

Case Discussion

Researching Scabies Outbreaks among People in Residential Care and Lacking Capacity to Consent: A Case Study

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Infectious disease outbreaks in residential care are complex to manage and difficult to control. Research in this setting that includes individuals who lack capacity must conform to national legislation (specifically in England and Wales, the Mental Capacity Act 2005). We report here on our study that is investigating outbreaks of scabies, an itchy skin infection, in the residential care setting in the southeast of England. There appears to be a gap in legislative advice regarding the inclusion of people who lack capacity in research that takes place during time-limited acute scenarios such as outbreaks. We received inconsistent advice from experts regarding, in particular, the role of nominated consultees. There is a potential inequality for vulnerable populations who cannot themselves provide informed consent in terms of their access to participation in a range of health-related research.

Background

Scabies is an intensely itchy infestation of the skin caused by the mite *Sarcoptes scabiei* (Heukelbach and Feldmeier, 2006). There are an estimated 300 million cases worldwide annually (Chosidow, 2006). In the UK, scabies often causes outbreaks affecting the residents and staff of residential care facilities for older people (Millership *et al.*, 2002; Fuller, 2013; Hewitt *et al.*, 2014). Scabies is not a notifiable disease in the UK and its true incidence is unknown, but there is anecdotal evidence of under-reporting.

The presentation of scabies in older people differs from that seen in younger individuals and it may be difficult to diagnose (Chosidow, 2006). The high prevalence of other skin conditions in this population may complicate diagnosis, resulting in incorrect or delayed diagnosis and treatment (Wilson *et al.*, 2001). Our research was initiated due to the concerns of public health staff. A recent analysis of infectious disease research, awarded by the major research funders and carried out by UK institutions, revealed no studies related to scabies (Head *et al.*, 2013).

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While there are several reports of individual outbreaks and their management (Parish *et al.*, 1991; Andersen *et al.*, 2000; de Beer *et al.*, 2006), there has been no systematic attempt to describe scabies in older people, in order to improve clinicians' ability to diagnose in a timely manner. A particular challenge in such research is the high proportion of elderly residents experiencing scabies who also have dementia, which is often advanced, and some will lack capacity to consent (Hewitt *et al.*, 2014).

In England and Wales, research involving individuals who lack capacity requires compliance with the national regulatory framework, the Mental Capacity Act (MCA) 2005. The MCA allows an individual who lacks capacity to give informed consent to still participate in research. A personal consultee (usually next-of-kin, or alternatively a relative, friend, legal representative or other person known to the patient) is identified and if satisfied, they provide an opinion on what the person lacking capacity would have done if they had had the capacity to make the decision. A nominated consultee may be used if there is no personal consultee—this is a person not connected to the study, but who knows the individual and is willing to be consulted about their participation.

Our Journey

We are undertaking a study describing suspected outbreaks of scabies in residential care facilities, with a view to improving clinical diagnosis and management of outbreaks. In most outbreaks, there is no visit by a dermatologist and topical treatment is given to all residents once an outbreak (≥ 2 cases) is confirmed, usually by a general practitioner.

Our study involves dermatologists examining the skin of residents and staff, seeking to make a definite diagnosis where possible, recording all signs of scabies and other skin conditions, and taking photographs of the affected areas where appropriate. All accessible skin is inspected, in the presence of a chaperone known to the individual. Anonymized demographic data and limited clinical information are recorded. We sought to include individuals lacking capacity to give informed consent because the evidence, although limited, suggests that this group is at higher risk of scabies in residential care facilities. This evidence is based on the initial needs assessment undertaken by our research group, and published uncontrolled studies (Wilson *et al.*, 2001; de Beer *et al.*, 2006; Tsutsumi *et al.*, 2005).

The protocol for the study was submitted to the National Research Ethics Service for consideration by

a committee 'flagged' as being able to consider research involving those who may lack capacity. Our original proposal suggested using the nursing home manager, or other senior member of staff, as the nominated consultee for those who lack capacity and do not have a personal consultee available to contact. The initial decision of the committee was unfavourable, highlighting the consent process as a major concern on the grounds that: '... that the Mental Capacity Act states that the consultee must not be a paid person'.

Throughout the study development, we had taken advice from patient and public representatives of the UK-based Alzheimer's Society and they provided excellent insight into UK residential care institutions. After this unfavourable decision, they introduced us to a research group at University College London (UCL) who had developed a system for obtaining consultee opinion which had been approved by an MCA 'flagged' ethics committee. The UCL group had led the BePAID study, investigating the management of pain (Scott *et al.*, 2011). The process used in this study involved a member of study staff using a simple screening tool to assess the capacity of the patient. If the patient was deemed to lack capacity, then the personal consultee was telephoned and verbal agreement for the individual's inclusion in the study obtained (though the final decision to include is taken by care home and study staff). A form confirming the consultee's opinion was obtained within 48 h, but verbal personal consultee agreement was sufficient for the individual to be recruited.

This process was modified and incorporated into our scabies study (Figure 1a). A revised ethics application for the scabies study was submitted to the original committee. The committee was broadly satisfied by the revisions and accepted the methods for obtaining consent. A new issue was then raised by members of the committee with respect to section 31, part 2 of the MCA 2005 which states '*The research must be connected with—*a) *an impairing condition affecting P (patient), or b) its treatment*'. While scabies is not caused by cognitive limitations which lead to loss of capacity, it is believed that those lacking capacity and in residential care are at increased risk of acquiring scabies. The ethics committee was divided on whether scabies was likely to be connected to the impairing condition. In response we provided a written justification including the following text:

We believe that this research is connected with the impairing conditions in older people population we are studying. Previous small studies of single scabies outbreaks in residential facilities have suggested

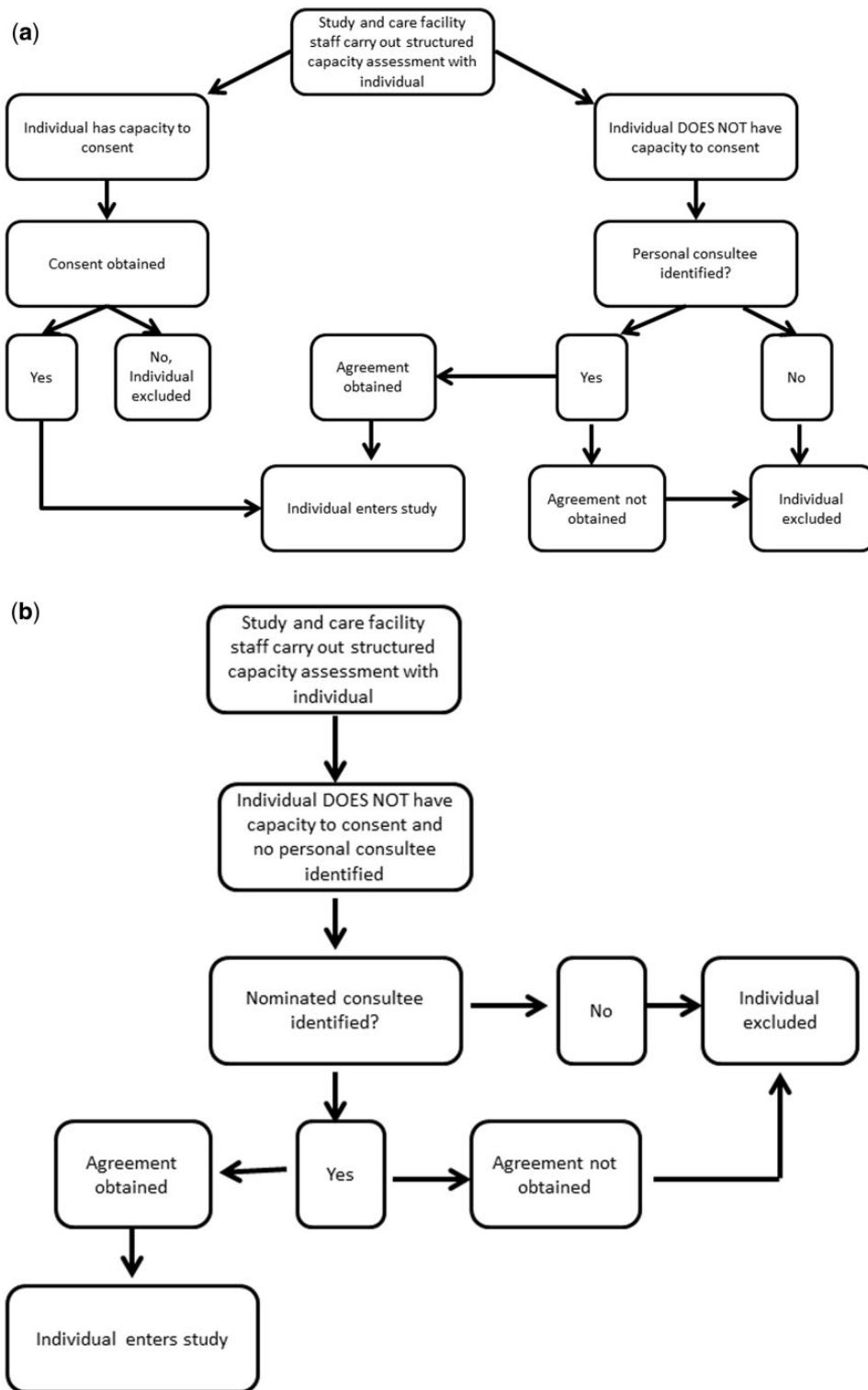


Figure 1. (a) Scabies study protocol for enrolment of participants. (b) Protocol for nominated consultee approval.

dementia as a possible risk factor for having scabies during an outbreak in those facilities.' (Wilson *et al.*, 2001; Tsutsumi *et al.*, 2005; de Beer *et al.*, 2006)

The response to the committee included a letter of support from Dr Elizabeth Sampson, lead researcher of the BePAID study. We received a favourable opinion from the committee. The study commenced in 2014 and study staff has attended several suspected scabies outbreaks in residential institutions in the south-east of England. The methodology has been demonstrated to be feasible, and care homes (and consultees) have been satisfied with this approach.

Case Discussion

Is There a Gap in the MCA?

The usual approach for obtaining agreement from a personal consultee is suitable for most studies examining the chronic effects of dementia in individuals lacking capacity. The MCA also addresses research in emergency settings when a written response cannot be waited for. However, the Act does not address the obtaining of agreement in research which necessarily requires a rapid response but which is not an emergency situation. Recruitment needs to happen rapidly during any outbreak of a communicable disease, since the research must delay any healthcare interventions such as treatment. Such outbreaks are unlikely to be regarded as the kind of emergency that would justify over-riding the need for consultee approval, and we would have felt such a justification inappropriate. The MCA does not appear to adequately address such situations.

Reflections on the Requirement for Research to Relate to the Impairing Condition

Interpretation of the clause in the MCA requiring the subject of the research to be 'connected to the impairing condition' may vary, and we found this challenging. It could reasonably be argued that scabies is unrelated to dementia, even if the need for residential care (resulting from dementia) is a risk factor. Older people who lack capacity have multiple health needs which are not directly related to dementia, including increased vulnerability to infection (Lopman *et al.*, 2003; Henderson *et al.*, 2010), and may live with them for many years. We would have preferred to make a justification which related more directly to the impact of the condition we proposed. Where research is aimed at improving

services, we feel it is important that groups lacking capacity should have participation enabled, particularly when they are an important user group. Moreover, this clause could restrict the ability to carry out research on hypothesized links between the risk of other conditions and the presence of dementia.

Nominated Consultees

Many have noted inconsistency in decisions and advice from the ethics committees reviewing research applications which contain such issues (Dixon-Woods and Angell, 2009). We received, and continue to receive, conflicting advice on whether nominated consultees can be paid carers from the various experts we have consulted, and who have commented on various versions of this case report. This continues to be a challenge in developing acceptable methodologies when undertaking research involving individuals who lack capacity, who often live in a setting where all those close to them are paid carers. We did in fact subsequently apply for and receive a substantial amendment to our original ethical approval to enable us to use a nominated consultee if a personal consultee is not available (Figure 1b). On this particular issue, there seems to be limited consensus about how nominated consultees may be used.

The Dementia and Neurodegenerative Diseases Research Network is addressing some of these issues in the UK through initiatives such as the Enabling Research in Care Homes toolkit. The wider issues that should be considered include the fine detail surrounding the logistics and feasibilities of how best to carry out research in a complex population such as the vulnerable institutionalized. The protection of the interests of the participant must continue to be paramount, yet there need to be mechanisms to carry out research in these populations. For example, might individual consent be waived in the event of an urgent acute situation where research can usefully be carried out, such as an outbreak? In our study and with a chaperone known to the participant present, we examine individuals who lack capacity and request they be partially undressed in order to participate in the research—should this be considered ethical and where should the line be drawn? How much flexibility should ethics committees have with regards their interpretation of what is considered ethical?

There is also the question of the research being connected to the impairing condition; given that those who lack capacity frequently present at least one other serious co-morbidity (Smith *et al.*, 2014), perhaps research covering conditions that are unlikely to be related to, or necessarily clearly impact upon, the dementia should be

explicitly permitted subject to the usual regulations. While more thorough knowledge of legislation and guidance would have pre-empted some of the difficulties we experienced, we hope that this description of some of the outstanding ambiguities and further questions will be interesting to others, and provoke further discussion and guidance. It would also be interesting to solicit the guidance of international colleagues who will operate under different legislations and ethical boundaries.

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Conflicts of Interest

J.B. is a member of the NHS Research Ethics Committee that reviewed the scabies study. However, she did not review the scabies study nor did she attend the meetings where the study was discussed. She became involved with the scabies study after ethical approval was granted in 2012. The decision to involve her in the scabies study was not influenced in any way by her role within the ethics committee. All other authors have no competing interests.

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