UNIVERSITY OF OXFORD

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Diagnosis of serious infection in elderly patients and the decision to admit

Participant information sheet

Thank you for considering taking part in our research study. This sheet provides information to help you decide whether to take part. Please take time to read it carefully.

What is the purpose of the study?
Diagnosis of serious infection in the growing elderly primary care population is important, because it carries high mortality, but challenging, because the signs, symptoms and tests which we use in younger patients can be less accurate in the elderly. This study aims to find out how GPs diagnose serious infection in the elderly in the community and how they decide whether a patient needs admission. In order to get a useful answer to this question it is important that we explore the views and experiences of currently practising GPs working in a variety of different settings.

What will the interview involve?
Participating in this research will involve an audio recorded interview which will take no more than 45 minutes. This can be either face to face, or by telephone if face to face is not possible. The interview will be based, in part, on cases of suspected serious infection in elderly patients (age approximately 75 or older) which you have encountered recently in your normal clinical practice.

What do I need to prepare for the interview?
In order to understand the reality of general practice management of this patient group, we are keen to base our interviews on real clinical cases of suspected infection in elderly patients, which you have encountered on home visits or surgery appointments in the last 2 months. We are particularly interested in cases where it was difficult / challenging to reach a diagnosis. It would be helpful if you could review the notes of 3-4 patients who fit this criteria, and at least one case where you chose to admit this type of patient. If you assess any elderly patients with suspected infection between now and our interview, discussing these cases would be particularly helpful, so please keep their details in mind. We will not require any identifying details of the patients during our discussion.

Do I have to take part?
No. Participation is entirely voluntary.

What will happen if I decide to take part?
We will contact you by e-mail or telephone to schedule a time for an interview, which can include non-working hours if this is more convenient for you. We would like you to complete a short response form and a consent form. The response form includes details about yourself and your practice which will help us to ensure we are interviewing GPs working in a variety of roles. After the interview, the recording will be transcribed (written up word for word, usually within 2 weeks), and made anonymous by removing names of people and places. It will then be analysed along with other interviews to identify themes.

What are the possible benefits of taking part?
There is no direct benefit to you in taking part in the study. However, participation in the study may encourage you to reflect on your practice and this could form part of your appraisal. We will provide a certificate of participation in research which could be used as part of appraisal or revalidation. We will also reimburse you £60 for your time. We hope that the findings of this study will inform improvements in diagnosis and management of elderly patients with infection in primary care settings.

What are the possible disadvantages or risks of taking part?
There are no disadvantages or risks to you, other than the time taken for the interview. The intention of this research is not to test your clinical knowledge or practice but to find out about existing practice in the "real world" of general practice, where management of clinical uncertainty is commonplace. In the unlikely event that the research were to uncover potentially significantly harmful practice, this would have to be reported to the appropriate authorities.

What will happen to the information I provide?
The interviews will be audio recorded and transcribed. The audio recording will be listened to only by the interviewer, transcriber and on occasion members of the research team directly involved in the interview analysis for quality assessment. Responsible members of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure we are complying with regulations. Within ten years of the study finishing, the data will be destroyed. On transcription, all identifiable information will be removed and the original recording will be destroyed. Your demographic information and themes identified from the interview transcript will be combined with those of other participants, analysed and published. Anonymised quotes of parts of your interview transcript may also be published, but we will not publish any details that identify you personally. Your reply form and consent form will be stored securely.

What will happen if I don't want to carry on with the study?
You are free to withdraw from the study at any time up until the point when your data is anonymised, without giving a reason. You may also refuse to answer certain questions asked during the interview. If you do decide to leave the study, we will use the information we have collected up to that time as follows. If the tape recording has been transcribed (and anonymised) at the point where consent is withdrawn, then the data will still be included in the study. If, however, the tape recording has not been transcribed at the point where consent is withdrawn, then the data will not be used.

What will happen if there is a problem or something goes wrong?
The University has arrangements in place to provide for harm arising from participation in a study for which the University is the Research Sponsor. If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Gail Hayward using the details above or you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 572224 or the head of CTRG (Heather House) by e-mail, ctrg@admin.ox.ac.uk.

Who is organising and funding the research?
This study is funded by the Royal College of General Practice Scientific Foundation Board. Gail Hayward is an Academic Clinical Lecturer in the Department of Primary Care Health Sciences in the University of Oxford, and is working with Dr Abigail Moore who is an Academic Clinical Fellow and Dr Caroline Jones who is a Senior Researcher in General Practice. The University of Oxford is acting as Research Sponsor.

Who has reviewed the study?
The study has been reviewed by the University of Oxford Ethics committee, and has received ethics clearance (approval number MS-IDREC-C1-2015-054).