Ethical concerns raised by research in care homes – getting it right

We spoke to Mike Head, Network Manager for the Infectious Disease Research Network and Research Associate at University College London, and Stefania Lanza, Research Co-ordinator at the Brighton & Sussex Medical School about their study of suspected scabies outbreaks in residential care facilities. They describe some of the ethical challenges they have faced and how they overcame them.

Background

Scabies is a contagious skin condition caused by a mite, and transmitted mainly via skin-to-skin contact. It can be intensely itchy and distressing. It is difficult to diagnose and if left untreated can spread easily. This study is researching scabies in care homes to improve diagnosis and outbreak management.

The project began in February 2014 and by April 2015, 22 affected homes will have completed an outbreak questionnaire, and site visits will have taken place at 10 homes. Each site receives three visits, the first for assessment and recruitment, the second to carry out clinical examinations, and the third, six weeks later, to check that treatment has worked. There have been a number of ethical challenges in setting up this project. This case study describes how they have been overcome.

Obtaining informed consent

Obtaining informed consent is often challenging in care home research, because residents with dementia typically lack mental capacity. If a resident does not have the capacity to consent, researchers contact the next-of-kin (a consultee), asking them to give their assent for their relative to take part. The consultee is asked to consider whether they believe the resident would have wanted to participate, if they still had capacity. The whole process is very time-consuming. It can take weeks to obtain agreement in writing. As Mike explained, this was not an option for this project, “When we’re notified about a scabies outbreak, we need to be in the care home within 2-3 days. There was no clear guidance in the Mental Capacity Act about how to obtain consent or assent in this scenario. The Ethics Committee rejected our first application and we wondered if the project would go ahead.”
The team then heard about a project that had faced a similar dilemma, but had successfully obtained ethical approval, as Mike described, “Representatives from the Alzheimer’s Society on our advisory group put us in touch with other UCL-based researchers who had overcome this difficulty. We adopted their novel approach, which then got us approval. We now seek the consultees’ assent over the phone, and then follow up by post, sending out the information sheet and asking for signed forms to be returned in an SAE.”

Minimising any distress from participation

Stefania explained that the diagnosis and treatment of scabies can be distressing for residents, “To diagnose scabies in older people, a doctor needs to look at all of their body. This means asking the residents to undress to examine them properly. If two or more people are diagnosed, all staff and residents, regardless of whether they have symptoms need to be treated with a lotion at the same time. This is put all over the body, including the genitals, left on for 8 hours, and then showered off. The whole thing is repeated a week later. It’s very difficult for care homes to manage. Residents with dementia may not understand why this is happening and can become very distressed”.

During the site visits, the research team wanted to ensure that residents would feel at ease, as Stefania described, “To make this comfortable for residents, we ask the care homes to provide a chaperone, who the residents know. We’ve offered the homes funding to back-fill this post because the chaperone is usually with us all day. They help us enormously and our dermatologist and GP have a lovely bedside manner - they’re used to working with people with dementia.”

Giving something back

The team have been careful to ensure that care homes benefit from their participation. Stefania has found that the input from researchers has been very welcome, “Care home managers are often confused and quite stressed about managing an outbreak, and because we’re bringing in clinical expertise, we give something back. Rather than just extracting information, they feel we’re helping them.”

The team are also thinking about how they can share their findings more widely, as Mike described, “The advice on how to manage scabies is not consistent, and not always used. So we’re looking at ways to provide clear guidance for staff, and particularly to help overcome the stigma of reporting an outbreak… we want to ensure our research genuinely benefits the care home communities we’ve been working with.”

Key messages for care home researchers

- Don’t underestimate the time it takes to set up the project, especially to assess capacity of residents and obtain consent or assent.
- Use your networks and contacts to link up with other care home researchers – they can help solve your problems
- Ensure your research team is trained and experienced in working with people with dementia
- Think about ways that care homes can get something back from their participation – what’s in it for them? Why should they take part in your research?
- Plan to disseminate your findings to the people who can directly benefit

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For further information, contact:

Mike Head, Email: m.head@ucl.ac.uk
Stefania Lanza, Email: S.Lanza@bsms.ac.uk