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Experiences of an inpatient penicillin allergy de-labelling pathway: capturing the patient voice

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Background: Non-allergist-delivered penicillin allergy de-labelling (PADL) is supported by UK and other national guidelines but is not yet routine practice in UK hospitals. Those who have undergone PADL report high rates of acceptance, but it is unknown why some continue to avoid penicillin, and why some decline testing.

Objectives: To explore the experiences of patients recently approached for penicillin allergy (penA) assessment and de-label by non-allergists in a UK hospital to determine the barriers and enablers to patient acceptance of PADL.

Methods: Qualitative study using semi-structured interviews with patients who were penA assessed and de-labelled during an inpatient stay between November 2022 and January 2023. Thematic analysis was used to analyse the data.

Results: Nineteen patients were interviewed. Patients were largely unaware of the negative impact of penA on their healthcare. Patients had differing views on challenging their penA status while they were acutely unwell, some agreeing that it is the right time to test and others not. Patients declined testing because they felt they were at higher potential risk because they were older or had multiple comorbidities. Some patients who declined testing felt they would have been persuaded if they had received a better explanation of the risks and benefits of PADL.

Conclusions: Patients who were successfully de-labelled were positive about the experience. Those who declined testing did so for a variety of reasons including frailty/comorbidities or a fear of testing whilst unwell. Patients highlighted the importance of good communication about the personalized risks and benefits of testing.

Introduction

Patients with a record of penicillin allergy (penA) are often given 'second choice' antibiotics, which can be less effective, are more likely to cause side effects, and put people at risk of MDR infections.[1] Fifteen percent of hospitalized patients have a record of penA, but approximately 95% of these patients can safely take penicillin after formal allergy testing.[2] The process for assessing patients and removing incorrect penA labels is called 'penicillin allergy de-labelling (PADL)'. Removing incorrect allergy records enables more patients to safely take penicillin antibiotics instead of the second-choice antibiotics, benefiting patients and healthcare systems.

Non-allergist-delivered PADL is supported by the British Society of Allergy and Clinical Immunology (BSACI), the UK's Department of Health and Social Care (DHSC) and the WHO but is not yet routine in UK hospitals.[3–5] An Australian telephone survey of inpatients who had recently been de-labelled found that patients felt safe during testing and would recommend the test to others, but a third of patients de-labelled on history alone (direct de-label; DDL) and 5% of those de-labelled by direct oral challenge (DOC) continued to avoid penicillin.[6] The survey was limited in that it didn't explore the views of those patients who had declined testing.[6] Likewise, a Scottish study sought feedback from inpatients who had recently been de-labelled and reported them experiencing low levels of anxiety during the testing process, but again the study was limited because it did not explore the views of those declining testing.[7] In a US study exploring

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patient barriers to PADL, although some patients reported a reluctance to discuss their penA records, the majority expressed interest in PADL.[8] While patient acceptance of PADL appears to be high, it is unknown why some of those who have tested negative continue to avoid penicillin and why some patients decline inpatient testing.

Hearsey *et al*.[9] recently reported the results of a 3 month PADL feasibility study at an English hospital. The aim of this work was to explore the experiences of those patients.

Methods

Study design and setting

The study hospital is a 760-bed district general hospital serving a population of 450 000 people in a largely rural part of the UK. In 2022, there were 120 627 hospital admissions and 83 555 Emergency Department attendances.

A qualitative study was conducted using semi-structured interviews with patients with a penA record, which was risk stratified, and de-labelled if appropriate, during an inpatient stay between November 2022 and January 2023. During this period, a total of 7214 inpatients spent some, or all, of their inpatient stay on a ward visited by the antimicrobial stewardship team; median age was 71 years (IQR 55–81 years) and 3483 were (48.3%) male. Of 7214 inpatients, 1133 (15.7%) had a penA record on admission to hospital, of which 587 (51.8%) were prescribed an antibiotic.[9] The PADL pathway in summary was: inpatients with a penA label receiving non-penicillin antibiotics were identified by a search of electronic prescription records and approached by a member of the antimicrobial stewardship team who then took a penA-focused history and risk stratified the patient's penA history using a risk stratification tool.[10] Low-risk patients could be de-labelled on history alone or by DOC. Patients eligible for de-labelling were given an information leaflet and verbal explanation on the risks of a penA label and potential benefits of de-labelling by a member of the study team. Patients were then consented to de-label before switching antibiotic therapy to a penicillin. Patients de-labelled by DOC were observed for an hour after administration of a penicillin dose with regular observations.

Participant selection

From a group of 140 patients identified with low risk penA histories, we used purposive sampling to identify participants in one of the five following groups: (1) penA history eligible for DOC but patient declined testing; (2) penA history eligible for DOC and patient tested; (3) penA history eligible for DOC but patient met acute exclusion criteria for testing (e.g. prescribed concurrent beta-blockers and/or haemodynamic instability) and not tested; (4) penA history eligible for DDL and patient declined de-labelling; and (5) penA history eligible for DDL and patient de-labelled. Eligible patients were telephoned and invited to participate in a one-to-one telephone interview. The telephone conversation included a brief outline of the study, and permission to either e-mail or post a participant information sheet to the participant. Patients were contacted after at least 24 h to answer any questions and to book an interview time that was convenient to the participant.

Data collection

An interview guide was developed based on the primary research question and informed by existing literature and the Theoretical Domains Framework (TDF).[6,11–14] The TDF provides a robust theoretical basis for implementation studies, with the findings of this study intended to inform the design of a future PADL implementation study.[15] The interviewer (N.P.) explained to participants that he wanted to hear about their opinions and experiences of living with a penA record and their recent experience of having their penA challenged.

Participants were asked general questions that explored their understanding of penA and then more specific questions about their experience of being approached by healthcare workers (HCWs) and having their penA challenged (where relevant). Interviews were conducted over the telephone and audio recorded and transcribed verbatim by an independent transcription services company. N.P. conducted the interviews after obtaining recorded verbal consent. Data saturation was considered as interviews were completed and the data reviewed.

Data analysis

Data collection and analysis took place concurrently. Transcripts were uploaded to NVivo 12. Inductive thematic analysis was used to analyse the transcripts.[16] N.P. read and familiarized himself with all transcripts before independently coding five transcripts, with participants from different sampling groups, before discussing these with S.T.C. to agree on preliminary codes. These codes were then used to develop an initial coding framework, discussed with S.T.C., which was then used to analyse the remaining transcripts. Additional codes were added as new data were identified in later transcripts and the framework adapted as necessary.

Ethics

This study was reviewed and approved by the Liverpool Central Research Ethics Committee (IRAS Project ID 299708).

Results

Participants

Thirty-eight patients were invited to interview, of which 19 declined, and 19 agreed and were interviewed. Interviews were conducted between 3 March 2023 and 22 April 2023, approximately 5–6 months after patients had been invited for PADL. Interviews lasted between 9 and 30 min (mean 17 min). Interviewed participant characteristics are reported in Table 1. Those who were invited to interview but not interviewed are shown in Table S1 (available as Supplementary data at *JAC-AMR* Online).

Two broad themes captured the views of patients on living with a penA record and of their experiences of having their penA challenged in hospital. Data saturation was likely met given the relatively homogeneous patient population from a single centre and the absence of new identified themes early in the interview schedule.[17]

Theme 1: Patient beliefs and understanding about their penA status

All patients reported their first (index) allergic reaction to penicillin occurred a long time ago, often in childhood. Most patients could not remember their index reaction, instead relying on what they had been told by a relative. Being told to never take penicillin again by either a HCW or a relative was commonly described.

> *She said, 'You've had a bad reaction to penicillin and now you must remember never ever to have penicillin again in your life'.* DOC_ineligible_2

Nearly all patients said their penA record hadn't been explored by HCWs in the past and that they were prescribed alternative

Table 1. Interviewees by penA group, gender and age

Patient group	Number of participants	Age range (mean), years	Gender	Years since index reaction, median (IQR)
DOC declined	5	57–82 (69)	M (2)	50 (19–63)
DOC ineligible	4	59–80 (73)	M (3)	57.5 (32.5–67.5)
DOC PADL	6	64–84 (73)	M (4)	50 (40–60)
DDL PADL	4	69–78 (75)	M (3)	62.5 (60–67.5)
Overall	19	57–84 (73)	M (12)	60 (40–60)

M, male; DOC declined = penA history eligible for DOC but patient declined testing; DOC PADL = penA history eligible for DOC and patient tested and de-labelled; DDL PADL = penA history eligible for DDL and patient de-labelled; DOC ineligible = penA history eligible for DOC but patient met exclusion criteria for testing and therefore not tested.

antibiotics. One participant said a doctor, during a recent inpatient stay, had been sceptical about whether their penA record was genuine and one patient had been de-labelled, peri-operatively.

> *They say, 'Oh, you're allergic to penicillin.' So they sort of gave me something else.* DOC_ineligible_1

Many patients believe(d) their penA to be genuine for a variety of reasons. These included having a family history of penA or a personal history of multiple allergies. Some hadn't questioned it because they were told they were allergic by a person of authority (their mother or HCWs). Others had not thought about it because they had not required penicillin since their index reaction.

> *So basically when the matron at my school said, 'Don't ever have it.' I've never had it and that's it. I never questioned it.* DOC_ineligible_2

However, some patients did have doubts about the authenticity of their penA record for several reasons, which included wondering whether they 'might have grown out of it', believing their symptoms to be inconsistent with an allergy and one patient said they had tolerated amoxicillin several times since without adverse effect. One patient had asked for penicillin during a previous inpatient stay because she was told it was the best treatment option for her, but she was denied it due to her penA.

> *I don't recall having a rash or anything. I recall I vomited a fair bit but I don't recall being poorly with the penicillin particularly. You know that was the local GP's decision to decide I was allergic to it.* DOC_PADL_2

Several patients said that having a penA record hadn't negatively impacted their healthcare, either because they hadn't recalled needing antibiotics, or because they were prescribed alternative antibiotics that worked and didn't cause them problems.

> *The treatment I've always had has been really good so I don't think it [penicillin allergy history] would make a lot of difference.* DOC_ineligible_1

Having an incorrect penA record removed was important to some patients because it was viewed as important to have accurate medical records and removal of their penA gave more prescribing options. Some patients acknowledged that alternatives to penicillin were potentially more harmful in terms of side effects or potentially less effective.

> *I think it's pretty important [to have accurate records], especially in later years of life, you're going to get more illnesses and it's [penicillin] an extra option, isn't it?* DOC_PADL_8

Theme 2: Patient experiences and views on PADL

Patients who had completed testing said that they had confidence in the PADL process and confidence in their negative PADL test result. Those who underwent testing felt that the explanation of the procedure by the HCW delivering PADL was provided in a way that was kind, convincing and reassuring. Participants who were successfully de-labelled did not provide any suggestions on improving the PADL process. One patient who agreed to testing said the PADL information leaflets were difficult to understand because of the language used, but that the verbal explanation was clear.

> *It was a seamless process to be perfectly honest. I was very happy with it and very interested in it.* DOC_PADL_2

Many patients agreed to testing while acutely unwell, with some agreeing to testing either because they were told by an HCW that it was the best treatment for them, or due to a belief that having penicillin would help them. Some patients agreed to PADL for more altruistic reasons because they thought the study sounded interesting, and because they believed their involvement might help others.

> *I think it was because, as I say, I was very ill and anything that would have helped was welcome.* DDL_PADL_10

Several de-labelled patients expressed that they were pleased to have their penA record removed because it meant they could receive potentially more effective treatment. Participants also mentioned that penicillins would be less expensive than other antibiotics (for the NHS) and it would be more straightforward for HCWs to choose an appropriate treatment for them.

> *Well I thought it was good [to be delabelled]. I felt, 'Well I don't have to go through a variety of antibiotics to find one that might be suitable.'* DOC_PADL_3

In contrast, several patients felt that whilst they were acutely unwell was not the right time to test their penA record, expressing concerns that having a reaction whilst unwell could make them worse. Some felt too unwell to even discuss the opportunity for PADL, with one patient suggesting that she shouldn't have even been approached, given how unwell she was, and one patient reporting feeling upset at having to decide about being tested when so acutely unwell. Others declined testing because of their frailty or multiple comorbidities, expressing concerns that if they were to have a reaction, they feared that they would find it difficult to recover.

> *At the time, I just thought I shouldn't have been approached. I had enough to cope with trying to just exist. I did feel really unwell without thinking about becoming worse if I still had my penicillin allergy. I just thought it was unnecessary.* DOC_declined_4

> *It scared me. Very simple, scared me 'cause at the time I didn't really know exactly what was wrong with me and I didn't wanna risk any medication that was given me in case it affected it. I know there can't be ever a good time to try I presume but it did scare me.* DOC_declined_3

Some patients did not have confidence in the PADL process and expressed anxiety about having a dose of penicillin, viewing it as too risky. Some patients who declined testing said that a better explanation of the risks and benefits may have helped them feel more reassured of the safety of PADL, as would have more time to consider testing. Two patients questioned the validity of testing using only a single dose, suggesting that a longer test course might be more reassuring for them that they weren't allergic to penicillin.

> *I would [like to] have time to think about it more or even discuss it with one of my visitors. Just to give me that bit more time. I think that's the only difference I would say.* DOC_declined_3

> *The one thing that did play on my mind a little bit was having one tablet, what if I had a course of tablets, would that be different?* DOC_PADL_8

Not everybody remembered being approached for testing or could recall having the PADL process explained to them. In the main, these were patients who were either ineligible for testing, due to concomitant medication or clinical instability, or had declined PADL.

Lastly, when asked about testing more broadly, some patients said they thought PADL in the community would be acceptable as long as it was under direct clinical supervision in their home or GP surgery, or they were a short distance from the GP surgery.

> *I can go to my local doctor and take this medicine which has got penicillin in it and see if there is a reaction after an hour or so and if not I'll leave it as I'm not allergic to it any longer. I don't mind.* DOC_ineligible_2

Discussion

Main findings

In this population of hospitalized patients, a common finding was that the index reaction occurred decades ago, often in childhood, with patients often unable to recall their index reaction. Patients were largely unaware of the negative impact of penA on healthcare and reported that their penA had not impacted the care they had received. Patients had differing views on challenging their penA status while they were acutely unwell. Some patients agreed to be de-labelled whilst acutely unwell because it allowed them to receive the most appropriate antibiotic for their infection and those who were de-labelled remembered the intervention, with all de-labelled patients reporting a positive experience of the testing process and all de-labelled patients having confidence in the negative test result such that none of the de-labelled patients reported continued avoidance of penicillin after their negative penA test result. Others felt that whilst acutely unwell was not the right time to have their penA record tested because of the multitude of concurrent investigations they were undergoing and because of their heightened fear about their predicament. Being asked to consider testing during that time caused further anxiety for some at a time when they were feeling most vulnerable, which made some patients feel angry. Reasons given for declining testing included advanced age and having multiple comorbidities, although across all the different PADL scenarios there appeared to be no difference in age. Some of the patients who declined testing said they may have been persuaded if they had received a better explanation of the risks and benefits of PADL.

Comparison with literature

Vague histories of reactions more than 10 years ago or childhood reactions are a common finding in PADL studies.[18] Many patients in our study were told by a HCW or a relative to avoid penicillin in case it caused a more severe reaction upon further exposure, a common belief in the early years of penicillin use when the risk of anaphylaxis was higher due to impurities introduced during the manufacturing processes.[19]

An Australian survey of de-labelled patients found that 99% felt safe during testing and would recommend the test to others, indicating high levels of patient satisfaction.[6] Similarly we found that those patients who agreed to testing had confidence in the PADL process and in the negative result.

A thorough testing process, such as the one delivered to the patients in our study,[9] has been reported by patients in another study to instil confidence in the negative test result.[11] Two patients thought that a single dose might not be enough to rule penA out and a longer course might be more appropriate to identify a reaction. The option of longer, 3 day courses, could be a shared decision discussing the uncertainties and the pros and cons of longer courses verses single doses with patients.[5] Ensuring the patient information is clear and easy to understand, with a good verbal explanation, were considered important to participants, as previously reported.[11]

Age has been identified as a barrier to testing, with those over 75 years old less likely to agree to penA testing.[20] Reasons participants in our study gave for declining testing included their advanced age and their comorbidities, although not all elderly patients viewed it a barrier. We have not collected data on patient comorbidities to see whether those with comorbidities were less likely to agree to testing.

Similarly to our findings, Wanat *et al.*[11] found patients to be unaware of the consequences of their penA records, largely because they had not needed antibiotics or not suffered negative consequences because of their penA label and therefore not sought penA testing. Of those patients who had sought penA testing, the reasons for doing so were because of experiencing negative consequences of their penA label.[11] Similarly to our findings, there was a recognition amongst some patients that PADL would give patients more antibiotic options in the future.[11]

Strengths and limitations

This is the first qualitative study to provide in-depth understanding of patient experiences of PADL in a UK hospital and the findings are comparable to similar patient experience studies in the USA and Australia. This study captures the views of patients who were successfully de-labelled and the reasons why patients accepted testing, as well as providing insight into why patients declined testing.

This is a single-centre study and therefore the findings may not be transferable to other hospitals in England. We were unable to get the views of those patients eligible for DDL but who declined de-labelling, but this was the smallest group of participants, and the reasons are likely to be similar to patients declining DOC. We interviewed more male than female patients. However, we were able to obtain views from both sexes and do not believe this impacts our findings.

Implications for practice and research

This study reinforces the need for a good explanation of the risks and benefits to testing and that patients need adequate time to consider PADL. Giving an adequate explanation can be a challenge during the inpatient stay due to heightened patient anxiety and the competing priorities during inpatient stays and how to meet that need requires careful consideration. Age and comorbidities are reported patient barriers to engaging with PADL, which potentially highlights a need to tackle incorrect penA earlier in life, and highlights a need to determine when might be best to capture patients for testing. Knowing the benefits of testing motivated some patients to agree to PADL, which highlights a need for either public awareness-raising about the risks of incorrect penA records, or a targeted approach to those with a penA. The acceptance of potential PenA assessment in general practice requires further study because it may provide greater capacity for testing whilst patients are not acutely unwell, which was a barrier for testing for some patients.

Conclusions

PenA labels in elderly inpatients are often acquired decades ago, are often vague, and had not been challenged by HCWs. Although the majority of patients considered their penA to be genuine, some patients had questioned their penA status. Patients who were successfully de-labelled were positive about the experience, reporting that the process was well explained and that they had confidence in the negative test. Those who declined testing did so for a variety of reasons, including frailty/comorbidities or a fear of testing, particularly whilst acutely unwell. The importance of communication was highlighted; some of the patients who declined testing felt that if they had received more information about penA records and PADL and were given more time to consider testing they might have been more agreeable to testing.

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Transparency declarations

None to declare.

Supplementary data

Table S1 is available as Supplementary data at *JAC-AMR* Online.

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