Health Research Authority

Qualitative Protocol Guidance and Template

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- **This protocol has regard for the HRA guidance and order of content**

FULL/LONG TITLE OF THE STUDY

Learning about and learning from GP Federations in the English NHS – a qualitative investigation

SHORT STUDY TITLE / ACRONYM

GP Federations in the English NHS

- **This protocol has regard for the HRA guidance and order of content**

RESEARCH REFERENCE NUMBERS

PROTOCOL VERSION NUMBER AND DATE Version 2 11/09/16

SPONSOR University of Manchester

GP Federations in the English NHS

FULL/LONG TITLE OF THE STUDY

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RESEARCH REFERENCE NUMBERS

IRAS Number: 196980

FUNDER'S Number: 14/196/04

SIGNATURE PAGE

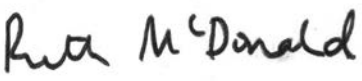
The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirement.

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.

Chief Investigator:

Date:03/08/2016

Signature: 

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Name: (please print): RUTH MCDONAD

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KEY STUDY CONTACTS

Chief Investigator	Ruth McDonald
Study Co-ordinator	As for CI above
Sponsor	Ms. Genevieve Pridham
Joint-sponsor(s)/co-sponsor(s)	Not applicable
Funder(s)	NIHR Health Services and Delivery Research (HS&DR) Programme
Key Protocol Contributors	See CI above
Committees	Full contact details including phone, email and fax numbers

STUDY SUMMARY

Study Title	Learning about and learning from GP Federations in the English NHS – a qualitative investigation
Internal ref. no. (or short title)	GP Federations in the English NHS
Study Design	Qualitative case studies
Study Participants	GP practice staff, patients and carers, practice staff, acute and community care providers and representatives of the social care sector
Planned Size of Sample (if applicable)	N/A
Follow up duration (if applicable)	N/A
Planned Study Period	26 months
Research Question/Aim(s)	The study aims are • To provide a wide ranging and in depth exploration of GP federations in England • To strengthen the evidence base on the organisation and management of general practice for the twenty first century. In order to achieve these aims our objectives are to: • Develop a typology of federations • Identify and classify federations nationally Develop an in-depth understanding of how federations are working in a small number of case study sites • Provide lessons for the wider implementation of new organisational forms in English primary care

ROLE OF STUDY SPONSOR AND FUNDER

The sponsor is responsible for securing the arrangements to initiate, manage and finance a study. In practice this means satisfying itself the research protocol, research team and the research environment have passed appropriate scientific quality, satisfying itself that the study has ethical approval before it begins; satisfying itself that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions and ensuring arrangements are in place for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm arising from the research. Decisions relating to data analysis and interpretation, manuscript writing, and dissemination of results will be made by the research team at the University of Manchester. The funder will be kept informed by the team and made aware of results prior to publication but published outputs will contain a disclaimer reflecting the fact that results and related interpretation are those of the researchers and not the funder.

ROLES AND RESPONSIBILITIES OF STUDY MANAGEMENT COMMITEES/GROUPS & INDIVIDUALS

Study Advisory Group – Independent Chair, 3-4 lay members, 2 academics not involved in the study and not connected to the host University, 1 NHS representative

Terms of Reference:

Comment on emergent findings

Alert the team to relevant research and/or policy papers

Advise on dissemination plans and opportunities

Offer pathways into particular user groups/stakeholders for dissemination purposes

Ensure the project is appraised of external influences and developments that may impact on its conduct

Advise on ways of making the results relevant to the needs of users

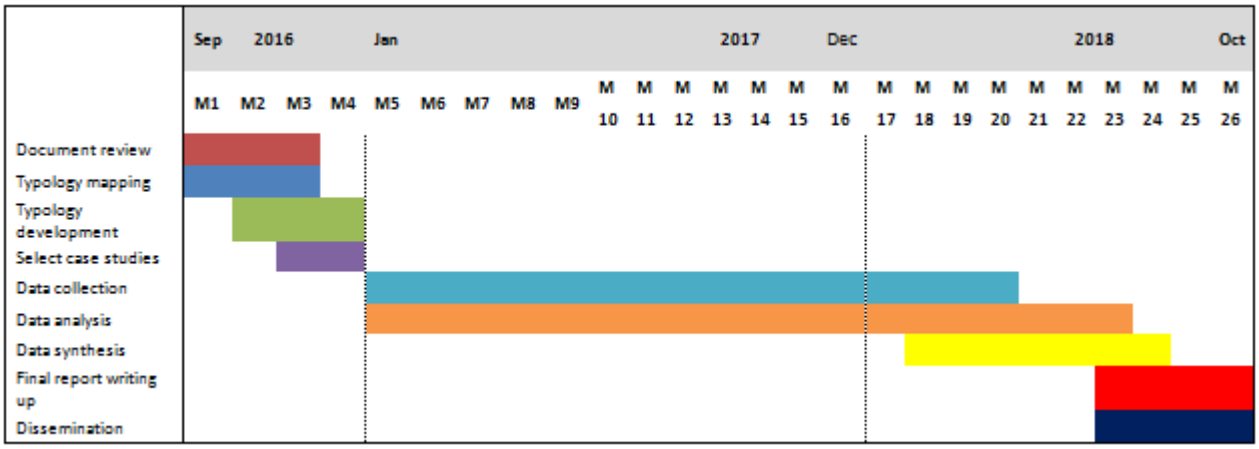
Highlight possible areas of collaboration with other projects

Protocol contributors

The protocol was designed and written by the research team following feedback from anonymous external peer review and discussion with the Primary Care Research Engagement Group (PRIMER) at The University of Manchester and Adele Cresswell, deputy chair of Nottingham Healthwatch.

KEY WORDS: Primary Care; Meta-organisations; Federations

STUDY FLOW CHART



STUDY PROTOCOL

Learning about and learning from GP Federations in the English NHS – a qualitative investigation

1 BACKGROUND

This study is concerned with GP federations. Several years ago the Royal College of GPs, in conjunction with various organisations published a primary care federations toolkit (RCGP Toolkit 2010) which included advice, evidence, case studies and other resources intended to help practices navigate the changing organisational landscape. This document defined federations as groups 'of practices and primary care teams working together, sharing responsibility for developing and delivering high quality, patient focussed services for their local communities'(RCGP Toolkit 2010.). Our study draws on this definition of federations, but since some groups of practices have become 'superpractices', we include these in our definition.

Federations vary in scope and organisational form, from loose alliances of a small number of local practices, to much larger publicly limited provider companies. Potential benefits of federations include efficiencies of scale and scope, strengthening capacity to deliver services outside hospital and improving local integration. Federations present many challenges including balancing individual practice ways of working, autonomy and identity with the requirements of more centralised and standardised procedures which federations imply.

As part of the work involved in producing the RGCP Toolkit (2010), international literature was reviewed and a survey and interviews were undertaken to explore what was happening and how to best achieve the potential of federations. This work highlighted that there are various motivations for practices working together including achieving economies of scale and strengthening their ability to provide services. The authors noted that federations have cost implications, as well as benefits. They also highlighted that involving GPs tends to be easier than involving other members of the primary care team. This raises questions about how and to what extent to involve other staff and patients. Additionally, practices need to consider the extent to which they are willing to give up a degree of independence. The Toolkit authors highlight that although evidence suggests shared governance, peer review and audit are facilitated when practices work together, there is much less evidence with regard to other possible aims of federations. Leadership and high quality management are important for federations to succeed as is highly organised and appropriately incentivised primary care. Whilst there are widespread perceptions that there has been a transfer of responsibilities from secondary to primary care, with practices expected to undertake tasks previously performed in secondary care, there has been no associated shift in resources or significant disinvestment in secondary care provision.

Building a common purpose and gaining external support were seen as important factors impacting on the establishment and sustainability of federations. The Toolkit also provided advice on issues such as organisational structures, staff development and employment contracts as well as providing case studies of a range of federations with related lessons.

2 RATIONALE

The Toolkit research was conducted in 2010 and the landscape is changing. Federations are substantially different to the traditional partnership model, yet little is known about how federations are working in practice today and the implications of these different organisational forms for the organisation of primary care. We will explore how GP federations are working in practice.

3 THEORETICAL FRAMEWORK

Federations involve GP partnerships working together and the extensive literature on partnership working is relevant here. Hunter & Perkins (2014) undertook a systematic review of the literature relating to partnerships in the field of public health. They identified a number of important determinants of successful partnership working, both in terms of process (i.e. the development of mechanisms by which organisations are able to work together) and in terms of outcomes achieved. For the former, establishing clear roles, responsibilities and purpose at an early stage were seen as vital (Hunter & Perkins 2014, p75). However, they also found that conceptions of what constitutes 'success' in partnership working were often confined to this narrow assessment of the extent to which joint working was established, with little focus on actual measurable outcomes (ibid p 68). This latter point is taken up by Fishbacher-Smith (2015), who found that the dominant discourse of 'success' often seen at senior level within developing partnerships, can act to prevent serious discussion of the issues which divide organisations. Sheaff et al. (2012) highlight that partnerships are characterised by concertive control, 'legitimation of collective decisions by appeal either to an organisational culture or to technical knowledge; and as a last resort expulsion of non-compliant members' (p. 15). This raises questions about the mechanisms through which the internal management of federations, which are much larger than GP partnerships, operate to secure compliance.

The literature on networks is also relevant here. Studies focusing on public services suggest that networks are particularly effective in tackling 'wicked problems' (Ferlie et al. 2011; Rittle and Webber 1973). However, this assumes that networks involve groups of people from different types of organisations, whereas Federations involve GP practices as opposed to a variety of different agencies. More generally, there is a literature that is concerned with organisational forms (called variously alliances, partnerships, networks, collaborations) in relation to and as a response to problems facing public service provision. This is concerned with the mechanisms by which such forms are theorised to improve outcomes. Most commentators agree that organisations find autonomy preferable to dependence, but that they may sacrifice some of this to gain access to increased resources. Theories which focus on resource acquisition (Pfeffer and Salancik 1978, Dyer and Singh 1998; see also Oliver 1990) suggest that by forming collaborative alliances, organisations will gain access to a wider range or volume of resources and/or capacity than would otherwise be the case. This may not be enough, however to motivate organisations to actively engage in participation (O'Leary and Bingham 2009; Thomson, Perry and Miller 2009). Other factors, such as having shared goals and linked to this, a perception of organisational legitimacy (DiMaggio and Powell 1983) are also

important. For example, if practices wish to bid for resources, they may appear to have greater legitimacy to external funders if they are collaborating as part of a group, compared with bidding as individual entities. Studies theorise collaborative, inter-organisational arrangements as involving the building of trust, which is important, since such arrangements have implications for autonomy (Thomson and Perry 2006). Perceived trust has been shown to be linked to achievement of goals and increased interactions (Chen 2010).Theorising autonomy as involving more than loss, O'Leary and Bingham (2009) suggest that whilst organisations may relinquish control over some aspects of organisational business, they may develop new sources of autonomy, linked to new forms of power, so that the relationship between collaborative alliances and autonomy is complex and nuanced.

We can conceive of GP federations as a form of network which is developing into an organisation. Early literature on networks (e.g. Miles and Snow, 1986) describes network organising as a consequence of the disaggregation of large firms, but the process of Federation building involves the 'aggregation' of smaller organisations. Federating can be theorised as transforming a network of related but non-competing suppliers of services from an informal arrangement into a more formal organisation, or as part of a 'meta-organisation' (Ahrne and Brunsson, 2008). Meta-organisations are established for the purpose of knowledge creation and exchange, collaboration and the construction of a common set of rules. In addition they involve the formation of a new entity and the creation and reinforcement of status and identity hierarchies within an organisational field (Ahrne and Brunsson, 2010). To survive, they must manage differences between members and between the meta-organisation and its members. This involves continually having to balance their own identities (e.g. 'Smalltown Federation') with those of its members (e.g. SmallStreet Practice). Critics have suggested that the distinction made by Ahrne and Brunsson between organisations and meta-organisations is less clear in practice than suggested (Malets 2010). The authors themselves acknowledge that their work represents a basis for future research, rather than the final word on meta-organisations. However, the ideas contained in the concept of meta-organisations appear helpful. If we view Federations as classifiable along a spectrum comprising Superpractices at one end and loose alliances at the other, we might classify a Superpractice as an organisation and other forms as meta-organisations. Our non-Federation case study also involves organisations as opposed to meta-organisations. We will use the concept of meta-organisations to inform our theoretical approach and we will also compare the extent to which theorised differences between organisations and meta-organisations are confirmed or refuted, based on our empirical data.

4 RESEARCH QUESTION/AIM(S)

The aims of the research are to:

• Provide a wide ranging and in depth exploration of GP federations in England

• Strengthen the evidence base on the organisation and management of general practice for the twenty first century.

4.1 Objectives are to

- Develop an in-depth understanding of how federations are working in a small number of case study sites

- Provide lessons for the wider implementation of new organisational forms in English primary care

4.2 Outcomes

• An in-depth understanding of how federations are working in a small number of case study sites

• Lessons for the wider implementation of new organisational forms in English primary care

5 STUDY DESIGN and METHODS of DATA COLLECTION AND DATA ANALYIS

General Approach

The topic of federations is one which is generating a huge amount of interest. Various researchers are interested in adding to knowledge on this topic. We have designed our study to be different to but also complementary to other approaches which emphasise large scale data collection at the expense of depth.

Prior to commencing our research we have started a mapping exercise to enable us to construct a national picture of the types of federations and their locations. We are using data collected by the Health Services Journal earlier in 2016 and updating this so that it reflects the current state of play. We will use this national picture to inform our research, selecting four case study sites in which to undertake in-depth qualitative research. One of these sites will be a non-federation site to enable us to explore the extent to which the issues we identify are present more generally beyond federations. This will add breadth to our analysis to enable comparison across a wider range of organisational forms. This will also allow us to explore whether federation as a model is perceived as inevitable or whether there are alternatives which are perceived as desirable and legitimate. Since our study is aimed at identifying processes and impacts in relation to federations, it is important to try to isolate the specific issues relating to federations, as opposed to attributing things to federation status which may be the result of other factors. The non-federation case study will enable us to test out emerging findings and preliminary interpretations by comparing federation sites with the non-federation case study site. Based on our earlier work examining 2 federations (GM CLAHRC 2014), we suggest that it is not possible at this stage to simply measure the impact of changes on health (proxy) outcomes, given the diverse objectives of federations and evolving nature of the organisations concerned. Yet it is important to understand how federations are emerging and operating and to produce early lessons to inform their future development.

We will use qualitative methods to explore the stated aims of federations and the mechanisms by which such aims are intended to be achieved. We will also assess progress against these aims. Other

foci will include the perceptions of member practices, including their motivations for joining, the mechanisms by which practices are working together within the federation, enabling and constraining factors regarding establishment and operation of the federation and the impact on the constituent practices (in the widest possible sense including practical impacts on their work, impacts on practice identity etc.). In addition, we will explore impacts on patients in our case study sites using interviews. We will also explore activities in a non-federation site, as well as examining motivations in terms of not federating.

Case study site selection

We will select four case studies to reflect a range of types of organisations, defined according to their form and function. In broad terms although organisational forms differ, a mapping exercise undertaken by the Health Services Journal suggests that it may be possible to group federations into a relatively small number of types. This means that in addition to one non-federation case study (ideally one CCG where no federation exists), we plan to select

a. a set of GP practices with collaborative arrangements but without a significant provider function (sharing back office functions, staff or premises)

b. the creation of a provider entity separate to but owned by GP practices

c. a formal merger of GP practices into a super-practice

In a recent survey, many CCGs declared an intention to incentivise practices to federate (Welika 2015). In a substantial number of CCGs the majority of practices are already in federations. The landscape is evolving and although we plan to select a CCG with no or low GP federation coverage, it may be that our non-federation site is engaged in setting up and running a federation during our study. If this is the case, we will have an opportunity to observe this process as it unfolds. Data collection will include interviews with a range of stakeholders. We will also observe relevant meetings and conduct documentary analysis to add to our understanding of what is happening in case study sites.

Data collection and analysis will be undertaken concurrently. In addition to observations recorded and reflected on and interview transcripts, we will use documentary analysis and any relevant quantitative data produced or discussed in these settings to provide 'thick description' (Geertz 1972) of events. Thick description entails going beyond surface activities, selecting data to create understanding, but 'thickness' is not necessarily concerned with the volume of description. Indeed 'haphazard descriptiveness' (Wolcott 1995) will be avoided. Instead, rather than being distracted due to a well-intended effort at thoroughness by attempting to capture as much data as possible, we will seek out systematic relationships and patterns to enable us to describe thickly and aid understanding.

The selection of four case studies is a compromise between breadth required to capture sufficient variation and the depth that we need for detailed exploration (Segar et al. 2015). We will select case studies in month 4, beginning data collection in month 5. Our plan is to follow these federations and the non-federation site for 16 months from January 2017, enabling us to observe activities through a full annual round of planning and activity.

We will analyse relevant documentation to understand the objectives of the federation and build an initial programme theory. We will interview staff to explore the creation of the federation and its history

and context, how the federation is intended to achieve its aims, as well as views on progress towards these aims. We recognise from our earlier work the difficulty in assessing performance of federations (GM CLAHRC), in part due to the different goals of different federations and the tendency for goals to shift in light of changes in the wider policy environment. Nonetheless, we will subject performance claims and measures by federations to careful scrutiny, seeking to understand the mechanisms underlying any claimed benefits. We will compare federation sites with each other but also with what is happening in the non-federation site.

We expect that federation activities will impact on a range of different staff (for example, standardisation of software and/or documentation may result in changes for clinicians, managerial and administrative staff). We will therefore interview a range of different types of staff and include a range of practices for staff interviews, again adopting a maximum variation approach to this. Selection of interviewees will in part be informed by the aims and activities of the federation, but as a minimum we expect to interview clinicians (doctors and nurses), practice managers, administrative staff, local providers (hospital and/or community) and social care representatives. We will interview patients and carers in a targeted way i.e. we will use the plans and activities of federations to identity potential impacts on patients, and choose relevant respondents. We have budgeted for 200 interviews during the study (i.e. approximately 50 per case), including repeat interviews to capture development over time where indicated. We will observe relevant federation meetings, which will allow us to understand in much more detail the actual functioning and activities of the federation.

All interviews will be digitally recorded and transcribed verbatim. Field notes will be taken during observation of meetings. These will be added to at the earliest opportunity following the end of the meeting. Data collection and analysis will run concurrently. Analysis will initially involve coding transcripts using NVivo software and identifying themes. Whilst we will not adopt a framework approach (Ritchie and Spencer 1994), we will use some of the concepts from the literature on organisational partnerships, as well as organisational behaviour to inform our understanding of the data and focus for data collection. At the same time, we will adopt a sufficiently broad approach to ensure that we do not miss important issues or factors by restricting analysis in too narrow a fashion. Having identified relevant 'first order' codes, we will conduct further analyse to refine what is likely to be a large number of codes to consolidate findings in a smaller number of second order codes which though grounded in the data reflect a higher level of abstraction. This process is aimed at providing generalisable lessons beyond the immediate cases.

Data collection will cease at the end of month 20. This will leave 6 months for further analysis and synthesis to bring our evidence together. For each federation we will produce an in depth description of organisational form, processes and activities, factors that influenced events and actions and a description of the extent to which 'success' (in terms of its stated aims) has been achieved. We will compare across sites to look at common and site-specific factors to generate wider learning. We will be able to explore and build on issues highlighted in the Toolkit in much more detail. For example, many studies in healthcare settings highlight the issue of leadership. However, this raises questions about what 'leadership' means (for example, is it distributed or seen as a property of particular individuals?) and what activities are involved. This makes it difficult for target audiences to use research findings. Our study will focus on producing clear messages in a format which is easily

understood and able to be translated into practice. This is not merely about the presentation of data and the production of outputs which have practical application, but it also arises from our method, which involves in depth exploration. Additionally our exploratory approach will provide invaluable baseline data which will support and enable future quantitative assessment of relevant outcomes.

All study staff and investigators will endeavour to protect the rights of the study participants to privacy and informed consent, and will adhere to the Data Protection Act, 1998. Source data will be held securely, in a locked cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data including the study database and audio files of interviews will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

6 STUDY SETTING

We will have 4 case study sites. These will be 3 Federations and 1 non-Federation site. Federations are groups of GP practices and we expect data collection to be concentrated in practices. However, where relevant we may also interview staff from local provider and local authorities. Data collection will include interviews with a range of stakeholders. We will also observe relevant meetings and conduct documentary analysis to add to our understanding of what is happening in case study sites. These activities will be undertaken at all sites.

7 SAMPLE AND RECRUITMENT

7.1 Eligibility Criteria

- **Staff working in relevant organisations, patients and carers from practices which form relevant organisations**
- **Members of practice patient participation groups**

7.1.1 Inclusion criteria

- **Staff working in relevant organisations, patients and carers from practices which form relevant organisations who consent to be interviewed/observed in meetrings**
- **Members of practice patient participation groups who consent to be interviewed**

7.1.2 Exclusion criteria

- **Staff and patients outside of relevant organisations**
- **Staff and patient group members who refuse consent**

7.2 Sampling

Selection of interviewees will in part be informed by the aims and activities of the federation, but we expect to interview clinicians (doctors and nurses), practice managers, administrative staff, local providers (hospital and/or community) and local authority social care representatives. We will interview patients (and carers where identified) who are involved in the practice patient group.

7.2.1 Size of sample

We will cease interviews when saturation is reached. We have budgeted for 200 interviews during the study (i.e. approximately 50 per case), including some repeat interviews to capture development over time where indicated.

7.2.2 Sampling technique

We will use the stated aims of the federation to help us to identify staff who are likely to be most impacted upon by the news ways of working. However, we will also interview other staff to avoid overstating the impact of federations.

We will adopt a relatively opportunistic approach to patient group interviews/ focus groups since we do not know in advance which issues are likely to be raised/noticed by these groups.

7.3 Recruitment

We will initially approach the Chief Officer of the Federation and investigate their process for considering participation in the study. For the non-Federation site we will approach the relevant CCG. Following agreement of to take part in the study, we will approach the senior leaders of the federation to take part in some initial context-setting interviews in order to explore the structure, governance and operation of the federation. Interviewees will be approached via email, by phone or in person at relevant meetings and asked if they would consider taking part. Prior to any interview they will be provided with a copy of the information sheet and will have adequate time to decide whether or not they wish to and have capacity to take part. Interviews will focus upon staff members' experiences in their job roles, and are not expected to cover any contentious or sensitive personal issues. Once we have developed an understanding of the structure and operation of the Federation, we will ask the Federation to facilitate recruitment of their member practices. Within practices, initial contact will be made with a key informant suggested by the Federation, either by email, phone or in person (e.g. at a federation meeting), based upon the federation's advice as to their preferences. The study will be discussed with this informant, and they will be provided with the study information sheet. If appropriate

we will offer to attend the practice to discuss the study with relevant staff. Once the practice agrees to take part, we will discuss with the key informant the range of staff to be approached to take part in the study, and be guided by them as to the most appropriate mode of contact. We anticipate that interviewees will include nurses, GPs, managers and administrative staff. All of those approached will be provided with the study information sheet, and allowed time to consider whether or not to take part. As with the federation personnel, interviews will focus upon staff members' experiences in their job roles, and are not expected to cover any contentious or sensitive personal issues.

We will ask the Chief Officer to liaise with participating practices in order to identify patient groups at practice level. We will ask participating practices to pass on a request for interview (either with individual members of the group, or if they prefer as a group interview) to their practice patient group. All of those approached will be provided with the study information sheet, and allowed time to consider whether or not to take part. As with the federation personnel, interviews will focus upon experiences in the practice since the federation was created as well as comparing this with their experiences before the new arrangements came into being.

7.3.1 Sample identification

We will ascertain the types and numbers of staff working in the study organisations. We will construct a sampling frame based on this but also based on the types of staff who may be most involved in / impacted on by Federation. Patient groups will be approached by their local practice manager.

7.2.2 Consent

Prior to any interview interviewees will be provided with a copy of the information sheet and will have adequate time to decide whether or not they wish to or have capacity to take part. If appropriate we will offer to attend the practice to discuss the study with relevant staff and/or patient group. Once the practice agrees to take part, all of those approached will be provided with the study information sheet, and allowed time to consider whether or not to take part. As with the federation personnel, interviews will focus upon staff members' experiences in their job roles, and are not expected to cover any contentious or sensitive personal issues.

It will be explained to the potential participant that entry into the study is entirely voluntary. It will also be explained that they can withdraw at any time but attempts will be made to avoid this occurrence. Interviews will be conducted in the host organisation of the participants. If patient groups prefer a focus group form of data collection, then we will use this format as opposed to an individual interview. Patients may be concerned about making critical remarks about their practice, using patient groups who report on behalf of patients is one way of reducing such concerns. Similarly, focus group settings may also help group members to speak freely, although others may prefer the confines of an individual interview.

All interview and focus group participants will provide written informed consent. The Informed Consent Form will be signed and dated by the participant before they enter the study for all interviewees. An original copy of the participant information sheet and consent form will be given to the participant in

addition to the copy retained by the researcher. The Investigator will explain the details of the study and provide a Participant Information Sheet, ensuring that the participant has sufficient time to consider participating or not. The Investigator will answer any questions that the participant has concerning study participation.

For meetings, we will seek permission to attend meetings from the relevant meeting chairpersons. We will ask the Chairs to inform meeting participants in advance that we will be attending (unless they object) and at the beginning of meetings introduce ourselves and the research and allow time for those present to ask any questions. Information sheets will be provided before the meeting and will also be available at the time of the observation. Verbal consent will be confirmed at the start of the meeting. For observation of meetings, verbal consent will be obtained at each meeting. If confidential items are discussed at the meeting the researcher will leave and return only when called back into the meeting. If consent is withdrawn during the meeting the researcher will leave at that point.

The decision regarding participation in the study is entirely voluntary. The investigator or their nominee shall emphasise to them that consent regarding study participation may be withdrawn at any time without penalty.

8 ETHICAL AND REGULATORY CONSIDERATIONS

The research will receive ethical approval and cannot commence until this is given. The research will protect the privacy and personal information of patients. The methods chosen (interviews/focus groups, observation and documentary analysis) are unlikely to pose risks to participants. However, it is important that the identity of participants is kept confidential and we will take steps as described in the protocol to do this.

8.1 Assessment and management of risk

Consent is an ongoing process.

If the interviewer feels that the participant is showing signs of distress or is uncomfortable with the interview, they will be asked if they wish to continue with the interview.

If the participant is clearly distressed, the interview will be terminated immediately and support will be offered from either the interviewer or an appropriate person, e.g. a carer, a relevant healthcare practitioner.

The focus of the interviews will be on understanding systems, processes and outputs in Federations and a non-Federation site. The study is not concerned with the performance of individual practitioners. However, the following statement will be given to all participants as part of the interview introduction:

“What we will talk about today will be confidential, but there are limits to confidentiality. For example, if you were to tell me something new that could put someone at risk of harm, or unsafe practice, I may

have to inform a relevant person. If this happened, I would discuss this with you, and tell you what I was going to do."

8.2 Research Ethics Committee (REC) review & reports

- Before the start of the study, approval will be sought from an NHS REC (for the study protocol, informed consent forms and other relevant documents).
- Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study and where necessary reviewed and accepted by R&D departments, and/or other research governance mechanisms.
- All correspondence with the REC will be retained.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- The Chief Investigator will notify the REC of the end of the study.

For NHS REC reviewed research

- An annual progress report (APR) will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

8.3 Peer review

The funder obtained external peer review comments from several independent expert reviewers. Revisions were made to the design and these were reviewed by an external independent committee convened by the funder.

8.4 Patient & Public Involvement

The aim of PPI in this study is to involve patients, through consultation and in providing advice to the research team, throughout the research process.

To achieve this aim, we have adopted a stakeholder involvement approach to PPI; we will involve patients and members of the public, by consulting them and seeking their advice on the research. This will achieved partly through collaboration with the Primary Care Research Engagement Group (PRIMER) at The University of Manchester. PRIMER members have already reviewed and provided advice on the proposed research, which has been taken account of in the preparation of the research

proposal and this strategy. The PRIMER group have also offered ongoing support, for example, acting as a sounding board for queries on an ad hoc basis, as the study progresses. The proposal has also been reviewed by Adele Cresswell, deputy chair of Nottingham Healthwatch. In addition, a stakeholder advisory group will be established for the study, which will include professional and PPI members. Martin Rathfelder who is a member of the PRIMER group and Adele Cresswell have already agreed to join this group and a further two to three members will be recruited.

The Manchester PRIMER group is made up of patients, carers, service users and other members of the public with an interest in health and social care research. One member of this group, Martin Rathfelder, has agreed to join the stakeholder group, as has Adele Cresswell. Both these people are very experienced in PPI activity and their expertise is likely to be advantageous. In order to ensure involvement from a more 'grassroots' lay perspective, we will recruit two to three people who have used services at the federation case study sites. We have given careful consideration to who is likely to be best placed to contribute from this perspective, as most patients are unlikely to be aware of the existence of GP federations, even if using their services, a view shared by PRIMER; taking this into account, we propose to recruit the PPI collaborators based at the case study sites from the people who are involved with PPI at these federations. Gaining understanding of and views about PPI being undertaken at federations relates to the study research objectives, therefore, we will also be recruiting people involved in PPI at federations to take part in research interviews. We will take the opportunity when contacting these people about the research to also invite them to become PPI collaborators in our study; for example, a tick-box will be included on the consent form or contact form within the recruitment literature, that will indicate willingness to be contacted about being a PPI collaborator for our study. We will be careful to keep research and PPI activity separate and to explain the differences to potential participants and/or PPI collaborators. It would be possible for someone to join as a PPI collaborator, without being a participant.

3.1 Supporting the PPI collaborators

The key attribute of the PPI collaborators recruited from the case study sites will be experience of services at the federation. The PPI collaborators will be asked to undertake the activities outlined in table 1. They will be asked to attend up to three stakeholder advisory group meetings in person during the course of the project, other communication will take place by email or telephone as necessary, for example, feedback on an information leaflet could be provided by email. Collaborators will be supported by the research team, for example, if the team is asking for feedback on an information sheet, we will provide guidance on what to look for. The level of support needed will gauged and discussed with individual PPI collaborators taking into account their skills and experience.

3.2 Management of PPI collaboration activities

Dr Rebecca Elvey (RE) will take responsibility for ensuring the implementation of this strategy and will keep senior members of the team informed through regular project updates and meetings and their support or input will be available as necessary. The practical work involved in facilitating the PPI activity and supporting the PPI collaborators will be carried out by RE, who will oversee the activity and support other, less experienced, members of the team to undertake this on a day to day basis. RE has undertaken PPI training provided by PRIMER and has experience of co-ordinating and undertaking PPI work on previous studies, including supporting PPI collaborators, facilitating

consultation on, for example, recruitment strategies and materials, obtaining feedback on research findings and chairing stakeholder advisory group meetings. The PRIMER group is based within the same faculty where RE and several other team members are based, so further support and/or training will be accessed through PRIMER, if required by staff.

8.5 Regulatory Compliance

- Before any site can enrol staff or patients into the study, the Chief Investigator/Principal Investigator or designee will apply for NHS permission from the site management organisation, HEI or NHS Research & Development (R&D).
- For any amendment that will potentially affect a site's NHS permission, the Chief Investigator/ Principal Investigator or designee will confirm with that site's R&D department that NHS permission is ongoing (note that both substantial amendments, and amendments considered to be non-substantial for the purposes of REC may still need to be notified to NHS R&D).

8.6 Protocol compliance

- Accidental protocol deviations can happen at any time. They must be adequately documented on the relevant forms and reported to the Chief Investigator and Sponsor immediately.
- Deviations from the protocol which are found to frequently recur are not acceptable, will require immediate action and could potentially be classified as a serious breach.

8.7 Data protection and patient confidentiality

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.

Source data will be held securely, in a locked cabinet. Access to the information will be limited to the study staff and investigators and relevant regulatory authorities (see above). Computer held data including the study database and audio files of interviews will be held securely and password protected. All data will be stored on a secure dedicated web server. Access will be restricted by user identifiers and passwords. A file containing linking codes will be held in a separate location from interview transcripts and study field notes using encrypted digital files within password protected folders and storage media. Only study team members will have access to study data.

Electronic data will be backed up every 24 hours to both local and remote media in encrypted format.

The Chief Investigator is the data custodian and will maintain all records and documents regarding the conduct of the study. These will be retained for 10 years or for longer if required. Audio files will be retained for a minimum of 5 years. If the responsible investigator is no longer able to maintain the study records, a second person will be nominated to take over this responsibility.

8.8 Indemnity

The University of Manchester as research Sponsor indemnifies its staff, research participants and research protocols with both public liability insurance and clinical trials insurance. These policies include provision for indemnity in the event of a successful litigious claim for proven non-negligent harm.

8.9 Amendments

If the sponsor wishes to make a substantial amendment to the REC application or the supporting documents, the sponsor will submit a valid notice of amendment to the REC for consideration. It is the sponsor's responsibility to decide whether an amendment is substantial or non-substantial for the purposes of submission to the REC.

Amendments will also be notified to the HRA. The amendment will be submitted in IRAS to HRA, which will determine whether the amendment requires notification to English sites or may be implemented immediately (subject to REC approval were necessary). The research team in consultation with the funder will be responsible for the decision to amend the protocol. The research team in consultation with the sponsor will be responsible for deciding whether an amendment is substantial or non-substantial taking into account HRA guidance. The amendment history will be tracked using version numbers to identify the most recent protocol version.

8.10 Access to the final study dataset

Only members of the study team will have access to the full dataset.

9 DISSEMINATION POLICY

9.1 Dissemination policy

On completion of the study, the data will be analysed and a Final Study Report prepared for the funder. This will be accessible free of charge via the funder's website. All of the participating investigators will have rights to publish any of the study data.

The funding body will be acknowledged within any study publications and they have review and publication rights of the data from the study.

It is possible for any participant to specifically request results from the CI and these would be provided after the Final Study Report has been peer reviewed and published.

The full study report including anonymised quotations will be made publicly available in the final study report which is due for submission at the end of the study. This will be available following external independent peer review and revisions on the funder's website.

9.2 Authorship eligibility guidelines and any intended use of professional writers

All study team members who make a substantive contribution to reading and writing the final report will be granted authorship on the final study report

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11. APPENDICES

11.1 Appendix 1- Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made

List details of all protocol amendments here whenever a new version of the protocol is produced.

Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC committee.