

Participant Information Leaflet – Patient Participants in Quantitative Data Collection (PQDC)

Study Title

General Practice Management After Transition Events (GP-MATE) - Developing an intervention to assist older patients' communication with their GP practice after discharge from hospital in order to improve patient safety

Investigators

Dr Rachel Spencer, (Associate Professor of general practice) who is based at the University of Warwick, is responsible for this project.

Introduction

You are invited to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others about the study if you wish. Please ask us 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. If you have any questions, would like any further information, or want to discuss participating further, please call us on 02476151193.

In this research study we will use information from you, your medical record and from your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it AND/OR for future research. We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this.

How will we use information about you?

We will need to use information from you, your medical record and from your GP for this research project. This information will include all elements of your medical records being viewed at your GP site, but only non-identifiable information will ever leave your GP site. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for

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the research to be reliable. This means that we won't be able to let you see or change the data we hold about you. If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study on secure University of Warwick servers.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients, by asking one of the research team, by sending an email to r.spencer.2@warwick.ac.uk, by ringing us on 02476151193 or emailing the sponsor's data protection officer on: infocompliance@warwick.ac.uk. Find out more technical information about patient data and research here: <http://www.hra.nhs.uk/patientdataandresearch>.

Who is organising and funding the study?

The study is being co-ordinated and sponsored by the University of Warwick and is led by Dr Rachel Spencer. The study is funded by the National Institute for Health Research Advanced Fellowship (Award number 301328).

What is the study about?

We would like you to take part in this study that is developing a communication tool for older patients who have been discharged from hospital to better enable them to interact with their general practice. We aim to make and test an approach ('GP-MATE') to assist older patients and their carers to discuss with their GP practice their care after coming home from hospital. This is to make care safer and prevent mistakes from occurring. Older patients and their carers have a key role to play in preventing these errors and harms. GP-MATE will be designed to help them take a more active role in their general practice care after coming home from hospital. It will help empower them to do so with greater success.

What would taking part involve?

You have important experiences of recently being discharged from hospital (or of caring for somebody who has been discharged) that you can share with the research team. We want to focus on older people as we think they have the most to gain from our work. As part of the study your general practice has been using the GP-MATE communication tool and there is a copy of it for you in this pack. This copy of GP-MATE is yours and you can use it as you choose. We would like you to use GP-MATE for the consultation that you will be offered by your general practice to talk about your care since coming home from hospital. We have included a questionnaire too which we would like you to complete after your appointment. If you are happy to proceed, then please have GP-MATE to hand when you have your appointment with your GP practice. If you want to write notes on it prior to or during the appointment, feel free to do so – it is yours to keep. The appointment might be face-to-face, by phone or by video call depending on what you and your GP practice have chosen.

After your appointment, please fill out the questionnaire while the ideas are still fresh in your mind. You can return these in the pre-paid envelope.

If you think you would be willing to be interviewed as part of the study, then please read the enclosed information sheet for interviews. If you are happy to proceed then please fill out an expression of interest form (enclosed) and post it back to us with your questionnaire.

If you think it would be OK for us to take a photo copy of your GP-MATE and the notes you have made then please indicate this on the expression of interest form. Don't think about agreeing to this until you have finished using your GP-MATE. This is because you might need to write something

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personal on the GP-MATE that you wouldn't want to share with us. We don't want concerns about that to affect how you use your GP-MATE.

The entire study runs over four years and will finish in 2025. The stage you are taking part in will be conducted in 2023/4. You will be participating for around an hour's time in total depending on how much you want to get involved.

Do I have to take part in the study?

No. It is up to you to decide whether you want to take part. Your GP practice will be ready to use the GP-MATE with you if you want to, but you do not have to. You do not have to attend the appointment that your GP practice offers you for the purposes of the study but do please tell them if you are not willing to have the appointment when they contact you. You are free to change your mind and withdraw from the study at any time and you do not have to give a reason why. You can choose which parts of the study you want to take part in, and you can choose how you use GP-MATE. Your future care with your general practice team will not be affected by taking part in the study. We are also looking at patients' medical records at the practice as part of this study and taking anonymised data from them. If you don't want your medical records to be used at all for the study please contact your practice to let them know or fill in the opt out form enclosed.

What are the possible benefits of taking part?

You will be helping others by taking part. You will help: other patients and carers; general practice staff (including your own general practice); hospital teams; other researchers looking to promote patient voices.

What are the possible disadvantages, side effects or risks, of taking part in this study?

We do not believe there are any major risks to taking part in this study. An experienced GP is leading the study. There is a procedure in place to relay information to your clinical team if it is necessary for the safety of your care.

Expenses and payments

There are no payments for taking part in the study and we do not anticipate any expenses for those who take part.

Will my details be kept confidential?

We will be collecting data from your medical records at your general practice and putting it on to a paper form or an electronic database. This is special data, so we handle it especially carefully. We will assign all patients a unique identifier code – once your data leaves your practice it is anonymised, the only key to crack this code is held at your general practice. We may also be collecting paper questionnaires from you if you choose to fill them in (these have your unique code on them). If you return an Expression of Interest Form for an interview, we will separate your contact details immediately from your questionnaires. We will always ensure that any material that may identify who you are, has the identifiable data removed before there is any analysis of the data. All information that is collected during the study will be kept confidential at all times and held in compliance with the Data Protection Act 2018. All electronic data will be stored in a secure format. Study documentation and data will be archived for at least ten years. The only reason we would break confidentiality would be in an emergency. If your own health, or somebody else's health, was

in danger, we would contact your GP. We might agree to share anonymised data with other, carefully selected, researchers; any such sharing will be closely monitored by the University

What will happen to the data collected about me?

As a publicly-funded organisation, the University of Warwick have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, such as this, we will use your data in the ways needed to conduct and analyse the research study. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. We are committed to protecting the rights of individuals in line with data protection legislation. The University of Warwick will only keep identifiable information about you if you fill in the expression of interest form and they will keep this contact information for 2 years after the study.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe. This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project.

Research data gathered from your medical record will be **anonymised** at the point of collection, before the data leaves your general practice, and it will not be possible to withdraw your data after this point. Your questionnaire returns are also anonymous to us unless you choose to fill in an expression of interest form. We will use a special participant number to link your questionnaire to the anonymised data we have gathered from your medical records. If you return an expression of interest form we will separate this from your questionnaire results immediately so that your contact details are never kept in the same place as your medical data. It is not our intention to ever link your contact details with our study data, but we do need to be able to get hold of you if you decide to participate in an interview.

Data Sharing

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. The University of Warwick has in place policies and procedures to keep your data safe.

This data may also be used for future research, including impact activities following review and approval by an independent Research Ethics Committee and subject to your consent at the outset of this research project. For further information, please refer to the University of Warwick Research Privacy Notice which is available here:

<https://warwick.ac.uk/services/idc/dataprotection/privacynotices/researchprivacynotice> or by contacting the Legal and Compliance Team at GDPR@warwick.ac.uk.

What will happen if I don't want to carry on being part of the study?

You are free to change your mind and withdraw from the study at any time and you do not have to give a reason why. Please note that if you withdraw from the study, it will not be possible to withdraw your questionnaire or medical record data which have already been collected because they have been anonymised. Even if you filled an expression of interest form we won't be able to remove your data because we will have separated this form from the rest of the study data. To safeguard your rights, we will use the minimum personally-identifiable information possible and keep the data secure in line with the University's Information and Data Compliance policies.

What will happen with the results of the study?

We will present the findings in a study report and in health and medical journals. You will not be identified in any of the publications. The study team will let your GP practice know about the results by sending a brief summary of the study findings. You can opt to have a copy of the results sent to you by email if you desire (please indicate this on the expression of interest form).

Who has reviewed the study?

Any research that involves the NHS and patients is subject to review by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This study has been reviewed and given favourable by East of England - Essex Research Ethics Committee, Reference 21/EE/0227. It has also been reviewed by the Confidentiality Advisory Group who have deferred a decision until after we have undertaken our co-production process.

Who can I contact if I need more information?

This study is covered by the University of Warwick's insurance and indemnity cover. If you have any concerns about this study, please contact the Chief Investigator of the study. If you have any questions about the study, or your involvement in it, either now or in the future, do please contact the study team using the details below:

Dr Rachel Spencer (Chief investigator and study co-ordinator)

Unit of Academic Primary Care,
Warwick Medical School,
University of Warwick, Coventry,
CV4 7AL

Email: r.spencer.2@warwick.ac.uk

Telephone: 02476151193

Who should I contact if I wish to make a complaint?

Any complaint about the way you have been dealt with during the study or any possible harm you might have suffered will be addressed. Please address your complaint to the person below, who is a senior University of Warwick official entirely independent of this study:

Head of Research Governance,
Research & Impact Services,
University House,
University of Warwick,
Coventry,
CV4 8UW

Tel: 02476 575733

Email: researchgovernance@warwick.ac.uk

Thank you for taking time to read this information leaflet and for considering the study.