Exploring the care pathway to diagnosis for patients with autoimmune blistering diseases: a qualitative study of General Practitioners' views

Study Protocol version 1.0

Short title: Exploring the care pathway to diagnosis for autoimmune blistering diseases

Study co-ordinating centre: Centre for Evidence Based Dermatology

Ethics Reference: FMHS 321-0723

Funding: NIHR School of Primary Care Research

Study Personnel

Principal Investigator	Dr Sonia Gran (née Ratib) Associate Professor of Medical Statistics sonia.gran@nottingham.ac.uk
Co - Investigators	Dr Lydia Tutt Research Fellow Lydia.Tutt@nottingham.ac.uk Dr Paul Leighton Associate Professor of Applied Health Services paul.leighton@nottingham.ac.uk
Collaborators	Dr Vibhore Prasad Clinical Lecturer in General Practice vibhore.prasad@kcl.ac.uk Dr Karen Harman Consultant Dermatologist at University Hospitals of Leicester NHS Trust karen.harman@uhl-tr.nhs.uk Mrs Isobel Davies Patient and Public Involvement advisory group (PPI) member and PEM Friends Spokesperson isobel@pemfriends.org.uk Mrs Ingrid Thompson PPI member ingrid@pemfriends.org.uk

List of Abbreviations

PPI	Patient and Public Involvement advisory group
AIBD	Autoimmune Blistering Disease
GP	General Practitioner
MS	Microsoft

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Synopsis

Title	Exploring the care pathway to diagnosis for patients with autoimmune blistering diseases: a qualitative study of General Practitioners' views
Short Title	Exploring the care pathway to diagnosis for autoimmune blistering diseases
Principal Investigator	Dr Sonia Gran
Objectives	• Determine the challenges of recognising AIBDs • Identify how referral decisions are made when the cause of blistering is unclear • Explore potential tools to aid recognition of AIBDs
Study Configuration	Individual semi-structured interviews with General Practitioners
Setting	Primary care
Number of Participants	Approximately 15-20
Eligibility criteria	Able to provide informed consent Currently practicing as a GP in the UK At least 1 year of experience working as a GP
Description of intervention	One online (MS Teams) interview lasting 30 mins to 1 hour
Duration of study	December 2023 - August 2024
Methods of analysis	Iterative thematic framework analysis

Study Background and Rationale

Autoimmune blistering diseases (AIBDs) are a group of chronic autoimmune disorders affecting the skin and mucous membranes (Schmidt & Zillikens, 2013). They are characterised by bullae (blisters) or erosions resulting from the immune system mistakenly attacking structural proteins in the layers of skin or mucosa. AIBDs are differentiated based on the exact protein targeted and where that protein sits in the skin or mucosal layers. (Patrício et al., 2009; Sticherling & Erfurt-Berge, 2012)

The most common type of AIBD in the UK is bullous pemphigoid. Here, the affected proteins are relatively deep in the skin's layers; at the junction between the dermis and epidermis. Consequently, the blisters that form are often robust and tense. In contrast, pemphigus conditions produce blisters nearer the surface of the dermis; these are therefore more fragile and may instead present as raw erosions. (Patrício et al., 2009; Schmidt & Zillikens, 2013; Sticherling & Erfurt-Berge, 2012)

AIBDs cannot be cured, and management strategies often rely on immunosuppressants or oral corticosteroids to relieve symptoms. Although rare, AIBDs are becoming increasingly prevalent (Langan et al., 2008). Bullous pemphigoid, which mainly affects those over 60 years of age, is no longer categorised as a rare disease amongst this age group (Persson et al., 2021). Additionally, these conditions are associated with high mortality rates (Langan et al., 2008) and poor quality of life (Kouris et al., 2016). Consequently, these are both of increasing concern.

Also of concern, are the difficulties associated with identifying this group of conditions. An international survey exploring unmet needs of patients, clinicians and researchers in relation to pemphigoid diseases found that 66% of patients expressed a need for faster diagnosis, the majority of whom reported misdiagnosis or long diagnostic delays. (Lamberts et al., 2018) Additionally, a recent multi-centre study has shown that patients with bullous pemphigoid respond better to treatment if diagnosed earlier, further emphasising the importance of early recognition. (Williams et al., 2017).

As with many conditions, GPs are often the first healthcare providers to see people with undiagnosed AIBDs. Many factors are likely to contribute to diagnostic delays, such as the wide range of ways in which this group of conditions may present, the similarities to other conditions and differential diagnoses, and the rareness of this group of conditions. In addition, there is often a need for specialist involvement in the diagnostic and management processes, therefore requiring referrals from General Practice. In 2021, the Government published The UK Rare Diseases Framework; a policy paper that set out four high-level priorities to address the challenges faced by those living with a rare disease in the UK. The document highlights the importance of supporting patients to get diagnosed sooner, raising healthcare professionals' awareness of rare diseases, improved co-ordination of care and improved access to specialist care and treatments. (Department of Health and Social Care, 2021) Since recognising and referring autoimmune blistering diseases is linked to all these health policy priorities, the need for this research is evident.

Study Aim and Objectives

Aim

This study aims to explore the views of GPs across the UK regarding recognition and referral of patients with AIBDs in primary care.

Objectives

The specific objectives of this study consist of:

- Determining the challenges of recognising AIBDs
- Identifying how referral decisions are made when the cause of blistering is unclear
- Exploring potential tools to aid recognition of AIBDs

Study Methods

Study Design

This qualitative approach will involve individual semi-structured interviews, conducted within the constructivist paradigm, which recognises the co-construction of knowledge between the participants and the research team. (Fodouop Kouam, 2024)

The design and reporting of this study is being conducted in accordance with the Consolidated criteria for reporting qualitative research (COREQ) guidelines (Tong et al., 2007).

Recruitment and Sampling

The sampling strategy will involve recruiting up to 20 UK-based GPs, who had at least a year of clinical experience in General Practice. The study was advertised online using social media (for example within a Facebook group for GPs) and via several GP mailing lists. Recruitment began in December 2023 and prospective participants were invited to express their interest by completing an online form. Purposive sampling was then employed to select a sample of individuals that most closely represented the UK GP population. Factors considered included UK country, gender, years of experience, practice size, rurality of practice, dermatology specialist interest, GP type (salaried/locum/partner/other) and practice type (teaching/research/research and teaching/other); data for which was collected on the expression of interest form. Selected participants were then sent further information about the study (Appendix 1) via email and were invited for an interview. They were additionally asked to return a consent form once signed (Appendix 2). Where individuals withdrew or were not contactable, replacements were chosen that, as far as possible, retained the representative nature of the sample. Fifteen interviews were conducted, then a further five were added to ensure data saturation.

Data Collection

Interviews were conducted by a researcher with training and experience in qualitative interviewing and a background in healthcare. In addition to the topic guide (Appendix 3), which was developed in collaboration with both our clinical and expert patient members of the research team, some vignette sheet was also developed, containing photos of 5 different cases of autoimmune blistering diseases. (Appendix 4). The aim of this document was to further aid the discussion through providing contexts, particularly for GPs less familiar with this group of conditions, that would help them think about what information they would need to gather and what management or referral options they might consider.

Consenting individuals were interviewed online over Microsoft (MS) Teams. All interviews were digitally recorded using MS Teams. Audio files were subsequently extracted, securely saved, transcribed verbatim and transcripts were then pseudonymised

Data Analysis

Data analysis was conducted in NVivo 14. Data were analysed using Framework analysis (Spencer et al., 2003) with a predefined theoretical framework put together by the research team, which included a GP (VP) and a Consultant Dermatologist (KH) with specialist expertise in AIBDs. During analysis, inductive coding was used to add to and revise the original framework to reflect new areas of interest found within the data.

Framework analysis was originally developed to ensure the quality of Government-funded qualitative social policy research (Spencer et al., 2003). Since then, framework analysis has been widely used in health research as it provides a systematic, rigorous and transparent approach to data analysis, making it an appropriate choice for this study (Gale et al., 2013).

Ethical Approval

This protocol was reviewed by the University of Nottingham's Faculty of Medicine and Health Sciences Research Ethics Committee and the project was given a favourable research ethics opinion (Reference Number FMHS 321-0723) (Appendix 5).

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Appendix 1: Participant Information Sheet

University of Nottingham
UK | CHINA | MALAYSIA

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Study Title: Exploring the care pathway to diagnosis for people with autoimmune blistering disease: A qualitative study of General Practitioners' views

PARTICIPANT INFORMATION SHEET

Research Ethics Reference: [FMHS 321-0723]
Version 1.0 Date: 29.06.2023

We would like to invite you 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 involve. One of our team will go through the information sheet with you and answer any questions you have. Please take time to read this carefully and discuss it with others if you wish. Ask us anything that is not clear.

What is the purpose of the research?

The purpose of this study is to explore the views of GPs with regards to recognition and referral of patients with autoimmune blistering diseases in primary care, in order to understand better the care pathway for these patients.

Why have I been invited to take part?

You are being invited to take part because you are a GP with at least one year of experience. We are inviting up to15 participants like you to take part.

Do I have to take part?

It is up to you to decide if you want to take part in this research. We will describe the study and go through this information sheet with you to answer any questions you may have. If you agree to participate, we will ask you to sign a consent form and will give you a copy to keep. However, you would still be free to withdraw from the study at any time, without giving a reason, simply let the research team know.

What will happen to me if I take part?

A researcher will contact and explain the procedures. If you are still happy to take part, then you will then be asked to complete a screening questionnaire. The researcher will then select 15 GPs from the group of eligible participants. The researcher will need to make sure the participants come from a variety of GP practices (e.g., rural/urban) and have a range of clinical experience to make sure the study is as representative of all GPs as possible. If your name has been chosen, the researcher will then contact you to arrange a day/time for a one-hour online one-to-one interview via Microsoft Teams. You will be asked to sign a consent form.

The interview will take place at a time that is convenient for you including evenings or weekends, if you prefer. You will be asked to conduct the interview in a quiet and private room. You can choose if you prefer for the interview to be conducted as video or audio only. You will also be asked not to disclose any patient names. After the interview, you will be sent a retail voucher (for £100) to thank you for participating. You will be offered the opportunity to listen to the interview and make any changes if you wish to do so.

Are there any risks in taking part?

The study has been deemed as a low-risk study. We foresee no risk in participating in the study. However, if you have any concerns, our contact information is at the end of this document and we will be happy to answer any queries you might have.

Are there any benefits in taking part?

We cannot promise the study will help you but the information we get from this study may help improve recognition and referral of people with autoimmune blistering diseases in primary care. We will provide a letter of thanks on University letter-headed paper which you can use for your annual appraisal. You may wish to record your reflections and use this to show your continuing professional development as a GP.

Will my time/travel costs be reimbursed?

Participants will receive an inconvenience allowance to participate in the study (a £100 retail voucher).

What happens to the data provided?

The **research data** will be stored confidentially using a password protected database at the University of Nottingham. To help ensure your privacy, you will be assigned a volunteer study identification number (for example P01 for participant number 1), and it will be used instead of your name. We will save all the recordings and research data using that volunteer study identification number so that none of the data will have your real name or other individual identifiers associated with them. Your name and any information about you will not be disclosed outside the study centre. The interview will be audio recorded using Microsoft Teams and a transcription company will transcribe the data. The recordings will be deleted once the anonymised transcripts have been checked.

Personal data from the expression of interest, online screening questionnaire and consent form will be stored confidentially using a password protected database at the University of Nottingham.

Only the research team will have access to personal data. Only the research team and the transcription company will have access to the anonymised research data.

We would like your permission to use fully anonymised direct quotes in research publications.

All research data and records will be stored for a minimum of 7 years after publication or public release of the work of the research.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. All personal information that could identify you will be removed or changed before information is shared with other researchers or results are made public.

Data sharing in this way is usually anonymised (so that you could not be identified).

What will happen if I don't want to carry on with the study?

Even after you have signed the consent form, you are free to withdraw from the study at any time without giving any reason. Any personal data will be destroyed. If you withdraw, we will no longer collect any information about you or from you, but we will keep the anonymous research data that has already been collected and stored as we are not allowed to tamper with study records. This information may have already been used in some analyses and may still be used in the final study analyses.

Who will know that I am taking part in this research?

Data will be used for research purposes only and in accordance with the General Data Protection Regulations. Any audio/video digital recordings and electronic data will be anonymised with a code as detailed above. All such data are kept on password-protected databases sitting on a restricted access computer system and any paper information (such as your consent form, contact details and screening questionnaire) would be stored safely in lockable cabinets in a swipe-card secured building and would only be accessed by the research team.

Under UK Data Protection laws the University is the Data Controller (legally responsible for the data security) and the Chief Investigator of this study (Dr Sonia Gran) is the Data Custodian (manages access to the data).

You can find out more about how we use your personal information and to read our privacy notice at:

https://www.nottingham.ac.uk/utilities/privacy.aspx/

Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.

With your consent, we will keep your personal information on a secure database in order to contact you for future studies.

Anything you say during an interview will be kept confidential, unless you reveal something of concern that may put yourself or anyone else at risk. It will then be necessary to report to the appropriate persons.

Due to the professional responsibilities of some University staff, if you mention something during the interview which may require reporting the research team will discuss it with you and decide on a course of action.

What will happen to the results of the research?
The results will be submitted to a peer-reviewed journal within 3 months the project end date. We will send you a copy of the final report. You will not be identified in any report/publication.

Who has reviewed this study?
All research involving people is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests.

Who is organising and funding the research?

The research is being organised by Dr Sonia Gran at the University of Nottingham and is being funded by the National Institute of Health Research's School of Primary Care Research.

What if there is a problem?
If you have a concern about any aspect of this project, please speak to the Principal Investigator [Dr Sonia Gran] who will do their best to answer your query. The PI should acknowledge your concern and give you an indication of how she intends to deal with it. If you remain unhappy and wish to complain formally, you can do this by contacting the FMHS Research Ethics Committee Administrator, Faculty Hub, Medicine and Health Sciences, E41, E Floor, Medical School, Queen's Medical Centre Campus, Nottingham University Hospitals, Nottingham, NG7 2UH or via E-mail: FMHS-ResearchEthics@nottingham.ac.uk.
Please quote ref no: FMHS-321-0723

Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Dr Sonia Gran
Centre of Evidence Based Dermatology
Applied Health Research Building
University Campus
Tel: 0115 8468631
Email: sonia.gran@nottingham.ac.uk

Appendix 2: Consent form

University of Nottingham
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Participants Consent Form
Final version 1.0: 29.06.2023

Title of Study: Exploring the care pathway to diagnosis for people with autoimmune disorders: A qualitative study of General Practitioners' views

REC ref: FMHS-321-0723

Name of Researchers: Dr Lydia Tutt, Dr Sonia Gran, Dr Laura Howells, Dr Vibhore Prasad, Dr Karen Harman

Name of Participant: **Please initial box**

1. I confirm that I have read and understand the information sheet version number 1 dated 29/06/23 for the above study which is attached and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without disadvantage. ☐
3. I understand that relevant sections of my data collected in the study may be looked at by the research group and by other responsible individuals for monitoring and audit purposes. I give permission for these individuals to have access to these records and to collect, store, analyse and publish information obtained from my participation in this study. I understand that my personal details will be kept confidential. ☐
4. I understand that the interview will be audio recorded using Microsoft Teams, a transcription company will transcribe the data, and that anonymous direct quotes from the interview may be used in the study reports. ☐
5. I understand that information about me recorded during the study will be made anonymous before it is stored in a secure database. Data will be kept for 7 years after the study has ended and then deleted. ☐
6. I understand that what I say during the interview will be kept confidential unless I reveal something of concern that may put myself or someone else at any risk. It will then be necessary to report this to the appropriate persons. ☐
7. I agree to take part in the above study. ☐
8. **Optional:** I agree that my anonymous research data will be stored and used to support other research during and after 7 years and shared with other researchers including those working outside the University. ☐
9. **Optional:** I agree to my contact details being stored for the purpose of being invited to participate in future research studies. ☐

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

2 copies: 1 for participant, 1 for the project notes.

Appendix 3: Interview topic guide

about recognising and making referrals for people with autoimmune blistering diseases, such as bullous pemphigoid and pemphigus vulgaris, in primary care.

Question 1

- What is your clinical experience of autoimmune blistering diseases?
  Prompts:
  - How often do you see them in your clinic?
  - What kind of blistering diseases do you tend to see?
  - Tell me what goes through your mind if a patient comes into your clinic with a rash?
  - Tell me what goes through your mind if a patient comes into your clinic with a blister?

IF GPs DO NOT HAVE ANY OR VERY LITTLE EXPERIENCE OF AUTOIMMUNE BLISTERING DISEASES WE WILL USE THE PATIENT VIGNETTES HERE (SEE SEPARATE DOCUMENT)

Question 2

- What are the challenges of managing autoimmune blistering diseases in primary care?
  Prompts:
  - Is there anything about managing them that is particularly difficult?
  - Is there anything that makes them easier to manage?
  - How do you think they could be managed better?

Question 3

- What goes through your mind if a patient may need a specialist opinion?
  Prompts:
  - What are you looking for to help you decide whether to make a referral?
  - What are the challenges in making a referral decision?
  - Do you use any tools or tests to help make a referral decision? If you do: Can you tell me a bit about how you use that test/tool to help with your decision.

Question 4

- If we could design a tool to help you decide which patients with blisters need a specialist opinion, what would you like that tool to look like?
  Prompts:
  - What would the tool need to include?
  - What would make you more likely to use this tool in practice?
  - What would make you less likely to use this tool in practice?
  - PEM Friends have currently designed an online photo library with photos of different autoimmune blistering diseases-what are your thoughts on this?

Question 5

- How do you think digital technologies have changed in terms of how you deal with autoimmune blistering diseases?

Prompts:

- How does using videos/photos influence how you deal with autoimmune blistering diseases
- How would you like to use digital technologies in the future to help this condition?

Question 6

Finally, is there anything else you would like to share?

Appendix 4: Vignettes

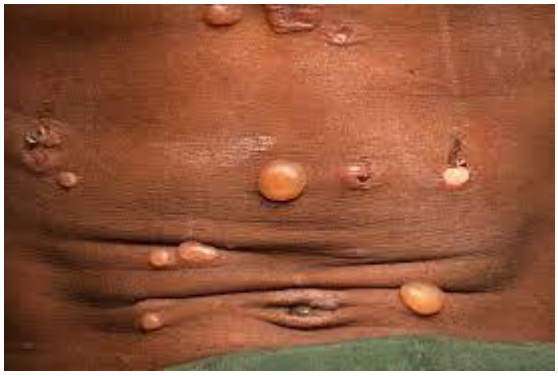
Patient Vignette Outline

These are to be used with GPs who have limited experience of seeing patients with autoimmune blistering disease.

Example 1

An Asian female patient of 62 years comes to see you with a complaint of blisters on their stomach.

You examine them and it looks like this:



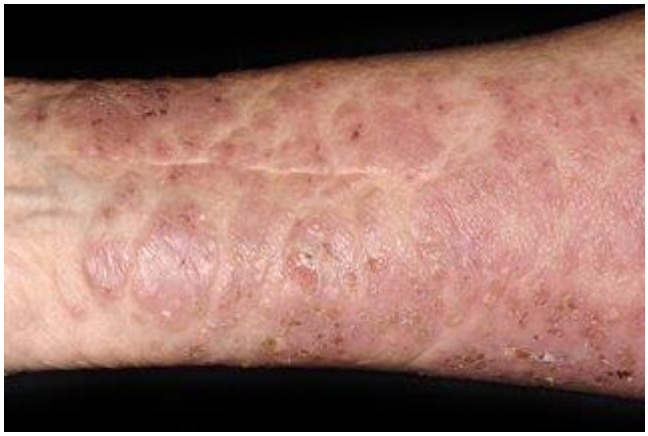
Taken from https://www.nhs.uk/conditions/pemphigus-vulgaris

And then we will use questions 2 to 6 in the topic guide

Example 2

A Caucasian male patient of 81 years comes to see you with a complaint of a rash on their arm.

You examine it and it looks like this:

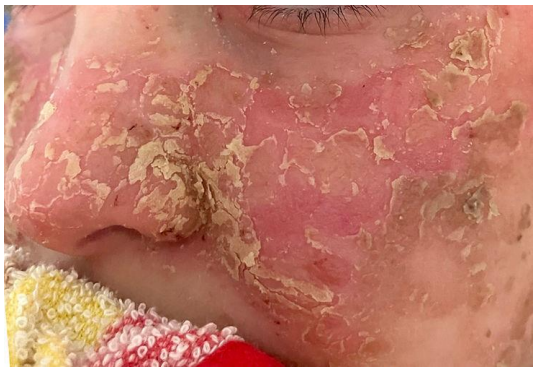


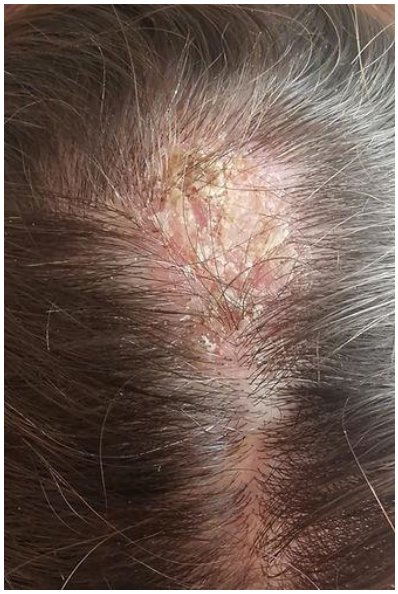
Taken from https://www.nhs.uk/conditions/bullous-pemphigoid

Example 3

A Caucasian female patient of 19 years comes to see you with a complaint of a crusty rash on her face and scalp

You examine it and it looks like this:



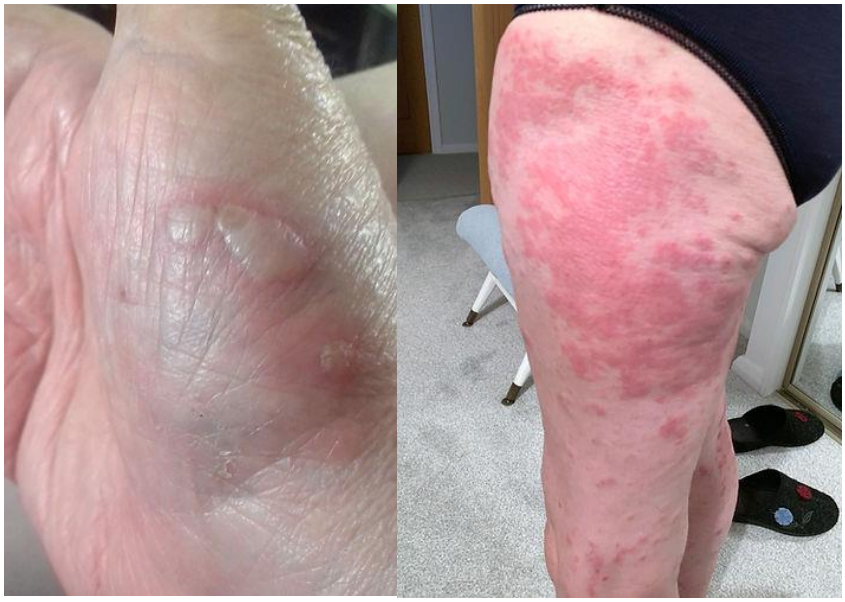


Taken from: https://www.pemfriendsuk.co.uk/diagnostic-photo-library

Example 4

A Caucasian female patient of 70 years comes to see you with a complaint of an itchy rash on her hands and legs.

You examine them and it looks like this:

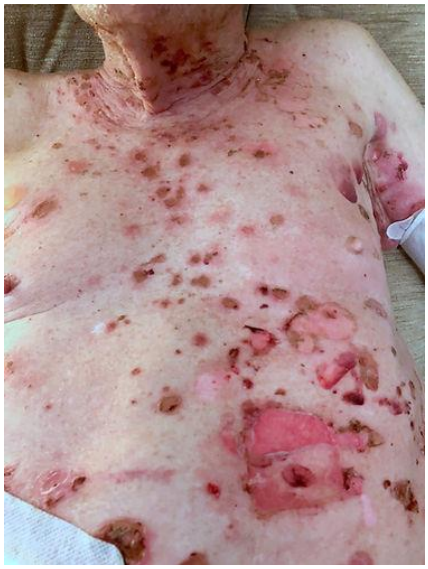


Taken from: https://www.pemfriendsuk.co.uk/diagnostic-photo-library

Example 5

A Caucasian male patient of 80 years comes to see you with a complaint of a rash on their torso.

You examine it and it looks like this:



Taken from: https://www.pemfriendsuk.co.uk/diagnostic-photo-library

And then we will use questions 2 to 6 in the topic guide

Appendix 5: Ethical approval letter

University of Nottingham
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21 August 2023

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Dear Dr Gran

Ethics Reference No: FMHS 321-0723 – **please always quote**
Study Title: Exploring the care pathway to diagnosis for people with autoimmune blistering diseases: A qualitative study of General Practitioners' views
Chief Investigator/Supervisor: Sonia Gran, Associate Professor of Medical Statistics, Centre for Evidence Based Dermatology, Lifespan & Population Health, School of Medicine.
Other Key investigators: Dr Laura Howells, Senior Research Fellow, Centre for Evidence Based Dermatology, Lifespan & Population Health, School of Medicine, Dr Vibhore Prasad, General Practitioner, Brierley Park Medical Centre, BHS Mansfield and Ashfield, Dr Karen Harman, Consultant Dermatologist, University Hospitals of Leicester.
Proposed Start Date: 21/08/2023 — **Proposed End Date:** 30/09/2024

Thank you for submitting this clearly explained application which was considered at the meeting held on 14 July 2023. The following documents were received:

- FMHS REC Application form and supporting documents version 1.0: 29.06.2023

These have been reviewed and are satisfactory and the project is given a favourable research ethics opinion.

A favourable research ethics opinion is given on the understanding that:

1. All gatekeeper permissions are checked if required and are in place before recruitment starts
2. The protocol agreed is followed and the Committee is informed of any changes using a notice of amendment form (please request a form).
3. The Chair is informed of any serious or unexpected event.
4. An End of Project Progress Report is completed and returned when the study has finished (Please request a form).

Yours sincerely

pp

Dr John Williams, Associate Professor in Anaesthesia and Pain Medicine
Chair, Faculty of Medicine & Health Sciences Research Ethics Committee