

**Views and experiences Of primary Care
penicillin allergy de-labelling (ALABAMA-VOICE study)**

PATIENT INTERVIEWS

Participant Information Leaflet

Chief Investigator: Professor Sue Pavitt, University of Leeds

What is the research study about?

The main aim of the study is to find out peoples' views and experiences of having a penicillin allergy recorded in their medical notes.

Why have I been invited to take part?

We are inviting people who have taken part in a consultation with a health care professional from their GP practice, most likely a pharmacist or GP, to talk about the penicillin allergy recorded in your medical notes. We would like to interview you to find out about your views and experiences of taking part in the consultation.

Do I have to take part?

No. Taking part is voluntary, it is up to you to decide whether to take part. Please take time to consider the information provided in this information sheet before making your decision.

What do I have to do?

We would like you to take part in a telephone or online (Microsoft Teams) interview. The interview will be arranged at a time to suit you. The interview should take between 30 to 45 minutes.

If, once you have read this leaflet, you would like to take part please contact the research team using the contact details at the end of this sheet. The research team will be able to answer any questions you have and make sure you understand the study information. You will be given as long as you need to decide whether to take part or not.

The researcher will start the interview by confirming you are eligible to take part. You will be asked to provide verbal informed consent to confirm that you fully understand what taking part in the study will involve and that your questions about the research have been answered.

The interview will be carried out by telephone or online (Microsoft Teams). The interview will be audio-recorded then typed up. This will provide our research team

with an accurate record of the interview which we will later analyse. The interview completes your participation in the study.

What are the risks and benefits of taking part?

There are no direct risks or benefits to you. We hope the information gained from the study will be used to improve the care of people with a penicillin allergy recorded in their medical notes and to provide information to health care professionals in making treatment decisions for patients with a penicillin allergy.

Will I be reimbursed for taking part?

Taking part in this research is voluntary. You will not incur any additional expenses by taking part in this study. You will be offered £50 in high street vouchers as a thank you for your participation in the interview.

Who is organising the study?

The study is funded by The University of Leeds Higher Education Innovation Fund (reference MIF136). The study is Sponsored by The University of Leeds.

This study has been reviewed and received favourable opinion by the Leeds West NHS Research Ethics Committee (REC Ref: 26/YH/0077).

How can I find out more about how my information is used?

As study Sponsor, the University of Leeds provides a Privacy Notice that explains how and why it uses personal data for research, your individual rights under the Data Protection Act 2018 (DPA) and who to contact if you have any queries or concerns. You can find out more about how we use your information by following the link below or by contacting the Data Protection Officer: dpo@leeds.ac.uk

<https://dataprotection.leeds.ac.uk/research-participant-privacy-notice/>

The Health Research Authority (HRA) has produced a patient data and research leaflet which is available to all patients involved in research. This is available at:

<https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/>

How will you use information about me?

We will need to use information from you for this research study. This information will include your:

- Name
- Age at date of interview
- Gender
- Ethnicity

- Telephone number
- Email and/or postal address
- Postcode
- Name of GP practice
- How long you have had a penicillin allergy record (if known)

The University of Leeds is responsible for looking after your information. Your information will only be shared with authorised individuals within the research team, this includes colleagues from the University of Oxford. Your data will not be shared outside the UK.

We will use the information collected to do the research or to check our records to make sure that the research is being done properly. We will keep all information about you safe and secure by:

- People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.
- Personal data in informed consent forms, participant log, audio recordings of interviews plus anonymised written interview transcripts will be stored in electronic files with restricted access at the University of Leeds.
- The interview will be audio-recorded to make an accurate record of what is said and then stored on a secure computer on University of Leeds premises.
- The recording will be sent securely to an independent transcription company who will transcribe the interview verbatim. This company will hold a confidentiality agreement with the University of Leeds. The written transcript will not include any names or other defining details that can identify you, to ensure confidentiality.
- Audio recordings and anonymised written interview transcripts will be shared with the members of the research team at the University of Oxford to help us analyse the data we have collected from participants.
- Once transcribed, audio recordings and transcripts of interviews will be stored separately and securely at the University of Leeds for 5 years following the end of the study then permanently deleted following university procedures.

How will you use information about me after the study ends?

Once we have finished the study, we will store the information collected so we can check the results. Personal data will be kept securely for up to 5 years following the end of the study at the University of Leeds according to university policies, then deleted. Anonymised written transcripts will be stored securely at the University of Leeds and may be accessed by researchers for future research studies in the UK upon request. They will be stored for up to 5 years following the end of the study then deleted.

The findings from this study will be used in research outputs (including scientific articles, presentations, reports, conference papers). We will write our reports in a way that no-one can work out that you took part in the study. No names or other

identifying details will be included in reports - any quotes from the interview will be anonymous.

Some of the data collected in this study will be analysed by a postgraduate student and written up as part of their Masters degree project.

What happens if I change my mind?

You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

You can stop being part of the study at any time, without giving a reason, and without negative consequences, by telling a member of the research team (listed at the end of this sheet) of your decision. You have up to two weeks after the interview to withdraw from the study if you wish. Two weeks is generally the period of time when transcription is completed and data is made ready for analysis. If you withdraw from the study during this time, then your data will not be used. If you withdraw after this time your data will still be included in the analysis. You can also withdraw from the study and allow us to keep existing information we have collected (for example, if you had to stop the interview early).

What happens if something goes wrong?

Every care will be taken in the course of this research. However, in the unlikely event that you are injured as a result of your participation in this research the University, when acting as Sponsor, has insurance cover in force. The insurance in place meets claims arising from death or injury, which are brought against the University and where those claims arise from the Universities own negligence in its role and activities relating to the study (and which is subject to the terms, conditions and exceptions of the relevant policy). Clinical negligence indemnification will rest with the participating NHS Trust under standard NHS arrangements. If you wish to complain about any aspect of the way you have been treated, please contact the research study co-ordinator in the first instance (contact details on the next page). Any claims will be subject to UK law and must be brought in the UK.

For independent complaints please contact the University of Leeds Sponsor representative at governance-ethics@leeds.ac.uk

If you have any questions or concerns about the consultation/appointment with a health care professional where your penicillin allergy was discussed, please contact your GP practice.

What will happen to the results of the research study?

The results will be published in scientific journals and meetings. A summary of the findings will be sent to all participants who would like to see the results. The researcher will ask if you would like to receive the results by email or by post, or if you would prefer to not receive them.

Where can I get more information?

If you would like to take part in the study or if you have any further questions during your participation, please do not hesitate to get in touch with the research team using the contact details below.

Research team contact details:

Name: Ms. Catherine Porter
Address: School of Dentistry, University of Leeds, Room 6.090 Worsley Building, Clarendon Way, Leeds, LS2 9LU, United Kingdom
E-mail: c.e.porter@leeds.ac.uk
Work mobile: 07596 886 490

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION