Martha's Rule Study:
Do people know about and how do they use Martha's Rule

Patient and Family Participant Information Sheet

Thank you for your time and for completing the initial screening questions, during which you answered some questions about your experience as an inpatient. We would like to invite you to participate in an interview. Before you decide whether you would like to take part, please take time to read the following information carefully and discuss it with others if you wish. Do ask the researcher who sent this information if you have any questions, if anything is unclear, or you would like more information.

What is the study about?

We are doing interviews with patients, family members and staff to look at how Martha's Rule is being rolled out across three NHS Trusts in England. Martha's rule intends to give patients and their families, as well as staff, an easy way of asking for advice (or a medical review) at any time when they feel themselves or a loved one is getting worse (or more poorly), and they don't feel that their concerns are being taken seriously by the healthcare staff who are looking after them. This review will be from a nurse or doctor who works in a different clinical team, normally called a critical care outreach team (CCOT). Martha's Rule also involves healthcare staff having to ask patients and their families about a patient's condition at least once a day.

We are inviting a small number of patients to participate in an interview to understand their views about Martha's Rule and their experience of being asked about their condition on a daily basis. We are also interested to hear their decision about whether or not to raise any concerns about their care through [local activation system e.g. Call4Concern helpline]. The aim of the research is to understand how this service works, improve this service and the support available to people receiving inpatient treatment and care, as well as to help healthcare providers and policy makers further develop Martha's Rule in the next stage of the rollout.

Who is carrying out this study?

The interviews are being carried out by researchers from the NIHR Quality Safety and Outcomes Policy Research Unit and Yorkshire Quality and Safety Research Group. The study is led by Professors Rebecca Lawton and Beth Fylan. The research is funded by the National Institute of Health Research (NIHR) and the Department of Health and Social Care.

Why have I been invited to take part?

You have received this information sheet because you were or your loved one was recently an inpatient on a ward and/or you contacted the research team after seeing an advert about the study, and were one of the people chosen to be interviewed. Our selection of who to interview is based on the need to hear from a range of people with different backgrounds and experiences, including those from diverse ethnic, religious, sexual and gender groups as well as disabled people.

We would like to know more about people's experiences of receiving NHS inpatient care as well as their awareness and views of Martha's Rule. The interview will focus on topics that are related to your personal experience of healthcare.

What will taking part in the study involve?

If you decide to take part, you will be interviewed by a member of the research team. During the interview, you will be asked to briefly describe your/your loved one's healthcare experience in your own words, and the researcher will then ask you some follow-up questions about this experience as well as your views on Martha's Rule. You can choose to have a friend or family member with you for support if you wish. The interview would take place at a convenient time for you, either in person or using video-conferencing software (such as Zoom, Teams, Skype, or Facetime) or over the telephone. In exceptional circumstances, it may be possible to do the interview in your home – please let the researcher know if this is your preference. The interview will usually last between 30 and 60 minutes. With your permission, this time may be extended when needed to allow you to tell us about your experience in a way that is meaningful to you.

The interviews will be audio-recorded with your permission so that the researcher can concentrate on what you have to say rather than having to write your views and experiences down at the same time. If you do decide to take part, it is important to remember that you do not have to answer any question that you do not want to, and you can end the interview or ask to pause the recording at any time. Once the interview is over, the researcher will explain what will happen to the information you have provided and will thank you for your time. At this point you will have another chance to ask any questions you have about the study.

Do I have to take part?

No, it is entirely up to you whether or not you decide to take part. If you would like more information about the study, please contact the researcher who sent this information sheet and they will be happy to provide it or to answer any questions you might have.

Taking part will not affect the care or treatment you receive from your healthcare provider. If you decide to take part you are still free to withdraw at any time without giving a reason, after which you will not be contacted again by the researcher.

What will happen to the information I give? Is the study confidential?

This study will help policy makers and healthcare providers in the NHS to improve patient safety, as well as to ensure they can support and address the needs of a wide range of people who might need to raise their concerns about their worsening condition whilst admitted in hospital.

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor for the research and have full responsibility for the project including the collection, storage and analysis of your data, and will act as the Data Controller for the study. This means that we are responsible for looking after your information and using it properly.

Everything you tell us will be strictly confidential and you will not be identified in any reports of the study results. However, there are some exceptions to this. If you tell me about:

- a serious risk to yourself or others
- a serious concern or risk to health, welfare or safety of children or vulnerable adults

In this case, the researcher will discuss this with you and the rest of the research team, and will inform you if there is a need for confidentiality to be broken.

No one outside of the research team will be able to trace anything said in the interview back to you as an individual. The interviews will be typed up by professionals who have signed confidentiality agreements with the research team. The data from this study will not include any names or identifiable information. Electronic files, including audio-recordings, will be encrypted and password-protected, and stored securely on Bradford

Teaching Hospitals NHS Foundation Trust computer network and in line with the General Data Protection Regulation (2018). Your personal details, meaning your name and other identifiable information, will be kept in a different safe place to the other study information. Personal contact details will be kept for 1 year after the end of the study to allow the research team to send you the results of the study. All other study information (which will not contain any of your personal information) and a securely stored copy of your consent form will be destroyed 10 years after the end of the study.

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 Jane Dennison, Bradford Teaching Hospitals NHS Foundation Trust, Jane.Dennison@bthft.nhs.uk

What will happen to the results of this study?
The study results will be published in scientific journals and presented at conferences so that NHS healthcare organisations, professionals, and academics can learn from them. Your personal information will not be included in the study reports and there will be no way that you can be identified from them.

What are the possible benefits?
We cannot promise that the study will help you personally. However, we have found that people often appreciate being interviewed, as it's an opportunity to talk about your experience to an attentive listener. At the same time, you will be contributing to research of national importance. The information we get from the study will help our knowledge and understanding of patient experiences of Martha's Rule. If you decide to participate, we will give/send you a total of £15 shopping vouchers following the interview(s) as a thank you for your time.

What are the possible risks or disadvantages of taking part? If you decide to take part in this research, you would need to give up some of your time to complete the interviews with the researcher. Due to the nature of this research, the interview would involve discussing aspects that may be particularly sensitive for you. You do not have to discuss anything you don't feel comfortable with and you can refuse to answer any questions. The research team can provide support if you are finding it upsetting or provide details of other sources of support if you need extra support.

What can I do if I have any concerns about the study?
If you have a concern about any aspect of this study, you should ask to speak to the research team who will do their best to answer your questions 07919035899. If you remain unhappy and wish to complain formally, you can do this by contacting: Jane Dennison at Jane.Dennison@bthft.nhs.uk or +44 (0)1274 272575.

Bradford Teaching Hospitals NHS Foundation Trust holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

What will happen if I don't want to carry on with the study? You can stop taking part in the study at any time. You do not have to give a reason why you want to stop, but this information can be helpful because it can help us identify problems with the study and areas for improvement. If you decide to stop taking part in the study the researcher will ask if you are able to give a reason why but you do not have to. If you decide to stop taking part in the study it will not affect your future care. If you decide to stop taking part in the whole study, the researcher will ask whether you would like us to destroy the information you have given us in the research so far or if you are happy for this to be included in the study.

What do I do if I am interested in taking part?
One of the research team will contact you to talk with you about whether you would like to take part in an interview and to arrange this with you if you decide to go ahead. You can also contact the researcher on 07919035899 if you prefer.

Who has reviewed the study?
The study has been looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been given a favourable opinion by the Yorkshire & The Humber - Leeds West Research Ethics Committee Research Ethics Committee (Ref: 24/YH/0184).

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form.

If you have any questions or would like to know more, please contact Lavanya Thana at QSO PRU 07919 035899 or marthasrule.study@bthft.nhs.uk. At the end of the study, findings from the study will be made available on our website: https://yqsr.org/our-research-programmes/pru/ and will be sent to you if you would like this to happen.