LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

Information for Participants

Study title: Developing methods for assessing avoidable severe harm due to problems in hospital care

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will entail. Please take time to read the following information carefully and to talk to others about the study, if you wish. 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.

1. What is the purpose of the study?

This study is funded by the Department of Health in response to a call for studies which are designed to improve the detection and measurement of harm to patients caused by hospital treatment. The World Health Organisation/ World Alliance for Safer Healthcare defines healthcare-related harm as '*an injury arising from or associated with plans or actions taken during the provision of healthcare, rather than an underlying disease or injury'*. Harm may result in temporary or permanent loss of physical or mental functioning. We currently lack good systems to identify patients who might be at risk of harm or who have experienced harm during hospital admissions.

According to the National Reporting and Learning System (NRLS), the NHS database that collects reports of harm or near misses sent in by healthcare staff, about 1.3m incidents were reported by NHS organisations between July 2011 to June 2012 in England, although it is recognised that probably only about 25% of incidents in hospitals are ever reported. The majority of incidents (875k) caused no harm, with 7,773 causing severe harm and 3,263 resulting in death. The most common type of incident reported was a patient accident (usually referring to falls) (25.8%), followed by errors in treatments (12.7%) or medication (12.1%). Given that the proportion of patients who suffer severe harm is low compared to those in which harm is avoided, the question arises how best to identify and investigate such incidents arises. Agreement on the definition of severe harm needs to be established prior to the development of approaches to screen for it. To this end we will be interviewing a range of hospital staff, patients and their relatives to determine their views on what constitutes healthcare-related harm.

2. Why have I been chosen?

We are holding group meetings with a number of patient groups who are likely to hold views on this topic. You will have been recommended as a potential participant by the organisers of your group.

3. Do I have to take part?

It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason.

4. What will happen to me if I take part?

We would like to talk to you and other members as a group (from 4-9 participants) for an hour in a location convenient to you. During the group interview you will be asked a number of questions related your thoughts on the quality and safety of hospital care and also on the types of harm that might result from healthcare. You are free not to answer any of the questions or to divulge personal information. The interviewer will take notes and will also record the interview on audio-tape. This audio recording will be used to clarify any issues that are not clear from the field notes. After this point, the tape will be destroyed.

The interview material will be used to help develop a form to be used by doctors to help them identify patient harm from patient case notes. Your name will not appear in any study documentation.

5. What are the possible disadvantages and risks of taking part?
This study will require around one hour of your time.

6. What are the possible benefits of taking part?
There is no direct benefit but the information we get from you will help to improve the safety of patients in hospital

7. What if something goes wrong?
If you have a concern about any part of this study, please let us know and we will do our best to answer your questions. If you wish to make a complaint about any aspect of this research then please contact Research Governance and Integrity Office (RGIO) by email RGIO@lshtm.ac.uk or telephone +44 (0)20 7927 2221.

8. Travel Expenses
We will be happy to reimburse reasonable out of pocket travel expenses.

9. What will happen to the results of the research study?
The study will be completed in January 2017 and we anticipate publishing the findings shortly after that. Reports will also go to the Department of Health and NHS England. We will let you know when any articles describing this study are published in journals and will send you a copy.

10. Who is organising and funding the research?
The study is funded by the Department of Health. The team conducting the research are from the Health Services Research and Policy Department at the London School of Hygiene and Tropical Medicine (LSHTM). LSHTM is the sponsor of this study.

11. Who has reviewed the study?
This study has been given NHS and London School of Hygiene ethical approval and NHS R&D approval.

12. Contact Details
For further information about the study please contact kaushik.chattopadhyay@lshtm.ac.uk.

You will be given a copy of the information sheet and a signed consent form to keep.

Thank you for considering taking the time to read this sheet.

Dr Helen Hogan (Chief Investigator)
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