

Evaluation of new guidance to support more meaningful involvement of patients and families in serious incident investigations

Participant Information Sheet: Investigators

Invitation to take part

We are inviting you to take part in this research in the hope that you find it beneficial in your role as an investigator. The aim is to test new guidance that has been developed to more meaningfully involve patients and families in serious incident investigations. The guidance has been developed in partnership with patients and families who have been through a serious incident investigation, investigators, and other relevant stakeholders such as healthcare staff, researchers and policy makers. We want to know if the new guidance influences serious incident investigations in terms of depth of learning, focus of recommendations and action plans, and decisions to litigate. Before you decide if you would like to take part, please read this information sheet to understand why the research is being done and what it might mean for you as an investigator. Don't hesitate to get in touch with any questions you might have (contact details can be found at the end of this sheet).

What is the purpose of the study?

We know that greater involvement of patients and families in serious incident investigations can lead to better learning, meaning that incidents are less likely to occur in the future. However, until now, there has been very little guidance to support patient and family involvement.

To develop our guidance, we interviewed 50 people with first-hand experience of serious incident investigations. This included patients and family members as well as healthcare staff, investigators and legal representatives. We also brought people from each of these groups together in a series of workshops. They helped us to design the guidance by using their own experiences and professional expertise to think about what they would like to happen differently in the future.

We understand that you have specific policies and procedures to adhere to when conducting an investigation. We have worked closely with the organisation you are employed by to ensure that our new guidance complements the existing serious incident investigation procedure. We understand that each investigation is unique, but the new guidance might (where appropriate) include:

- Contacting the patient or family member(s) more regularly with updates about the investigation;
- Inviting patients and family members to be involved throughout the investigation by sharing their experience of the incident, and their expectations of the investigation process;
- Inviting patients and family members to work with the Trust to help make recommendations and action plans for improvement.

This work is part of a 3-year research project running until 2023 which aims to develop, test and evaluate the new guidance. Data from this study will be used to refine the new guidance, and to share learning with those who will be using the new guidance in the future.

Why have I been invited to take part?

You have been invited to take part because you are employed by one of our partner organisations and as part of your role you investigate serious healthcare incidents. If you agree to take part in this research, you are agreeing to implement the new guidance, alongside the standard investigation protocol you currently work to, in selected investigations. You will be trained in the new guidance, and will be involved in any discussions about implementing the new guidance in investigations you have been assigned. This will only proceed if the patients and family members also give their consent. Through the course of the study, we would like to hear about your experience of implementing the new guidance; anything that you feel works well, any barriers or challenges to implementation, and any ideas you might have for refining it further.

Do I have to take part?

No.

It is entirely up to you to decide whether or not to take part. If you agree to take part, you can change your mind and/or withdraw at any time without providing a reason. If you decide to take part, you may wish to keep this information sheet in a safe place for future reference.

What will happen to me if I take part?

If you agree to take part, we will ask you to sign a consent form in which you will be asked to agree to undertake some short training in the new guidance, as well as to implement the new guidance in certain serious incident investigations if asked to do so by the research team. Once you have completed some short training, you will be offered the opportunity to ask the research team any questions about the new guidance, and will be provided with resources to support your use of the new guidance during investigations. You will also be asked to agree to two research interviews:

- An initial briefing interview before the investigation begins with the member of the research team who will be following the specific investigation. During this interview you might be asked questions about how you plan to use the new guidance during the investigation, and any potential barriers or challenges you have identified. This interview is expected to last around 60 minutes.
- A debriefing interview after the investigation with the same member of the research team. During this interview you might be asked questions about your experience of implementing the new guidance during the investigation, and the impact of using the new guidance during the investigation. This interview is expected to last around 90 minutes.

The interview can be conducted face-to-face, over the telephone, or using video software such as Zoom or MS Teams. You will be able to choose how you would prefer to be interviewed, and the time and location of the interviews will be mutually agreed with the researcher. Face-to-face interviews will be carried out in accordance with local Covid-19 guidance. The researcher will verbally check that you still give consent for the interview before it begins, and you will be able to ask for the interview to be stopped or paused at any point, decline to comment on specific issues, or decline to answer specific questions without giving a reason.

Researcher Observations

You will also be asked to give your consent for a researcher to observe the training process and to follow investigations in which you implement the new guidance. A member of the research team will be assigned to observe the delivery of the training, and follow each of these investigations. During the training, they will not be observing you directly, but will be capturing notes about how the training is delivered and might informally ask you for your reflections about what went well and what could be improved. During the investigation, they might ask to observe you working on the investigation, and will ask to observe key interactions you might have as part of the investigation including, but not limited to:

- Meetings or discussions with patients and their family members;
- Meetings or discussions with healthcare staff and any other stakeholders involved in the investigation;
- Any meetings you attend within your organisation linked to the specific investigation being observed.

During the investigation, if everyone involved in the meeting has given consent for the researcher to observe, the researcher will communicate with you and any other stakeholders to decide how the meeting will be observed (either in person or recorded for retrospective observation). If the researcher is to be present at the meeting, whether the meeting is virtual or in-person, they will not actively participate in the meeting but may keep notes about how the new guidance is being implemented and experienced. If a face-to-face meeting is to be recorded, the researcher will be present to set up the camera and remotely start and stop the recording. If a virtual meeting is to be recorded, the researcher might ask you to record the meeting and send them a copy of the recording. The researcher will work with you to ensure any transfer of the recording is done securely and adheres to your organisational confidentiality and information governance policies. The researcher will use the recording to take notes about the implementation and experience of the new guidance as outlined above. Before any and each meeting, the researcher will check consent with all participants verbally. No identifiable information will be captured in researcher notes, and they will be anonymised by the researcher at the point of writing.

Optional Research Interview

As part of the research, you have the option of taking part in a further interview:

- A follow up interview around 2 months after the investigation ends with the member of the research team that followed the investigation. During this interview you might be asked about your reflections on the use of the new guidance, any impact this has had on your practice as an investigator, and the outcomes of the investigation report.

This interview is expected to last around 60 minutes. The interview will follow the same guidance as the two interviews outlined above. The researcher following your investigation will discuss your preferences with you before the interview if you decide you would like to take part.

Optional Reflective Diary

You will also be given the option to capture your experience of the investigation and the new guidance in a diary. This is not a compulsory part of the research, but the researcher will offer you the option of filling out a reflective diary. The diaries can be completed online or as a hard copy, and will include prompts about your thoughts on, and experiences of, implementing the new guidance. There will also be space for you to capture your own personal reflections, or any other reflections you think may be beneficial for the research team to know, for example reflections on the training and how it prepared you to deliver the new guidance. If you do choose to fill out a diary, you will be asked to return this to the researcher at the end of the investigation. If you use an online diary, you can email this to the researcher. If you use a paper diary you will be able to return the hard copy in person or in a pre-paid envelope (these copies can be returned to you at your request once they have been scanned by the researcher), or take pictures of the diary and send them electronically. If you start to use a diary, you are able to pause or stop using it at any time without being asked to give a reason.

How will I benefit from being involved in this study?

We hope that your involvement will be of benefit to you in your role as an investigator, providing you with training in and experience of new guidance to help you more meaningfully involve patients and families in serious incident investigations. We know this can be a difficult task following a serious incident. We hope that implementing the new guidance will lead to better learning from serious incidents, and mean they happen less frequently. The information you provide might also help us to further refine the training and guidance, and implement it more widely across the NHS to ensure that more investigators will have access to it.

If you choose to be interviewed somewhere (other than your place of work) that you will have to travel to, your travel expenses will be paid.

What are the possible disadvantages and risks of taking part?

We will work closely with you during any investigations we follow to ensure that our research interactions do not disrupt the schedule or content of the investigation process. You may find that talking about your experiences of involving patients and family members is sensitive or upsetting. If this is the case, we will ensure you are provided with the relevant sources of support. You might find it useful to talk to friends or colleagues, or contact the Occupational Health department at your organisation. We will support you in seeking alternative sources of support through your GP or other organisations where appropriate.

Will taking part in the study be kept confidential?

Yes, any information you provide will be kept confidential. All personal information about you and the investigation will be handled in confidence. Data collection is strictly limited to the process of implementation of the new guidance. Specific details about the serious incident will not be collected. Data will be kept in secure locked cabinets and/or stored on encrypted, password-protected computers at the Bradford Institute for Health Research. We will keep these files for up to ten years after the end of the study in line with research protocols, but after that, they will be destroyed.

What will happen to the data generated by the study?

The data will consist of audio and/or digital recordings of interviews and observation activity, researcher notes and/or reflective diaries. Data will be directly transcribed by experienced in-house administrators at Bradford Institute for Health Research where possible, or securely sent to a trusted transcription company who have a contract with the Bradford Institute for Health Research. Following transcription, original recordings will be immediately deleted. During transcription, any identifying details (e.g. names and places) will be removed. Each transcript will be given an anonymous code number and transcripts will be stored in encrypted, password-protected files on computers at the Bradford Institute for Health Research for up to ten years after the end of the study. We need to manage your records in specific ways for 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. However, if you wish to obtain an anonymised transcript of data you provided during an interview, the research team will provide you with a copy on request.

How will we use information about you?

Bradford Teaching Hospitals NHS Foundation Trust is the sponsor for this study. We will need to use information from you for this research project. This information will include your name and contact details. 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. All information about you will be stored in line with data storage protocols at the sponsor site. 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 withdraw from the study at any time, without giving a reason. If you choose to withdraw, we will keep any anonymised data you have provided up to that point, unless you request otherwise. This request can be made up until the point the data has been analysed (expected to be October 2022 but may be sooner). If you wish to make this request, we advise that you do so as soon as possible.

We need to manage your records in specific ways for 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.

You can find out more about how we use your information

- at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team or,
- by sending an email to dataprotectionofficer@bthft.nhs.uk

What will happen to the results of the research study?

We will share the findings with those people who helped us design this guidance during the workshops outlined above via a final sharing event. We will publish the results as academic papers and these will be used to develop more research which aims to continue to improve healthcare services for patients and families. We will share the findings in a plain English summary alongside academic publications. We may also make a series of short film clips to summarise the findings from the research and these will be available on a public website that will be developed during the project. When we write up the results, all personal details will be removed so that no-one will know who you are. We may quote what you have said but real names or other identifying details will not be used. You will have the option of receiving a final summary document about the research, as well as links to any publicly available guidance material we develop.

What will happen if I reveal information that indicates a risk of harm to myself or others while participating in the interview?

If you share any information during the study which reveals that you or somebody else is at risk of harm, or has been harmed, in such a way that would be reduced if the information you provided was disclosed, the research team may be required to act on this information. We would not do this without your involvement. This may include the decision to disclose the information that you have provided, your identity, and the identity of any individuals you have named, to an appropriate person who may decide to take further action. You will also be encouraged to discuss the disclosure with a trusted individual.

Who is organising and funding the research?

The research team comprises experienced health services researchers at the Bradford Institute for Health Research. The Chief Investigator is Jane O'Hara, Professor in Patient Safety & Improvement Science. The research is funded by the National Institute for Health Research.

Who has reviewed this study?

This study has been reviewed and given a favourable opinion by the NHS Ethics REC Committee (Wales REC 6; REC Reference: 21/WA/0287) and the NHS Health Research Authority.

What if there is a problem?

Any complaint about the way you have been dealt with during the study will be addressed. Please contact the study Chief Investigator: Professor Jane O'Hara on (01274) 383692 or email Jane.O'Hara@bthft.nhs.uk

What do I do now?

If you have decided that you are interested in taking part, a member of the research team will get in touch with you and you can discuss your participation with them. If you would like to discuss any aspect of your participation before you decide whether to take part, or if you have not yet heard from a member of the research team, please contact [Insert RF name here] on the contact details below:

Dr. Siobhan McHugh (Research Fellow)
Siobhan.McHugh@bthft.nhs.uk

What do I have to do if I want to take part?

If you decide that you would like to take part, please confirm this with the member of the research team who contacts you to discuss the consent process, or you can contact Siobhan directly on the contact details provided above.

Thank you very much for taking the time to read this information.