Patient-related factors drive high rates of reported antibiotic allergies: a qualitative study

Renee Berry\textsuperscript{1}, Susan Herrmann\textsuperscript{2}, and Michaela Lucas\textsuperscript{1}

\textsuperscript{1}Sir Charles Gairdner Hospital
\textsuperscript{2}University of Western Australia

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Abstract

**Background** Unnecessary antibiotic avoidance due to allergy fears has adverse cost and health implications however, the problem is difficult to resolve because patient and provider-related factors leading to avoidance are multifactorial. The perspectives of patients can be explored using qualitative research methods to reach the heart of the problem. **Objective** To reveal factors leading patients to report antibiotic allergy, and determine what education is required to prevent the cycle of erroneous allergy reporting. **Methods** The 29 patients were a sample of convenience recruited from a tertiary public hospital in Western Australia; 18 were inpatients and 11 outpatients, with a median age of 64.2 years, and 15 (55\%) were female. Semi-structured interviews assessed patients’ understanding and knowledge of three topics: (1) antibiotic allergy, (2) antibiotic allergy testing, and (3) outcomes of testing. Interview transcripts underwent thematic analysis by two researchers, independently. **Results** Three overlapping themes emerged as influential across topics: (1) Severity of the Index Reaction, (2) Trust in family and health care providers, and (3) Health literacy. Patients were largely unaware of the benefits of confirmatory testing, and the detrimental health consequences of unnecessary avoidance. Patients displayed trust in health care providers’ expertise, and assumed that medical records were accurate to prevent prescribing errors. **Conclusions** The findings provide evidence for an effective patient education strategy, and highlight failures among hospital and primary health providers to recognise the potential harm of unverified antibiotic allergy. Healthcare professionals are influential at multiple steps of a patient’s healthcare journey and addressing unconfirmed antibiotic allergy should be taken at each opportunity.
Conflicts

No conflicts of interest.

Abstract (250 words)

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The findings provide evidence for an effective patient education strategy, and highlight failures among hospital and primary health providers to recognise the potential harm of unverified antibiotic allergy. Healthcare professionals are influential at multiple steps of a patient’s healthcare journey and addressing unconfirmed antibiotic allergy should be taken at each opportunity.

Key Words

Antibiotic allergy, Patient Perspective, Qualitative

Abstract (250 words) Main article (2483 words)

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Introduction

Experience of an adverse drug reaction (ADR), associated with antibiotic use can lead a patient to avoid all future exposure to the culprit and related drugs. Commonly, the patient or parent has poor recall of the reaction, and the assumption of an immune-mediated allergy to the antibiotic arises after discussion with a trusted doctor. Once reported within the medical system, an allergy alert or label (AAL), attached to clinical documentation prevents prescription of the culprit antibiotic, and often the entire antibiotic class. Reported allergy is questioned rarely during a patient’s journey through health facilities (Figure 1) but is seldom determined to be a true immune-mediated ADR. The adverse clinical implications of unverified AAL, including suboptimal clinical outcomes, suboptimal antimicrobial stewardship, and increased healthcare costs go largely unnoticed by patients, who are unlikely to seek referral for testing (Figure 2).
To address the high rate of AAL in Australia, confirmatory testing is recommended, and is safe and effective. Despite recommendations, AAL remain prevalent, due partly to the lack of resources funding services, and largely an under-appreciation of the health detriments posed by AAL. Patient education encouraging self-referral and improving communication of ADRs is required. Additionally, to be effective and prevent relabeling, it is necessary to identify deficits in health literacy to assist correct identification of antibiotic allergy.

Qualitative research in the field of AAL is growing, and informative data concerning patient perspectives and knowledge deficits regarding AAL evaluation has emerged from the US and UK. However, without an Australian based study, findings cannot be generalised. Ethnographic accounts are useful in clinical environments, because of the emphasis on fieldwork, field notes, and information from key informants. Using this conceptual framework, we explored: 1) What factors led patients to report an antibiotic allergy; 2) Their existing knowledge and/or experience of allergy testing; and 3) What happened to their antibiotic avoidant behaviour following testing.

Methods

Setting and sampling strategy

Twenty-nine adult inpatients and outpatients, with a history of AAL, volunteered for the study. The ‘inpatient’ group (n=18) comprised a convenience sample of patients pre-screened for an inpatient delabeling study. The ‘outpatient group’ was recruited from the Drug Allergy Outpatient Clinic (n=11) following general practitioner referral. We conducted the study at Sir Charles Gairdner Hospital, a 600-bed tertiary hospital in Western Australia, between February and July 2020. The Sir Charles Gairdner Osborne Park Hospital Human Research Ethics Committee approved the research as a sub-study of an inpatient antibiotic delabeling study (RGS 0844) and patients gave written informed consent.

Data collection techniques

Published research and field notes, made by the research team during recruitment for the inpatient delabeling study, informed the development of the semi-structured interview guide. Open-ended questions, refined over the data collection period, explored three broad topics. (1) The patients’ initial experience of the adverse reaction; (2) Awareness and importance of AAL testing; and (3) Understanding of results and outcomes of testing. Patients interviewed following testing were within one year of evaluation (n=16). A Clinical Immunology registrar was the primary researcher, and a participant observer. Interviews were conducted face-to-face or by telephone, recorded and transcribed.

Review of Medical Documentation

Following AAL assessment, patients and their general practitioners received a notification outlining testing results, and recommendations for future antibiotic use. We compared patients’ reported allergy status with the notification content, the patient electronic health record (My Health Record), and activation of a Hospital-wide Clinical Alert.

Analysis

Data collection and analysis took place concurrently. Interview transcripts were imported to NVivo 12 (QSR International Pty Ltd), and analysis was undertaken independently by two researchers (RB and SH) using an inductive thematic approach. Text representative of themes emerging from the interviews was coded to three main topics. Common themes were identified and analysis continued until data were considered saturated. Demographic information is presented as mean (SD).

Results

Patient Characteristics

Twenty-nine patients were interviewed (n=18 inpatients; n=11 outpatients). Table 1 provides a summary of demographic and clinical characteristics. Hospital inpatients were more likely to report a distant drug
reaction (89%), or a history consistent with a low-risk reaction (61%). In contrast, outpatients were more likely to have a history of a high-risk reaction (72%), and report multiple antibiotic allergies (72.2%), as expected.

**Interviews**

Three overlapping themes emerged as influential across the three topics, these were: (1) ADR severity; (2) Trust in family and health care providers; and (3) Health literacy (**Figure 3, Table 2**). In particular, we found that the severity of the index reaction, and the trust placed in advice given by family and health care providers following the reaction, was influential in strengthening and maintaining the personal belief of antibiotic allergy. Subsequently, the level of health literacy modulated allergy beliefs over the life span and prompted reporting. We found that the intensity of symptoms supported clear recall, with one-third experiencing adverse reactions in adulthood.

Recollection of childhood reactions (n=5) to penicillin featured in family anecdotes, and some questioned the ‘label’ applied by a parent in the distant past. Advice from doctors also encouraged future avoidance and trust of parental or medical advice was prevalent among all patients. Appreciation of the detrimental health implications associated with antibiotic allergy was limited, particularly in the inpatient group who had not received pre-test counselling from their GPs as did outpatients. Most assumed there would always be an alternative antibiotic and were unaware these could be less effective, more costly, have side effects, or increase the chance of developing antimicrobial resistance. Patients with multiple antibiotic allergies (41.4%) acknowledged difficulties for prescribers, and older age influenced attitudes. When asked about antibiotic resistance, some patients understood the phenomenon as developing ‘immunity’. Few recognised that antibiotic resistance could have personal health implications.

Patients used the term ‘allergy’ interchangeably with ‘side-effect’; many believing antibiotic allergy resulted from high doses or were expected actions of antibiotics. Some believed the risk of subsequent reactions could wane, nonetheless, avoidance continued. Most concerning were the eight patients reporting symptoms of anaphylaxis who did not understand the potential consequences. One underappreciated the seriousness of the reaction describing the reaction as a ‘mild anaphylaxis’.

We explored the patients’ awareness and importance of AAL testing to identify motivators and barriers. Ten of the 11 outpatients with a history of a severe reaction were referred for specialist testing by their GP. A primary motivation ‘to test’ for this group was to confirm allergy status and increase treatment options for infectious conditions. In contrast, inpatients were largely unaware that AAL testing was possible, or how to access the service. Other barriers included misplaced concerns about the cost, testing is free in the public health system following referral; and the distance to facilities for country patients was an issue.

Again, increasing age was a disincentive to test, and those in good health were ambivalent. Overall, the patients balanced the risks and benefits of testing. Trust in the providers and the testing environment was evident; thirteen patients scheduled for testing reported confidence in the test and intention to take the culprit antibiotic if the test result was negative. Three patients continued to report penicillin allergy unaware they had tolerated penicillins since the index reaction. The result of antibiotic allergy testing was more meaningful to patients than delabeling on clinical history. Comprehension and recall of the test (Topic 3) swayed patients’ attitudes and behaviour and varied between the two groups. Of the inpatients and outpatients who received AAL testing (n=16), thirteen underwent an oral provocation challenge, and ten had their AAL removed. All the inpatients who had been tested, were delabeled (n=8) but half were unable to recall details surrounding the challenge at the time of the interview. Three inpatients with equivocal skin test results continued to avoid penicillin despite negative oral provocation challenges to amoxicillin. Patients who accepted the results of skin testing and oral challenge as proof of their AAL status saw health advantages.

Women were more likely to report feeling worried at the time of the index reaction and some expressed hesitation concerning re-exposure to penicillin despite medically supervised testing, and they feared a subsequent ADR. Men appeared pragmatic, saying they would just put up with the reaction. In general, the
original reaction did not contribute to avoidance of testing, but did influence the likelihood of accepting re-exposure to a prior culprit. Patients with a history of severe reaction admitted they would continue to avoid the antibiotic they assumed caused the index reaction, even after testing.

Our interviews revealed expectations of the health care system. Commonly patients believed that details concerning allergy history carried across the hospital record system and, similarly, that outcomes of testing were readily available to all health care providers. In contrast with these assumptions, clinical alerts were not attached to the record charts of 7/12 (58%) patients reporting severe antibiotic allergies. The My Health Record, active for 75% of patients, showed 68% were incorrect. Ten of 16 patients tested had received copies of the drug allergy notification, and most found this resource useful. However, only 17% of patients with confirmed antibiotic allergy carried personal medical alerts, with the remainder rationalising that accurate hospital records, trust in providers, and self-reporting would prevent adverse prescribing. The importance of carrying a medical alert on their person was low priority, but some attitudes changed after interaction with the researcher who raised their awareness of the personal medical alert.

Discussion

This study has identified content key to addressing the high rate of self-reported and clinically unassessed AAL seen in health settings. Our study included two disparate and representative populations: outpatients referred by general practitioners for specialist assessment of antibiotic ADRs, and inpatients who carried historic AAL with no referral for specialist testing. Three themes emerged as influential in patient reporting: health literacy, trust in family and health providers, and ADR severity.

Our research and others show that patients err on the side of safety and avoid the culprit antibiotic; and are largely unaware of the benefits of confirmatory testing, and the detrimental health consequences of unnecessary avoidance, unless it is brought to their attention by health care providers. Patients did not view reporting an unconfirmed allergy as a potential health issue, because it had always been easy to avoid the antibiotic believed to be the culprit.

Trusted family, and medical advice provided at the time of the ADR, and the perceived risk of recurrent reactions perpetuated the cycle, coupled with re-validation of the erroneous label at each subsequent interaction with a healthcare provider. Notably, women carried greatest concern of developing a severe reaction, despite negative testing, similar to studies conducted in the US, and the UK.

Medication literacy was limited among our participants and driving the rate of AAL in an older population, as has been described by others. Antibiotic resistance was variously understood, a problem which has been described by others. In addition, being ‘too healthy’ or ‘too old’ tended to diminish the importance of the problem; and further deficits in health literacy concerning allergy nomenclature, and the recognition and management of anaphylaxis, also contributed to patients’ limited motivation to confirm or correct an allergy label.

Specialist evaluation initiated by the GP occurred only when serious consequences ensued, such as a severe reaction or difficulties with antibiotic prescribing. We found that addressing the issue of unconfirmed allergy as a potential health problem, led to patient motivation for either authentication of the allergy label or for optimising antibiotic choice for future treatment. These issues represent educational targets for patients and their doctors.

We found positive attitudes concerning the testing service and providers, concordant with other research, which suggests a willingness to undergo testing. Notably, a history of severe ADRs did not limit uptake in testing because patients felt safe in the hospital environment, and trusted healthcare providers’ expertise. However, the severity of the index reaction, and a long history of carrying an AAL contributed to hesitation with future antibiotic re-exposure and acceptance of delabeling by history alone, in common with other research.

Inpatients were the most ambivalent concerning testing, and had a higher rate of continued antibiotic avoidance due to misunderstanding, or forgetting results of the test, or even the procedure itself. Despite a
negative oral provocation challenge, it was easy for patients to misinterpret skin test results as positive, implying the importance of clear post-testing communication. We also identified reluctance among inpatients to consent to antibiotic allergy testing because of inter-current health issues ("too much going on") and a reluctance to accept that unintended exposure to penicillin could confirm ‘delabeling’ without testing. We speculate that, for these patients, hospital doctors and primary health care providers overlooked the importance of delabeling, for reasons that have been described by others as time constraints\textsuperscript{21, 24}, lack of knowledge regarding AAL\textsuperscript{26}, or testing services. Arguably inpatient delabeling may not be the most effective or timely strategy to reduce the prevalence of AAL.

The incorrect assumption among patients that medical records are accurate and available across health settings was demonstrated in ours and other studies\textsuperscript{27}. Notable safety concerns were the underuse of personal medical alert cards or jewellery, and incorrect or absent medical records. Follow-up from GPs was uncommon, and we conclude that if patients cannot remember being tested, and documentation is sub-standard, the likelihood of an AAL persisting is high, regardless of effective diagnostic testing to remove or confirm an AAL. However, paying greater attention to pre and post-test counselling can improve adherence to antibiotic label modification\textsuperscript{14, 24, 28}, and is particularly important for older patients, and those with multiple comorbidities.\textsuperscript{29}

Qualitative research methods enable deeper understanding of patient factors involved in self-reporting and persistence of AAL. This approach ensures high internal validity. Analysis of interviews by two researchers reduced potential bias. Patients received information concerning AAL, either from the researcher, their GPs at the time of referral, or from the study information sheets. This information may have influenced their attitudes to testing, and account for the discrepancy between willingness to test but reluctance to take the culprit in future. The researcher’s medical status may have influenced the perspectives of patients. However, the paradigm of ethnography accommodates the researcher as, in effect, a primary research instrument.

Conclusion

Our sample was heterogeneous, and representative of a spectrum of risk concerning likelihood of true antibiotic allergy, and varied comprehension of the harm associated with reporting an unconfirmed allergy. The three key themes, which represent our findings, are grounded in an Australian health context, but are universal. It is evident that patient and healthcare provider discussions around antibiotic allergy testing have begun, as referral to Australian drug allergy services has increased exponentially. However, it is clear there is ongoing need for education of both the wider community and health providers to recognise the potential harm associated with unconfirmed AAL. Our study also highlights that these conversations must continue beyond specialist allergy referral to ensure acceptance of post-testing outcomes and to prevent the perpetuating cycle of erroneous reporting.

References


**Figure 1.** Multiple opportunities for intervention by healthcare providers.

**Figure 2.** Patient safety is compromised when antibiotic allergy is not evaluated.

**Figure 3.** Three common themes influencing patient reporting of antibiotic allergy, understanding of antibiotic allergy testing, and testing outcomes.

**Table 1.** Characteristics of the patients (N=29)

<table>
<thead>
<tr>
<th>Demographic Table</th>
<th>Outpatients n=11 (%)</th>
<th>Inpatients n=18 (%)</th>
<th>Total N=29 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y), median</td>
<td>60.81</td>
<td>62.28</td>
<td>64.2</td>
</tr>
<tr>
<td>Sex, female</td>
<td>6 (54.5)</td>
<td>9 (50.0)</td>
<td>15 (55.2)</td>
</tr>
<tr>
<td>Residence, rural</td>
<td>2 (18.2)</td>
<td>4 (22.2)</td>
<td>6 (20.7)</td>
</tr>
<tr>
<td>Immunocompromised+</td>
<td>1 (9.09)</td>
<td>11 (61.1)</td>
<td>12 (41.4)</td>
</tr>
<tr>
<td>Penicillin Allergy</td>
<td>11 (100)</td>
<td>17 (94.4)</td>
<td>28 (96.6)</td>
</tr>
<tr>
<td>Severity of antibiotic allergy++</td>
<td></td>
<td></td>
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<tr>
<td>High risk Low risk</td>
<td>8 (72.7) 3 (16.7)</td>
<td>7 (38.89) 11 (61.1)</td>
<td>15 (51.72) 14 (48.3)</td>
</tr>
<tr>
<td>No of participants with multiple AAL</td>
<td>8 (72.7)</td>
<td>4 (22.2)</td>
<td>12 (41.4)</td>
</tr>
<tr>
<td>Time since index reaction</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>[?] 3-12 months [?] 1-5 yrs [?] 10 yrs [?] 50 yrs</td>
<td>4 (36.4) 6 (54.5) 1 (11.1) 2 (18.2) 10 (55.56)</td>
<td>0 (33.3) 2 (18.2) 10 (55.56) 6 (20.7) 6 (20.7) 11 (37.9) 6 (20.7)</td>
<td></td>
</tr>
<tr>
<td>Antibiotic allergy testing Tested Delabeled Positive</td>
<td>8 (72.7) 2 (18.2) 6 (37.5)</td>
<td>8 (44.4) 8 (100) 0 (37.5)</td>
<td>16 (55.2) 10 (62.5) 6 (37.5)</td>
</tr>
</tbody>
</table>

**Notes:** +Immunocompromised: haematological malignancy, oncological malignancy, autoimmune disease;++High risk = immediate Immunoglobulin E mediated reactions (anaphylaxis, angioedema, urticaria), or severe T cell mediated reaction (drug eruption with eosinophilia, drug-induced liver injury). Low risk = benign rash > 1 year ago, childhood exanthema, pruritus, intolerance, inaccurate documentation.

**Table 2.** Patient perspectives of antibiotic allergy, antibiotic allergy testing and post testing outcomes. Representative quotes mapped against the three main themes emerging from the topics: Severity of Reaction, Trust, and Health Literacy.

<table>
<thead>
<tr>
<th>Topic</th>
<th>Themes</th>
<th>Representative quotes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factors leading to self-reported antibiotic allergy</td>
<td>Severity of the index reaction Fear and uncertainty</td>
<td>“I remember it because it was dramatic.” (F, 75 yrs) “It was terrible... I can’t describe how bad it was.” (M, 77 yrs) “I thought ‘nap’ this is it, I’m dead.” (F, 72 yrs)</td>
</tr>
<tr>
<td>Topic</td>
<td>Themes</td>
<td>Representative quotes</td>
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<tr>
<td>Trust in family</td>
<td>Family anecdotes</td>
<td>“It was something that I was not sure about... I don't remember anything to do with it, it was something my mum used to always say.” (M, 42 yrs) “Mum is anaphylactic, and my Dad is allergic to [penicillin] as well. So, they stopped my sister and I having it.” (F, 36 yrs)</td>
</tr>
<tr>
<td>Trust in doctors</td>
<td></td>
<td>“My memory is a bit dim, but I do remember the doctor... our family doctor for about 40 years... he said my reaction was so severe. He said, ‘don’t ever have penicillin again.’” (M, 80 yrs) “You know in those days you relied on the doctor, and you believed what the doctor said.” (F, 71 yrs) “I said I was allergic to Penicillin, and they said oh we won’t give you penicillin we’ll give you something else.” (M, 80 yrs)</td>
</tr>
<tr>
<td>Health literacy</td>
<td>Lack of awareness of implications of AAL</td>
<td>“I never really thought about it in any serious way...” (M, 70 yrs) “I didn’t know what was going on, and it was never really explained to me very well.” (M, 62 yrs) “Oh, well, we will just have to look for an alternative.” (F, 63 yrs) “Given that I haven’t had any antibiotics now for close on four years then I wouldn’t think that it was a problem.” (F, 75 yrs)</td>
</tr>
<tr>
<td>Existing knowledge and/or experience of allergy testing</td>
<td>Severity of index reaction GP initiated referrals</td>
<td>“If I became sick again, to know whether I was allergic to penicillin or not would be helpful.” (F, 81 yrs)</td>
</tr>
<tr>
<td>Health literacy</td>
<td>Erroneous assumptions</td>
<td>“I did think about it when I was younger, but it cost such a lot of money and I thought well, it’s just as easy to say to people, no [I have a penicillin allergy].” (F, 63 yrs)</td>
</tr>
<tr>
<td>Topic</td>
<td>Themes</td>
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<tr>
<td>Identifying implications for prescribers</td>
<td>“So consequently, for anybody, knowing what to give me is a real problem.” (M, 67 yrs) “Because every time if I get an infection, it gives my doctor a headache, cause these allergies.” (F, 74 yrs)</td>
<td></td>
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<tr>
<td>Following education</td>
<td>“I mean it’s a risk that maybe I should take for something that’s worthwhile, in that I could be treated more effectively with penicillin.” (F, 81 yrs) “...somewhere in that period of time, the allergy has sort of watered itself down and disappeared.” (M, 70 yrs)</td>
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<tr>
<td>Trust in expertise</td>
<td>“I was expecting to have a reaction... but I was very much assured of medical assistance there in place.” (F, 58 yrs) “Well, I was in hospital for a start, so if I had an attack, I’d have all the best treatment there.” (F, 72 yrs)</td>
<td></td>
</tr>
<tr>
<td>Antibiotic avoidant intention/behaviour following testing</td>
<td>Severity of the index reaction Fear and uncertainty</td>
<td>“But what if I tell the doctor ‘well I’m not allergic to anything’ and then he gives some penicillin and I get a reaction?” F, 66 yrs) “Hypothetically, if I hadn’t reacted, I would still have avoided penicillin because I didn’t want to go through [the reaction] again.” (F, 58 yrs)</td>
</tr>
<tr>
<td>Health literacy</td>
<td>Assumptions/expectations</td>
<td>“That’d be on my notes in hospitals anyway... because I think they’re all linked... is that right or not?” (F, 63 yrs) “...because I have had a few things done, that’s why I tell people go look in my file.” (F, 63 yrs)</td>
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<tr>
<td>Topic</td>
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<tr>
<td>Trust in expertise</td>
<td>“I mean you just trust the doctor; they know what you’re allergic to, I know there are mistakes made but yeah, I just trust them.” (F, 63 yrs) “Every time I got to a doctor, ‘can I have penicillin’, ‘no, no we can see here that you’... it is not worth their life if I have a reaction.” (M, 67 yrs) “I know that I have had sulphur in stuff... that I eat... I report sulphur allergy because of what the doctor and nurse ended up saying...” (M, 42 yrs)</td>
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</table>