# 2 Participant information sheets

## An investigation of the scale scope and impact of skill mix in primary care

## Participant Information Sheet (PIS) - GP practices

This PIS should be read in conjunction with The University privacy notice

You are being invited to take part in a research study to look at what happens when new types of practitioners work in GP practices. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

#### Who will conduct the research?

Dr Sharon Spooner, School of Health Sciences, University of Manchester, Williamson Building, Oxford Road, Manchester M13 9PL

## What is the purpose of the research?

GP practices teams are changing; in recent years, a greater number a wider range of practitioners from different professions re now employed to see patients in GP practices. There is limited information about how many and what types of practitioners are working, about what they do and how they do it, or about what they and their patients think about these new arrangements.

This study will look at a wide range of information to understand what is happening, what works well and how much it costs to deliver general practice care using a different sort of team. Newer types of team members include advanced practitioners, physician associates, community pharmacists, paramedics, and others and this is generally referred to as 'skill mix'.

#### Why have I been chosen?

You have been chosen to participate because you are a GP practice team member.

## What would I be asked to do if I took part?

There are different levels of participation in this study:

Semi-structured interviews with practice staff (clinical and non-clinical)

Practice staff will be invited to participate in a semi-structured interview lasting no more than one hour. The purpose of the interview is to obtain their views on working with skill mix in an individual interview with a member of the research team. Their anonymity protected by use of a Study ID number. The interview will be audio-recorded and anonymised quotes may be used to illustrate the points that participants raise in the interview.

#### Focus group with members of the Patient Participation Group (PPG)

PPG members will be invited (usually by a member of the practice team) to participate in a group interview. Their anonymity protected by use of a Study ID number. The interview will be audio-recorded and anonymised quotes may be used to illustrate the points that participants raise in the interview.

#### Patient survey and focus group

Patients at your practice will be invited to complete a short survey about their experiences of interactions with your GP practice team members on the day of their consultation. Patients will be asked to return the completed survey on the day by dropping it in a collection box located in the reception area of your GP practice. At the end of the survey, patients will be asked if they are happy to be contacted about being involved in a focus group to explore their views about seeing different types of practitioner. If they are, they will be asked to provide their contact details at the bottom of the survey sheet. If not, they do not need to do anything further. We will not collect any personal or medial information. The focus group will be audio-recorded. Quotes may be used to illustrate the points raised but participants will remain anonymous (known only by study IDs).

## **Observations**

We will ask if you are willing to allow us to observe how practice staff (clinical and non-clinical) manage their day-to-day work and interactions between team members. Observations will be recorded by the researcher in handwritten fieldnotes and typed up soon after the event is observed. The researchers will make notes to gather their impressions of the observation and will privately check their understanding of these with practice staff. For observation of clinical consultation, this will be limited to 60-120 minutes in total.

#### What will happen to my personal information?

We will not hold personal information at a GP Practice level – our access to and the secure storage arrangements for personal information necessary for individuals participating in the research is described in the relevant Participant Information Sheets.

Only the research team will have access to information linking the practice to data gathered at each practice site.

**For information**: We are collecting and storing all personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our <u>Privacy Notice for Research Participants</u>.

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained, and your data will be looked after in the following way:

As indicated above, the **study team** at the University of Manchester will have access to personal identifiable information, that is data which could identify anyone, but they will pseudonymise it **as soon as is practical**. Data will be given a Study ID as soon as possible, the research team will then use the study ID when reporting on this study or linking it into future research. Data will be securely stored and it will only be used for the purpose it has been collected before being destroyed. However **consent forms** will be securely retained at the University of Manchester for a minimum of five years. No third-party software or remote IT systems will be used to store or process personal data.

# Your rights as a participant

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our <u>privacy notice for research</u> and if you wish to contact us about your data protection rights, please email <u>dataprotection@manchester.ac.uk</u> or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

Will my participation in the study be confidential?

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above.

#### For audio recordings:

- The recordings will be used to create transcripts. This will be carried out by a professional transcribing company, who is a UoM approved supplier. The transcribing company will not have access to your personal data and will have signed a Confidentiality Agreement.
- Audio-recordings will be encrypted for added security and kept in accordance with the UoM retention schedule. The recordings will only be accessible to the research team and transcriber.
- Any devices used must be encrypted by UoM and be exclusively for research use.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident and so may be made aware of the participation of your GP practice.

In the event that there are concerns about any participant's safety or the safety of others we may need to contact their GP/care team/family member and we will seek to obtain your agreement in such circumstances.

If other circumstances mean that there is a professional obligation to report misconduct/poor practice we may need to inform an employer/professional body or report current/future illegal activities to the authorities.

# What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been pseudonymised and reported as part of the dataset since we may not be able to identify your specific data. This does not affect your data protection rights.

It is not possible to include you in the interviews if you decline to be part of the audio-recording since this is essential to their participation in the interview part of the study. If you become uncomfortable with the recording process at any point, you are free to stop recording at any time.

## Will my data be used for future research?

When you agree to take part in this research study, the information about your views on the topics that you discuss may be provided to researchers running other research studies in this organisation. The future research should not be incompatible with this research project and will concern delivery of services in general practice. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the <a href="UK Policy">UK Policy</a> Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you personally.

## Will I be paid for participating in the research?

The NIHR Clinical Research Network (CRN) will support back-fill payments for the time spent by GP practice staff participating in the research. The levels of payments vary according to the band or payment allocated by CRN across a range of different types of practitioner and staff roles and are dependent on the type of research activity.

Please contact the PI (sharon.spooner@manchester.ac.uk) to discuss this further.

## What is the duration of the research?

The duration of your participation depends on the part/s of the study in which you are involved:

- The patient survey should be completed in less than 5 minutes
- Semi-structured interviews may take up to 60 minutes
- Focus group with patients and PPG members may take up to 60 minutes per group
- Observations will last between 60-120 minutes

#### Where will the research be conducted?

The research will be conducted at your GP practice site. If focus groups must be arranged in another public building, participants will be advised in advance and they can change their decision to take part if the location is not suitable.

## Will the outcomes of the research be published?

We will be preparing reports, papers and presentations to share the results of our research.

#### Who has reviewed the research project?

The project has been reviewed by experienced researchers and approved by the NHS Research Ethics Committee

## What if I want to make a complaint?

If you have a complaint, you should first contact <a href="mailto:sharon.spooner@manchester.ac.uk">sharon.spooner@manchester.ac.uk</a>

# **Minor complaints**

If you have a minor complaint, then you need to contact the researcher(s) in the first instance.

Dr Sharon Spooner sharon.spooner@manchester.ac.uk

## **Formal Complaints**

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact

The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

<a href="mailto:research.complaints@manchester.ac.uk">research.complaints@manchester.ac.uk</a> or by telephoning 0161 275 2674.

#### What Do I Do Now?

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s) **Dr Sharon Spooner (sharon.spooner@manchester.ac.uk) or** 

This Project Has Been Approved by the NHS Research Ethics Committee.

#### An investigation of the scale, scope and impact of skill mix in primary care

# Participant Information Sheet (PIS) - Patients

This PIS should be read in conjunction with <u>The University privacy notice</u>

You are being invited to take part in a research study to look at what happens when new types of practitioners work in GP practices. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

#### Who will conduct the research?

Dr Sharon Spooner, School of Health Sciences, University of Manchester, Williamson Building, Oxford Road, Manchester M13 9PL

#### What is the purpose of the research?

The people working in GP practices are changing; many practices now offer appointments with 'practitioners' from a wide range of backgrounds in addition to doctors and nurses. Newer types of team members include advanced practitioners, physician associates, community pharmacists, paramedics, and others and this is generally referred to as 'skill mix'.

We have limited information about how many different types of practitioner are employed, or about the sort of services they offer to patients. This study will look at a wide range of information to understand what is happening, what works well and how much it costs to deliver general practice care using a different sort of team.

We want to find out what you think about what happens at your GP practice.

#### Why have I been chosen?

You have been chosen to participate because your GP practice is helping with this research.

#### What would I be asked to do if I took part?

We will ask your consent for a researcher to observe your consultation. We are interested in how the consultation is managed by the practitioner rather than in your medical problem. Observations will be recorded by the researcher in handwritten fieldnotes and typed up soon after the event is observed. The researcher will make notes to gather their impressions of the observation. We will

not have access to any medical records and the researcher will position themselves so that they are not able to read your records on the computer during your observation.

Whether you agree or do not agree to participate, your care from your GP practice team will not be affected either way. Even after you give consent to participate, you may withdraw from the study at any time with no consequences for your health care or your relationship with your GP practice.

#### What will happen to my personal information?

Your name will appear on your Consent Form which will be held separately from other information about your consultation. You do **not** need to supply any further personal information when agreeing for our researcher to observe your consultation. Notes on the observation of your consultation will be assigned a study ID.

All personal information will be held securely (in a locked cabinet or secure computer storage) until no longer needed for this research then destroyed.

We will not include any identifying details in the observation notes and the notes will be securely stored.

Where quotes are used in reports or publications, it will not be possible to identify the person or place where these quotes were obtained.

Personal data (i.e. contact details) will be destroyed when no longer required – in keeping with GDPR requirements. Consent forms will be locked away and retained in compliance with Good Research Practice and GDPR requirements before being destroyed (see below)

Only the research team will have access to information about study IDs.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please ask for our university's document; <u>Privacy Notice for Research Participants</u>.

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

As indicated above, the **study team** at the University of Manchester will have access to your personal identifiable information, that is data which could identify you, but they will pseudonymise your research data **as soon as is practical**. Your data will be given a Study ID as soon as possible, the research team will then use the study ID when reporting on this study or linking it into future research. Personal information will be securely stored and it will only be used for the purpose it has been collected before being destroyed. However, your **consent form** will be securely retained at the University of Manchester for a minimum of five years. No third-party software or remote IT systems will be used to store or process personal data.

#### Your rights as a participant

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our privacy notice for research and if you wish to contact us about your data protection rights, please email <a href="mailto:dataprotection@manchester.ac.uk">dataprotection@manchester.ac.uk</a> or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

## Will my participation in the study be confidential?

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident and so may be made aware of the participation of your GP practice.

In the event that there are concerns about any participant's safety or the safety of others we may need to contact their GP/care team/family member and we will seek to obtain your agreement in such circumstances.

If other circumstances mean that there is a professional obligation to report misconduct/poor practice we may need to inform an employer/professional body or report current/future illegal activities to the authorities.

What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been given a study ID and is in the digital record alongside the data from other participants because we will not be able to identify your specific data. This does not affect your data protection rights.

#### Will my data be used for future research?

When you agree to take part in this research study, the information about your views on the topics that you discuss may be provided to researchers running other research studies in this organisation. The future research should not be incompatible with this research project and will concern delivery of services in general practice. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the <a href="UK Policy">UK Policy</a> Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you personally.

## Will I be paid for participating in the research?

We are unable to make payments to you for your participation in this research.

#### What is the duration of the research?

The observation will last as long as your consultation continues, unless you request that the observation is discontinued at any point.

#### Where will the research be conducted?

The research will be conducted at your GP practice site

# Will the outcomes of the research be published?

We will be preparing reports, papers and presentations to share the results of our research.

## Who has reviewed the research project?

The project has been reviewed by experienced researchers and approved by the NHS Research Ethics Committee

## What if I want to make a complaint?

If you have a complaint, you should first contact <a href="mailto:sharon.spooner@manchester.ac.uk">sharon.spooner@manchester.ac.uk</a>

# **Minor complaints**

If you have a minor complaint, then you need to contact the researcher(s) in the first instance.

Dr Sharon Spooner sharon.spooner@manchester.ac.uk

## **Formal Complaints**

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The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

<a href="mailto:research.complaints@manchester.ac.uk">research.complaints@manchester.ac.uk</a> or by telephoning 0161 275 2674.

#### What Do I Do Now?

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s) **Dr Sharon Spooner (sharon.spooner@manchester.ac.uk) or** 

This Project Has Been Approved by the NHS Research Ethics Committee

# An investigation of the scale, scope and impact of skill mix in primary care Participant Information Sheet (PIS) – Patient Participation Group (PPG)

This PIS should be read in conjunction with The University privacy notice

You are being invited to take part in a research study to look at what happens when new types of practitioners work in GP practices. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

#### Who will conduct the research?

Dr Sharon Spooner, School of Health Sciences, University of Manchester, Williamson Building, Oxford Road, Manchester M13 9PL

#### What is the purpose of the research?

The people working in GP practices are changing; many practices now offer appointments with 'practitioners' from a wide range of backgrounds in addition to doctors and nurses. Newer types of team members include advanced practitioners, physician associates, community pharmacists, paramedics, and others and this is generally referred to as 'skill mix'.

We have limited information about how many different types of practitioner are employed, or about the sort of services they offer to patients. This study will look at a wide range of information to understand what is happening, what works well and how much it costs to deliver general practice care using a different sort of team.

We want to find out what you think about what happens at your GP practice.

#### Why have I been chosen?

You have been chosen to participate because your GP practice is helping with this research.

#### What would I be asked to do if I took part?

You would have completed a short survey about your experiences of your GP practice team members on the day of your consultation. The purpose of this **FOCUS GROUP** is to explore your views about seeing different types of practitioner. The focus group will take **no more than one hour**. You will not be asked to provide any personal or medial information. The focus group will be audio-

recorded. Your words may be used to illustrate the points you have raised but you will remain anonymous (known only by the Study ID of your group).

Whether you agree or do not agree to participate, your care from your GP practice team will not be affected either way. Even after you give consent to participate, you may withdraw from the study at any time with no consequences for your health care or your relationship with your GP practice.

If you are a member of a Patient Participation Group, you will be invited (usually by a member of the practice team) to participate in a FOCUS GROUP. The focus group will be audio-recorded. Quotes may be used to illustrate the points you have raised but you will remain anonymous by being assigned a Study ID number.

## What will happen to my personal information?

The personal information we will have access to will be your name and contact details (e.g. address, phone number or email address) depending on how you prefer us to contact you.

All personal information will be held securely (in a locked cabinet or secure computer storage) until no longer needed for this research then destroyed.

All audio-recordings will be made on encrypted devices and transcribed by a company approved by the university for this confidential work.

We will promptly remove any identifying details from the transcripts of interviews and the data will be securely stored for use in this and other research studies.

Where quotes are used in reports or publications, it will not be possible to identify the person or place where these quotes were obtained.

Personal data (i.e. contact details) will be destroyed when no longer required – in keeping with GDPR requirements. Audio recordings and consent forms will be locked away and retained in compliance with Good Research Practice and GDPR requirements before being destroyed (see below)

Only the research team will have access to information about study IDs.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about

the way we process your personal information and comply with data protection law please ask for our university's document; <u>Privacy Notice for Research Participants</u>.

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

As indicated above, the **study team** at the University of Manchester will have access to your personal identifiable information, that is data which could identify you, but they will pseudonymise your research data **as soon as is practical**. Your data will be given a Study ID as soon as possible, the research team will then use the study ID when reporting on this study or linking it into future research. Personal information will be securely stored and it will only be used for the purpose it has been collected before being destroyed. However, your **consent form** will be securely retained at the University of Manchester for a minimum of 5 years. No third-party software or remote IT systems will be used to store or process personal data.

#### Your rights as a participant

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our <u>privacy notice for research</u> and if you wish to contact us about your data protection rights, please email <u>dataprotection@manchester.ac.uk</u> or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

## Will my participation in the study be confidential?

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above.

#### For audio recordings:

 The recordings will be used to create transcripts. This will be carried out by a professional transcribing company, who is a UoM approved supplier. The transcribing company will not have access to your personal data and will have signed a Confidentiality Agreement.

- Audio-recordings will be encrypted for added security and kept in accordance with the UoM retention schedule. The recordings will only be accessible to the research team and transcriber.
- Any devices used must be encrypted by UoM and be exclusively for research use.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident and so may be made aware of the participation of your GP practice.

In the event that there are concerns about any participant's safety or the safety of others we may need to contact their GP/care team/family member and we will seek to obtain your agreement in such circumstances.

If other circumstances mean that there is a professional obligation to report misconduct/poor practice we may need to inform an employer/professional body or report current/future illegal activities to the authorities.

## What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been given a study ID and is in the digital record alongside the data from others in a focus group because we will not be able to identify your specific data. This does not affect your data protection rights.

It is not possible to include you in the interviews if you decline to be part of the audio-recording since this is essential to your participation in the interview part of the study. If you become uncomfortable with the recording process at any point, you are free to request that we stop recording at any time or you may leave a group interview.

#### Will my data be used for future research?

When you agree to take part in this research study, the information about your views on the topics that you discuss may be provided to researchers running other research studies in this organisation. The future research should not be incompatible with this research project and will concern delivery of services in general practice. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only

be used by organisations and researchers to conduct research in accordance with the **UK Policy** 

Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that

could identify you. The information will only be used for the purpose of health and care research and

cannot be used to contact you regarding any other matter or to affect your care. It will not be used

to make decisions about future services available to you personally.

Will I be paid for participating in the research?

We are unable to make payments to you for your participation in this research however we

anticipate that light refreshments will be provided from research funds for group interviews.

What is the duration of the research?

The focus group may take up to 60 minutes.

Where will the research be conducted?

The research will usually be conducted at your GP practice site (you will be advised in advance if the

focus group must be arranged in another public building and change your decision about taking part

if that is not suitable for you)

Will the outcomes of the research be published?

We will be preparing reports, papers and presentations to share the results of our research.

Who has reviewed the research project?

The project has been reviewed by experienced researchers and approved by the NHS Research

**Ethics Committee** 

What if I want to make a complaint?

If you have a complaint, you should first contact <a href="mailto:sharon.spooner@manchester.ac.uk">sharon.spooner@manchester.ac.uk</a>

Minor complaints

If you have a minor complaint, then you need to contact the researcher(s) in the first instance.

Dr Sharon Spooner <u>sharon.spooner@manchester.ac.uk</u>

**Formal Complaints** 

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance, then please contact

The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

## What Do I Do Now?

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s) **Dr Sharon Spooner sharon.spooner@manchester.ac.uk** 

This Project Has Been Approved by the NHS Research Ethics Committee

## An investigation of the scale scope and impact of skill mix in primary care

## Participant Information Sheet (PIS) - Practice staff

This PIS should be read in conjunction with <u>The University privacy notice</u>

You are being invited to take part in a research study to look at what happens when new types of practitioners work in GP practices. Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for taking the time to read this.

#### Who will conduct the research?

Dr Sharon Spooner, School of Health Sciences, University of Manchester, Williamson Building, Oxford Road, Manchester M13 9PL

#### What is the purpose of the research?

GP practices teams are changing; in recent years, a greater number a wider range of practitioners from different professions re now employed to see patients in GP practices. There is limited information about how many and what types of practitioners are working, about what they do and how they do it, or about what they and their patients think about these new arrangements.

This study will look at a wide range of information to understand what is happening, what works well and how much it costs to deliver general practice care using a different sort of team. Newer types of team members include advanced practitioners, physician associates, community pharmacists, paramedics, and others and this is generally referred to as 'skill mix'.

## Why have I been chosen?

You have been chosen to participate because you are a GP practice team member in a practice which is interested in taking part in this research.

## What would I be asked to do if I took part?

You may be asked to take part in an interview and/or allow a researcher to observe you while you work.

#### **Interviews**

You will be invited to participate in a semi-structured interview lasting no more than one hour. The purpose of the interview is to obtain your views on working with skill mix in an individual interview with a member of the research team. Your anonymity protected by use of a Study ID number and this will not be known to anyone apart from the research team. The interview will be audio-recorded and anonymised quotes may be used to illustrate the points that you raise in the interview.

#### **Observations**

We will ask if you are willing to allow us to observe how you manage your day-to-day work and your interaction with other team members. Observations will be recorded by the researcher in handwritten fieldnotes and typed up soon after the event is observed. The researchers will make notes to gather their impressions of the observation and will privately check their understanding of these with you. Researchers will not have access to patients' medical records or record identifying details during periods of observation. For observation of clinical consultations, this will be limited to 60-120 minutes in total and take place only where the patient has also consented to the observation.

You (or your patient) can ask to stop the interview and/or observation at any time you wish to do so with your data deleted or kept according to your (or your patient's) preference.

## What will happen to my personal information?

The personal information we will have about you will be your name, your role, your training background and your level of experience in your current role.

All personal information will be held securely (in a locked cabinet or secure computer storage) until no longer needed for this research then destroyed.

All audio-recordings will be made on encrypted devices and transcribed by a company approved by the University of Manchester for this confidential work.

We will promptly remove any identifying details from the transcripts of interviews and the data will be securely stored.

Where quotes are used in reports or publications, it will not be possible to identify the person or place where these quotes were obtained.

Personal data (i.e. contact details) will be destroyed when no longer required – in keeping with GDPR requirements. Audio recordings and consent forms will be retained in compliance with Good Research Practice and GDPR requirements before being destroyed (see below)

Only the research team will have access to information linking individual participants to their data.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is "public interest task" and "for research purposes" if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our Privacy Notice for Research Participants.

The University of Manchester, as Data Controller for this project, takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University has safeguards in place such as policies and procedures. All researchers are appropriately trained and your data will be looked after in the following way:

As indicated above, the **study team** at the University of Manchester will have access to your personal identifiable information, that is data which could identify you, but they will pseudonymise it **as soon as is practical**. Your data will be given a Study ID as soon as possible, the research team will then use the study ID when reporting on this study or linking it into future research. Data will be securely stored and it will only be used for the purpose it has been collected before being destroyed. However, your **consent form** will be securely retained at the University of Manchester for a minimum of five years. No third-party software or remote IT systems will be used to store or process personal data.

## Your rights as a participant

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you, including audio recordings. This is known as a Subject Access Request. If you would like to know more about your different rights, please consult our <u>privacy notice for research</u> and if you wish to contact us about your data protection rights, please email <u>dataprotection@manchester.ac.uk</u> or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office, Tel 0303 123 1113

Will my participation in the study be confidential?

Your participation in the study will be kept confidential to the study team and those with access to your personal information as listed above.

#### For audio recordings:

- The recordings will be used to create transcripts. This will be carried out by a professional transcribing company, who is a UoM approved supplier. The transcribing company will not have access to your personal data and will have signed a Confidentiality Agreement.
- Audio-recordings will be encrypted for added security and kept in accordance with the UoM retention schedule. The recordings will only be accessible to the research team and transcriber.
- Any devices used must be encrypted by the University of Manchester and be exclusively for research use.

Individuals from the University, the site where the research is taking place and regulatory authorities may need to review the study information for auditing and monitoring purposes or in the event of an incident and so may be made aware of the participation of your GP practice.

In the event that there are concerns about any participant's safety or the safety of others we may need to contact their GP/care team/family member and we will seek to obtain your agreement in such circumstances.

If other circumstances mean that there is a professional obligation to report misconduct/poor practice we may need to inform an employer/professional body or report current/future illegal activities to the authorities.

## What happens if I do not want to take part or if I change my mind?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been pseudonymised and forms part of the dataset as we will not be able to identify your specific data. This does not affect your data protection rights.

It is not possible to include you in the interviews if you decline to be part of the audio-recording since this is essential to their participation in the interview part of the study. If you become uncomfortable with the recording process at any point, you are free to stop recording at any time.

#### Will my data be used for future research?

When you agree to take part in this research study, the information about your views on the topics that you discuss may be provided to researchers running other research studies in this organisation. The future research should not be incompatible with this research project and will concern delivery of services in general practice. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the <a href="UK Policy">UK Policy</a> Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research and cannot be used to contact you regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you personally.

## Will I be paid for participating in the research?

The Clinical Research Network is able to provide back-fill funding for the time that staff members step out of their normal roles to participate in interviews.

#### What is the duration of the research?

The duration of your participation depends on the part/s of the study in which you are involved:

Semi-structured interview may take up to 60 minutes

Observation last between 60-120 minutes

#### Where will the research be conducted?

The research will be conducted at your GP practice site

## Will the outcomes of the research be published?

We will be preparing reports, papers and presentations to share the results of our research.

#### Who has reviewed the research project?

The project has been reviewed by experienced researchers and approved by the NHS Research Ethics Committee

## What if I want to make a complaint?

If you have a complaint, you should first contact <a href="mailto:sharon.spooner@manchester.ac.uk">sharon.spooner@manchester.ac.uk</a>

## **Minor complaints**

If you have a minor complaint, then you need to contact the researcher(s) in the first instance.

Dr Sharon Spooner <u>sharon.spooner@manchester.ac.uk</u>

# **Formal Complaints**

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing:

research.complaints@manchester.ac.uk or by telephoning 0161 275 2674.

#### What Do I Do Now?

If you have any queries about the study or if you are interested in taking part, then please contact the researcher(s) **Dr Sharon Spooner sharon.spooner@manchester.ac.uk** 

This Project Has Been Approved by the NHS Research Ethics Committee