NHS
Health Research Authority

Models of Generalist and Specialist Care in Smaller Acute Hospitals

An Exploratory Study

Protocol version 1.2, September 2016

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FULL/LONG TITLE OF THE STUDY

Models of Generalist and Specialist Care in Smaller Acute Hospitals: An Exploratory Study

SHORT STUDY TITLE / ACRONYM

Medical Generalism in Smaller Hospitals

PROTOCOL VERSION NUMBER AND DATE

Protocol version 1.2, 6th September 2016

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Research reference numbers

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Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publically available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

For and on behalf of the Study Sponsor:

Signature: Date:

..../...../.....

Name (please print):

.....

Position:

.....

Chief Investigator:

Signature: Date:

..../...../.....

Name: (please print):

.....

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Study summary

Study Title	Models of Generalist and Specialist Care in Smaller Acute Hospitals: An Exploratory Study
Internal ref. no. (or short title)	Medical Generalism in Smaller Hospitals
Study Design	This study will use a mixed-methods approach, with five interlinking work packages. The overall approach to analysis will be dynamic and iterative, allowing each stage of the study to inform the next. This study will focus on smaller NHS hospitals in England, according to Monitor's definition of 'smaller' providers as having an operating revenue of under £300 million in the 2012/2013 financial year.
Study Participants	Participants in the study will include: Stakeholder Seminars • A maximum of 150 representative stakeholders will participate in three seminars (June 2016, November 2016 and August 2017) and one patient and public event (September 2017) designed to explore meanings of medical generalism Telephone Survey – first stage • One member of staff at 25 trusts in the New Cavendish Group (which consists of the Chief Executive Officers of 33 trusts and is hosted by the Nuffield Trust) to take part in a scoping telephone survey; Telephone survey – second stage (this replaces the online survey initially planned) • One contact person at each of the remaining 50 small trusts in England; • One member of staff at each of the remaining 50 small trusts in England to take part in a telephone survey. If we have a 50% response rate (in addition to the trusts in the NCG) this would give a total sample of 67.7% of the 75 small trusts in England for which we will have extended data and a capacity to categorise according to our preliminary typology. Case Studies • Three to five interviews with key members of staff (including senior and middle-grade doctors, senior nurses and managers) at each hospital in a purposively selected sample of 12-15 hospitals • Eight to twelve healthcare professionals from 4-6 sites considered to be 'most typical' of each care model to participate in focus groups • Six to eight patient representatives and carers from 4-6 sites considered to be 'most typical' of each care model to participate

	in focus groups Discrete Choice Experiment • Two focus groups, consisting of five patients and five health professionals respectively, to drive a final list of attributes for the DCE • A national sample of 500 doctors, 100 patients and 50 managers to complete the online DCE questionnaire
Planned Size of Sample (if applicable)	The total planned size of the sample for the qualitative components of the study will be of 1 075 individuals. The total planned size of the sample for the quantitative and economic components of the study is estimated at 7 500 000 emergency medical admissions over 5 years.
Follow up duration (if applicable)	There is no follow-up period in this study
Planned Study Period	From April 2016 to September 2018 (30 months)
Research Question/Aim(s)	The overarching aim is to identify the models of medical generalism used in smaller hospitals and explore their strengths and weaknesses from patient, professional and service perspectives. The specific objectives are: 1. To create a typology of the different models, considering workforce deployment, skills mix and service configuration, of generalist and specialist care used in smaller hospitals 2. To create a case mix classification that identifies patients which may benefit from generalist care and use this to describe and compare workload, resource utilisation and outcomes between hospitals and models of care. 3. To assess the degree of alignment between patient case mix and medical generalist/skills mix in smaller hospitals 4. To identify the strengths and weaknesses of the different models from patient, professional and service perspectives. 5. To investigate the economic costs attached to different models 6. To assess the types, utility and relevance of potential variables and measures of outcome for a more detailed evaluation of the different models of medical generalism 7. To explore the different meanings, definitions and boundaries of medical generalism in the context of smaller hospitals

Funding

Funder	Financial and non-financial support given
National Institute for Health Research (NIHR) Donna White Research Fellow/ Research Manager (Monitoring) Address: University of Southampton, Alpha House, Enterprise Road. Southampton SO16 7NS Email: d.m.white@southampton.ac.uk Telephone: 023 8059 7472	This project is being supported by a grant from NIHR following an application for funding as part of the call "14/195 Medical generalists (in hospital)". NIHR funding will cover a period of 2.5 years.
Royal College of Physicians Contact: Clive Constable Address: 11 St Andrew's Place, Regents' Park, London NW1 4LE Email: clive.constable@rcplondon.ac.uk Telephone: 020 3075 1649 Northwest London CLAHRC Contact: Rachel Matthews Address: Chelsea and Westminster Hospital 369 Fulham Rd, London SW10 9NH Email: r.matthews@imperial.ac.uk Telephone: 020 3315 8144	The research team will recruit service user researchers (SUR) to assist with the hospital visits in case study sites and with the coding of the focus group material. The Royal College of Physicians of London and the North West London CLAHRC will provide ongoing, non-financial support to the study, namely by supporting the development and provision of bespoke training for those SURs.

Role of study sponsor and funder

This study is funded by the National Institute for Health Research (NIHR) through the "Medical generalists (in hospital)" funding stream.

According to the *UK policy framework for health and social care research* (version issued for public consultation)[128], the **funder** is the organisation or organisations providing funding for the research project.

The funder is responsible for:

a) assessing (or arranging for assessment of) the scientific quality and, where appropriate, value for money of the research as proposed, involving patients, service users and the public effectively in funding decisions;

b) reviewing information about attribution of costs to confirm that costs to all parties have been identified and described, in accordance with national guidance where applicable, and that costs to the health and social care system are not disproportionate compared to research costs;

c) considering whether the research is really achievable within the settings as a whole in which it is intended to be carried out, particularly in view of the priorities and constraints in health and social care if the research will have an impact on care provision;

d) making funding conditional on a sponsor and on relevant approvals being in place before research requiring those approvals begins;

e) using contracts and conditions of funding to confirm specific requirements and to promote compliance with the UK policy for health and social care research, in particular chief investigators should arrange to make information about research publicly available, normally before it starts, and make accurate findings accessible in a timely manner and where appropriate, data and tissue.

The research team's contact person at NIHR is Mrs Donna White, Research Fellow/Research Manager, who the team will liaise with for all matters regarding the work progress and meeting NIHR requirements.

The **sponsor** if defined as the organisation or partnership that takes on overall responsibility for appropriate arrangements being in place to set up, run and report a research project[128].

According to the *UK policy framework for health and social care research*[128] the sponsor has overall responsibility for the design and management of the research, including:

a) verifying that everything is ready for the research to begin in a safe and timely manner;

b) putting and keeping in place arrangements to finance and manage the research project, including its competent risk management;

c) identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications;

d) ensuring that the research proposal or protocol is scientifically sound (e.g. through independent expert review, if appropriate) and that the investigators, research team and research sites are suitable;

e) satisfying itself that, where expected or required, the research has a favourable research ethics committee opinion and all relevant approvals before it begins;

f) satisfying itself that the chief investigator has made appropriate arrangements for making information about the research publicly available, normally before it starts, and for retaining and making accurate findings, data and tissue accessible, as appropriate, after it has finished;

g) ensuring that roles and responsibilities of the parties involved in the research are agreed and appropriately documented;

h) ensuring appropriate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project and any commercialisation of the findings;

i) ensuring that appropriate, effective procedures and arrangements are kept in place and adhered to for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

The Nuffield Trust is the study's host organisation and the employer of part of the research team. The Nuffield Trust's Chief Executive, Nigel Edwards, is the study sponsor. Candace Imison, Director of Policy at the Nuffield Trust, is the study's sponsor representative.

The Nuffield Trust's *Research Governance Policy* refers that "For externally funded research projects the Trust will adhere to the peer review arrangements and research governance requirements of the project sponsor."[129].

Roles and responsibilities of study steering groups & individuals

Study Steering Committee

According to the Health Research Authority's *Research Governance Guidelines* for the Study Steering Committee (SSC), the role of the SSC is to provide overall supervision for a project on behalf of the Project Sponsor and Project Funder and to ensure that the project is conducted to the rigorous standards set out in the Department of Health's Research Governance Framework for Health and Social Care and the Guidelines for Good Clinical Practice.

The main responsibilities of the SSC include:

- To provide advice, through its Chair, to the Chief Investigator, the Project Sponsor, the Project Funder, the Host Institution and the Contractor on all appropriate aspects of the project
- To concentrate on progress of the project, adherence to the protocol, patient safety (where appropriate) and the consideration of new information of relevance to the research question
- The rights, safety and well-being of the participants are the most important considerations and should prevail over the interests of science and society
- To ensure appropriate ethical and other approvals are obtained in line with the project plan
- To agree proposals for substantial protocol amendments and provide advice to the sponsor and funder regarding approvals of such amendments
- To provide advice to the investigators on all aspects of the project

The SSC has the following requirements:

- An independent Chair (UK based and/or holding a substantive UK based appointment)
- Independent statistician, health economist and clinician(s) along with others relevant to the project with relevant expertise (where appropriate)
- At least one individual who is able to contribute a patient and/or wider public perspective.
- Ideally, the SSC should invite observers, including a representative of the sponsor and a representative from the research network to meetings
- An indication of any proposed overseas members should have been given at the full application stage and feedback on such proposals supplied following the Commissioning Board's consideration of the application
- Although there may be periods when more frequent meetings are necessary, the SSC should meet at least annually
- Where a DM(E)C is required, SSC meetings should be scheduled to follow shortly after DM(E)C meetings so that reports from that group can be considered if appropriate
- Minutes of meetings should be sent to all members, the sponsor, the funder and the study master file

- The responsibility for calling and organising SSC meetings lies with the Chief Investigator, in association with the Chair.

The chair of the SSC is additionally responsible for:

- Liaising with the Chief Investigator to arrange a meeting to finalise the protocol and to set up a schedule of meetings to align with the project plan
- Establishing clear reporting lines – to the Funder, Sponsor, etc.
- Being familiar with relevant guidance documents and with the role of the DM(E)C if appropriate
- Providing an independent, experienced opinion if conflicts arise between the needs of the research team, the funder, the sponsor, the participating organisations and/or any other agencies
- Leading the SSC to provide regular, impartial oversight of the study, especially to identify and pre-empt problems
- Ensuring that changes to the protocol are debated and endorsed by the SSC; letters of endorsement should be made available to the project team when requesting approval from the funder and sponsor for matters such as changes to protocol
- Being available to provide independent advice as required, not just when SSC meetings are scheduled
- Commenting on any extension requests and, where appropriate, providing a letter of recommendation to accompany such a request
- Commenting in detail (when appropriate) regarding the continuation or termination of the project

The SSC has already been put together (please see pages 7-8) and it will be responsible for providing guidance and advice at key moments in the study's development. Its members have been selected to cover a range of fields of expertise and they are entirely independent from the study's sponsors and investigators.

The SSC will meet twelve times over the course of the study, with a meeting taking place every three months (please see Gantt chart in the Appendices section). Some meetings will take place face to face, while some other will be held through teleconference. Members are expected to attend five face to face meetings over the course of the project.

Project Management

Project Managment	Responsibilities
National Institute for Health Research (NIHR)	Funder of the study, to whom the project's investigators are accountable throughout the several stages of the work (see 'Role of study sponsor and funder' above).
Nuffield Trust	Study's host organisation, which will provide access to facilities and administrative support to the investigators. As an employer[1], according to the *UK policy framework for health and social care research*[128], the Nuffield Trust is responsible for: a) encouraging a high-quality research culture: • ensuring employees are supported in and held to account for the professional conduct of research, including research integrity, and • ensuring effective management of employees and their work, including employees' safety and well-being, financial management and calculation of costs in support of financial probity, and agreement with their partners37 (e.g. funders, sponsors, collaborators, commercial partners, network members, integrated board etc) and employees about accountability and division of responsibilities, including arrangements for any intellectual property arising from research; b) ensuring researchers understand and discharge their responsibilities; c) following good HR practice and providing written procedures, supervision and training that support accountability and effective collaboration, encourage care with financial resources and raise awareness of the wider environment within which health and social care research is conducted; and d) taking appropriate action in the event of errors and breaches or if misconduct or fraud are suspected. The Nuffield Trust's *Conditions for Award of a Research Grant* establish that, as a charity, the Trust must ensure that the results of any research supported by it are disseminated for public benefit. The Trust therefore requires Grantholders to: • agree with the Trust at the outset the approach to communicating the project and its outputs • ensure that the Trust is informed, in advance, of any activities that formally communicate their research projects (e.g. published outputs, press releases, presentations at conferences, media interviews and

[1] The *UK policy framework for health and social care research* defines an employer as "the organisations employing the chief investigator and members of the research team, including research teams at individual sites, [which] may also be research sites, sponsors and/or funders."

Project Managment	Responsibilities
	articles, and material published on the Grantholder's website). A lead from the Trust's communications team may be appointed to liaise with the Grantholder on communications activities, and a strategic Communications Plan may be agreed.
Nigel Edwards	Sponsor of the study, as Chief Executive of the Nuffield Trust (see 'Role of study sponsor and funder' above).
Dr Louella Vaughan	Chief Investigator, responsible for the design of the study and for overseeing the progress of its five work packages. According to the Nuffield Trust's *Research Governance Policy*[129], the Chief Investigator takes responsibility for the conduct of the research and is accountable for this to their employers. The principal investigator shall have responsibility for: • ensuring the study complies with all legal and ethical requirements and that the Trust's Research Governance Process is adhered to • timely monitoring and reporting of the progress and outcomes of the work required by the sponsor, funders or others with a legitimate interest and ensuring they are of an acceptable standard • the findings of the work being open to critical review through accepted scientific and professional channels • ensuring arrangements are in place for the management of any intellectual property arising • ensuring procedures are in place to ensure collection of high quality, accurate data and the integrity and confidentiality of data processing and storage • ensuring arrangements are in place for the appropriate archiving of data when the research has finished • ensuring appropriate arrangements for the dissemination of research methods and findings The Chief Investigator is additionally responsible for: • ensuring that each member of the research team is qualified by education, training and experience to discharge his/her role in the study • new researchers receive adequate supervision, support and training and receive appropriate recognition in the authorship of paper/reports • detecting and preventing research misconduct by adopting the role of guarantor for published outputs Dr Vaughan will also be responsible for coordinating the delivery of Work Packages 4 and 5, and actively participate in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results from the study.

Project Managment	Responsibilities
Ms. Candace Imison	Sponsor representative, will lead Work Package 1 and be responsible for its timely delivery. Ms Imison will actively participate in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results from the study.
Dr Martin Bardsley	Study co-applicant, will lead Work Package 2 and quantitative elements of WP4 and be responsible for their timely delivery. Dr Bardsley will actively participate in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results from the study.
Professor Steve Morris	Study co-applicant, will lead Work Package 3 and be responsible for its timely delivery. Professor Morris will actively participate in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results from the study.
Professor Anne-Marie Rafferty	Study co-applicant, will support the delivery of WP5 and actively participate in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results from the study.
Ms. Silvia Machaqueiro	Lead researcher in Work Package 1, will undertake the research activities in this package and provide some input in Work Packages 4 and 5. Ms Machaqueiro will actively participate in the design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results from the study. According to the Nuffield Trust's *Research Governance Policy*[129], the Researcher is responsible for: • undertaking research in line with agreed proposals and to agreed standards • adhering to relevant Trust policies on research governance ethics, and information handling • undertaking work in ways that are consistent with this code of practice

All co-applicants will be responsible for overseeing and conducting the research activities outlined in their respective Work Packages (see figures 1-3), as well as the researchers that each lead recruits to collaborate with them.

There has been patient and public involvement (PPI) at all stages of the development of this study. The first round proposal was developed in conjunction with a trained member of the public (Fran Husson) and the senior engagement officer of the NWL CLAHRC. It was at Ms Husson's suggestion that we included patient researchers to assist with coding of the focus groups. Relevant sections of this application have been reviewed by two appropriate member of the public (Fran Husson and Marilyn Frampton). Please see the section on PPI for further details.

Key words: Medical generalism; small hospitals; acute care trusts; case mix; models of care; medical patients

Study flow chart

The following flow diagrams provide a schematic overview of the study, including its five work packages (WP), how these are linked, each WP's objectives and a summarised timeline of the study.

For more detailed information about the several stages of the study and how the work is going to be undertaken, please see the Gantt chart in the appendices.

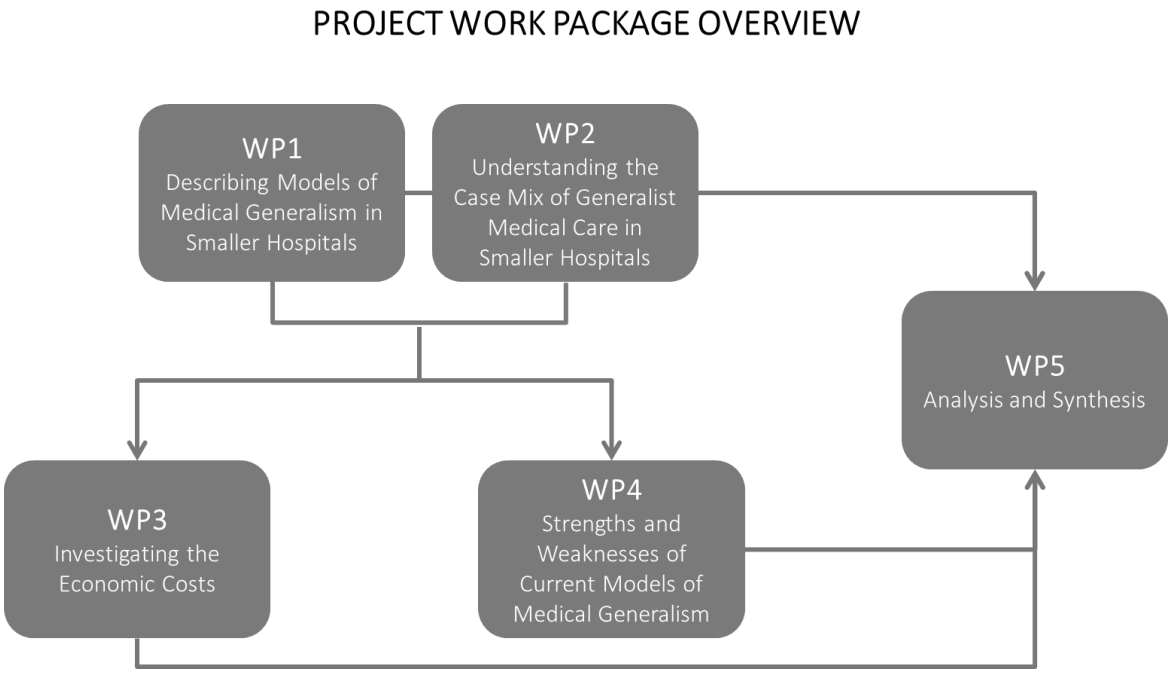

Figure 1 – Overview of the project's interlinking work packages

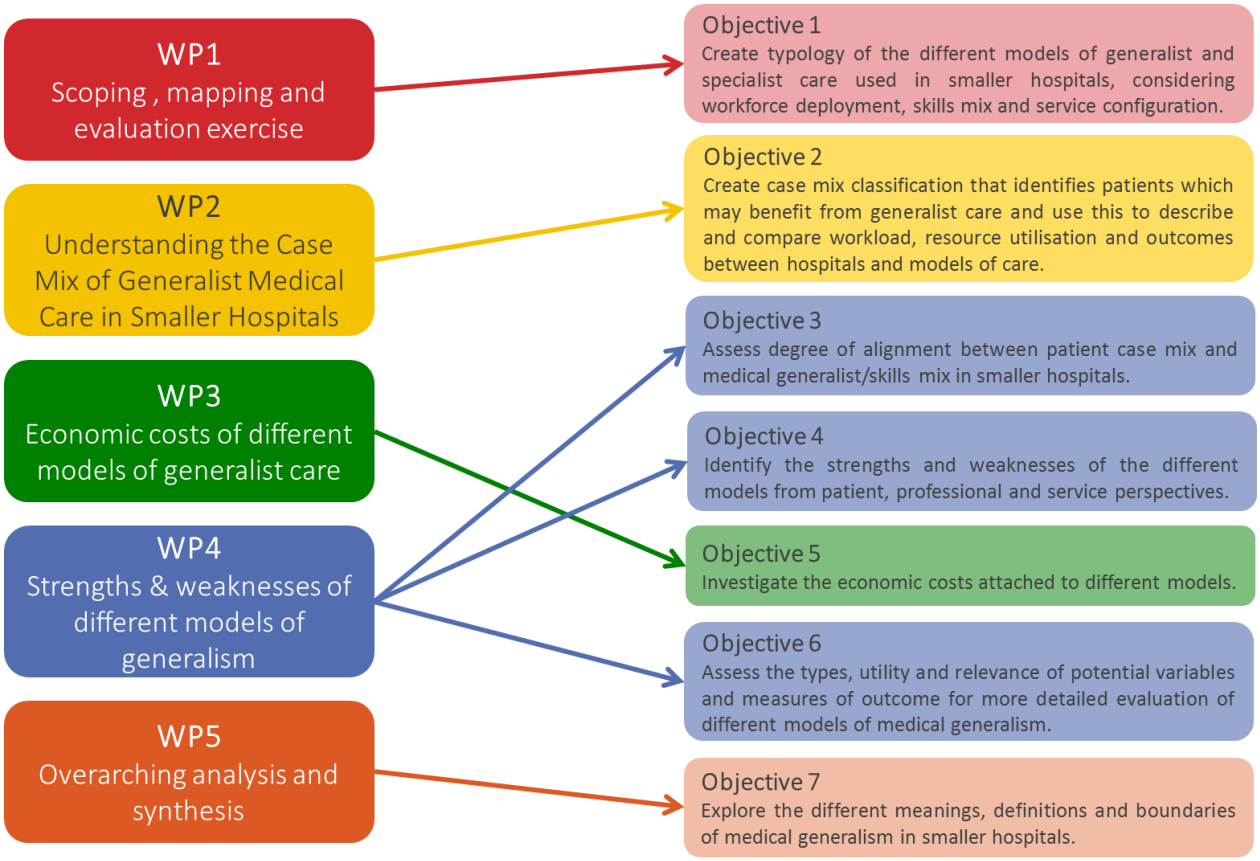

Figure 2 – Overview of work packages and objectives

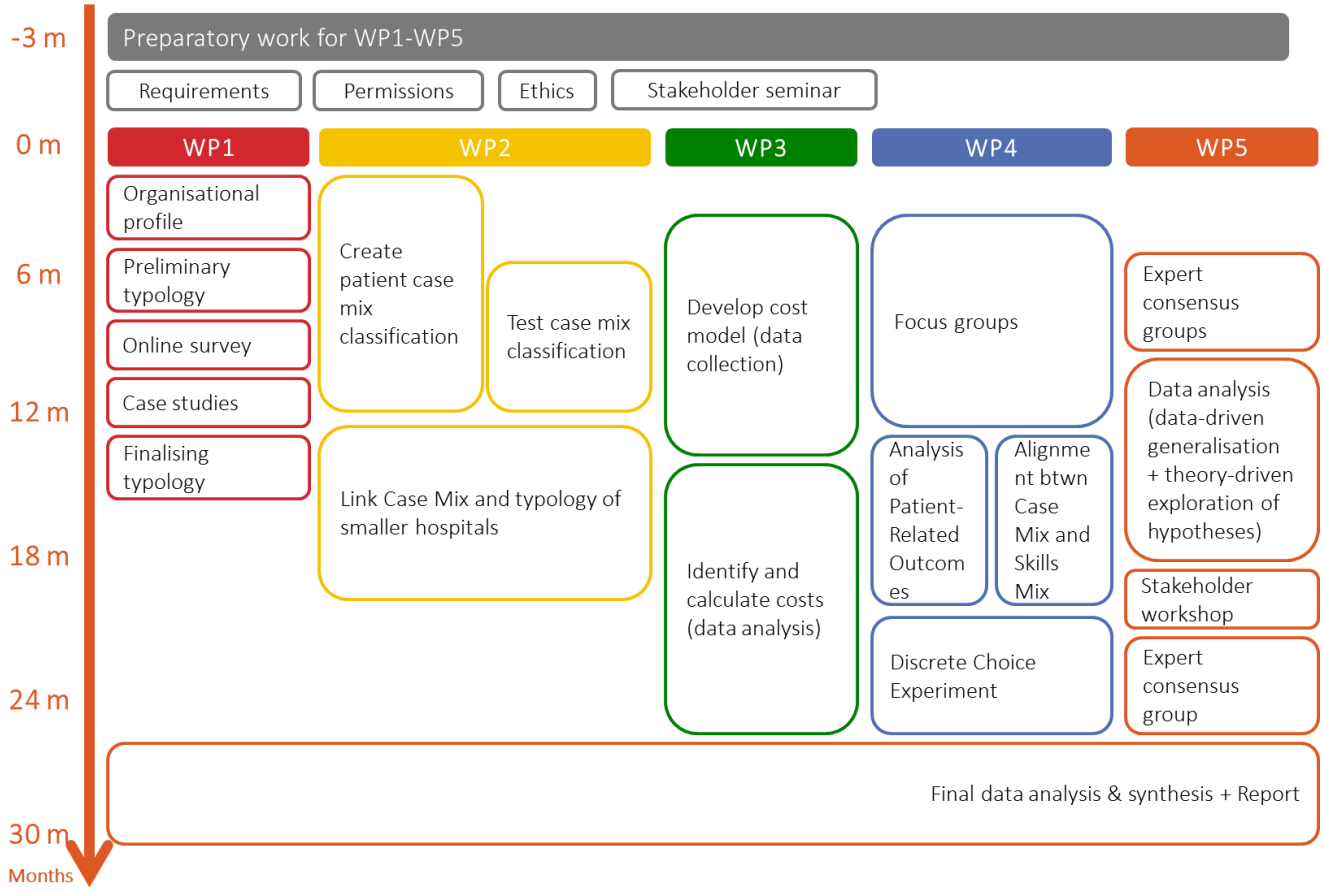

Figure 3 – Study flow diagram

Study protocol

Models of Generalist and Specialist Care in Smaller Acute Hospitals: An Exploratory Study

1. Background

The rising numbers of older and more complex patients is considered to be one of the most pressing problems facing the NHS.[1] Although they receive the most resource-intensive care, their problems are less likely to be accurately diagnosed and have more adverse outcomes than other age groups.[2-5] The emerging consensus is that current models of hospital care, which are heavily based around specialists delivering disease-specific care, serves these patients poorly, as it is often fragmented and poorly co-ordinated. A revival of medical generalism has been suggested to provide better and more cost-effective care.[6-9]

Although this appears to be an excellent suggestion, it is based on assumptions that:

1) What is meant by 'medical generalism' is clearly understood
2) The patients who would benefit most from a revival of medical generalism have been identified
3) Current service models are uniform and well-delineated
4) Changing these service models will necessarily result in better outcomes

The reality is that there is poor evidence on which to base new models of medical generalism. As noted by the Australian '2020' review, the policy discourse is heavily dominated by opinion and commentary.[10] Here, we will review the evidence across each of these aspects of the debate – professional, service model and patient need.

Professional Concepts of Generalism

Since the emergence of modern concepts of physiology and pathology in the late 19th century, there has been a tension between those who provide a broad scope of services to their patients and specialists with a restricted range of expertise, usually focussed on a single organ.[11] While generalism dominated for much of the 20th century, medical and technical advances have led to an almost continuous increase in the number of and variety of specialties and subspecialties, with 60 now recognised in the UK and over 120 in the USA.[12] In parallel with these changes, concerns have been expressed about the increasing complexity of clinical services, rising costs and the fragmentation of care for patients.[13]

In the mid-1990s, the debate between generalism and specialism become particularly heated.[14-16] The 'overspecialised' American physician workforce was seen as a threat to the provision of affordable, equitable and high quality health care.[17-18] Research noted that whilst generalism was often defined solely in terms of being 'not specialism',[12] generalists had a strong sense of professional identity.[15] They were usually the first point of contact for the patient in their care pathway, were skilled at diagnosing illness and were able to provide comprehensiveness and continuity of care.[19-20] Contrary to the notion of generalists as 'failed specialists', they were found to have a better knowledge base, which was maintained for longer than their specialist counterparts.[21-2] However, there was evidence of better outcomes for selected patient groups of receiving specialist care, such as the treatment of

myocardial infarction by cardiologists,[23,24] depression by psychiatrists,[25] AIDS by infectious diseases experts[26] and some rheumatic conditions by rheumatologists.[27] Conversely, generalist care was found to match or outperform specialist care in other areas.[28,29] More importantly, variations in quality of care between individual generalists and between individual specialists were often larger than the variations between the two generalists and specialists as groups.[15]

In the USA, policy makers at the time interpreted the evidence in favour of increasing the number of medical graduates entering post-graduate training programmes in general internal medicine.[17,18] However, this failed to halt the march of specialism. The same evidence was used in the UK, and elsewhere, to support increasing centralisation, hospital mergers and major service reconfiguration of acute medical services (discussed further below).[30-32] The result has been the virtual disappearance of the general physician in the UK, Australia and the United States.

There have been increasingly urgent calls for the revival of general medicine in the last five years.[6-8,33,34] This has been almost entirely fuelled by the perceived gap between models of care and the needs of patients, leading to the concept of the generalist being both idealized and reimagined with little or no reference to either current models of care or 'traditional' general medicine.[10,35]

More rigorous attempts to redefine 'generalism' have struggled with the lack of a clear definition of what generalism actually is, pointing to the lack of evidence on which to base change. The Australian '2020' review of generalism found that the literature is heavily dominated by commentary and opinion; out of the ~600 abstracts reviewed for inclusion, only 14 empirical studies were identified, most of which were generated during the debate in the 1990s.[10,35] The current debate has been influenced by newer concepts of generalism emerging from attempts to reinvigorate general practice,[6,36] with little effort to systematically investigate concepts of generalism in secondary care.

Service Models and Generalism

Until the early 1990s, the bulk of secondary care in the UK was delivered by general physicians. Unscheduled medical patients were admitted by the medical team of the day and remained under the care of the admitting general physician on a general medical ward until discharge or referral to a specialist service.[37,38]

Alongside the evidence that certain patient groups fare better when cared for by specialists rather than generalists, a large number of observational studies reported that poor outcomes, particularly mortality, reduced as patient volume increased.[39-44] These findings added weight to the NHS policy drive to reconfigure services within hospitals, shift increasing numbers of patients from generalist to specialist services and close or merge smaller hospitals.

By the early 2000s, it was becoming clear that these changes were impacting on the 'front door' of hospitals. The loss of the general medical beds meant that patients were being boarded for long periods in Emergency Departments[45] or being admitted directly to inappropriate beds in other parts of the hospital.[46] This coupled with the erosion of the traditional medical 'on take' system,[37,38] led to the development of Acute Medical Units (AMUs) in Scotland. These units are designed to improve patient safety by cohorting newly admitted patients in a highly-resourced, purpose-built space.[47] Although the initial studies demonstrated benefit,[48] they did not become wide spread until the introduction of the

four-hour waiting time Emergency Department target in 2004. It is now estimated that over 95% of acute hospitals in the UK have an AMU.

These twin drivers, the increasing specialisation of the medical workforce and the introduction of AMUs, have transformed the landscape of medical secondary care. Consultant working patterns, undergraduate medical education, junior and middle grade post-graduate training, the configuration and staffing of hospital wards, patient pathways and patterns of referral and investigation have all needed to be aligned with the new models of care.[49,50] More strikingly, a whole new medical specialty, Acute Medicine, has been developed,[51] while training in stand-alone General (Internal) Medicine has virtually disappeared (now available only in Oxford and Scotland).

The underlying evidence and the assumptions around these changes are now being questioned. There is a recognition that much of the research examining the relationships between health outcomes and volume and specialist services did not take sufficient account of the effects of differences in patient case mix or the additional resources often attached to specialist services.[15,52-54] Further, mergers of hospitals have failed to produce gains in efficiency or save costs.[55,56]

More importantly, there has been no wholescale evaluation of the impact of AMUs. The systematic review of AMUs in 2009 found that while studies on the introductions of AMUs all reported positive improvements in patient and/or hospital related outcomes, only nine studies from six hospitals were found.[48] Concerns have been raised that while they do benefit some patients, they disadvantage those patients with more complex needs by increasing the fragmentation of care, with nearly 30% of physicians considering that care in their own institutions lacks continuity.[57] There is a perception that management of the 'acute take' has become more onerous since the introduction of the AMU, as a result of the loss of traditional 'on take' teams.[58] Although guidelines do exist for the structure of and processes contained with an AMU,[59] several smaller studies have found that these are not uniformly adhered to and that the variability between AMUs results in poorer outcomes for patients and hospitals alike.[60,61]

Attempts to fill the space once occupied by general medicine has also led to suggestions that Acute Physicians should extend their scope of practice outside of the AMU and onto the downstream wards,[62] while the British Society of Geriatrics has suggested that all geriatricians should consider themselves as generalist physicians, rather than confining themselves to caring for patients with diseases relating to aging and degeneration.[63]

It is unclear to what extent medical generalism still exists.[64] To the knowledge of the research team, the only one hospital in England which continues to operate a traditional 'consultant of the take' model of general medicine is the John Radcliffe Hospital in Oxford. Around 5% of hospitals appear to have systems where patients are seen within the Emergency Department by Acute Physicians, acting in a generalist type role, and then triaged to specialty teams, without a stay on an AMU. Mapping exercises of unscheduled emergency care suggest that most hospitals operate some type of hybrid model,[65] although these have never been systematically investigated.

Patients and Generalism

Patient demography has been changing rapidly over the past two decades. The population is becoming older, with one-in-six the UK aged over 65 years old. The latest projections are that this is

to double to around 19 million people by 2050. Within this total, the number of very old is expected to grow even faster, with the number of over 80 year olds to reach 8 million by 2050. This group of the 'oldest old' are the main consumers of health and social services.[1] Almost 75% of those over 65 years old have multiple chronic medical conditions,[66] while 25-50% of those over 85 years old are thought to have a frailty syndrome, as a result in the general decline in their physical and psychological reserves.[67]

The rising numbers of patients with co-morbidities or complex disease is not confined to the over 65 years old. A recent Scottish study found that around a quarter of patients had two or more morbidities and that although the presence of multi-morbidity increased with age, the absolute number of co-morbid patients is greatest in those younger than 65 years old.[68] Other studies have found associations between multi-morbidity and increased risk of mortality, disability, poor quality of life and adverse drug events.[69,70] They also have substantially higher general practice consultation rates, experience less continuity of care and are more dissatisfied with the care they receive.[71]

It is then, perhaps, not entirely unexpected that there has been a sharply rising demand for unscheduled medical care, with the number of English hospital admissions rising by 2 million patients per annum over the last 6 years.[72]

These patterns of demographic change and the accompanying rise in healthcare usage have led to calls for the whole system of medicine to be realigned with the needs of this patient population.[8,73] However, the impact of the changing patterns of age and disease on secondary care is not fully understood. Recent work by the Nuffield Trust, for example, found that there were 60% more hospital admissions than could be accounted for by the ageing population.[74] There is also an increasingly compelling body of evidence that poor outcomes for patients are more directly the result of poor processes of care contained *within* a model, rather than the model itself. Misdiagnosis is increasingly held at the international level to be the commonest cause of potential preventable deaths.[75-77] Adverse events relating to diagnostic errors are associated with the highest mortality rate.[78] A whole series of similar factors has been found,[79-80] with suggestions that while patients with complex disease do experience higher morbidity and mortality during hospital admissions, this may be because as a group they are more susceptible to the impacts of poor care than their less co-morbid counterparts.[81]

It is also worth noting that there have been no high quality studies relating to the secondary care of multi-morbid patients and that a recent systematic review found very little evidence for primary care interventions in this group.[82]

The acceptability of generalist care to patients is yet to be explored, a key consideration given that patients value and actively seek specialist care.[83]

2. Rationale

There is a growing concern that current models of secondary medical care are failing to meet patient need. Much of this stems from the recent and gross failures of hospitals to provide high quality of care for patients, as epitomised by the tragedy at the smaller Mid-Staffordshire Hospital.[86] However, meeting the needs of an ageing population and those of all ages with complex disease in a time of unprecedented financial constraint is a daunting task.

Three separate panels of experts – the Independent Commission for the Royal College of General Practitioners and the Health Foundation,[6] the Royal College of Physicians of London's (RCPL) Future Hospital Commission (FHC)[8] and the General Medical Council's Shape of Training review[7] – have all recommended a revival in general medicine to better provide high-quality, cost-effective care. More recently, NHS England's Five Year Forward View[87] has signalled a retreat from the centralisation of services. Not only does this relieve the immediate pressure on smaller hospitals, but the Dalton review has proposed a series of changes to smaller hospital in order to secure their long-term viability.[88]

The history of the disappearance of medical generalism is not only immediately relevant, but salutary. The last twenty years of increasing and centralisation in the NHS were based on partial or overly optimistic readings of the available evidence, which actually suggested that not only should a balance between generalist and specialist services be struck, but that it was more important that *all* services should reduce variability in practice.[15] Further, as noted by the King's Fund[89] and the Dalton Review,[88] the emphasis in the NHS has been on rapid transformation, without sufficient pause to consider models of care or the impact of previous rounds of changes. While these reviews of medical generalism, particularly the FHC, broadly scoped the landscape for novel models of general medicine, they did not provide an overview of or assess current medical care.

The Five Year Forward View and the FHC have been explicit about the desirability of diverse models of medical care. However, general medicine cannot be rapidly reintroduced, nor can hospitals reconfigure services (let alone smaller hospitals) unless there is a clear understanding of patient need and how different models of current medical care meet these. With NHS England's Viable Smaller Hospitals workstream of the New Models of Care programme already underway, there is an urgent need for clear and comprehensive evidence to guide future policy and service reconfiguration.

From the overview of the literature, it is clear that there are a number of gaps in the evidence that need to be addressed. There is a lack of clarity around the meaning of 'general medicine' and the professional identity of the 'general physician'. There is a paucity of information about the current models of care in England and to what extent general medical care still exists within them. Similarly, there has not been a considered assessment of the impact of the wholescale changes driven by the increase in specialist care and the advent of the AMU. It is also unclear what the case mix of patients presenting acutely to hospitals actually is and what the needs of patients actually are.

It is the intention of this study to begin to fill in these gaps in the evidence base and in particular concentrate on generalist care in smaller hospitals. The rationale for the focus on smaller hospitals is that:

a) A recent study by Monitor suggests that the tensions in the wider health service around generalist versus specialist care are concentrated in smaller hospitals.[84]

b) As a group, they provide care for nearly half of all medical patients.[84]

c) Their patient populations are older, more vulnerable and have more complex needs, and hence could be considered to be more 'general medical' than those attending larger hospitals.[84]

d) The trends towards subspecialty care have impacted them significantly. With the shift of services to larger sites, they are often left struggling to balance inpatient services and the need to hit targets for outpatient specialist clinics and procedures.[85]

e) They are financially constrained and understaffed, with mismatches between service capacity and workload and difficulties in innovating services.[85]

In short, smaller hospitals are an ideal microcosm in which to investigate what the needs of patients are, how well these are being met by the different models of medical generalism, and what medical generalism means to medical and other staff.

3. Theoretical framework

This study explores medical generalism in the setting of smaller hospitals using a mixed methods approach.

Models of care in English hospitals are not currently mapped at any level of detail. The literature suggests that models of medical general care have been driven by three main paradigms[12]:

1. General medical care as the default provider for all medical patients, unless/until a patient is referred to a specialist service
2. General medical care provided in response to patient need
3. General medicine providing the 'undone work' of the specialists

However, maps of care pathways of emergency care suggest the organisation of the care of the acutely unwell patient tends to be parsed around the pragmatics of deploying available medical, nursing and other staff either on the AMU (where present) and the downstream medical words. Subsequently, systems of triage often reflect attempts to manage workload, rather than theoretical considerations.[65] This study will attempt to bridge this gap between the theoretical and pragmatic aspects of general medical care.

Our theoretical framework of medical generalism builds on the Australian '2020' conceptual model of generalism.[10] The resulting conceptual model views 'ways of being' (ontological frame), 'ways of knowing' (epistemological frame) and 'ways of doing' (practical frame) as a continuum that captures the attributes of 'generalism'. This sits with Abbott's work, which considers that professional ways of working are 'ecologically driven' and situated in the context of actors, tasks, locations and the relationships between these.[90] We therefore will consider that hospital generalists and their ways of working are therefore not only ideologically or theoretically driven, but also 'ecologically' determined by the locations in which they work, the tasks they are required to perform and the relationships between these and professional identity and attributes of physicians. Our theoretical framework will therefore address medical generalism in hospital through three different perspectives:

a) The patient' perspective - the needs of the patient and the tasks required to meet these
b) The 'professional' perspective – in particular, the knowledge and skills of the professional.
c) The 'service' perspective – the context of the hospital in which they work, including their deployment, the configuration of beds and the allocation of resources.

This framework will inform theoretical explorations of the essential dimensions of generalism in the English hospital context. We will seek also to define and understand the duties and responsibilities of the general physician, the boundaries between generalist and specialist care and what is considered to constitute the 'general medical patient'. These definitions will be used to inform the body of the study, before being refined as part of the final study analysis.

The three core levels of theoretical inquiry - patient, professional and service - will allow us to categorise, describe and begin to understand the empirical evidence gathered from multiple sources about smaller hospitals, their patients and how they deploy resources. We will use a mixed methods approach, with the construction of a framework that combines both induction (data-driven

generalisation) and deduction (theory-driven exploration of hypotheses).[91,92] The overall approach to analysis will be dynamic and iterative, allowing not only each stage of the study to inform the next, but to allow for theories of how and why different models of medical generalism are implemented in different hospitals to be generated. This approach will also allow for highly structured comparisons between hospitals and models to be made and begin to identify what the differences between these models and hospitals are and to what extent these differences explain variability in outcomes. The results of the study, both theoretical and pragmatic, should therefore be capable of informing future planning, setting standards and influencing policy. Stakeholders, patients and the public will be actively engaged at every stage to ensure the applicability and usability of interim and final results. This approach will allow for a highly integrated analysis and robust policy recommendations which are applicable at national, hospital and frontline team level.

Development of the theoretical framework will be ongoing during the course of the project.

4. Research question/aim(s)

The overarching aim is to identify the models of medical generalism used in smaller hospitals and explore their strengths and weaknesses from patient, professional and service perspectives.

4.1. Objectives

1. To create a typology of the different models, considering workforce deployment, skills mix and service configuration, of generalist and specialist care used in smaller hospitals
2. To create a case mix classification that identifies patients which may benefit from generalist care and use this to describe and compare workload, resource utilisation and outcomes between hospitals and models of care
3. To assess the degree of alignment between patient case mix and medical generalist/skills mix in smaller hospitals
4. To identify the strengths and weaknesses of the different models from patient, professional and service perspectives
5. To investigate the economic costs attached to different models
6. To assess the types, utility and relevance of potential variables and measures of outcome for a more detailed evaluation of the different models of medical generalism
7. To explore the different meanings, definitions and boundaries of medical generalism in the context of smaller hospitals

4.2. Outcomes

The study's five interlinking work packages will address the different aims outlined above, with specific outcomes and outputs for each package:

- Work Package 1 will explore the boundaries between specialist and generalist care and capture the characteristics and skills mix of the medical workforce to create a **typology of models of medical generalism**.
- Work Package 2 will create and test a **classification of patients that might benefit from general medical care**. The classification will be used to separate the workloads of smaller hospitals into generalist and specialist and to provide a **descriptive analysis of hospital workload**.
- Work Package 3 will carry out a detailed **economic analysis** of the economic costs of the different identified models of generalist care.
- Work Package 4 will explore the **strengths and weaknesses of the different models of generalism** from patient, professional and service perspectives.
- Work Package 5 will draw together all results and outcomes from the other work packages and provide an overarching **analysis and synthesis**.

5. Study design and methods of data collection and data analysis

We will use a mixed methods approach, with the construction of a framework that combines both induction (data-driven generalisation) and deduction (theory-driven exploration of hypotheses).

The overall approach to analysis will be dynamic and iterative, allowing each stage of the study to inform the next. This approach will allow for a highly integrated analysis and for robust policy recommendations which are applicable at national, hospital and frontline team level.

This study will focus on smaller NHS hospitals in England, according to Monitor's definition of 'smaller' providers as having an operating revenue (income) under £300 million in the financial year 2012/2013. We identified 75 out of the 142 general acute NHS trusts that fit into this category.

5.1. Project set up

1. A seminar will be held to launch the study
2. Stakeholder workshops – there will be two stakeholder workshops throughout the project:
   a) A first workshop held to engage with key policy makers and begin to explore theoretical concepts and themes relating to medical generalism. Attendees will include representatives from key stakeholder organisations.

      The first workshop will be aimed at developing shared understandings of concepts, exploring assumptions that underpin models of care and drivers of change and identify gaps in knowledge.

   b) The second workshop will present the key study findings so that the audience can 'sense check' the accuracy and utility of the research and maximise its relevance at clinical, managerial and policy levels.

Agendas will be set and allocated group work will be facilitated by Nuffield Trust staff to discuss topics and complete tasks. Whole group discussions will be moderated by Nigel Edwards, Chief Executive at the Nuffield Trust.

3. A patient and public involvement (PPI) Open Space event

These planned events will be used to inform the theoretical aspects of the study. .

Each Work Package (WP) will use different, but complementary data collection methods:

WP1: Describing Models of Medical Generalism in Smaller Hospitals

WP1 will be led by Candace Imison (CI), supported by Louella Vaughan (LV). Silvia Machaqueiro (SFM) has been identified as a mixed methods researcher to assist with this WP. Additional experienced Nuffield Trust research staff will be internally seconded to assist with the fieldwork. Expertise on workforce skills mix will be provided by Anne Marie Rafferty (AMR). Expertise on acute medical care will be provided by Derek Bell (DB). Expertise on medical generalism will be provided by Andrew Goddard (AG). LV, CI, AMR and DB will all help to oversee the site visits. Skills for Health will provide expertise on medical rostering.

1. Aims

The aims of the WP1 are to:

a) Describe and explore the specialist and generalist medical workforce, their roles, skills mix and clinical responsibilities. Of interest will be the definitions of and boundaries between specialist and generalist care.

b) To create and refine a typology of the models of medical generalism used.

2. Overall Design

This work package will draw on the experience of the research team with the RN4CAST, RCPL consultant working and workforce surveys and Nuffield Trust work on models of care. From publicly available sources we will generate a high level profile of all the smaller trusts in England, including their medical workforce. An overview of the dominant models of acute medical care will be obtained through the New Cavendish Group (NCG), which includes 25 (33%) Chief Executive Officers (CEOs) of smaller hospitals, allowing us to develop a preliminary typology. This will then be tested with a convened expert group. We will then undertake an online survey of the medical leads in all the other (50 – 67%) smaller trusts in England (i.e. those not within the New Cavendish Group). This will allow us to test the typology and categorise a significant proportion of all trusts according to the typology. Site visits will be undertaken in 12-15 hospitals – purposively sampled to be representative of the different models of care within the typology, as well as different organisational and geographical contexts. The site visits will explore care processes and workforce skills mix in more depth as well as the hospital workforce strategy and staff and patient attitudes. The finalised typology will inform the analyses in WP2-5. A descriptive analysis of the medical workforce of smaller hospitals will be undertaken.

3. Organisational Profiles

Organisational profiles for all of the smaller trusts (n=75) will be generated from a combination of publically available data (such as Trust annual reports and Care Quality Commission (CQC) reports) and hospital-level data collected by organisations such as Monitor and the Health and Social Care Information Centre (HSCIC). The profile in combination with the findings of the surveys will be used to control analyses for differences at institutional level and aid site selection for the case studies.

Data will include:

- General hospital characteristics, such as operating revenues (‘smaller’ vs ‘smallest’), bed numbers, teaching status
- Geographical factors, such as rurality, coastal location, distance from next nearest emergency department
- External indicators of care quality, such as CQC inspection ratings
- Specialist service profile - presence of high-level medical services (e.g. Hyper-acute stroke unit, primary coronary angioplasty, intensive care and dialysis)
- Workforce data - consultant staffing by specialty, junior doctor and nurse staffing.

4. Preliminary Development of Typology with the New Cavendish Group

A telephone survey will be undertaken of all the 25 smaller trusts within the New Cavendish Group. The survey will obtain the following information.

a) Hospital medical department characteristics, such as the presence or absence of an AMU and/or short-stay wards; the distribution and type of beds in all medical wards.

b) Construction of the acute medical take during day, night and weekend and levels of consultant and junior doctor commitment (by specialty).

c) Local definitions of which patients are considered to need general medical care will be explored, as well as decisions around triage of patients from the A&E to the AMU (if present), and from there to downstream wards.

d) Networking arrangements with other hospitals, both in terms of medical staff working across multiple sites and provision of urgent services to patients

e) Others factors which are considered to impact on the quality and safety of acute medical care, such as multi-disciplinary teams, advanced nurse practitioners, ambulatory care services, outreach/hospital-at-home services.

Using this information we will develop the key staffing and service dimensions of our typology. This early framework will be tested with our expert group before framing our online survey (see below). Permission for Trusts to participate in the study will be obtained directly from the CEOs, all of whom regularly attend meetings of the New Cavendish Group and have previously agreed to support the study. The CEOs will be asked to nominate a contact person, likely to be the Clinical Lead for Medicine. The telephone interviews will be contacted at a time convenient for the nominated person and should not take longer than 20 minutes.

Analysis of the survey will occur as described in point 6 below.

5. Online Survey of Smaller Trusts

We will undertake an online survey of 50 trusts. If we have a 50% response rate (in addition to the trusts in the NCG) this would give a total sample of 67.7% of the 75 small trusts in England for which we will have extended data and a capacity to categorise according to our preliminary typology.

5.1. Site Inclusion and Exclusion Criteria

Inclusion Criteria:

- NHS Trust providing acute medical care in England
- Operating revenue <£300 M in 2012/13

Hospital Exclusion Criteria:

- In trusts with multiple sites, hospitals which provide maternal or paediatric care only
- Trusts that are part of the New Cavendish Group

5.2. Survey

The survey will obtain the following information:

a) How the acute medical take is constructed during the day, night and weekend – levels of consultant and junior doctor commitment (by specialty). Options will be given, based on our emerging typology

b) Local definitions of which patients are considered to need general medical care. Options will be given, based on our emerging typology

c) Hospital medical department characteristics, such as the presence or absence of an AMU and/or short-stay wards; the distribution and type of beds in all medical wards.

d) How decisions around triage of patients from the A&E to the AMU (if present), and from there to downstream wards. Options will be given, based on our emerging typology

e) Networking arrangements with other hospitals, both in terms of medical staff working across multiple sites and provision of urgent services to patients

f) Others factors which are considered to impact on the quality and safety of acute medical care, such as the presence of multi-disciplinary teams, advanced nurse practitioners, ambulatory care services, outreach/hospital-at-home services.

The Chief Executive Officers (CEOs) of all smaller hospitals that are not members of the New Cavendish Group will be approached for participation in the study, using a standard protocol, using a combination of letter and email61 Consenting CEOs will be asked to nominate an appropriate contact person, likely to be the Clinical Lead for Medicine, Where Trusts consist of more than one site, contacts will be requested for each site. Where no nomination is received with two weeks, a reminder letter will be sent and after a further two weeks the personal assistants of non-responding CEOs will be telephoned to solicit a response. The nominated person(s) will be approached for consent to participate, by their preferred means (phone or email) to further explain the study and obtain consent. If the nominated contact declines to participate, an alternative contact will be sought via further contact with the CEO.

Responding contacts will be sent electronic invitations to the complete the survey within two weeks.

The survey will be hosted on a commercial site called Survey Monkey® (http://surveymonkey.com). Survey Monkey is secure and responses are collected in a way that preserves respondent confidentiality. Automatic email reminders will be sent to non-responding contacts by the Survey Monkey system after two weeks. Contacts who still have not responded to the survey after a further two weeks will be telephoned by the study administrator and the reason for non-completion sought and recorded. Where possible, any difficulty with completion (such as a technical problem) will be addressed and the contact encouraged to complete the survey. Contacts who have still not started the survey two weeks after this will be classed as non-responders and no further attempt will be made to solicit their participation. Contacts who have part-completed the survey will be telephoned once by a member of the team and encouraged to complete the remaining questions.

Telephone follow-up will be conducted to clarify missing or potentially inaccurate data where appropriate.

6. Finalising the Typology

The final typology will be derived from three components:

a) Preliminary exploration of the dominant models of care through the New Cavendish Group

b) Survey of smaller hospitals

c) Creation of organisational profiles

In order to construct the typology,[93] the literature will be reviewed and set against the study theoretical models of medical generalism. Important conceptual categories will be defined. Preliminary analyses of the raw hospital-specific datasets derived from the three components will be performed iteratively. Conflicting results and missing values will be identified and correction of data entry errors will be performed. Telephone follow-up will be conducted to clarify missing or potentially inaccurate data where appropriate. A clean version of the different data sources will be organized in an inter-related multilevel meta-database. Empirical variables will be scanned, looking for differences between hospitals, with a view of creating a hierarchy of key categories. These theoretical and empirical categories will be combined into a framework, which will be used to first construct and then classify models of generalist care in smaller hospitals.

7. Case Studies: Investigating the Typology

As outlined above, data from 5, 6 and 7 will be used to iteratively construct the typology. Exemplars of models of care and outlier sites will be purposively sampled for each of the two rounds of fieldwork, based on the emerging typology. Interviews, site visits, Day of Care Survey (DCS) and document review will be used to clarify definitions, care processes and workforce skills mix.

Two to three service user researchers (SURs) will be recruited and trained. They will join the team for the site visits and interviews. SURs identify different perspectives, insights and priorities to professional staff and can add value to ethnographic data collection.94 Bespoke training will be created for the SURs, which will be supported by the RCP, NWL CLAHRC and the Nuffield Trust. Training will be underpinned by INVOLVE material and will cover: the roles and tasks of the SURs; assessing skills and learning needs; understanding accountability and research governance; specific research methods and techniques. For the site visits, the SURs will accompany a member of the Research Team. For the observational work, they will shadow the researcher and then reflect with the researcher on their findings, which will be included in the field notes. The SURs will be encouraged to take their own notes, which will be analysed independently as part of the collective field data. When interviews are taken with a SUR present, they will be encouraged to lead on topics relating to patients.

7.1. Sampling Strategy

It is expected that the typology will identify 4-5 different models of medical generalism. 12-15 trusts will be selected, using a purposive sampling strategy. Selected sites will represent each model in the typology, as well as any outliers. This will take place over two rounds – the first after the work with the NCG and the second after the completion of the online survey. It is expected that the first round will explore the more common models, with ease of access (CEOs of the NCG being aware and supportive of the study), while the second will focus more on outlier models. We will seek to achieve an even geographical representation (urban vs rural) and an even representation of the ‘small’ and ‘smallest’ sites. Any other factors which emerge as important in the literature review and creation of the typology may also be included as variables in the sampling strategy.

The nominated contact at each hospital will be asked to confirm participation and then provide the names of key members of staff involved in the Department of Medicine (or equivalent). Although this will vary from site to site, this may include: Director of Medicine, Clinical Director of Medicine, AMU clinical lead, Specialties clinical lead, a members of the senior management team, a senior nurse, a member of the organisation's board. Contacts will also be asked to identify one to two staff members (ideally middle medical or senior nursing staff) to conduct the DCS. These people will be approached to further explain the study, respond to any queries, obtain consent to participate in the interviews and arrange suitable times. In the case that any person declines consent, a suitable alternative will be sought. Approval from Trust Research and Development Offices will be sought prior to site visits and interviews commencing.

7.2. Site Visits and Day of Care Survey

Each hospital site will be visited over 1-2 days by two team members and a lay researcher (when available). Consent will be sought for researchers to attend meetings, interview staff and map patient trajectories. The team have experience in gaining ethical consent for this and in conducting observations sensitively. Patients and staff will be given the opportunity to verbally opt out of any observations (see section 7.3, 'Consent'). All staff contacts will be asked for their email addresses and permission to be included in the discrete choice experiment in WP5. The site visits will also give an opportunity to explore local workforce development strategies of the organisation with regard to medical staffing and appointments; the practice environment and organisational stability, which will draw on tools with a high predictive value for workforce stability and quality of care.

Particular attention will be given during the general site visit to:

a) Geographical layout of the hospital and medical services

b) Overview of patient trajectories across boundaries, such as emergency departments, acute medical units/acute admission ward, general wards and critical care

c) Attendance at a patient triage or handover meeting

d) Ensuring that observed patient trajectories match descriptions of processes of care in the surveys and interviews (see below)

An adapted Day of Care Survey (DCS) will be conducted at each site.[95] The DCS is a validated tool that consists of 12 'severity of illness' variables and 16 'service intensity' variables to identify appropriateness of inpatient care using ward visits, case records and bedside charts. Training in using DCS takes 15 minutes and review of a whole hospital takes 1-2 hours to complete. The tool will be adapted to identify whether a patient is a 'general medical' or 'specialty' patient. The results of the DCS will be compared with speciality of the patient's named consultant and the ward in which they are located. At each site, the nominated staff member(s) will be briefed on the use of the DCS tool; data will be captured anonymously. Each staff member will be accompanied by a researcher, who will oversee the conduct of the DCS, provide guidance and ensure consistency. The overall results will help to determine whether the care provided matches the descriptions of processes of care given by hospital staff.

It should be noted that patients will not be the specific focus of any observations. However, as key decisions around types of care are sometimes made in the presence of patients and their carers, such

as the bedside or during ward rounds, researchers will witness interactions between staff and patients. In these circumstances and where otherwise appropriate, patients/carers will be informed of the presence of the researcher and asked if they are happy for the researcher to be present. If the answer is no, the researcher will withdraw and rejoin staff at the earliest opportunity.

7.3. Interviews

Three to five interviews with key members of staff (as identified above) will be conducted as part of the site visits. Where staff are not available, telephone interviews will be conducted at a later time.

Interviews will be based on review of the typology and organisational profile, with a view to identifying key topics and important issues to be explored in semi-structured interviews. Particular attention will be given to:

a) Numbers and types of doctors contributing to the management of the acute take, ward-based care, procedural work and outpatients. Where non-medical staff have extended roles, these will also be documented.

b) Local definitions and systems used to triage patients during inpatient stays;

c) Organisational workforce strategy and rationale behind recent new medical consultant appointments (if any);

d) Perceived tensions between generalist and specialist workloads (i.e. acute take versus urgent outpatient waiting times);

e) Local networking arrangements (particularly when a trust consists of more than one hospital site)

f) Exploration of how and why the current service model was implemented;

g) Experiences of facilitators and barriers to implementing change to service models.

All interviewees will be asked to sign a written consent. When telephone interviews are conducted, we will consider explicit email agreement as being the equivalent of signed consent; informal consent will be sought again at the start of the telephone interview. All interviews will be digitally recorded.

7.4. Document Review

Hospitals will be asked to provide key documents for analysis. This is likely to include:

a) Consultant and middle-grade rosters, including those for acute take and speciality on-call

b) Representative consultant job plans

c) Standard operating procedures where triage of patients is included, such as those for the AMU

d) Minutes of meetings where organisational workforce strategy has been decided

7.5. Analysis and Typology Refinement

Field notes, interview and focus group data will be transcribed verbatim and organised using NVivo 10. The DCS will be analysed according to methods described elsewhere.[95] All other qualitative data, such as from the stakeholder workshops, will be similarly organised and a database constructed. Key topics and issues emerging from the qualitative data will be identified through familiarisation with the

data, as well as reference to the original theoretical framework and objectives. Convergent and divergent evidence will be sought between data sources. A framework approach will be used to chart and analyse data and guide the identification of key themes and examples.96 Outcomes and other key findings will also be charted and used to triangulate findings. This allows for an iterative process of analysis, which will allow for topic guides for interviews and questions/areas of interest for other aspects of the qualitative study to be updated continuously. It will also enable identification of the salient factors of the different models of care, as well the continuous refinement of the underpinning theoretical models of medical generalism. Preliminary analysis of data will be undertaken by the mixed methods researcher (SFM), assisted by Nuffield Trust staff. Secondary analysis will be led by LV, with assistance from CI and AMR. Care will be taken to ensure that the conduct of fieldwork and analysis of data is consistently and reliably performed. As two members of the team will visit each site, disagreements will be settled by consensus. Inter-rater reliability of the indexing of the data will be assessed. Service users will support the analysis, providing feedback and sense checks for validity.

8. Typology Testing

An expert consensus group, drawn from the research team, Study Steering Committee (SSC) and relevant professional bodies, will be convened. The expert group will be used on two occasions – the first after the construction of the preliminary typology based on work with the NCG and the second following the completion of the case studies. In each, the group will be presented with anonymised sets of results and the constructed typology. The group will make a qualitative assessment of the final typologies and their generalisability.

9. Descriptive Analysis of Workforce

A descriptive analysis of the workforce data obtained throughout WP1 will be undertaken. This will explore the balance between:

a) Generalist and specialist physician staff and their duties

b) The different physician specialities for the management of acute take, ward-based care, procedural work and outpatients

WP2: Understanding the Case Mix of Generalist Medical Care in Smaller Hospitals

WP2 will be led by Martin Bardsley (MB). MB will be assisted by Dr Paul Smith and Dr Liz Fisher, both Senior Analysts at the Nuffield Trust.

1. Aims

The aims of WP2 are to:

a) Create a classification of patients that might benefit from general medical care

b) Based on the classification, provide a descriptive analysis of the workloads of smaller hospitals

2. Overall Design

This work package will draw on the experience of the research in using novel methods to analyse data from Health and Social Care Information Centre Hospital Episode Statistics (HES). A classification of patients that might benefit from general medical care will be created, based on Healthcare Resource

Group (HRG), primary diagnosis, chronic condition flags and multiple morbidities. The classification will be tested with an expert consensus group before being used to separate the workload of smaller hospitals into specialist and generalist, based on HES data. A descriptive analysis of the workloads of smaller hospitals in terms of activity and resource utilisation will be undertaken.

3. Approach

In order to compare different service models, account needs to be taken of possible differences in the types of patients treated. There are a range of case mix descriptors that have been applied in UK hospital settings, ranging from classifications of disease[97] or procedures to more complex approaches that use a range of patient-level variables to identify homogenous patient groups, such HRGs,[98] Adjusted Clinical Groups,[99] or various risk-scoring methods, such Euroscore,[100] APACHE,101 Charlson,[102] or models to predict hospital admission.[103]

For this study, patients need to be grouped in ways that are representative of workload in generalist medical care. Information from HES will be used as the basis for the analysis. The HES dataset records individual episodes of care that can be linked into spells of admission and longer patient histories. The ability to link over time means that the analysis can exploit information about prior hospital activity before an admission spell and to track subsequent events, such as readmission. The Nuffield Trust has considerable experience in using linked HES datasets and will extend its current agreements with Health and Social Care Information Centre to use the HES data it already holds. Permission will be sought to use Office of National Statistics linked mortality data, which will allow investigation of mortality out of hospital. The work will be undertaken in four stages.

4. Stage 1: Create a Classification

Exploratory analyses of diagnostic/specialty codes will be performed to produce candidate case mix classifications. The classification will draw on the theoretical model, outcomes from the stakeholder workshop and a range of existing classification schemes, as well as markers of specific chronic problems and multiple morbidities.

The analysis will start by identifying ‘index episodes of care’, looking for emergency admissions for medical specialities, in the age range >18 yo. Using HES from 2010/11-2015/16 we will create an initial data file consisting of hospital spells indicated as emergency admissions (admission code 21-28) and for medical specialties.[103,104] Records will be excluded where:

- Discharge status indicates transfer to another hospital within 2 days of admission
- Specialist care – as identified by NHS England coding scheme for national and regionally funded care. Count of remaining and excluded case types will be shared with clinical staff to test for validity.

We will cross tabulate 3 digit (ICD 10) diagnostic code by specialty code to assess how cases fall in specific cells and so see which cells map best to the general medical caseload. These will be used to identify broad screening criteria and used to create a specification which enables us to identify patients experiencing relevant episodes of care linked to an index admission event. We can then create a data set at patient-level capturing information about the index admission as well as prior and subsequent hospital activity.

The patient level data sets will be used in creating and testing classifications. The different groups will be explored empirically and tested for homogeneity in resource use using bed days. We will aim to develop groupings that minimise within group variability, yet make some clinical sense.

A set of variables will be created for each index event that summarises for that patient:

a) Current and previous diagnoses
b) Previous admission events typically in the form of numbers of hospital attendances (A&E, Inpatient, Outpatients within a given time frame
c) Numbers of episodes per spell, and generated variables indicating transfers between specialty and complexity treatment
d) Age, gender and ethnicity
e) Deprivation of area of residence based on IMD of lower super output area
f) Treatment specialty
g) Any procedure codes
h) Discharge status (alive, died, transferred)
i) Lengths of stay
j) Provider hospital and hospital type.

The tools for constructing these variables have been previously applied at the Nuffield Trust in work developing and validating prognostic models based on HES data as well as in evaluative studies.[103,104]

We will use clinical advice to explore some simple hierarchies within the data to test for common groupings We will also test the utility of clustering algorithms in SAS and regression trees as a starting point to generating initial groupings. We wish to identify groups (<50) that are mutually exclusive and exhaustive and with sufficient cases in each to generate meaningful analysis. The statistical performance of the grouping will be assessed by looking at the variability in mean length of stay (as measured by analysis of variance – within group sums of squares) using log transformed or trimmed values. Groups will also be tested for similarity on other variables – in particular discharge destination and prior health history.

5. Stage 2: Test Classification with Professional Consensus Group

In addition to satisfying certain statistical criteria, it is important that the groups make clinical sense and imply a broadly similar treatment or service response. We propose creating a panel of expert clinicians (n=10) to review the possible emerging case mix groups using a combination of virtual and face to face meetings. An iterative process would be used, with the group's input refining and adapting the emerging classification scheme. Where possible, we would use clinicians from hospitals involved in the study.

We will select clinicians opportunistically but seek to cover individuals working covering a range of hospital size and type. We would first generate initial comments on the candidate groups in terms of their comprehensiveness and ability to capture key subsets of patients. In addition we would probe for specific views on the utility of individual case types. We propose conducting the first survey through

email contact and then following up with selected meetings to explore the feedback we have received and possible changes.

6. Stage 3: Separating the Workloads of Smaller Hospitals

The agreed classification would then be use to separate the workload of smaller hospitals into specialist and generalist, based on HES data. The classification would be applied to hospital activity over from 2010 to 2016 in all acute hospitals in England.

Hospitals would be classed into groups according to teaching status, operating revenue, number of beds and whether in urban /rural locations. We will analyse data over consecutive years by hospital to test whether the groupings are reasonably consistent over time and work across a range of hospital types. We will also look at the consistency of treatment specialities for the case types across hospitals. One test will be to look at the frequency of case types relative to the resident population, the aim being to identify groups that are not unduly influenced by individual providers but exhibit stable admission rates within a population. Therefore, age and sex (and optionally deprivation) standardised admission rates by local authority populations will be estimated.

During this stage we would apply the case mix classifications to national data sets to calculate the numbers of cases of each case type for each acute hospital in the country. Hospitals will be characterised in terms their size, revenue and the classification as generalist or specialist.

We will also estimate case mix specific admission rates based on recorded area of residence initially defined in terms of 152 local authority areas. For each local authority we will calculate specific age/sex/deprivation adjusted admission rates for the case types.

These data sets will be used to assess a number of questions and specifically to test for differences associated with hospital types:

a) Is the case mix profile for a given hospital stable over time? This will involve simple Chi-squared test to compare distributions plus identification of any outlying or atypical groups.

b) Are characteristics of the hospital associated with specific patterns of case mix?

c) Do hospitals vary in the treatment specialties associated with each case mix group?

d) Are case-mix specific admission rates stable over time?

e) Are differences in area-based admission rates linked with individual providers? To do this we will use person-level models and include variables representing individual hospitals

7. Stage 4: Linking Case Mix and Descriptive Analysis of Smaller Hospitals

A descriptive analysis of workload of smaller hospitals in terms of activity and resource utilisation will be undertaken. The case mix descriptor will be tested against more detailed information about the structure and organisation of medical generalists within the hospitals obtained in WP1. We will aim to see the extent to which case types differ within and between hospital types and models of generalist care. In addition, a descriptive analysis of the typical patterns of bed use by case mix group will be undertaken.

This will mean estimating for each hospital subtype and each case type: the numbers of cases, length of stay (mean, median and measures of the distribution), readmission rates (at 30 days and 12 months), survival (30 days and 12 months).

This data will be used to provide specific profiles for each hospital in our detailed study and will provide the means to test specific hypotheses to identify cases types associated with specific models of care.

WP3: Investigating the Economic Costs

WP3 will be led by Steve Morris. He will oversee a Research Associate in Health Economics (to be appointed).

1. Aims

The aims of WP3 are to:

a) Calculate the aggregate costs of different staffing models (hospital level analysis)

b) Investigate the impact of staffing model on patient-level costs (patient level analysis)

2. Design

Hospital level analysis: We will calculate the total staffing costs per year in smaller hospitals of England and explore the association of these costs with staffing model and organisational characteristics.

Patient level analysis: We will calculate patient level cost-weighted activity figures based on HES data and local tariffs, and analyse the association between patient level costs and staffing model controlling for organisational and patient level factors.

3. Data collection

Hospital level analysis: data on numbers, roles and skill-mix of medical staff will be collected via the survey of smaller hospitals in WP1. Annual costs for 2014/15 of delivering care using different staffing models will be calculated as the sum of the cost of each staff input, computed by multiplying time allocation by NHS unit costs.[106] Resulting costs will be validated against Trust annual reports. We will assemble a hospital-level dataset of aggregate staffing costs, total income and expenditure, and organisational characteristics (general hospital characteristics, geographical factors, hospital medical department characteristics, networking arrangements and other factors that may be related to hospital level costs), with the latter taken from the organisational profiles assembled during WP1.

Patient level analysis: We will use the patient-level HES data assembled during WP2 for all patients treated in smaller hospitals in England in 2014/15. Patient level treatment costs will be calculated from HES records on admitted patient length of hospital stay, readmissions, outpatient visits, plus services received. Unit costs will be assigned to each item of resource use[107] to calculate total costs per patient. We will then assemble a multilevel dataset of patients nested within hospitals including total costs per patient, diagnostic codes, age, gender, admission source, staffing model and hospital organisational characteristics as described above.

4. Data analysis

Hospital level analysis: we expect to assemble a dataset comprising approximately 75 hospitals. We will undertake exploratory analyses of the impact of staffing model on hospital costs tabulating staff costs against staffing models. We will run cross-sectional simple regression models to investigate the association between overall staffing costs and staffing model controlling for organisational factors. The use of observational data and small sample size will limit the ability to draw causal inferences.

Patient level analysis: we will regress patient level costs against staffing typology controlling for patient and organisational characteristics. Our preferred model to account for skewness of the cost data is to use a generalised linear model with gamma family and log link.[108] To be able to draw useful inferences the analysis relies on the representativeness of the survey. We will compare the characteristics of smaller hospitals who responded to the survey to all smaller hospitals extracts to investigate systematic differences between responders and non-responders, e.g., whether non-responders have different patient case-mixes, provide a different range of activities, or have different organisational characteristics. Where systematic differences are identified we will use selection models (e.g., based on Heckman[109]) in our regression analyses using the survey data to account for the propensity of participating in the survey.

WP4: Understanding the Strengths and Weaknesses of Current Models of Medical Generalism

WP4 will be led by LV, supported by CI. The discrete choice experiment will be led by SM. Analysis of patient-related outcomes will be led by MB. Expertise on workforce skills mix will be provided by AMR. Expertise on acute medical care will be provided by DB. Expertise on medical generalism will be provided by AG.

1. Aims

The aim of WP4 is to understand the strengths and weaknesses of the current models of medical generalism from patient, professional and service perspectives

2. Overall Design

The strengths and weaknesses of the current models of medical generalism from patient, professional and service perspectives will be gathered using a number of different mechanisms. Focus groups will be used to explore the lived experiences of patients and staff with models of care. A discrete choice experiment will be conducted to examine and quantify the relative importance of the different attributes of the models of medical generalism and the preferences of patients and healthcare and managerial professionals. The variability in case mix, skills mix and the alignment between these in different hospitals will be assessed using an expert reference panel. Appropriate outcomes, such as adjusted mortality and adverse events, will be identified. Sensitivity testing of these will be performed against the different models of care and the degrees of alignment between case mix and medical skills mix.

3. Patient, Carer and Healthcare Professional Focus Groups

In order to gain an in-depth understanding how healthcare professionals and patient/carer representatives experience the model of care in their hospital, we will conduct a series of focus groups.

3.1. Patient and Carer Focus Groups – Selection and Recruitment

In order to capture patient and carer experiences in each model of care, patient/carer focus groups will form part of the site visits in WP1. The Research Team will be visiting two hospitals that represent each model of care in the typology; the hospital which is 'most typical' of the other hospitals that have the same model of care will be sampled for the focus groups. Focus groups will also be held in hospitals with outlier models of care that are of interest. This will make a total of 6-8 focus groups, as we expect 4-5 different models of care and 1-2 outlier models of interest. Each patient focus group will have 6-8 participants and will be conducted, where possible, on hospital sites. Patient and carer representatives will be recruited from local Healthwatch organisations and local hospital volunteer organisations, including those supporting carers. We will also disseminate appropriate advertising materials via the participating hospitals through channels such as leaflets and posters, the hospital website and via contact with the patient governors.

3.2. Professional Focus Groups – Selection and Recruitment

Although senior health care staff almost universally will have experience of more than one model of medical generalism, we will still conduct these as part of the site visits alongside the patient and carer focus groups. Contacts at each hospital will be asked to nominate a range of healthcare professionals, including senior and middle-grade doctors, senior nurses and managers. Invitations will be sent ahead of the site visits. The focus groups will be conducted either at lunchtime or in the late afternoon in order to facilitate attendance. Based on previous experience, we expect a group size of 8-12 participants at each site.

3.3. Conduct of Focus Groups

The focus groups will be moderated by members of the Research Team who have received appropriate training. A second team member will record the orders of the speakers and non-verbal communications. Participants will be asked to sign formal consent prior to the start of the group.

Different approaches will be used for the patient/carer and staff focus groups. Patients/carers will be first encouraged to discuss their experiences of care in their hospital and then the degree to which the model of care was perceived to meet their needs will be explored. A discussion about whether different types of care (generalist versus specialist) might have led to different outcomes will be facilitated. Staff groups will be more structured. Professionals will be encouraged to discuss their experiences of providing care in their hospital and to consider the benefits and weaknesses of their service from professional, patient and service perspectives. The competing demands of generalist and specialist work and the boundaries between these will be explored. The group will then be presented with the typology and given more information about their model of care in comparison with others. A facilitated discussion will then attempt to tease out whether the perceived strengths and weaknesses of working in that particular hospital is a function of the model of care or other aspects of the organisation.

3.4. Analysis of Focus Groups

An iterative approach to focus group data collection and analysis will be taken. Groups will be recorded and transcribed verbatim. Analysis will be performed as described in WP1 (see section 8, 'Typology testing').

4. Assessment of Alignment between Case Mix and Skills Mix

In order to explore whether hospitals are appropriately staffing to meet patient need, an initial analysis of the variability in case mix, skills mix and staffing levels will be performed. The degree of alignment between these will be then be assessed. All Trusts will then be graded along a spectrum of whole/partial/no alignment. This will be set against the models of generalism to explore whether certain models facilitate better alignment. Trusts which represent the outcomes across the spectrum of alignment will be selected and their data anonymised for presentation to an expert consensus group, drawn from the research team, Study Steering Committee and relevant professional bodies and stakeholders. A two-stage Delphi-style process will be used, with members of the consensus group asked to individually grade each case. Results will be aggregated and then presented back to the group before a second round of grading and the establishment of a final consensus.

5. Exploratory Analysis of Patient-Related Outcomes

For this analysis we are proposing initially testing six outcome measures:

a) Mortality – survival in hospital and out of hospital

b) Differential mortality at weekend.

c) Readmissions within 30 days and 360 days

d) Readmissions for a specific diagnosis indicative of complications in the index episode

e) Length of stay beyond normal expectations. We would test either HRG level trim points or create specific trim points for our defined case mix groups (based on either statistical criteria and/or professional judgement).

f) Hospital free survival i.e. for how long patients survive without being admitted to hospital

g) Annualised hospital expenditure per patient after index event

For each of these we will:

a) Develop or apply an appropriate risk stratification model – using established models where they exist 114,115 or if needed develop models de novo based on patient level variables from prior (current) hospital episodes and use all hospitals.

b) Estimate risk adjusted outcomes for small hospitals and test the distributions to see whether the predictive power of the risk models are able to differentiate for sample sizes seen in smaller hospitals

c) Examine the probability of observed differences by hospital subtype:

- Are there significant differences between hospitals?
- Are there significant differences between types of care models?

We will also explore whether any natural experiments resulting from changes in care models could be used for testing change over time.

6. Discrete Choice Experiment

Design: We will conduct a discrete choice experiment (DCE)[110] to examine preferences between different workforce models in small hospitals. This will quantify the preferences of health professionals

(doctors, nurses, professions allied to medicine) and patients and carers, for different workforce models, the relative importance of different attributes of these models, and how preferences vary between different stakeholders. The DCE will follow international best-practice guidelines.[111]

Data collection: The DCE will include a nationally representative sample from each group, based on age, gender and region, plus specialty and experience in the case of health professionals, and diagnosis in the case of patients. Sample size calculations for DCEs are not straightforward but depend on the question format, the complexity of the choice tasks, the desired precision of the results, the degree of heterogeneity in the target population, the availability of respondents, and the need to conduct subgroup analyses. A sample size of 300 is commonly recommended.[112] We will aim for a minimum of 500 doctors, 100 patients and 50 managers. We will invite registration of interest from: participants in other parts of the study; via professional organisations, such as the Royal College of Physicians; via patient and carer networks and organisations.

We will establish preferences for the scenarios included in the analysis by asking respondents to complete a DCE survey. The survey will be designed as follows:

6.1. Stage 1: Identify key attributes for different models of medical generalism using the typology developed during WP1

Attributes will be constructed to capture the difference between the different models of medical generalism. These will be derived from multiple sources, including outcomes from WP1-3 and early analyses of other components of WP4; the emerging theoretical framework and the literature review. It is likely to include some or all of the following:

- Continuity of care throughout the care pathway
- Ease of access
- Impact on outcomes
- Knowledge beyond immediate medical needs of patient
- Extent of expertise in specific medical needs of patient
- Training requirements
- Staff costs and costs of care

The final list of attributes to be included in the analysis will be derived from two focus groups, each with five patients and five health professionals.

6.2. Stage 2: Assign levels to these attributes based on feasible ranges derived from systematic literature reviews, from the quantitative data collected during the survey in WP1, and the descriptive analysis of workload in WP2

6.3. Stage 3: Design the DCE questionnaire

At this stage we propose to use a pairwise choice framework and will compile a set of pairwise scenarios that describe the feasible combinations of levels and attributes of specialist versus generalist workforce models. The number of pairwise choices will be reduced to a practical number for participants to answer using an orthogonal fractional main effects design.[113]

6.4. Stage 4: Collect DCE results

Survey data will be collected by a mixture of online survey (Survey Monkey) and hard-copy postal questionnaires from the two stakeholder groups, depending on respondent preference. To elicit responses from health professionals, we will distribute the survey via the RCPL. Managers will be reached through the Nuffield Trust. To contact patients and carers, we will use the approach as described as above. Surveys will also be distributed to all staff who gave their contact details during the course of the site visits as above.

Data analysis: The DCE will allow estimation of the preferences held in pre-defined populations and the weighting of the relative value attached to attributes determining these preferences. It will also provide an indication of people's willingness to trade between attributes. We will analyse preference data using conditional logit regression analysis. The results will indicate which attribute is most important to respondents and how this compares with the other attributes. Data will be analysed for all respondents jointly and separately for each of the three subgroups.

To explore the trade-offs participants were willing to make between attributes we will calculate the marginal rates of substitution. We will also use the regression results to calculate the predicted probability that different combinations of the attribute levels used in the experiment would be selected. This allows us to rank different workforce models of their order of preference by the participants,[114] and to explore how this ranking varies by sub-group.

WP5: Analysis and Synthesis

WP5 will be led by LV, supported by AMR and the mixed-methods researcher. All members of the research team will have input to the analysis and final preparation of study outcomes.

1. Aims

The aims of this work package are:

a) To synthesise the qualitative and quantitative data to identify how models of generalist medical care are developed, enacted and perceived;

b) To synthesise the qualitative and quantitative data on the relative strengths and weaknesses of the different models of care;

c) To identify key learning points for clinical staff, hospital managers and policy makers.

2. Approach

This study is a mixed methods design in which quantitative and qualitative methods are used sequentially to deepen understanding of models of medical generalism[121]. WP1 and WP2 will provide a basic investigation of the models of care used in smaller hospitals and the patients that they service. These will form the bases for WP3 and WP4, in which the economic costs and strengths and weaknesses of the models will be examined from multiple perspectives.

Congruent with our aims of understanding the perceptions, meaning and activities surrounding models of care, priority will be given to qualitative methods to explore the subtleties and meanings of medical generalism to organisations, boards, staff, patient and relatives and policy makers[122].

Our approach to data analysis will be to use a preliminary theoretical framework, based around concepts of generalism, rather than a purely grounded theory, and consider that data analysis is a combination of induction (data-driven generalisation) and deduction (theory-driven exploration of hypotheses). This approach has been used previously by the team in organisational research. We aim to understand at a deep level how smaller hospitals consider the relationship between models of care and patient outcomes, and how this is modified by the realities of delivering patient care.

Data analysis will initially take place within each work package[123]. After the completion of each work package, synthesis and integration of data will then occur, with the aim of merging data from different sources[124]. In order to ensure that the study's overall research questions are answered, and given that data from more than one work package will be required to answer each research question, a process of sense making and interpretation will be needed. We will therefore map the results of each work package to our research questions and integrate the results. Examination of the complementarity and disparity between datasets will be undertaken and will enable identification of patterns and interpretations not obvious when examining data separately[123]. We will narrativise each dataset to facilitate integration[125], and present qualitative and quantitative data in combined figures and tables to facilitate interpretation[126]. The interpretive process will be iterative and will be tested and validated in team meetings in which the emerging conclusions will be discussed with peers[127], through the New Cavendish Group, and other stakeholders to create a framework for the application of study findings and plan for systematic dissemination of results. Two stakeholder workshops will be additionally convened to widen stakeholder participation and ensure the applicability of interim results and the final study report. This approach will allow for a highly integrated analysis which is not only theoretically robust, but readily applicable and usable at policy, hospital and individual unit level.

It is expected that the case mix classification and economic modelling may be useful as tools to hospital trusts. These will be appropriately prepared and packaged.

This study will be partly exploratory in nature. It is currently unknown whether there are sufficient differences between the models of care used in smaller hospitals to allow robust comparison between models and standard patient outcomes (such as mortality and length of stay). It is also unknown whether standard patient outcomes are appropriate for measuring the impact of different types of care on outcomes. These constraints mean that full economic and patient outcome analyses are beyond the scope of this study. The relevant outcomes of these aspects of the study will be assessed by the research team and the Study Steering Committee with a view to deciding on the feasibility of a larger study.

6. Study setting

This study will focus on smaller NHS hospitals in England. Monitor has previously defined 'smaller' as providers with an operating revenue (income) under £300 million in the 2012/13 financial year.[84] Of the 142 general acute NHS trusts, 75 were found to fit into this category. It is appreciated that this approach may miss a number of smaller hospitals that sit within much larger trusts. However, the Monitor definition seems to capture virtually all single-hospital trusts, with trusts with operating revenues of <£300M having an average of 1.1 sites per trust and those >£300M having an average of 2.1 sites per trust.

Monitor additionally suggests that while there are many differences between smaller providers, they share more characteristics with each other than they do with larger trusts. However, Monitor noted that there were differences between 'smaller' trusts with operating revenues £200-300M and the 'smallest' with operating revenues <£200M, as well as between those in urban and rural settings. We will focus on recruiting the 'smallest' and rural hospitals, to ensure appropriate representation in the study.

7. Sample and recruitment

7.1. Eligibility Criteria

The focus of the study is on smaller hospitals in England, so that is our main eligibility criterion for hospitals participating in the study. This means we will likely have a sample of 75 organisations, which is the number of smaller acute care trusts identified in England.

The participants in each of the study's five working packages will be selected according to different eligibility criteria.

The inclusion and exclusion criteria are detailed below.

7.1.1. Inclusion criteria

Inclusion criteria for hospitals at whole study level:

- NHS Trust providing acute medical care in England
- Operating revenue <£300 M in 2012/13

Inclusion criteria for Discrete Choice Experiment:

- Previous participation in any aspect of the study
- Registration of interest to participate in the study in response to targeted invitations
- Profile of characteristics (age, sex, region, diagnosis) allows for representative sample to be constructed in the case of patient participants
- Profile of characteristics (age, sex, region, medical specialty, experience) allows for representative sample to be constructed in the case of healthcare professionals
- Profile of characteristics (age, sex, region, experience) allows for representative sample to be constructed in the case of healthcare managers

7.1.2. Exclusion criteria

Exclusion criteria for hospitals at whole study level:

- Operating revenue >300M in 2012/3
- In Trusts with multiple sites, hospitals which provide maternal or paediatric care only

Exclusion criteria for Discrete Choice Experiment

- Inability to participate in on-line survey because of language or communication impediment

7.2. Sampling and recruitment

7.2.1. Qualitative Components

For the qualitative components of the study, there will be several rounds of sampling and recruitment of the identified smaller hospitals for participation in various study elements.

We estimate that a maximum of 1075 participants will be directly involved.

Up to 260 individuals are expected to participate in the launch seminar, stakeholder workshops and PPI events, although it is highly likely that any one person may attend several events.

The telephone survey will sample hospitals where the CEO is a member of the New Cavendish Group (a support network for CEOs of small hospitals). We expect that 75% of members will participate in the survey and nominate a senior manager to respond (n=25).

The online survey will sent to all the remaining 50 hospitals which did not participate in the telephone survey. It is expected that 50% will respond (n=25).

This will bring the total sample size to 50 (67.7%).

Through these surveys, we expect to identify 4-5 different models of medical generalism and we will aim to include two case study Trusts that are representative of each model, as well as any outliers. This amounts to a sample of 12 to 15 Trusts. We will contact the medical director at each hospital to request they nominate a contact person for the team to liaise with. The contact person will help the research team set up the visits to their hospital, including:

- Recruiting 3-5 members of staff involved in the Department of Medicine (or equivalent) (e.g. Director of Medicine, Clinical Director of Medicine, AMU clinical lead, Specialties clinical lead, a member of the senior management team, a senior nurse, a member of the organisation's board) for the interviews with the research team (n=75).
- Recruiting 2 volunteer members of staff to conduct the Day of care Survey at that hospital. These will ideally be staff with greater availability to be able to conduct the survey at their hospital (e.g. junior doctors) (n=~30).

Focus groups will be conducted at hospitals considered to be the most representative of each model in the typology and any outlier models of interest (expected 6-8 models). Two focus groups will be held at each selected hospital, one for patients and carers (6-8 participants) and the other for healthcare professionals (8-12 participants). Maximum of n= 160. Professional staff will be nominated

by the hospital contact person. Patients and carers will be recruited from local Healthwatch and patient volunteer organisations, as well as advertising via local hospital channels.

For the Discrete Choice Experiment (DCE) we aim to obtain a nationally representative sample from each group of health professionals (doctors, nurses, professions allied to medicine) and patients and carers. Although sample size calculations for DCEs depend on the question format, the complexity of the choice tasks, the desired precision of the results, the degree of heterogeneity in the target population, the availability of respondents, and the need to conduct subgroup analyses, a sample size of 300 is commonly recommended in the literature. We will aim to have a minimum sample of 500 doctors, 100 patients and 50 managers, who will complete a questionnaire (n=~650). This sample will be selected based on age, gender and region, plus specialty and experience in the case of health professionals, and diagnosis in the case of patients. Recruitment will be via several routes. All participants in other aspects of the study will be asked whether they wish to register interest in participation in the DCE. Invitations to register interest will also be disseminated via appropriate professional channels, such as the Royal College of Physicians and Institute of Healthcare Management, and patient organisations, such as the Clinical Senates, Health and Wellbeing Boards and support organisations.

We will use different sampling techniques for different stages of the research work:

- We will use **purposive sampling** for selecting the Trusts who will participate in the case studies, based on our domains of interest (see inclusion criteria above).
- We will use **snowball sampling** for our telephone survey and our focus groups with health professionals and with patient representatives and carers. We will start with an initial contact (the medical director at each trust) and ask him/her to appoint a contact person to then refer our request to respondents at their hospital. In the case of patient representative recruitment, this will be done through external organisations.
- We will use **quota sampling** for the discrete choice experiment, where we will take account of a number of characteristics (see inclusion criteria above) for selecting our participant sample.

7.2.2. Quantitative Component – Sampling Considerations

The population of small hospitals approached will be approximately 75 and we expect to have detailed information on 15 and outcomes data on around 50.

The analysis of the associations of the case mix typologies and the models of care typologies will be performed using log-linear models generalising the usual chi-square analysis. To ensure the ability to detect a global difference (with 90% power) and then examine relevant subgroups of case mix / model of care combinations with type 1 error of 10% and power of 90% would require 1300 patients per combination to detect absolute differences in combinations of 5% assuming a baseline proportion of 10%. Thus for six models of care and 30 case mix categories a total population of 234,000 patients would be required.

The proposed analysis of outcomes is complex and not amenable to a straightforward power calculation. To obtain estimates of the sample size a simulation study was conducted using a range of assumptions. The calculations showed that power of 90% was exceeded at a total population of

around 100,000 patients. Examining hospital activity for 2013-14 there were 174,000 patients treated under general medicine in ten of the New Cavendish Group smaller hospitals group. It is likely we have outcome data on around 60 trusts classified to models of care so the estimate of 100,000 patients would easily be exceeded for a single year. If outcomes are pooled across years then the required sample size will easily meet the criteria defined above.

7.3. Consent

Participants in every stage of the qualitative research will be sent a participant information package that will include a project information sheet and an informed consent form.

We will uphold the principles of the Helsinki Declaration[130] and the ESRC Framework for Research Ethics[132], which states that participants "must be informed fully about the purpose, methods and intended possible uses of the research, what their participation in the research entails and what risks, if any, are involved"; and that consent has to be given in a voluntary way "free from any coercion."

The consent form will detail the nature of the study, why the organisation and/or person have been identified as potential participants in the research, and what the risks and benefits are from participating in the research.

The Chief Executive Officers of all selected smaller hospitals will be asked for consent using a standard protocol, including an email and attached letter explaining the study, laying out the requirements for their hospital's participation, and asking for formal authorisation for undertaking the research at their hospital.

Our field research will include direct observations of staff in their working environment, attending meetings, interviewing staff and mapping patient trajectories. Although patients will not be research participants in this study, the researchers will carry out observations of patient and staff interactions. Both patients and staff will be given the opportunity to opt out of any observations. However, due to the ethnographic nature of this observation, and because patients will not be actively involved in these observations, nor will they be the main object of focus, the research team may not be able to gain consent from each individual observed. The research team will ensure the confidentiality and privacy of any patients observed in the course of the research.

The research team will ask all the staff observed about their contact details and consent for inclusion in the discrete choice experiment.

The health professionals nominated to respond to the survey at each hospital will also be approached via telephone or email to provide their consent to participate in the study. The research team will provide information on the aims of the study, how the survey will contribute to these, and what participating in the study implies.

Interviewed staff will also be asked to sign a written consent form at the beginning of each interview. They will be asked to agree with being interviewed and with the interview being digitally recorded. When telephone interviews are conducted, we will consider explicit email agreement as being the equivalent of signed consent. In this case informal consent will be sought again at the start of the telephone interview.

Participants in the focus groups will be asked to sign formal consent prior to the start of the group. Consent will be asked for their participation and for digitally recording the sessions.

We will attempt to maximise time given to potential participants invited to take part in the study to make a decision on whether or not to participate. We will give potential participants the opportunity to ask questions during at any point. They will be sent study information in advance and all consent forms will clearly specify each participant's requirements and implications.

We do not expect to have participants withdraw their consent for participating in this research. However, in the unlikely event that a case study hospital site accepts to participate in the study and then decides to withdraw prior to the visit taking place, for example, we will no longer include it in the study. If data has already been collected, however, we will consider the consent provided to be binding.

Specific consent is not required for the quantitative components (including the economic analysis), as only routinely collected data via Hospital Episode Statistics (HES) will be used.

8. Statistical considerations

For this study, patients need to be grouped in ways that are representative of workload in generalist medical care. Information from Health and Social Care Information Centre Hospital Episode Statistics (HES) will be used as the basis for the analysis. The HES dataset records individual episodes of care that can be linked into spells of admission and longer patient histories. The ability to link over time means that the analysis can exploit information about prior hospital activity before an admission spell and to track subsequent events, such as readmission.

Permission will be sought to use Office of National Statistics linked mortality data, which will allow investigation of mortality out of hospital.

The statistical analysis plan below condenses the relevant information regarding the analysis to be undertaken by the research team.

8.1. Work Package 2

8.1.1. Subject population

The subject population who will be analysed will be all patients with medical conditions admitted to the 75 smaller hospitals under focus in our study in the period 2010-2016. This data will be obtained from a Hospital Episode Statistics (HES) dataset.

8.1.2. Statistical analysis plan

The work will be undertaken in four stages:

1. Creating a classification

We will perform exploratory analyses of diagnostic/specialty codes to produce candidate case mix classifications. The classification will draw on the theoretical model, outcomes from the stakeholder workshop and a range of existing classification schemes, as well as markers of specific chronic problems and multiple morbidities.

The analysis will start by identifying ‘index episodes of care’, looking for emergency admissions for medical specialities, in the age range >18 yo. Using HES from 2012/13 we will create an initial data file consisting of hospital spells indicated as emergency admissions (admission code 21-28) and for medical specialties (tret spef).[103,104] Records will be excluded where:

- Discharge status indicates transfer to another hospital within 2 days of admission
- Specialist care – as identified by NHS England coding scheme for national and regionally funded care. Count of remaining and excluded case types will be shared with clinical staff to test for validity.

We will cross tabulate 3 digit (ICD 10) diagnostic code by specialty code to assess how cases fall in specific cells and so see which cells map best to the general medical caseload. These will be used to identify broad screening criteria and used to create a specification which enables us to identify patients experiencing relevant episodes of care linked to an index admission event. We can then

create a data set at patient-level capturing information about the index admission as well as prior and subsequent hospital activity.

The patient level data sets will be used in creating and testing classifications. The different groups will be explored empirically and tested for homogeneity in resource use using bed days. We will aim to develop groupings that minimise within group variability, yet make some clinical sense.

A set of variables will be created for each index event that summarises for that patient:

a) Current and previous diagnoses

b) Previous admission events typically in the form of numbers of hospital attendances (A&E, Inpatient, Outpatients within a given time frame

c) Numbers of episodes per spell, and generated variables indicating transfers between specialty and complexity treatment

d) Age, gender and ethnicity

e) Deprivation of area of residence based on IMD of lower super output area

f) Treatment specialty

g) Any procedure codes

h) Discharge status (alive, died, transferred)

i) Lengths of stay

j) Provider hospital and hospital type.

The tools for constructing these variables have been previously applied at the Nuffield Trust in work developing and validating prognostic models based on HES data as well as in evaluative studies.[103,104]

We will use clinical advice to explore some simple hierarchies within the data to test for common groupings. We will also test the utility of clustering algorithms in SAS and regression trees as a starting point to generating initial groupings. We wish to identify groups (<50) that are mutually exclusive and exhaustive and with sufficient cases in each to generate meaningful analysis. The statistical performance of the grouping will be assessed by looking at the variability in mean length of stay (as measured by analysis of variance – within group sums of squares) using log transformed or trimmed values. Groups will also be tested for similarity on other variables – in particular discharge destination and prior health history.

2. Test Classification with Professional Consensus Group

In addition to satisfying certain statistical criteria, it is important that the groups make clinical sense and imply a broadly similar treatment or service response. We propose creating a panel of expert clinicians (n=10) to review the possible emerging case mix groups using a combination of virtual and face to face meetings. An iterative process would be used, with the group's input refining and adapting the emerging classification scheme. Where possible, we would use clinicians from hospitals involved in the study.

We will select clinicians opportunistically, but seek to include individuals working covering a range of hospital size and type. We would first generate initial comments on the candidate groups in terms of

their comprehensiveness and ability to capture key subsets of patients. In addition, we would probe for specific views on the utility of individual case types.

We propose conducting the first survey through email contact and then following up with selected meetings to explore the feedback we have received and possible changes.

3. Separating the Workloads of Smaller Hospitals

The agreed classification would then be used to separate the workload of smaller hospitals into specialist and generalist, based on HES data. The classification would be applied to hospital activity from 2010 to 2015 in all acute hospitals in England.

Hospitals would be classed into groups according to teaching status, operating revenue, number of beds and whether in urban /rural locations. We will analyse data over consecutive years by hospital to test whether the groupings are reasonably consistent over time and work across a range of hospital types. We will also look at the consistency of treatment specialities for the case types across hospitals. One test will be to look at the frequency of case types relative to the resident population, the aim being to identify groups that are not unduly influenced by individual providers but exhibit stable admission rates within a population. Therefore, age and sex (and optionally deprivation) standardised admission rates by local authority populations will be estimated.

During this stage we would apply the case mix classifications to national data sets to calculate the numbers of cases of each case type for each acute hospital in the country. Hospitals will be characterised in terms their size, revenue and the classification as generalist or specialist.

We will also estimate case mix specific admission rates based on recorded area of residence initially defined in terms of 152 local authority areas. For each local authority we will calculate specific age/sex/deprivation adjusted admission rates for the case types.

These data sets will be used to assess a number of questions and specifically to test for differences associated with hospital types.

a) Is the case mix profile for a given hospital stable over time? This will involve simple Chi-squared test to compare distributions plus identification of any outlying or atypical groups.

b) Are characteristics of the hospital associated with specific patterns of case mix?

c) Do hospitals vary in the treatment specialties associated with each case mix group?

d) Are case-mix specific admission rates stable over time?

e) Are differences in area-based admission rates linked with individual providers? To do this we will use person-level models and include variables representing individual hospitals

4. Linking Case Mix and Descriptive Analysis of Smaller Hospitals

A descriptive analysis of workload of smaller hospitals in terms of activity and resource utilisation will be undertaken. The case mix descriptor will be tested against more detailed information about the structure and organisation of medical generalists within the hospitals obtained in WP1. We will aim to see the extent to which case types differ within and between hospital types and models of generalist care. In addition, a descriptive analysis of the typical patterns of bed use by case mix group will be undertaken.

This will mean estimating for each hospital subtype and each case type: the numbers of cases, length of stay (mean, median and measures of the distribution), readmission rates (at 30 days and 12 months), survival (30 days and 12 months).

This data will be used to provide specific profiles for each hospital in our detailed study and will provide the means to test specific hypotheses to identify cases types associated with specific models of care.

Finally, any changes or deviations from the original statistical plan will be captured and described in an amended version of the protocol, where appropriate.

8.1.3. Procedure(s) to account for missing or spurious data

The study of case mix in smaller hospitals will exploit existing operational information systems used for describing hospital activity and providing the basis for case mix based reimbursement. These systems are not perfect but there is generally thought to be a reasonable degree of completeness in terms of the numbers of admitted patients – a hospital income depends on it. The volume of cases recorded by organisation will be checked against other information streams recoding overall hospital activity. The major weakness is generally around the accuracy of some field within the records – in particular diagnostics codes. In dealing with these we adopt a range of strategies:

a. Undertaking some basic tests for logical inconsistencies between records (e.g. patient admitted when they have died in a previous episode).

b. Use multiple records linked over time to construct person level histories. This can be used to attach flags for longer term conditions and reduce the reliance in completeness of coding in every episode.

c. Where possible use diagnostic codes at higher levels of aggregation (e.g. 3 digit ICD-10) to reduce the reliance on accuracy of coding detail.

d. Grouping patients with incomplete data into 'bucket' categories that are then analysed alongside mainstream case mix groups. The numbers of cases and resource use within this category will be considered as marker of the overall utility of the case mix classification.

e. Tests for atypical patterns of coding between services/institutions. If any one hospital is too extreme we would consider removing them from aggregated analysis.

f. Test for sensitivity of the final results to differences in missing data (unclassifiable records).

8.2. Work package 3 – Economic evaluation

One of the key objectives of the study is to investigate the economic costs attached to different models of medical generalist care.

We will undertake an economic analysis in Work Package 3. This analysis will be two-pronged:

1. Hospital level analysis – we will calculate the total staffing costs per year in smaller hospitals of England and explore the association of these costs with staffing model and organisational characteristics.

2. Patient level analysis – we will calculate patient level cost-weighted activity figures based on HES data and local tariffs, and analyse the association between patient level costs and staffing model controlling for organisational and patient level factors.

For the hospital level analysis we will collect data on numbers, roles and skill-mix of medical staff via the survey of smaller hospitals in WP1. Annual costs for 2014/15 of delivering care using different staffing models will be calculated as the sum of the cost of each staff input, computed by multiplying time allocation by NHS unit costs.[106] Resulting costs will be validated against Trust annual reports.

We will assemble a hospital-level dataset of aggregate staffing costs, total income and expenditure, and organisational characteristics (general hospital characteristics, geographical factors, hospital medical department characteristics, networking arrangements and other factors that may be related to hospital level costs), with the latter taken from the organisational profiles assembled during WP1.

We expect to assemble a dataset comprising approximately 75 hospitals. We will undertake exploratory analyses of the impact of staffing model on hospital costs tabulating staff costs against staffing models. We will run cross-sectional simple regression models to investigate the association between overall staffing costs and staffing model controlling for organisational factors.

For the patient level analysis we will use the patient-level HES data assembled during WP2 for all patients treated in smaller hospitals in England in 2014/15. Patient level treatment costs will be calculated from HES records on admitted patient length of hospital stay, readmissions, outpatient visits, plus services received. Unit costs will be assigned to each item of resource use[107] to calculate total costs per patient.

We will then assemble a multilevel dataset of patients nested within hospitals including total costs per patient, diagnostic codes, age, gender, admission source, staffing model and hospital organisational characteristics as described above.

We will regress patient level costs against staffing typology controlling for patient and organisational characteristics. Our preferred model to account for skewness of the cost data is to use a generalised linear model with gamma family and log link.[108] To be able to draw useful inferences the analysis relies on the representativeness of the survey. We will compare the characteristics of smaller hospitals who responded to the survey to all smaller hospitals extracts to investigate systematic differences between responders and non-responders, e.g., whether non-responders have different patient case-mixes, provide a different range of activities, or have different organisational characteristics. Where systematic differences are identified we will use selection models (e.g., based on Heckman[109]) in our regression analyses using the survey data to account for the propensity of participating in the survey.

Some of the limitations and constraints of this section include:

- The use of observational data and small sample size in the hospital-level analysis will limit the ability to draw causal inferences.
- This study will be partly exploratory in nature. It is currently unknown whether there are sufficient differences between the models of care used in smaller hospitals to allow robust comparison between models and standard patient outcomes (such as mortality and length of stay). It is also unknown whether standard patient outcomes are appropriate for measuring the impact of different types of care on outcomes. These constraints mean that full economic and

patient outcome analyses are beyond the scope of this study. The relevant outcomes of these aspects of the study will be assessed by the research team and the Study Steering Committee with a view to deciding on the feasibility of a larger study.

9. Data handling

9.1. Data collection tools and source document identification

In addition to the qualitative data collection (see section 5), the quantitative component of the study will require access to Health and Social Care Information Centre Hospital Episode Statistics (HES) (see section 8).

The Nuffield Trust has considerable experience in using linked HES datasets and will extend its current agreements with Health and Social Care Information Centre to use the HES data it already holds. Permission will also be sought to use Office of National Statistics linked mortality data.

9.2. Data handling and record keeping

The data generated by the study will be analysed by members of the core research team only. This team will include the leads of each of the five Work Packages, as well as the researchers recruited to support with the work in each work package.

The core research team will analyse the data in their respective working places. The Nuffield Trust will be the host organisation for WP1, 2, 3 (through a sub-contract with the researchers responsible for this WP) and 4. WP5 will be jointly developed at the Nuffield Trust and King's College London.

Data will be transferred and exchanged when necessary between members of the research team working on different work packages. This will be done via email for regular exchanges of information. For transferring potentially sensible or confidential information, a secure transfer/file sharing system will be set up by the Nuffield Trust's IT manager. However, no personal and identifiable information will be shared at any point in the study.

We will use a commercial site (Survey Monkey®) to host the surveys, in order to preserve respondent anonymity and data confidentiality.

As for the Day of Care Survey, the members of staff who conduct the survey at selected hospitals will sign a confidentiality agreement as part of their consent form, and they will record the information in an anonymous way.

Direct quotations from respondents to our surveys, interviewees or focus group participants may also be used when drafting reports and presenting the study's results. These will not be identifiable, however.

All members of the research team will undertake to keep any personal data anonymous and confidential by presenting quantitative data in an aggregated manner.

We will use audio recording devices for recording focus groups and interviews with research participants.

Where surveys are done via telephone we will also record these for research purposes. All recordings will be confidential and subject to consent by all participants. Recordings will be stored anonymously and securely on a shared network drive that is password protected. Audio files will be sent to transcribers using secure data transfer websites, and transcribers will anonymise data while transcribing.

Technical expertise will be sought at the outset of the study for setting up safe and confidential information sharing systems between members of the research team.

The data will not be exported outside the UK.

9.3. Access to Data

The research team has significant experience in undertaking research studies involving sensitive data.

All staff working for the Nuffield Trust sign a policy on the handling of confidential information. This specifies that:

- Staff are expected to handle personal information in a sensitive and professional manner.
- Staff are under an obligation not to gain access or attempt to gain access to information which they are not authorised to have.
- Intentional or repeated accidental, unauthorised access to and/or disclosure of any confidential information by any member of staff will be subject to disciplinary action.

Members of the research team working for other organisations outside the Nuffield Trust will be advised of the Trust's security policy.

The data obtained from individual participants will be kept in a password-controlled file on secure servers at the Nuffield Trust, with a hard copy in the Trust safe. The Chief Investigator will determine which staff shall be authorised to have access to the project data. Authorised members of the research team will be able to access this folder online through a password-protected sign-up system. They will be required to keep their passwords confidential in line with our general policies and agree to use data according to the terms of the agreement.

Consent forms signed by participants will be stored in locked filing cabinets in an office at the Nuffield Trust. The key to these lockers will be held by one member of the research team. Hard copies of questionnaires (for those participants who prefer to receive a hard copy via post) will be stored in the same location until stored electronically.

10. Ethical and regulatory considerations

Since the study will not involve intrusive medical research, the WMA Declaration of Helsinki concerning Ethical Principles for Medical Research Involving Human Subjects[130] is not applicable to our study. However, the research team will uphold the general principles of respect for all human subjects involved in the research; right to self-determination; and confidentiality of personal information (see section 10.5, 'Data protection and patient confidentiality').

The study will also not involve individuals who are unable to make decisions for themselves, nor will it involve 'intrusive' research[2], so the Mental Health Capacity Act 2005[131] is similarly not applicable. The research team will ensure that all participants in the study are able to understand the information relevant to their decision of participating and that they are able to communicate their decision.

Protocols for the portions of this study which involve patient participation (direct observation as part of the site visits, patient focus groups and the DCE) will be submitted to the Health Research Authority for ethical approval, as outlined below.

The study has been constructed to minimize the ethical issues and it should be of very low risk.

The key ethical considerations pertain to patient and staff confidentiality in WP1 and the use of patients in the focus groups and the Discrete Choice Experiment in WP4. As such, there are several activities in the study which require ethical consideration:

1. Shadowing of staff and non-participant observation, with the aim of mapping processes in hospitals that pertain to the allocation of patients to either a 'general' or 'specialist' hospital service

The site visits and shadowing of staff in WP1 present the issues of patient and staff confidentiality. As the site visits will include the Emergency Department and acute wards, there is the potential risk that this may interfere with the delivery of patient care or otherwise impede staff in carrying out their duties. Patients will not be the primary focus of the non-participant observations and will be given the opportunity verbally opt-out of any observations. As the studies are strictly observational in nature, there is no direct risk of harm to patients and the research team is highly skilled in gaining permissions and consent and conducting this type of research.

2. Staff interviews and focus groups

The use of staff for interviews, consensus groups and focus groups should not represent any direct ethical problems, as we will be using NHS staff only and asking questions pertaining to their perceptions and experiences of process and service.

We will seek specific ethics approval for the case studies and the focus groups (see 10.2 below).

3. Day of Care Survey

The Day of Care Survey (DCS) will include the collection of anonymised data pertaining to all hospital medical inpatients on a single day. The DCS has been structured so that local hospital staff will be

[2] Research that is carried out "on or in relation to a person who had capacity to consent to it, but without this consent" (http://www.hra.nhs.uk/resources/research-legislation-and-governance/questions-and-answers-mental-capacity-act-2005/).

trained on the day to conduct the survey. The research team will not have direct access to any patient records. However, there is a low risk of the research team being asked questions about the DCE that may accidentally expose them to confidential patient data. However, none of this data will be captured by the research team, who are also highly trained and sensitive to issues around information governance.

4. Use of patients for interviews, focus groups and a discrete choice experiment

Patients will be recruited for focus groups and to participate in a discrete choice experiment (DCE). Patients will not be recruited directly through NHS hospital sites, nor will the research team recruit individual patients. Instead, patients will be recruited from local Healthwatch organisations and local hospital volunteer organisations, including those supporting carers, though contact with patient governors and through advertising materials in hospitals (and hospital websites). It is expected that patients will have had recent contact with the hospital, as we wish to explore their experiences around previous care and expectations of future care.

Ethical approval will be sought specifically for the DCE (see 10.2 below).

The study will include the use of data from HES, for which ethical approval is not required.

10.1. Assessment and management of risk

The potential risks for participants in the study include:

1. The time commitments required of each member of the staff, patient and carer recruited. A number of participants may be several stages of the research, including the hospital site visits, the Day of Care Survey, interviews and focus groups. However, it is expected that most participants will only be required for a single activity in the study and then for a limited amount of time (hours).
2. Potential disruption to staff activities and patient care. As the site visits will focus on busy areas of the hospital, such as Emergency Departments and Acute Medical Units, it is possible that they may impede staff from carrying out their duties and impact patient care. The study team are skilled in carrying non-participant observation in busy areas and will seek to minimize disruption.
3. Potential compromise of patient confidentiality. As the research team will be shadowing hospital staff, they may observe interactions between staff and patients. Patients, however, will not be the focus of any observations and so there is no risk of direct harm. Patients will be given the option of verbally opting out of any observations and the research team are highly skilled in obtaining permissions and consent.

As for the research team, the only risk is that of witnessing potentially sensitive interactions between hospital staff and patients during the site visits. During these visits the researchers may accidentally and unwillingly have access to confidential information.

The research team will keep a ‘risk log’ throughout the study to register the potential risks identified and how these are addressed.

10.2. Research Ethics Committee (REC) review & reports

The first six months of the project are allocated to undertaking preparatory work for the subsequent stages of research. Since our field research will not start until around October 2016, when we start the hospital site visits, we will submit deferred ethics approval. This means that we will still seek HRA Ethics approval before the start of the field research activities.

HRA Approval is the process that was recently implemented for assessing the legal, governance and ethical compliance of research projects undertaken in England. This new process replaces both the need to apply for NHS REC and the need for local checks of legal compliance and related matters by each participating organisation.

We will seek HRA approval at two different moments, according to the time frame of our research activities: we will first apply for HRA approval in August/September 2016 in order to be able to undertake the case studies and the focus groups; we will then apply for HRA approval for our Discrete Choice Experiment (DCE) in June/July 2017.

The Chief Investigator will maintain a regular correspondence with the contact person at the NIHR. A contact person for the study at the HRA has also been established. All correspondence will be retained and the Chief Investigator will ensure the production and delivery of the study's annual reports.

10.3. Peer review

The study was subject to extensive independent, expert and proportionate external review through the NIHR HS+DR competitive funding process. It was scrutinised on three occasions, with comments fed back to the study team by nine anonymous reviewers and the NIHR HS+DR board.

10.4. Patient & Public Involvement

We are strongly committed to active and meaningful patient and public involvement (PPI) in this study and we aim to ensure: that outcomes are relevant to patients and appropriately prioritised; that information is suitable for public consumption; and that high standards of research governance are adhered to.

There has been PPI at all stages of the development of this study. The first round proposal was developed in conjunction with a trained member of the public (Fran Husson) and the senior engagement officer of the NWL CLAHRC. It was at Ms Husson's suggestion that we included patient researchers to assist with coding of the focus groups. Relevant sections of this application have been reviewed by two appropriate member of the public (Fran Husson and Marilyn Frampton).

We have already identified two appropriate patient representatives to join the Study Steering Committee. David Steel, former CEO of NHS Quality Improvement Scotland, has agreed to chair the SSC. Marilyn Frampton was a Non-Executive Director of the Chelsea and Westminster Foundation Trust and is now a member of the Council of Governors at Kingston Hospital Foundation Trust. As part of the SSC, we will expect that they will give advice on the progress of the study and ensure that is completed on time and within budget.

We intend to co-opt these two members of the SSC at appropriate points to: help refine outcomes measures; draft aspects of the questionnaires, consent materials and study protocols relevant to patients; review any other materials produced for the public, including the final report. Where these two individuals are not available, we will draw on the resources of the RCPL Patient and Carers' Network and the Northwest London CLAHRC Patient Advisory Group (headed by Prof Bell) to find an appropriate replacement.

We will also use appropriately trained members of the public to actively assist with the conduct of research. We will recruit and train PPI representatives to assist with the hospital site visits in WP1 and with the coding of the focus group material. All lay members involved in the project will be provided with initial training, including bespoke training for service user researchers (SURs) and ongoing support by CLAHRC and the RCPL (see "funding", p.13). They will also be encouraged to join the RCPL's Patient and Carer Network, which also provides peer-to-peer support through newsletters, meetings and an on-line forum.

A member of the team will be designated as lead for PPI and a nominated contact person at NWL CLAHRC will be available to provide support and an impartial forum for any concerns to be raised.

All lay members will be reimbursed for travel and expenses and a day rate (£150 per day) for attendance at meetings, in accordance with good practice recommended by INVOLVE.

As the study progresses, we plan to link with regional and national patient organisations and public engagement networks, such as National Voices, Local Involvement Networks/Local Healthwatch, Health and Well-being Boards and, where possible, patient groups involved in patient safety and service delivery, to share emerging findings, obtain feedback and seek help with dissemination. We will do this through the organisations' membership mailing lists and by offering to speak at events, in addition to holding a bespoke PPI event. This strategy has been used previously by members of the study team and it was found to be highly effective at public engagement.

In order to encourage participation and attendance at our research activities, we will cover the expenses of participants in our research, at the rates suggested by INVOLVE.

10.5. Data protection and patient confidentiality

The identification of participants in this research will only involve information that is publicly available. It will not involve reviewing personal or sensitive information of patients and service users.

For the quantitative analysis, the research team will be provided with data which has had identifiable patient level information removed.

For the qualitative data collection, the research team will have access to the names and contact details of nominated contacts at hospitals and potential participants in the interviews and focus groups. For any interviews/focus groups, the names of the participants will be recorded on master key and the participant allocated a pseudo-anonymised identification (e.g. Staff Member 1). The master key will be stored securely and separately from other research materials.

The Day of Care survey will not include the research team reviewing the personal information of patients. Instead, a staff member at the hospital will review patient notes and then assign, for the purposes of the research: a severity of illness score; a treatment score; and an appropriate specialty

triage category. They will also record the specialty of the treating doctor and the type of hospital ward (i.e. general medical, specialty medical, etc). No demographic or other identifiable personal information will be recorded.

The data generated by the study will be analysed by members of the core research team only. This team will include the leads of each of the five Working Packages, as well as the researchers recruited to each.

Data will be transferred and exchanged when necessary between members of the research team working on different working packages. Technical expertise will be sought at the outset of the study for setting up safe and confidential information sharing systems between members of the research team. For regular exchanges of information this will be done via email. For transferring potentially sensible or confidential information, a secure transfer/file sharing system will be set up by the Nuffield Trust's IT manager. In addition, we will put in place sub-contracting arrangements for one member of the research team to work at the Nuffield Trust, in order to ensure that the data remains within the boundaries of the host organisation.

All investigators and study site staff will comply with the requirements of the Data Protection Act 1998 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.

The data obtained from individual participants will be kept in a password-controlled file on secure servers at the Nuffield Trust, with a hard copy in the Trust safe. The Chief Investigator will determine which staff shall be authorised to have access to the project data. Authorised members of the research team will be able to access this folder online through a password-protected sign-up system. They will be required to keep their passwords confidential in line with our general policies and agree to use data according to the terms of the agreement.

Audio recorded files from the focus groups, interviews and telephone surveys will be stored anonymously and securely on a shared network drive that is password protected. Audio files will be sent to transcribers using secure data transfer websites, and transcribers will anonymise data while transcribing.

Consent forms signed by participants will be stored in locked filing cabinets in an office at the Nuffield Trust. The key to these lockers will be held by one member of the research team. Hard copies of questionnaires (for those participants who prefer to receive a hard copy via post) will be stored in the same location until stored electronically.

The Chief Investigator will have control of and act as the custodian for the data generated by the study.

The data from the study will be stored for 12 months after the end of the study.

10.6. Indemnity

The Nuffield Trust's Combined Insurance provides cover for the study as the sponsor organisation and is limited to £5m. This cover would allow us to meet the potential legal liability for harm to participants arising from the management, from the design or from the conduct of the research.

The Nuffield Trust's collaborators will be required to have sufficient insurance cover in place and to indemnify the Nuffield Trust through the legally binding collaborator agreements against potential liability arising from harm to participants in the conduct of the research.

No equipment is to be provided to participating sites for the purposes of this study.

10.7. Amendments

Minor amendments deemed necessary throughout the study (e.g. format or timing of stakeholder workshops) will be made after discussion with the Nuffield Trust's Senior Management Team and included in an amended protocol. As the study sponsor, the Nuffield trust will ensure that any minor amendments are submitted through an amended protocol. We will notify the funder of any changes and of the new protocol uploaded in their management system.

For major amendments, we will submit a request for ethical review to the appropriate REC and we will notify the NIHR Coordinated System for gaining NHS permission (CSP) via the Integrated Research Application system (IRAS). We will likewise notify the funder of any changes and of the new protocol uploaded in their management system.

Each new version of the study protocol will be identified through the protocol number and date at the beginning of the document. This will allow the research team and the funder to track the amendment history.

10.8. Access to the final study dataset

The core research team – the leads of each of the five WPs and the researchers working on each – will have access to the final dataset.

The study's Steering Committee will have access to an aggregated set of results based on the final data, but not the complete dataset.

11. Dissemination policy

11.1. Dissemination policy

The Nuffield Trust as the sponsor organisation will own the data arising from the study.

The lead investigators for each work package will have the right to publish data and results from their work package.

We expect this study to have a major impact and that its results will inform and influence decision making around ways of working in hospitals; issues around workforce education, continuing professional development and contractual arrangements; and the future of smaller hospitals and their role in the wider healthcare system. As such, we aim to put in place a Communications plan that will allow us to disseminate the results of the study in an effective way.

Our dissemination plan will involve the main project partners – the Nuffield Trust, the RCPL, Imperial College London, King's College London and University College London – who are highly experienced at disseminating messages not only to frontline medical staff, but the public, NHS leaders, policy makers, researchers and academics.

The Nuffield Trust has a substantial presence in the press and alternative media, with its website receiving ~50 000 view per month and over 17 000 followers on Twitter and ~2 000 on Linkedin. A communication strategist, Zardia Edwards, has been assigned to the project to ensure that the findings reach a wide audience in the NHS and beyond. The planned activities include:

- Holding three stakeholder events – an initial workshop, a PPI Open Space event and a launch event.
- Publishing three policy papers, which will be advertised and available through the Nuffield Trust's website
- Sharing findings with print and other media through press releases
- Sharing findings with key senior stakeholders in Health Education England, NHS England, Monitor, the Department of Health, the Centre for Workforce Intelligence and other professional bodies.
- Publishing web-based blogs
- Using social media (e.g. Twitter), particularly during the planned stakeholder events
- Giving regular feedback to the New Cavendish Group, a network of 25 CEOs of smaller hospitals, supported by the Nuffield Trust

The RCPL will ensure that findings are disseminated to their membership and more widely through their professional networks. The work will also feed directly into their work programmes on medical generalism, workforce issues and the Future Hospital. This will include articles in their 'Commentary' newsletter and their professional journal, *Clinical Medicine*.

Additional outputs will include:

- A final study report to be prepared upon completion of the study, which will be available on the website of the Nuffield Trust and the NIHR
- An executive summary of the study
- A summary report with results for a lay audience
- Articles to be submitted for publication in leading journals, such as the BMJ, Health Policy and Planning and the Journal of Health Services Research and Policy
- Abstracts to be submitted to key conferences, such as Future Hospital Commission Conference of the RCPL, Quality and Safety in Health Care Forum, the NHS Confederation Conference, as well as NIHR events

The research team will also provide information about the findings from the research upon request from participants. This will be done after the final report has been drafted and published.

Other planned mechanisms for dissemination include:

- The packaging and provision of feedback to participating hospitals
- Workshops with user groups
- Face to face engagement with policy makers at national level
- Knowledge transfer and exchange initiatives, such as working with networks like the NHS Confederation. We have already begun to engage key stakeholders, particularly those involved in 'Viable Smaller Hospitals' workstream of the NHS England's New Models of Care programme. We intend to also engage with the Health Services and Delivery Research CLRN, as well as national patient organisations and public engagement networks to support dissemination and publicise results.

The main study team and the Study Steering Committee (SSC) also represent an excellent network through which to further disseminate study findings and learning. Professor Bell is currently President of the Royal College of Physicians of Edinburgh; Dr Vaughan is Research Lead for the Society for Acute Medicine; Professor Rafferty is an advisor to the Centre for Workforce Intelligence; Ms Imison is currently leading collaborative projects with Monitor and KPMG; Dr Mann is President of the Royal College of Emergency Medicine; David Steel is former CEO of NHS Quality Improvement Scotland and Dr MacDonald is President of the Adult Division of Medicine, Royal Australasian College of Physicians.

Funding from NIHR and support from the sponsor organisation and from other organisations providing support throughout the study will be acknowledged in our publications.

As per its contractual requirements with NIHR, the research team will:

- Notify the NIHR of all outputs (i.e. the final report; journal articles; press releases; media interviews; conference abstracts or presentations; dissemination events for research participants, newsletters or participant materials).
- Send the NIHR a copy of the output and any information pertaining to it, at the time of submission or at least 28 days before the date intended for publication, or it being placed in the public domain, whichever is earlier.

- Include an acknowledgement of programme funding and a disclaimer in all outputs.

The research team will do this through the NIHR online system.

Even though the upload of outputs is not a formal approval process and it is not used by the funder to suppress or alter publication plans, it is used by the NIHR as a way to notify the Department of Health in case of media or political interest following publication of the outputs, and as a way to understand the reach of the study's findings and their impact.

Finally, the study protocol will be publically available via the NIHR website and the full study report will be published by the NIHR. The dataset will not be made available, but the methods utilised for generating results will be packaged for use by interested bodies.

11.2. Authorship eligibility guidelines and any intended use of professional writers

According to the recommendations of the International Committee of Medical Journal Editors (ICMJE), the authors of the final study report will be all those who have:

- Provided substantial contributions to the design of the work and the collection and analysis of data;
- Drafted written content;
- Agreed to be accountable for all aspects of the work they have undertaken and for guaranteeing its accuracy and integrity, as well as having confidence in the integrity of the contributions of their co-authors.

Additionally, authors are expected to be able to identify which co-authors are responsible for specific other parts of the study.

We expect the individually named authors to be all the leads of the five WPs and the corresponding research team members.

All authors will have to approve the final version of the study outputs to be published.

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13. Appendices

13.1. Appendix 1 – Required documentation

For this study we will require a set of documents prior to initiating our research at a participating site. This will include, but not be limited to:

- A copy of the agreement we use for each hospital site we include in our research
- Copies of the different informed consent forms that we use for each type of participant in the research
- Patient information sheets
- Information packs (including project information sheets) prepared for participating sites

These documents will be added to this application at a later stage, at the point in the study when we will start planning and preparing the field research activities (see “Research Ethics Committee (REC) review & reports”).

13.2. Appendix 2 – Work plan (Gantt chart)

			PROJECT YEAR ONE (2016/2017)													PROJECT YEAR TWO (2017/2018)												YEAR THREE (2018)						
	LEAD	PREP	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct-Dec
Preparatory phase																																		
Finalise membership of Study Steering Committee (SSC)	MG																																	
Data approvals from HES	MB, PS																																	
Recruitment to research posts	STEVE M																																	
Typology seminar	CI/LV/MG																																	
Launch seminar (theory)	LV/MG																																	
HRA approval application (for WP1 activities)	SM, LV																																	
HRA approval application (for Discrete Choice Experiment (DCE))	SM, LV																																	
Finalise protocol and analysis plan	SM, LV																																	
WP1 Describing Models of Generalism																																		
Project Management	CI/SL																																	
Preparation of organisational profiles	CI/SL																																	
PPI advertisement	LV/SM																																	
PPI recruitment (CVs, interviews)	LV/SM																																	
Preparation of PPI training package	LV																																	
Delivering PPI training	?																																	
Draft of telephone survey	CI/LV/SM																																	
Obtain permissions & identify contacts at NCG sites	MG																																	
Conduct telephone survey of NCG sites	SM MG SL																																	
Survey response analysis	SM MG SL																																	
Literature review	LV/SM																																	
Creation of preliminary typology	CI LV SM																																	
Test prelim typology - expert group & theoretical framework	CI LV																																	
Purposive sampling of NCG sites	CI LV SM MG																																	
Recruitment of NCG sites	MG/SL																																	
Finalise plans for NCG site visits	LV/MG/SL/SM/CI																																	
NCG Site visits	LV/MG/SL/SM/CI																																	
Additional interviews	SM MG SL																																	
Document collation	CI SM SL																																	
Analysis of site visits	LV/SM																																	
Document review	CI/SM/SL																																	
Finalise wider telephone survey	CI/LV/SM																																	
Undertake telephone survey	SM MG SL																																	
Survey data analysis	SM SL LV																																	
Refinement of typology	CI LV																																	
Purposive sampling of sites	CI LV																																	
Recruitment of sites	SL/MG																																	
Arrange site visit schedules	SL/MG																																	
Site visits	LV/SL/SM/CI																																	
Additional interviews	SM MG SL																																	
Document collation	SM SL																																	
Analysis of site visits	LV CI SM																																	
Document review	CI SM LV																																	
Review of typology	LV CI SM																																	
Testing of typology with expert group	LV CI																																	
Finalise typology	LV CI																																	
Descriptive analysis of workforce	CI SM																																	
Report WP1 Outputs	CI LV SM																																	
WP2 Understanding Case Mix																																		
Stage 1: Create a classification																																		
Stage 2: Test Classification																																		
Stage 2: Separating the Workloads of Smaller Hospitals																																		
Stage 4: Linking Case Mix and Descriptive Analysis																																		
Planned reports																																		
WP3 Economic Costs																																		
Identify unit costs for staff inputs & patient level resource use																																		
Assemble Trust and patient level datasets																																		
Analyse Trust level dataset																																		
Analyse patient level dataset																																		
Write reports and paper																																		

		PROJECT YEAR ONE (2016/2017)													PROJECT YEAR TWO (2017/2018)												YEAR THREE (2018)						
	PREP	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr		May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct-Dec
WP4 Understanding Strengths and Weaknesses																																	
Review of literature																																	
Plan focus groups																																	
Conduct focus groups (as part of site visits in WP1)																																	
Analysis of focus groups																																	
Stakeholder event																																	
Review of literature relating to workforce																																	
Create model of appropriate levels of care																																	
Analysis of case mix vs skills mix																																	
Expert consensus group on alignment btwn case mix & skills mix																																	
Final analysis of case mix vs skills mix																																	
Analysis of patient related outcomes																																	
Set up and design discrete choice experiment (DCE)																																	
Run DCE																																	
Analysis and write up of DCE																																	
WP5 Final Analysis and Synthesis																																	
Initial stakeholder event																																	
First expert consensus group on typology																																	
Second expert consensus group on typology																																	
Expert consensus group on case mix classification																																	
Open Space Event (PPI)																																	
Stakeholder event																																	
Expert consensus group on alignment																																	
Analysis across different study phases																																	
Final analysis																																	
Report writing																																	
Study oversight and project management																																	
SSC Meeting (M) or Teleconference (T) (3 monthly)	M			T			M			T			T				M			T			T			T			M		T		M
Whole Project Team Meeting (monthly)																																	
Progress report/meetings with key stakeholders (6 monthly)																																	
Progress reports to NIHR (6 monthly)																																	
Tracking project vs schedule and capacity (fortnightly)																																	
Support to project delivery teams (on demand)																																	
Key milestones and outputs																																	
Progress report to HS&DR (6 monthly)																																	
Interim analyses of case mix data																																	
Modified Day of Care Survey tool																																	
Classification tool for estimating patient skills mix need																																	
Typology of models of medical generalism																																	
Results of discrete choice experiment																																	
Case mix model of workload in smaller hospitals																																	
Framework of potential outcome indicators																																	
Final study report																																	
Short reports for exemplar sites																																	
Study report papers x 3																																	
Launch event																																	
Journal publications																																	

13.3. Appendix 3 – Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
1	1.0	30/03/2016	Sílvia Machaqueiro	The information related to costs with Patient and Public Involvement was removed from this protocol.
2	1.2	02/09/2016	Sílvia Machaqueiro	• Appointment of two additional members of the Study Steering Committee. • Alteration to the project's stakeholder seminars: one of the stakeholder seminars has been separated into two different events (a practical workshop and a theory event). • The online survey to be undertaken in Work Package 1 will be replaced with a second round of telephone surveys.