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Title: Patient and primary care physician perceptions of penicillin allergy testing and subsequent use of penicillin containing antibiotics: A qualitative study

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Conflicts of interest

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Abstract

Background

Removal of an inaccurate penicillin allergy record following testing allows patients to access first-line treatment for infections, and reduce use of broad spectrum antibiotics which contribute to antibiotic resistance. However, it is seldom undertaken.

Objectives

To identify clinicians' working in primary care and patients' views on barriers and enablers for penicillin allergy testing and subsequent antibiotic use.

Methods

Fifty interviews with patients and clinicians; including 31 patients with a record of penicillin allergy, 16 with experience of testing, and 19 clinicians. Interviews were analysed thematically.

Results

Patients were often unaware of the benefits of penicillin allergy testing and only patients who had experienced negative consequences of having a penicillin allergy label were motivated to get tested. Clinicians were reluctant to change patient records based on their clinical judgment alone but had limited experience of referring patients with suspected penicillin allergy and were often uncertain about referral criteria and what the testing involved. Clinicians felt allergy testing could be beneficial and patients who had attended testing reported benefits of the test. Clinicians expressed uncertainty related to whose responsibility it was to make sure that patient understood allergy test results.

Conclusions

Clinicians would benefit from information about penicillin allergy testing in order to be able to use these services appropriately, and to discuss referral with patients. Patients might be more

motivated to seek testing if they were more informed regarding its benefits. Good communication between primary and secondary care would facilitate the updating of medical records, and promote better patient education.

Highlights

What is already known about this topic?

- Up to 15% of primary care patients carry an unsubstantiated label of penicillin allergy. Penicillin allergy testing offers an opportunity to confirm or exclude allergy but despite recommendations, clinicians rarely use allergy services.

What does this article add to our knowledge?

- This article fills an important gap by highlighting barriers and facilitators to using allergy services and subsequent consumption of penicillin from the perspective of both patients and primary care physicians.

How does this study impact current management guidelines

- Both patients and clinicians need to be supported to use penicillin allergy services, and be provided with the skills and information to prescribe and consume penicillins appropriately following a negative test result.

Key words:

penicillin allergy; antibiotic stewardship; prescribing; antibiotic resistance; qualitative

Abbreviations:

National Institute for Health and Care Excellence (NICE)

Methicillin-resistant *Staphylococcus aureus* (MRSA)

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Introduction

It is estimated that between 10% of patients registered with a UK general practitioner and up to 15% of primary care patients in the US carry an unsubstantiated label of penicillin allergy. Fewer than 10% of these patients are found to be allergic when formally tested (1-3). Therefore, a significant proportion of the population may, unnecessarily, be denied access to first-line antibiotic therapy.

The consequences of incorrect penicillin allergy records are significant. They include longer hospital stays(4), increased surgical site infections(5), and increased infections with Methicillin-resistant *Staphylococcus aureus* and *Clostridium difficile* through the use of non-penicillin antibiotics (5-8). Patients are also more likely to be prescribed broad spectrum antibiotics such as quinolones, clindamycin, tetracycline, and sulphonamides macrolides (6, 7), which are often more expensive and are associated with increased treatment failure (9). This research has recently informed the UK National Institute for Health and Care Excellence (NICE) advice to clinicians to "double check patients with penicillin allergy to avoid increased MRSA risk" (10). The Choosing Wisely initiative of the American Board of Internal Medicine Foundation recommends "don't overuse non-beta-lactam antibiotics in patients with a history of penicillin allergy, without an appropriate allergy evaluation" (11).

Patients are frequently given a label of penicillin allergy due to common side effects of the drug such as nausea, or rash caused by concomitant viral illness. Often, there is incomplete or inconsistent documentation of allergy in medical records; or patients received the allergy diagnosis in childhood and have no recollection of the index event (2, 12, 13).

Penicillin allergy testing offers an opportunity to confirm or exclude penicillin allergy; patients who test negative can be 'de-labelled' and advised that their risk of allergy is the same as for the general population. Testing with a combination of skin testing and oral challenge, offers 99% negative predictive value for penicillin allergy (14). Despite recommendations from key organisations such as the American Academy of Allergy, Asthma & Immunology and UK NICE to test patients with a penicillin allergy record (1, 14, 15), clinicians rarely use these services (16, 17), so it is vital to identify the barriers and enablers to uptake of testing among both physicians and patients. A recent rapid review assessing patient and clinician views on testing and subsequent antibiotic use found limited relevant literature, and no qualitative studies exploring these issues (18). We aimed to address this important gap by identifying clinician and patient views and experiences of referring to or attending for penicillin allergy testing, and the use of penicillins following negative allergy testing.

Methods

Participants and procedure

Design

Qualitative study using semi-structured interviews, UK primary care.

Recruitment

Patients

Patients were identified using two methods. Patients with experience of penicillin allergy testing were identified from a general adult hospital allergy clinic in the North of England. An audit of clinic records identified patients who had attended for testing between April 2015 and April 2017. In addition, patients who did not undergo testing were identified from general practices in the geographical area which the allergy clinic served. Each general practice identified 50-100 patients with a record of penicillin allergy. All potential participants were sent a recruitment pack and asked to contact the research team if they were interested in participating in an interview.

Primary care clinicians

Clinicians were identified using three methods. Firstly, clinicians working in practices with patients who had undergone penicillin allergy testing in the hospital allergy clinic were identified and invited; secondly clinicians working in general practices in the geographical areas served by the hospital were invited; thirdly clinicians who contacted the local microbiology services with queries during the study period were invited. All potential participants were sent a recruitment pack and asked to contact the research team if they were interested in participating.

Interviews

Two semi-structured interview guides were developed based on the primary research questions and informed by the existing literature on penicillin allergy (18). Interview guides were added to as necessary, when initial interviewees discussed additional relevant topics (Appendix 1). Patients were asked about their personal experience or hypothetical views on, penicillin allergy testing and subsequent use of penicillin. Clinicians were asked about their views of penicillin allergy testing and prescription of penicillins to patients who had a negative test result. After obtaining consent, interviews were conducted over the telephone by an experienced qualitative researcher (PhD qualified with substantial previous experience of conducting qualitative research, audio recorded and transcribed verbatim. Interviews continued until data indicated saturation in each participant group.

Analysis

Data collection and analysis took place concurrently. Data from all interviews were analysed. Transcripts were read and reread by MW both during and after data collection. To enhance the credibility of our analysis researcher triangulation was performed; this meant that one third of transcripts were read and analysed by the wider multidisciplinary team to ensure that data was accurately represented. An inductive thematic analysis approach was used to analyse data (19). One

author (MW) independently coded initial transcripts which were then discussed with the wider team who met to review and agree on preliminary codes. Following coding of further transcript, MW developed a draft coding framework which was discussed and agreed by the team. The remaining interviews were then analysed using this framework with changes made if needed. To enhance the trustworthiness of data, analysis was conducted and discussed by a multidisciplinary team consisting of psychologists, a sociologist, a primary care clinician and colleagues from hospital-based immunology with expertise in penicillin allergy and microbiology services.

Results

Participants

A total of 50 participants completed an interview. Of these 31 were patients and 19 were primary care clinicians. Table 1 provides a summary of participant characteristics. Interviews were conducted between December 2017 and August 2018 and lasted 20-60 minutes (average 46 minutes).

Insert Table 1

Three themes captured the variation in patient views and experiences of attending for penicillin allergy testing; three themes captured the clinician experience of utilizing penicillin allergy services.

PATIENT VIEWS

Personal relevance and benefits of the test

Patients both with and without experience of penicillin allergy testing reflected on the extent to which penicillin allergy created a problem for them. The majority of participants who were motivated to get tested had already experienced negative consequences of having a penicillin allergy label, such as not being able to have a planned operation, being denied first-line treatment, and having limited antibiotic choice because of other allergies or having the impression that other

antibiotics were not working for them. Importantly, they had not been aware of these consequences of penicillin allergy labelling before they experienced problems.

> *I said well look, I'd like [a penicillin allergy] test. I've been asking for years for a test [..] because I've had infections where it has been bad– I said my body's just used to erythromycin. My body's just used to it [..].t's like taking sweets. Doesn't do anything at all for me (P1, Female, 69, negative allergy test)*

In contrast, participants whose penicillin allergy status did not affect their day-to-day lives did not see an allergy test as personally relevant. This was often because they had not needed to take antibiotics and therefore had not experienced any negative impact of a penicillin allergy label. They also were not informed about benefits of having access to penicillin.

> *I suppose the only benefit would be it would be an alternative option to prescribe, I don't know whether that would be a benefit. As I say, I've not had a really negative impact, I've never had a condition where an antibiotic hasn't been prescribed to me that hasn't seemed to do the trick (P22, Female, 51, no allergy test)*

Finally, a small number of patients without experience of testing but who had sought additional information and were aware that penicillin is a first-line treatment for many infections, felt that having access to a wider range of antibiotics could be beneficial to them in the future.

> *If the test showed that I was not allergic, I would be pleased; it would be a relief to know I wasn't (P17, Female, 68, no allergy test)*

Importance of safety and perceived risks of test

Patients often considered risks involved in undergoing a penicillin allergy test. The first common concern was related to the possibility of having an allergic reaction. This was particularly true when patients had been told by their primary care clinician for many years to avoid penicillin:

> *The doctors were telling me I was allergic to them, then you worry that if you're going to do [a test] we'll get a bad reaction (P7, Female, 65, negative allergy test)*

Severity of the index reaction played a role in how patients perceived the risk of a further reaction; patients with previous severe reactions were more apprehensive about having the test. Patients with perceived severe co-morbidity worried that if they were to have a reaction this could worsen their overall state of health.

The second concern of patients was around the degree of invasiveness off the test. Skin testing was generally perceived to be less frightening than an oral challenge test.

> *Because it's on the skin, it's not going in your mouth is it? You're swallowing a tablet, or two or three tablets, that's going in your system and you don't know what the reaction is going to be. I think that's the fear bit, really (P18, Female, 68, no allergy test)*

Patients were concerned about how they would be monitored during a test. Assurance of access to trained medical staff at the time of the test seemed to counterbalance patient worries about reactions. Taking penicillin at home following allergy testing in the clinic to check for delayed reactions was particularly worrying for some.

Participants who had previously undergone penicillin allergy testing described the importance of feeling safe while undertaking the test. They commented that feeling 'properly monitored' was important but did not want the procedure to be overly medicalised (for example not having to lay in a bed). Participants felt reassured when testing took place on hospital premises.

Finally, participants also described the importance of the provision of information prior to testing, presented in lay terms. This allowed participants to know what to expect and addressed their concerns.

> *The [allergy] doctor I saw was very, very good. I mean he explained everything. He went through everything with me and you know, even made a joke about certain things that I was frightened of you know so it was – I was quite at ease in a way (P1, Female, 69, negative allergy test).*

Confidence in test result

Patients reported benefits and reassurance from having undertaken allergy assessment but also some uncertainties. Those who had had an allergy test often felt that the test result provided a definitive answer about their allergy status and was perceived as a proof.

> *You always have that bit of doubt in your mind of am I or aren't I [allergic]? My husband thought it was [psychological], because I was reading what can happen, but even when I didn't read what could happen, it still happened, so [the test result] put my mind at complete rest that it's not just in my mind, it is actually an allergy that I've got (P4, Female, 47, positive allergy test)*

Participants reported having confidence in the test when they felt they had undergone a thorough testing procedure. Other participants felt confident in the result after they had taken penicillin without a reaction following the test.

> *I think if I hadn't had all the thorough testing, I would have been quite nervous to take penicillin. Because obviously with what had happened before, when I was younger. But now,*

I'm fine. It doesn't bother me, I can take it and it won't scare me (P3, Female, 19, negative allergy test)

Of note, some participants reported that their clinician had doubts about a negative test result and continued to prescribe alternative antibiotics; other clinicians reversed changes to medical records to reapply the allergy label if participants experienced any side effects from penicillin. Re-labelling might have been appropriate in some cases; however, it was not possible to assess based on patients' reports.

A minority of participants felt anxious about taking penicillin after a negative test. This was often related to the fact that the allergy label had been in place for a long time; occasionally they (incorrectly) believed that they had only received small doses of penicillin during the test and were worried about having a full dose of penicillin for the first time without supervision.

Cause I've lived with that fear, if anybody gives me penicillin I'm gonna die sort of thing, for years you know, from being a baby so of course you can't just terminate a fear like that. It's still there in the back of your mind all the time (P1, Female, 69, negative allergy test)

Similarly some patients with no experience of testing doubted whether they would ever believe a result which indicated they were not allergic to penicillin, as they believed they had had very severe reactions in the past.

CLINICIAN VIEWS

Doubts about removing penicillin allergy labels

Clinicians often reflected on whether allergies recorded in medical records were likely to be accurate and often doubted whether allergy labels were correct. However for the majority their clinical

judgement alone was not enough to change the medical records and they were worried about being responsible for causing someone to have an allergic reaction.

> *In general practice quite often once something is coded, yes of course you can change the codes but quite often when something is coded it's kind of set in stone (Clinician 11)*

On occasions, this was due to the clinician's perceived lack of knowledge, for example being unsure whether allergy is hereditary and therefore avoiding penicillin in the children of penicillin allergic patients.

Some clinicians perceived patients taking penicillin without problems as convincing evidence that a patient was not allergic and felt confident in changing medical records in this situation.

> *Yes, if it's been demonstrated that they're actually okay with the antibiotic after that original documentation then I have removed it. For example, if it said allergy to amoxicillin and they've subsequently had amoxicillin and been fine with it then I'd remove the allergy warning (Clinician 13)*

However even after repeated penicillin prescriptions some clinicians were still reluctant to amend the records and for the majority, only penicillin allergy testing was perceived as definite proof of tolerance.

> *If I was 100% sure I had specialist advice that the patients did not have an allergy to penicillin I would remove it from the records (Clinician 4)*

Knowledge of the allergy service and referral process

While clinicians saw value in the allergy service they had very limited experience of it and thus poor understanding of what the service could offer. Even clinicians with experience of referral had limited

information on the actual test procedure and accuracy of the results. While some were familiar with skin testing, few were aware of the oral challenge test component. Clinicians described the importance of guidelines in learning about the allergy service as well as deciding which patients should be referred. Many felt that since they lacked information about tests, including benefits and risks, they were unable to advise or encourage patients to be tested.

> *Maybe some advice on what we can tell the patient about what it would mean for them, as in if they weren't penicillin-allergic, what actual benefit we'd be able to provide to them if we could give them penicillin [...] because they might say, 'Actually, I've never had penicillin, I'm not bothered, just don't give me it, I don't want to go and have any testing.' (Clinician 2)*

Clinicians had a range of experiences in referring patients for penicillin allergy testing, but none routinely referred. Clinicians with experience of referring patients mostly referred those reporting numerous allergies or who had developed an antibiotic resistant infection. They also referred patients who had suffered a severe reaction. Clinicians were particularly concerned about the appropriate referral criteria and whether they would overburden the allergy service; in many cases this resulted in never referring patients.

Clinicians with experience of referring had positive views on the service and the referral process and thought it helped them improve their management of patients. However some could not recall seeing patients' test results, indicating a possible lack of follow up.

Process of updating medical records

The majority of clinicians reported that it is easy to change a patient's allergy status on their electronic medical record if required provided a reason is given. Others highlighted that allergy alerts might still be active if the system did not differentiate between intolerance and allergy; this might prevent penicillin prescriptions despite negative testing.

Clinicians described their views on who should be responsible for the process of updating the records and how and whether the results should be communicated to patients. Some felt this was the responsibility of the allergy clinic; others believed it was their role to ensure the patient understood the results since they were responsible for ongoing care. Some felt it was important to discuss negative test results to address patients' potential concerns about taking penicillin.

> *You would have to discuss [the test results] with the patient, because some patients might say, 'I still don't want it.' [..] I think patients have their own opinion, so if information came back to me that it was safe to prescribe, I would have to speak to the patient, because they might just say, 'Oh, I don't care about that result, I don't want it anyway.' (Clinician 8)*

Discussion

This study is the first to provide an in-depth understanding of patients' and primary care clinicians' views of the consequences of a penicillin allergy record and penicillin allergy testing. It highlights key barriers and facilitators to effectively using penicillin allergy testing services and prescribing/using penicillins appropriately following a negative test result.

While most patients talked freely about their perception of risk many were unaware of the negative consequences of a penicillin allergy label; those who were had gained this understanding though direct experience. The majority of patients who had undergone testing felt confident to take penicillin after a negative test result; however some patients remained anxious about safety.

Clinicians were aware that penicillin allergy records were often incorrect but felt reluctant to change them based on their clinical judgement. They had positive views towards penicillin allergy services but reported numerous barriers to their use. They were uncertain about whose responsibility it was to make sure that patient understood the allergy test results.

Only two questionnaire studies have previously explored patients' views on, and satisfaction with, penicillin allergy testing (17, 20). These studies demonstrated that patients had positive views towards getting tested for penicillin allergy and those who had undergone testing felt it provided them with useful medical information (17, 20). Our study highlights that patients weigh the possible benefits of testing against the perceived risks. Not knowing the potential negative consequences of a penicillin allergy label meant that patients had reduced motivation to attend for testing. The results highlight that patients appeared to judge the risk of the test based on a number of factors; perception of likelihood and severity of a reaction; degree of invasiveness of the test, and the degree to which they felt they would be monitored.

In line with previous research (18, 21) we found that clinicians had limited experience of referring patients for penicillin allergy testing and were often unaware of the existence of allergy services. Even clinicians with experience of referral were sometimes unaware of the specific nature of the testing. Clinicians approved of the penicillin allergy service; however, they would benefit from more information about the harms of a penicillin allergy label and the process of testing to help them confidently refer and to be able to discuss referral with their patients. Patients' concerns about potential benefits and risks of testing need be addressed by both clinicians and allergists in order to increase their motivation to attend for testing. Appropriate evaluation of patients with a penicillin allergy label is rapidly becoming a focus point for public health and antibiotic stewardship initiatives (10, 12, 22).

We identified the potential barriers and facilitators to penicillin prescription and use following negative testing. This is an area not well defined in the literature; studies have highlighted patient anxiety around having a reaction (23-26), lack of confidence in the safety of penicillin administration (23-26), or uncertainty about which class of antibiotics could be safely received (27, 28). Patients were reassured by having undergone a "thorough" testing process and having a need for a penicillin

following a negative test motivated consumption of penicillin; a barrier to consumption was the presence of an allergy label for many years.

Clinicians expressed uncertainty about who is responsible for ensuring patients understand the results and for updating the medical record. This highlights the need for a clear and consistent approach to de-labelling with support from colleagues in secondary care. Documentation of side effects during future courses of penicillin needs to be clear and precise in order to prevent re-labelling of the patient (13).

Strengths and limitations

This is the first qualitative interview study to provide in-depth understanding of patient and clinician views and experiences of penicillin allergy testing and of subsequent penicillin use. It highlights key barriers and facilitators to clinicians referring patients, and to patients then attending for testing. As previous studies used mainly survey designs and often focused on clinicians' views, this study fills an important gap by providing a patient-centred perspective. This is a qualitative study with a purposeful sample which recruited from one region in England; the results should be interpreted cautiously in terms of their transferability to other settings. The next step could include conducting a survey with a representative sample pf patients, designed based on the results from this study.

Conclusions

Both patients and clinicians need to be supported to use penicillin allergy services, and be provided with the skills and information to prescribe and use of penicillins appropriately following a negative test result.

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Table 1 Summary of patient and PCP characteristics

	Patients	Clinicians
Mean age (years)	56	42
Age range	19-72	34-60
Gender (%)	25 women (80%)	16 women (84%)
Experience of penicillin allergy testing/referring patients for penicillin allergy testing	16 (51%); (4 reported testing positive; 11 reported testing negative and 1 reported an	9 (47%)

	inconclusive result)*	

478 * Patient reports of the test outcome have not been independently verified, rather these numbers

479 reflect patient understanding of the test result.

480