

Protocol: A study of suspected scabies outbreaks in residential care facilities

Article (Other)

Nalanbanda, A, Cassell, Jackie, Middleton, Jo, Hewitt, K, Head, MG, Lanza, Stefania and Walker, SL (2016) Protocol: A study of suspected scabies outbreaks in residential care facilities.

This version is available from Sussex Research Online: <http://sro.sussex.ac.uk/id/eprint/66209/>

This document is made available in accordance with publisher policies and may differ from the published version or from the version of record. If you wish to cite this item you are advised to consult the publisher's version. Please see the URL above for details on accessing the published version.

Copyright and reuse:

Sussex Research Online is a digital repository of the research output of the University.

Copyright and all moral rights to the version of the paper presented here belong to the individual author(s) and/or other copyright owners. To the extent reasonable and practicable, the material made available in SRO has been checked for eligibility before being made available.

Copies of full text items generally can be reproduced, displayed or performed and given to third parties in any format or medium for personal research or study, educational, or not-for-profit purposes without prior permission or charge, provided that the authors, title and full bibliographic details are credited, a hyperlink and/or URL is given for the original metadata page and the content is not changed in any way.

**PROTOCOL: A STUDY OF SUSPECTED SCABIES OUTBREAKS IN
RESIDENTIAL CARE FACILITIES**

A suspected scabies case/outbreak is reported to PHE

Public Health England (PHE) are contacted by a primary care physician (GP) or a member of staff of a residential care home who suspects it may have a single case or an outbreak of scabies.

Action: Day 1

PHE Health Protection Practitioner (HPP)

1. HPP records the details of the suspected case/outbreak on PHE database (HPZone) including the name and contact details (including email addresses) of the person reporting the case/outbreak, contact details of the residential care home manager and designated residential care home GP (if role exists) and information about the residential care home and the number of people affected (including members of staff).
2. HPP informs the residential care home manager about the scabies research study from a prepared script, explaining that it is an anonymised voluntary study of suspected scabies case/outbreaks in homes, that they do not have to participate in the study and that if they choose not to participate this will not affect PHE's response to the possible case/outbreak.
3. HPP advises the residential care home manager to expect a call from the research team at Brighton and Sussex Medical School (BSMS) with more details about the study and to arrange visits.
4. HPP contacts BSMS research team by email or by dedicated study mobile to advise that a suspected case/outbreak has occurred, providing all relevant information, including summary of correspondence to date.

BSMS Research Coordinator

1. RC contacts Clinician to establish available dates for clinical visit
2. RC contacts the residential care home manager to explain the study in more detail and answers any questions raised. RC emails protocol, information sheets, and consent forms to the residential care home manager and residential care home GP (if role exists).
3. RC organises a convenient date to undertake the preliminary visit and the clinical visit to the residential care home. A preliminary visit is still arranged if clinical visit cannot be organised before mass treatment has taken place in order that outbreak data can be collected.

4. RC asks the residential care home manager to arrange for a dedicated staff member to be available to assist during the visits as a chaperone.
5. If the care home manager wishes to contact relatives about the study, contact details of the research team's dedicated phone number will be provided and relatives encouraged to contact the research team with any questions or queries.

Preliminary visit to the residential care home

Action: Day 2/3

BSMS Research Coordinator and Project Assistant

1. On arrival the RC introduces herself to the residential care home manager and the dedicated staff member and checks that they both understand all aspects of study and deals with any questions or queries raised.
2. RC records information about the residential care home and details of the suspected outbreak, including suspected cases.
3. With the dedicated staff member acting as chaperone, the RC and PA will establish the capacity of all potential participants using the structured MCA guidance form. Participants will be given an information sheet (which can be read to them) the study will be explained to them in detail and any questions will be answered. Residents can choose to take more time to consider whether they want to take part, and will be able to confirm their consent during the clinical visit.
4. In the case of an individual who does not have the capacity to consent, the dedicated staff member will provide details of suitable contacts who could act as their personal consultee.

Following on from the preliminary visit

5. In cases where an individual is unable to give consent, the suggested suitable contact will be approached by the RC/ PA. The study will be explained over the telephone with any questions answered before their agreement obtained verbally and recorded by the RC/ PA. A study information leaflet and a personal consultee form will be sent by post for them to sign and return. If they wish, personal consultees can be given time to consider their options and a follow up call can be arranged to confirm consent before the clinical visit takes place.
6. If a personal consultee cannot be identified for an individual who does not have capacity to consent, we will ask a nominated consultee to consider whether the resident should take part in the study. The nominated consultee will be a member of care home staff or a GP who is involved in the resident's care.

Clinical Visit

Action: Day 3-5

Research team: Clinician/BSMS Research Coordinator

RC to introduce the research team to the residential care home manager and the dedicated staff member and explain what the visit will involve. The following priority criteria for examinations will be used for examinations.

- 1 Symptomatic residents (where an individual or carer describes signs or symptoms suggestive of scabies)
- 2 Residents and staff in contact with symptomatic residents in the preceding 4-6 weeks
 - a. In a small care home (less than 40 residents):
 - i. All residents and symptomatic staff will be examined
 - b. In a large care home (more than 40 residents)
 - i. Where the outbreak is confined to the same floor or wing: All residents and symptomatic staff will be examined
 - ii. Where the outbreak is not confined to the same floor or wing: As many symptomatic residents and symptomatic staff will be examined as possible given time constraints.

Re-establishing consent

To allow for the possibility of fluctuating capacity, consent for all residents will be re-established and confirmed before any examinations take place.

1. All individuals who had already consented or who had chosen to take time to consider taking part in the study will be asked to confirm their consent. If at this point any individual does not have capacity to consent, the research team will attempt to contact a personal consultee about their participation in the study. If no personal consultee can be identified, we will approach a nominated consultee (a member of the care home staff or a GP involved in their care) to consider whether the individual should take part in the study.
2. Individuals who did not have capacity at the preliminary visit but who now have capacity to consent will be provided with an information sheet (which can be read to them), and have the study explained to them with any questions answered, before being asked if they would like to take part and consent to the study.
3. Individuals who remain without capacity and whose personal or nominated consultee has agreed for them to take part will be included in the study.

Once consent has been confirmed

Residents will be examined in a private setting with a chaperone in attendance for all individuals.

Individuals are examined by the Clinician:

1. Anonymised personal details and clinical findings will be recorded on the data collection form.
2. Skin scrapings will be taken from individuals with lesions suggestive of scabies and collected with study number and date of birth.
3. A burrow ink test will be performed on individuals with lesions suggestive of scabies and results recorded on the data collection form.
4. Blood samples will be taken from individuals with a scabies diagnosis who specifically consent verbally or following personal/nominated consultee advice. Samples will be labelled with study number and date of birth.
5. Digital photographs will only be taken of skin lesions of patients who have consented verbally or following whose personal/nominated consultee advice.
6. Images in which individuals would be identifiable (due to facial features or unusual scar/tissue or skin lesion) will not be taken for patients who were enrolled in the study following personal/nominated consultee advice..
7. Information about health care and contact details of GPs will be recorded for each individual.

At the end of the visit

1. The Clinician will complete a summary clinical report about the outbreak as a whole in triplicate which should include the number of people examined and the diagnoses made at the end of the visit. One copy will be left for the Care Home Manager, one sent to the HPP and one retained by the study team. Identifying data will be anonymised.
2. The Clinician will complete a standard letter in triplicate to be sent to residents' GPs where symptoms of scabies and/or other conditions which require treatment are found. The letter will detail any important coincidental findings, particularly suspected skin neoplasia, and advice concerning management. The letter will include the contact details of the RC should the GP have any queries. The RC will coordinate communication between the GP and the Clinician. One copy will be left with the Care Home Manager, one sent to the GP and one copy retained by the study team with identifying data anonymised.
3. The Clinician will also complete a standard letter in triplicate for staff where where symptoms of scabies and/or other conditions which require treatment are found. All findings will be communicated directly to the staff member and a copy given to them. One copy will be retained by the study team with identifying data

anonymised. Staff may choose whether a copy is sent to their GP, if not this third copy will be destroyed

Following on from the clinical visit

Research team: Clinician/ BSMS Research Coordinator

1. An email of thanks will be sent to the residential care home manager and the dedicated staff member.
2. Data collected will be entered into secure anonymised database at BSMS. Digital photographs will be anonymised and stored on password protected computer and erased from the camera.
3. Microscopy of some of the skin flakes will be performed by the microbiology and infection service at Brighton and Sussex University Hospital (BSUH) and samples will be discarded.
4. Where permission is in place, blood samples and skin flakes will be stored indefinitely at Brighton and Sussex Medical School (BSMS) under the BSMS Human Tissue Authority Research Licence no: 12561. Samples will be labelled with a sample code and recorded on a sample sheet with study identifier. The sample record sheet and a key which links the study identifier will be stored separately.
5. Individual letters will be emailed or posted to respective GPs by close of business the next working day (i.e. within 72 working hours of visit)

Follow up Clinical Visit

1. A follow up visit will be arranged by BSMS RC to be undertaken approximately 42 days after the initial clinical visit to re-examine all residents. The same process to re-establish consent, undertake clinical investigations, store data and communicate results will take place as per the previous clinical visit.
2. The care home manager will be asked to complete a questionnaire to feedback the experience of taking part in the research study.

Completion of the study

1. The corresponding author of the publication will disseminate to the research group, including PHE.
2. BSMS RC will disseminate a copy of a final publication to the participating homes, personal consultees and the GPs of all participants involved. A lay summary of the research will also be prepared