved in advising on and developing participant information leaflets and recruitment processes.

Work-stream 1 will require only University research ethics review as research involving NHS staff only is not required to be submitted to NHS research ethics review. As we are approaching PAs through non-NHS routes, it will not require NHS research governance. Medical directors invited to participate will decide whether their involvement requires research governance permissions from their NHS Trust. As this work-stream is not a clinical study it is unlikely we will be permitted to use the CSP system and a judgement will have to be made as to the amount of study resource that can be allocated to gaining separate NHS permissions for individual questionnaires. Return of questionnaire will be taken as indication of consent.

Work-stream 3: the case studies involve NHS patients as well as staff and will require NHS ethics review and NHS research governance permissions. The use of anonymous management information and patient data from databases does not require ethics review but does require research governance permissions. The observation of PAs' working practices will require specific attention. The general ethical considerations are listed above. In addition, individual patient permission will be sought from the patient by the PA to observation of their work and assurances given as to how confidentiality and anonymity will be protected. The investigation of the patient experience and outcomes in attending the ED with a minor injury has been designed to ensure patient confidentiality is protected and complies with the Data Protection Act 1998.

6. Plan of investigation

The plan of investigation is detailed in the following Gantt chart.

7. Patient and Public Involvement

The patient and public voice is important to this study. The public and patient representative forum for the previous primary care study [13] stressed that the innovation of bringing in a new group of professionals is of concern to the public. This has also been demonstrated in the responses from the Patient Association to Jeremy Hunt's announcement of increased PA training numbers [7]. Key issues the forum have highlighted in discussion relate to: a) patient choice of the professional to consult or be attended by, b) whether some groups of patients will receive a 'second class 'or inferior service, c) how patients will judge whether this new professional is competent, and d) the ways in which the public and patients will be informed and understand this new role in different settings. These issues have been incorporated in

the design of this study. In this study there will be PPI in the following ways. Firstly, Sally Brearley, as a PPI representative, is a co-applicant and member of the research team and she will be paid for that time. Secondly, patient representatives from the previous study patient and public forum will be invited to join the research advisory group and offered a payment or gift to acknowledge, according to their preference, following NIHR INVOLVE guidance [71,72] . Thirdly, two patient research fora will be engaged in commenting on the design, research tools and interpretation of the study. One is the University Hospitals Birmingham's (UHB) patient research forum and the other will be in London formed of the previous study's patient and public forum and new members invited through the established NHS service user networks of the Centre for Public Engagement (in the principal investigator's Faculty). They will be offered a gift in the form of a voucher in recognition of their time, again following NIHR INVOLVE guidance [71.72]. All patients and public representatives engaged in this way will be invited to comment on emerging findings at a work shop held closest to them (work stream 4),.

Activity	-3	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Study Set Up																									
Recruitment of staff	x																								
Ethics applications to university and NHS	x																								
Recruitment of case study sites and governance permissions	x																								
Study Oversight																									
Research team meetings (bimonthly)		x		x		x		x		x		x		x		x		x		x		x		x	
Patient and public forum consultations		x		x									x											x	
Advisory Group		x												x										x	
Six monthly reports to funders							x							x						x					
Research Workstreams																									
Work-stream one –surveys																									
Work-stream 2 – review and policy update																									
Work-stream 3 – case studies																									
Work-stream 4 – synthesis Emerging findings workshops Drafting final report																							X		
Dissemination																									
Web site and twitter account established and updated																									
Feedback to case study participants and conference presentations								x					x			x				x				x	
Preparation of journal papers etc					x	x	x																x	x	x

8. Project management

The project will be led and overseen by the team at the Faculty of Health, Social Care & Education Kingston University and St. George's University of London, working closely with team members at other institutions. We have a good track record of working closely and collaboratively together. The core team (VMD, MH, JP, research associates) will meet or discuss on a weekly basis throughout the study, including other researchers (co-applicants) as appropriate to the work in hand. The research team will meet on a bi-monthly basis in person or by SKYPE throughout the study to oversee and plan for study progress. A research advisory group will be established to act as a 'critical friend'. This will meet up to 3 times during the life of the project. This will include two patient and public representatives, recruited from the Patient and Public Forum of the previous PA in primary care research. Additional members will come from the management, medical and academic communities who have an interest and experience of planning secondary care health workforces such as Health Education England.

9. Expertise and justification of resources required

The team from the primary care study VMD, MH, SB, JG, HG, RG, SdeL will be augmented by JP, PB and JE who bring expertise and knowledge of PA research (JP, PB), developments in PAs in secondary care from the NHS perspective (PB), from the educational perspective (JP) and from the PA perspective (JE). VMD brings health service research, workforce and NHS management expertise. She will direct the study as principal investigator, supported by MH as project manager, and lead on the policy review , the London and South case studies, and the workshops on emerging findings. MH brings expertise in health service change and in innovation in workforce research. She will be the project manager, ensuring overall co-ordination of activity, manage the London based researcher, leading the electronic surveys participating in the London and South case studies, and leading the systematic review. RG brings statistical expertise in medical and health service research and will lead on this aspect. HG is a health economist and will ensure resource and cost considerations are fully represented and analysed in each work-stream. JG is a sociologist who will lead on qualitative aspects of the study bringing particular expertise in observational health service research. He will be particularly involved in work-streams 2 and 3. SB is a patient and public representative and will ensure the patient and public voice is present in all parts of the study. Sde L has expertise in medicine, medical research, management, commissioning and health informatics which he will bring to bear across all the work streams. JP brings expertise from medicine, medical research, medical education and PA education. JP will manage the Birmingham based researcher,

leading on the West Midlands case studies. JE brings experience as a UK trained PA, who both practices and teaches on a PA course. He will ensure the PA perspective is heard throughout the work-streams and will contribute particularly to the PA survey and the review. PB brings expertise in innovation and research in the NHS, workforce innovation, and PA education. He will bring expertise to all the work-streams with particular focus to the case studies in the West Midlands and public involvement.

The study will commence 1st May 2015 for 24 months. Detailed costs are given in the application. The majority of the costs are for staff time in carrying out the study. Two senior researchers will be employed for the duration of the project. Patient and public involvement will also require resource to offer reimbursement and expenses in line with national guidelines [71,72]. Provision has been for NHS staff time to participate in interviews, if requested, and the administrative work for anonymising patient records in the case studies and as expert clinical reviewers. Additional costs relate to travel to the case study sites, expenses for the advisory group meetings, payment for a study web domain, hosting two emerging findings workshops, attendance at national conferences and open access publication payment.

10. Dissemination and impact

Our findings will be disseminated widely to managers, service commissioners, policy makers, clinical leaders in secondary care, PAs, the public and academics, through:

1. Study participant and stakeholder feedback,
2. Presentations at conferences, to professional and lay audiences. Submissions will be made to appropriate national conferences for clinicians and health service researchers (e.g. Health Service Research Network conference) and lay people (e.g. case study sites Foundation Trust Members' Conferences) to present the findings during and after study period.
3. Final report and other research papers. Other research papers will be prepared from the individual work-streams as they progress and submitted to appropriate high impact, peer-reviewed journals.
4. Website and social media: A study website and Twitter account will be created to publicise the study, emerging findings, events and linked materials such an end of study summary sheet and powerpoint slides directed at managers and senior clinicians.

References

1. Ross N, Parle J, Begg P, Kuhns D. The case for the physician assistant. Clin Med. 2012 Jun;12(3):200-6.
2. Royal College of Physicians . Hospitals on the edge? The time for action. London Royal College of Physicians 2012.
3. Future Hospital Commission. Future hospital: caring for medical patients. A report from the Future Hospital Commission to the Royal College of Physicians. London: Royal College of Physicians, 2013.
4. College of Emergency Medicine . Emergency Medicine Taskforce Interim Report. 2012 Accessed at College of Emergency Medicine /Downloads/CEM6723-EM-Taskforce---Interim-Report-2012-(Final)%20(1).pdf
5. Centre for Workforce Intelligence. Big picture challenges: the context .2013. accessed at http://www.cfwi.org.uk/publications
6. BBC News . NHS plans rapid expansion of 'doctor's assistant' jobs. 21st August 2014 http://www.bbc.co.uk/news/health-28902132
7. Rawlinson K NHS patient groups warn more doctor assistants may be 'healthcare on cheap' Theguardian.com, Friday 22 August 2014 01.18 BST Accessed at http://www.theguardian.com/society/2014/aug/22/fears-nhs-doctors-assistant-recruitment-healthcare-cheap
8. Health Education England Emergency Medicine:Background to HEE proposals to address workforce shortages. Health Education England 2013.
9. Reid W. Medical Director Health Education England. Plenary Speech. Conference on PAs , University of Birmingham March 9th 2014.
10. Nicoll P, MacVicar R. NES Supporting Scottish Remote and Rural Healthcare. NES/12/78 NHS Education for Scotland September 2012. Edinburgh: NHS Education for Scotland; 2012.
11. UK Association of Physician Associates Proposed established of a Faculty of Physician Associates in the Royal College of Physicians April 2014 posted on http://www.ukapa.co.uk/members/news/index.html
12. UK Association of Physician Associates . Physician Associates locations 2014. Accessed on October 2014 http://www.ukapa.co.uk/general-public/pa-locations/index.html
13. Drennan VM, Halter M, Brearley S, Carneiro W , Gabe J, Gage H, Grant R, Joly L, de Lusignan S. Investigating The Contribution Of Physician Assistants To Primary Care In England: A Mixed Methods NIHR Health Service & Delivery Research Journal 2014;2(16) Accessed at http://www.journalslibrary.nihr.ac.uk/hsdr/volume-2/issue-16
14. Department of Health. The Competence and Curriculum Framework for the Physician Assistant. London: Department of Health 2006.
15. Physician Assistant Managed Voluntary Register The Revised Competence and Curriculum Framework for the Physician Assistant. 2012 Accessed at http://www.ukapa.co.uk/files/CCF-27-03-12-for-PAMVR.pdf.
16. Mittman DE, Cawley JF, Fenn WH. (2002) Physician assistants in the United States. BMJ 2002 325:485-487.
17. American Academy of Physician Assistants. Physician Assistants: Quick Facts. 2014. Accessed at http://www.aapa.org/the_pa_profession/quick_facts.aspx
18. Hooker RS, Hogan K, Leeker E. The Globalization of the Physician Assistant Profession Journal of Physician Assistant Education 2007; 18:76-85.
19. Health Workforce Australia: The potential role of Physician Assistants in the Australian context – Final Report. Adelaide: Health Workforce Australia; 2012.
20. Health Workforce New Zealand. The Physician Assistant Role in New Zealand .2012 accessed at www.healthworkforce.govt.nz/new-roles-and-scopes/physician-assistant-role-in-new-zealand .
21. Frossard LA, Liebich G, Hooker RS, Brooks PM, Robinson L. Introducing physician assistants into new roles: international experiences. Med J Aust. 2008 Feb 18;188(4):199-201.
22. Buchan J, O'May F, Ball J. New role, new country: introducing US physician assistants to Scotland. Hum Resour Health. 2007 5:13. doi: 10.1186/1478-4491-5-13

23. Laurant M, Harmsen M, Wollersheim H, Grol R, Faber M, Sibbald B.The impact of non-physician clinicians: do they improve the quality and cost-effectiveness of health care services? Med Care Res Rev. 2009 Dec;66(6 Suppl):36S-89S. doi: 10.1177/1077558709346277.
24. Halter M, Drennan V, Chattopadhyay K, Carneiro W, Yiallouros J, de Lusignan S, Gage H, Gabe J, Grant R. The contribution of physician assistants in primary care: a systematic review. BMC Health Serv Res. 2013 Jun 18;13:223. doi: 10.1186/1472-6963-13-223.
25. Althausen PL, Shannon S, Owens B, Coll D, Cvitash M, Lu M, O'mara TJ, Bray TJ. Impact of hospital-employed physician assistants on a level II community-based orthopaedic trauma system. J Orthop Trauma. 2013 Apr;27(4):e87-91. doi: 10.1097/BOT.0b013e3182647f29.
26. Jeanmonod R, Delcollo J, Jeanmonod D, Dombchewsky O, Reiter M.Comparison of resident and mid-level provider productivity and patient satisfaction in an emergency department fast track. Emerg Med J. 2013 30(1):e12. doi: 10.1136/emermed-2011-200572.
27. Hamden K, Jeanmonod D, Gualtieri D, Jeanmonod R. Comparison of resident and mid-level provider productivity in a high-acuity emergency department setting.Emerg Med J. 2014 Mar;31(3):216-9. doi: 10.1136/emermed-2012-201904.
28. Stahlfeld KR, Robinson JM, Burton EC. What do physician extenders in a general surgery residency really do? J Surg Educ. 2008 65:354-8. doi: 10.1016/j.jsurg.2008.06.002.
29. Timmermans MJ, van Vught AJ, Wensing M, Laurant MG. The effectiveness of substitution of hospital ward care from medical doctors to physician assistants: a study protocol. BMC Health Serv Res. 2014 Jan 28;14:43. doi: 10.1186/1472-6963-14-43
30. Parle JV, Ross NM, Doe WF. The medical care practitioner: developing a physician assistant equivalent for the United Kingdom.Med J Aust. 2006 Jul 3;185(1):13-7.
31. Woodin J, McLeod H, McManus R, Jelphs K. Evaluation of US-trained physician assistants working in the NHS in England. Final Report. Birmingham UK, University of Birmingham, 2005.
32. Farmer J, Currie M, Hyman J, West C, Arnott N. Evaluation of physician assistants in National Health Service Scotland. Scott Med J. 2011 Aug;56(3):130-4. doi: 10.1258/smj.2011.011109.
33. White H & Round JC Introducing physician assistants into an intensive care unit: process, problems, impact and recommendations. Clinical Medicine 2013, 13: 15–18
34. Williams L and Ritsema T. Satisfaction of Doctors with the Physician Associate Role . Clin Med. 2014 Apr;14(2):113-6. doi: 10.7861/clinmedicine.14-2-113.
35. Ritsema TS, Paterson KE. Physician assistants in the United Kingdom: an initial profile of the profession. JAAPA 2011;24(10):60.
36. Ritsema TS, Paterson KE. Results of the Second Annual UK Physician Assistant Census. London, England, United Kingdom, May 2012. Accessed at www.ukapa.co.uk
37. Department of Health. Liberating the NHS: Developing the Healthcare Workforce. 2012 http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_132087.pdf dh_digitalassets/documents/digitalasset/dh_132087.pdf
38. Department of Health. Department of Health response to 2nd future forum report. 2012 Accessed at http://www.dh.gov.uk/en/Publicationsandstatistics/ DH_132075
39. Centre for Workforce Intelligence Horizon scanning – A strategic review of the future healthcare workforce: Informing the nursing workforce . 2013. Accessed at http://www.cfwi.org.uk/news/publications/horizon-scanning-a-strategic-review-of-the-future-healthcare-workforce-informing-the-nursing-workforce/
40. Physicians Assistants in the Workforce : national one day conference. University of Birmingham March 9th 2014.
41. Donabedian A. The quality of care. How can it be assessed? JAMA 1988; 260:1743-1748.
42. Maxwell R. Dimensions of quality revisited: from thought to action. Quality in Health Care 1992:1:171-177.
43. Greenhalgh, T., Robert, G., Macfarlane, F., Bate, P., & Kyriakidou, O. (2004). Diffusion of innovations in service organizations: systematic review and recommendations. Milbank Quarterly, 82(4), 581-629.

44. Nancarrow SA, Borthwick AM. Dynamic professional boundaries in the healthcare workforce. Sociol Health Illn. 2005 Nov;27(7):897-919.
45. Laurant M, Harmsen M, Wollersheim H, Grol R, Faber M, Sibbald B.The impact of non-physician clinicians: do they improve the quality and cost-effectiveness of health care services? Med Care Res Rev. 2009 Dec;66(6 Suppl):36S-89S. doi: 10.1177/1077558709346277.
46. Abbott A. The System of Professions – a Study of the Division of Expert Labour. London: University of Chicago Press. 1988
47. Bowling, A. Research methods in health. 3rd Ed. Maidenhead: Open University Press, 2009.
48. Boyzatis RE. Transforming Qualitative Information Thematic Analysis and Code Development. Sage Publications. 1998.
49. Centre for Reviews and Dissemination. Systematic Reviews: CRDs Guidance for Undertaking Reviews in Healthcare. York: Centre for Reviews and Dissemination, University of York; 2009.
50. Royal P , Milne R. Literature searching for randomized controlled trials used in Cochrane reviews: rapid versus exhaustive searches. International Journal of Technology Assessment In Health Care 2003, 19:591-603
51. Dixon-Woods M, Agarwal, S Young, B Jones, D. Integrative Approaches to Quantative and Qualitative Evidence Review. London: Health Development Agency. 2004.
52. Greenhalgh T, Peacock R. Effectiveness and efficiency of search methods in systematic reviews of complex evidence: audit of primary sources. BMJ 2005; 331: 1064-1065.
53. Critical Appraisal Skills Programme (CASP) Critical Appraisal Checklists. Accessed at http://www.casp-uk.net/#!casp-tools-checklists/c18f8. 2013
54. British Medical Journal. Guidance for peer reviewers. Br Med J. 2011. [http://www.bmj.com/about-bmj/resources-reviewers/guidance-peer-reviewers]
55. Silverman D. Interpreting Qualitative Data. Methods for Analysing Talk, Text and Interaction, London: Sage Publications. 1994.
56. Yin RK. Case Study Research: Design and Methods. 3rd Ed.Thousand Oaks, California:Sage Publications .Inc,. 2003.
57. Kessler I, Heron P, Dopson S, Magee H, Swain D. Nature and Consequences of Support Workers in a Hospital Setting. Final report. NIHR Service Delivery and Organisation programme; 2010.
58. Spilsbury K, Adamson J, Atkin K, Bartlett C, Bloor K , Borglin G ,Carr-Hill R , et al. HS&DR - 08/1619/159: Evaluation of the development and impact of assistant practitioners supporting the work of ward-based registered nurses in acute NHS (Hospital) Trusts in England. http://www.nets.nihr.ac.uk/projects/hsdr/081619159 2010
59. Kvale S. Doing Interviews. London Sage Publications. 2007.
60. Strauss A and Corbin J. Basics of Qualitative Research: Techniques and Procedures for Developing Grounded Theory. 2nd Ed. Thousand Oaks. Calif: Sage. 1998.
61. Hammersley, M., & Atkinson, P. Ethnography: Principles in practice. 2007. Routledge.
62. Pope, C., & Mays, N. Observational methods p 32-42. in Pope, C., & Mays, N. (Eds.). (2008). Qualitative research in health care. 4rd. Chichester; John Wiley & Sons.
63. Gipsen K ED/A and E discussion group. Physician Assistant Conference. University of Birmingham March 2014
64. Sakr M, Angus J, Perrin J, Nixon C, Nicholl J, Wardrope J. Care of minor injuries by emergency nurse practitioners or junior doctors: a randomised controlled trial. Lancet. 1999 Oct 16;354(9187):1321-6.
65. Cooper MA, Lindsay GM, Kinn S, Swann IJ. Evaluating Emergency Nurse Practitioner services: a randomized controlled trial. J Adv Nurs. 2002 Dec;40(6):721-30.
66. Department of Health .A&E Clinical Quality Indicators. Department of Health; London . 2010. Accessed at http://webarchive.nationalarchives.gov.uk/20130107105354/

67. Health & social Care Information Centre. Provisional Accident and Emergency Quality Indicators - England, by provider for December 2014. 2015. Accessed at http://www.hscic.gov.uk/searchcatalogue?productid=17635
68. Gardner M J, Altman D G. Confidence intervals rather than P values: estimation rather than hypothesis testing. British Medical Journal 1986;292:746 http://www.bmj.com/content/292/6522/746
69. Vittinghof E & McCulloch CE "Relaxing the rule of ten events per variable in logistic and Cox regression" Am J Epidemiol (2007);165(6):710-718. http://aje.oxfordjournals.org/content/165/6/710.full]
70. Noble M, McLennan D, Wilkinson K, Whitworth A, Barnes H, Dibben C. The English Indices of Deprivation 2007. London: Communities and Local Government; 2008.
71. NIHR INVOLVE Payment for involvement. 2010 http://www.invo.org.uk/posttypepublication/payment-for-involvement/
72. NIHR INVOLVE Changes to welfare benefit regulations – how do they affect payment for involvement? 2013 http://www.invo.org.uk/posttypepublication/payment-for-involvement/