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GRADED oral challenge for Drug allergy Evaluation—Delabelling described through families' voices

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Abstract

Background: Children are often diagnosed with an antibiotic allergy, with little investigation to confirm whether it is a true allergy. Recent studies support the use of oral challenges to confirm antibiotic allergy. Yet, little is known about families' perceptions of these challenges, or experiences of living with a misdiagnosis, often for many years.**Objective:** To describe how families with a child previously labelled as "antibiotic allergic," but who has subsequently been delabelled, perceive the experience of misdiagnosis and subsequent delabelling.**Methods:** We performed semi-structured interviews with parents whose children had recently completed a graded oral challenge for antibiotic allergy. Interview transcripts were analysed concurrently, but independently, by two investigators, using content analysis.**Results:** A total of 15 parents (14 individual interviews; 1 mother-father dyad) participated. Children were, on average, 5.04 ± 4.5 years and were first diagnosed in infancy (mean age: 1.82 ± 1.48 years) subsequent to a rash (14/14; 100%), and commonly at a walk-in clinic (6/14; 42.9%). We identified four themes: (1) A red, raised rash results in a quick diagnosis despite a lack of testing, (2) sensitive care allays concerns, (3) delabelling brings relief, but also mystery and calls for proper diagnoses, and (4) quick diagnoses are reckless, but manageable through downward comparisons.**Conclusion and Clinical Relevance:** These findings underscore the importance of a careful physical examination and clinical history of the patient, but also an ongoing dialogue to support families, both of which would ideally begin at the time of initial investigation.

KEYWORDS

amoxicillin, delabelling, drug allergy, paediatrics, qualitative

Ben-Shoshan and Abrams are denoted as co-senior authors.

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1 | INTRODUCTION

Common paediatric bacterial infections often require oral antibiotics including penicillin derivatives, cephalosporins, or macrolides.¹⁻³ Up to 10% of children develop rashes while on, or directly after cessation of antibiotic treatment. Without further investigation, these children are frequently labelled as “antibiotic allergic”.^{1,4} Yet, most children are not assessed by specialists and continue to avoid the suspect antibiotic, and others from the same family, to adulthood.^{5,6} This is problematic, as the overuse of second-line agents is associated with greater risk of antibiotic resistance and poorer health outcomes.⁷ Moreover, antibiotic therapy amongst those with beta-lactam allergy is associated with substantially higher direct costs for both inpatients (\$609 per patient) and outpatients (\$14-\$193 per patient), compared to non-beta-lactam allergy patients.⁸ Avoiding mislabelling of patients with antibiotic allergy will ensure that patients are managed with the most appropriate, safe, and cost-effective antibiotic.^{9,10}

Until recently, it was considered unethical to challenge children with suspected antibiotic allergy in the absence of skin testing. However, two recent studies,^{11,12} including one performed in Canada,¹¹ cast doubt on the utility of this guideline as they suggest that challenges, but not skin testing, are essential to the appropriate diagnosis of antibiotic allergy.¹³ Understandably, correctly diagnosing antibiotic allergy is important as it mitigates the potential for adverse health outcomes and financial costs.⁹ Despite these factors, antibiotic challenges are not routinely performed and families are often inappropriately burdened by a misdiagnosis. Moreover, the impact of being delabelled subsequent to a passed challenge remains unknown. As part of an overarching study in which antibiotic challenges were performed, we sought to describe how families with a child previously labelled as “antibiotic allergic,” but who has subsequently been delabelled, perceive the experience of misdiagnosis and subsequent delabelling.

2 | METHODS

2.1 | Study population

Participants in this qualitative study were purposively recruited¹⁴ from the Winnipeg, Manitoba site of the pan-Canadian overarching study, GRADE—GRAded oral challenge for Drug allergy Evaluation.¹⁵ Our study population was families whose child has successfully passed the GOC, as determined by a paediatric allergist. Additionally, families needed to be able to communicate comfortably in English.

2.2 | Data collection and analysis

Data collection followed a semi-structured interview guide (Table 1), with opportunities for supplementary questions.¹⁴ Interviews were audio-recorded and transcribed verbatim.

Participant characteristics were extracted from transcripts and subsequently analysed using descriptive statistics (n/N, %, mean $\pm$ SD, range), with Stata® 15.1.

Qualitative data analysis was performed independently, but concurrently by two investigators (JP, MG), via thematic analysis.¹⁴ First, transcripts were read for surface descriptive content, at which time we organized like-with-like ideas. Second, transcripts were re-read, and latent meaning was considered to better understand participants' meaning. During this second reading, each analyst independently generated themes, which they systematically applied across all transcripts. We performed semantic validity checks to ensure different words and phrases within a category had similar meanings. Constructs were considered to be saturated when no new or additional constructs were identified, analysts agreed on all overarching themes, and no alternative explanations were found with subsequent interviews. This study was approved by the University of Manitoba Biomedical Research Ethics Board (HS22901 (B2019:051)). Each participating family received a \$30 movie gift card as an honorarium.

3 | RESULTS

Of the 22 families approached, we recruited 15 parents (including one mother-father dyad) and conducted a total of 14 semi-structured interviews. Families who declined to participate cited personal (logistic, health) reasons, rather than an unwillingness to be interviewed. All interviews were conducted by the first author. Interviews were held over the telephone (10/14; 71.4%; mean duration 15 minutes 30 seconds) or face-to-face (4/14; 28.6%; mean duration 20 minutes 30 seconds). In total, 28.6% (4/14) families lived rurally, and most were 3 or 4 person households (Table 2). A total of 6 (42.9%) families reported an allergic history, including 4 with an immediate family member who had a confirmed antibiotic allergy. All

TABLE 1 Selected questions from the interview guide

Please think back to when you first gave your child an antibiotic. Can you describe this situation? What happened when you gave him/her the antibiotic?

What types of symptoms did your child have to suggest that he/she might have an antibiotic allergy?

Please describe a bit about the visit to the doctor who told you that your child had antibiotic allergy

Your child has now passed a graded oral challenge, during which you were told that he/she does not have this allergy. Please tell me the very first thing/ first few things that popped into your mind. Please tell me how it felt to receive such news.

Going forward, the allergist has indicated that your child may take these antibiotics safely when they are indicated. Can you talk a bit about how this news will change how you respond to the need for antibiotics?

Antibiotic allergy is often over-diagnosed. What would you like other families with children to know about antibiotic allergy? What would you tell a doctor?

children developed what parents described as a red rash, and which was often diagnosed as an antibiotic allergy at a walk-in clinic (42.9%; 6/14), typically in the absence of any additional testing (64.3%; 9/14).

Of the 14 children represented by their families in this study, 6 were boys. The mean age of the children was 5.04 ± 4.52 years. Nearly all (85.7%; 12/14) had been labelled with an antibiotic allergy by age 3 years. Likewise, children had lived with the label of an antibiotic allergy for approximately 3.2 years, although the range was from 0.5 to 16.5 years. In our qualitative analysis, we identified four themes (Table 3).

3.1 | Theme 1: A red, raised rash results in a quick diagnosis despite a lack of testing

All 15 parents described that their children presented with a red, raised rash and/or hives, over much of their bodies, days to weeks after starting a course of antibiotics. Families often described how their child's rash would be quickly diagnosed as an antibiotic allergy after the family indicated that the child had recently started antibiotics. Additional testing was rare, unless the child presented to his or her paediatrician or to the emergency department. Families often had to advocate for their children to have additional testing to determine whether the child truly was antibiotic allergic. As one mother, whose child had been diagnosed with an antibiotic allergy at a walk-in clinic, noted:

I don't find doctors are particularly good at rashes, at least the GPs, but she wasn't super helpful. She's like, "Yeah, it could be the penicillin, it could just be coincidental that he had the ear infection and also got a rash from, if it was viral." [T]hey didn't know whether it was bacterial or viral but he had a very high fever which is why they treated it. [The GP] said, "Yeah, [avoiding penicillin] is probably the best bet." I [mom] had to ask for the referral to allergy.

3.2 | Theme 2: Sensitive care allays concerns

The GOC performed in this study involved either a single low-dose injection of the antibiotic, or ingestion of small doses antibiotics at defined intervals, thereby necessitating that the patient and his/her family remain in the clinic for several hours. All participants in this study opted for ingestion. For parents, this raised concerns both about the potential for adverse events, but also about practical details, including how to occupy young children during the GOC. Yet, parents spoke of how their concerns were allayed through sensitive care and careful and clear explanations at every point of contact throughout the GOC. Parents also stressed how they appreciated that they had a voice in which type of GOC their child would undergo.

We [Mom and Paediatric Allergist] talked about all that and decided that this would be the best thing for [child] is just to try to rule it out now and, in a safe space.

TABLE 2 Participant characteristics (N = 14)

	n	%
Boys	5	35.7
Family size		
3	5	35.7
4	6	42.9
5+	3	21.4
Rural	4	28.6
Allergic History	6	42.9
Antibiotics	4	28.6
Food	2	14.3
Red, raised rash	14	100.0
Rash presentation days to weeks after starting antibiotics	13	92.9
No testing prior to labelling	9	64.3
Diagnosis at walk-in clinic	6	42.9
Mean $\pm$ SD		
Age of child, in years	5.04 ± 4.5	
Age at diagnosis, in years	1.82 ± 1.48	
Number of years living with diagnosis	3.21 ± 4.82	
Time since delabelling, in months	4.33 ± 2.02	
	Range: 1.2-7.2	

3.3 | Theme 3: Delabelling brings relief, by also mystery and calls for proper diagnoses

All families described delabelling as a "relief" and were grateful to have a conclusive answer. Although GOC were perceived as being occasionally time consuming or challenging, especially when the child was young, these concerns were displaced by the relief of being delabelled.

[V]ery quickly, we were done [the GOC] and we realized that she does not have an allergy to this medicine! We were able to go home and a great relief was had because we no longer have to be afraid of this medicine anymore!

Interestingly, only one family indicated they were frustrated by the misdiagnosis. For this family, frustration resulted from a lack of options for antibiotics. Those that the child tolerated prior to being delabelled were more costly and less available than many other antibiotics. Consequently, for this family, the relief of being delabelled came in many ways.

TABLE 3 Qualitative themes and explanations

Theme	Explanation
A red, raised rash results in a quick diagnosis despite a lack of testing	Every child presented with a red raised rash, which typically, and without further investigation, resulted in a diagnosis of allergy
Sensitive care allays concerns	Despite the described risks of a GOC, parents expressed gratitude—which amplified as trust—when each step of the GOC was explained to them
Delabelling brings relief, but also mystery and calls for proper diagnoses.	Parents were grateful that their child had been appropriately assessed and delabelled, but were still trying to understand what causes the initial rash
Quick diagnoses are reckless, but manageable through downward comparisons	Parents were frustrated that they had lived with a diagnosis of antibiotic allergy for some time (often years), but framed the allergy within the context of conditions associated with greater burdens

[Y]our hands get really tied as far as what you can actually give them to treat them. [Daughter] couldn't take amoxicillin and then she couldn't take Biaxin either and then it was like, "Okay well, I'm not sure what's left to treat this thing that she had." And it was really difficult and then it got really expensive also because now we're talking about using an antibiotic that isn't readily available. Now it's more expensive and I had to wait longer to get it. It created all these other issues. When I found out she wasn't allergic to it I was relieved in a lot of ways.

Despite being delabelled, families were often mystified as to why their children developed the rash that initially led to an antibiotic allergy. This mystery was described by some as "a layer upon what was still a question about whether or not he was also having [symptoms]" or "what the rash would be from." Whereas the rash was likely the result of a viral infection, some families perceived that their child had reacted because they received "an overdose" of antibiotics. Having passed the GOC, many families indicated that they were comfortable resuming first-line treatments, and confident that their child would not react in future as long as he/she was given a correct dosage.

Finally, in this theme, families spoke of the need for correct diagnoses upon the initial presentation of the rash. Families spoke of how physicians "have the power to make a referral" and to "send the families to get proof that [the child] actually has an allergy."

3.4 | Theme 4: Quick diagnoses are reckless, but manageable through downward comparisons

This theme was identified only amongst the families with a history of allergic disease. These six families spoke of how diagnosing antibiotic allergies quickly and in the absence of proper testing was reckless. For example, one participant said "just to call things an allergy and then move along, but it really isn't an allergy. It's important to differentiate between a reaction and an allergy." Some families described how healthcare professionals had questioned the label of antibiotic allergy prior to passing the GOC. These families described how they were met with disbelief and would "get lots of questions

on it" from sceptical health professionals, often resulting in "a huge explanation."

Finally, these families made downward comparisons, noting that they were grateful that their child had originally been diagnosed with an antibiotic allergy, versus food allergies. Although four families did have a member with a confirmed antibiotic allergy, they appeared to minimize the burden by making downward comparisons.

The nice thing about a drug allergy vs. like a nut allergy or something is that you don't have to worry that someone at school is going to give it to him because why would they. You have to sign a letter and bring in a prescribed, like it's pretty controlled with drugs, what they'll give out at school.

4 | DISCUSSION

Families with other confirmed allergies balanced the risks associated with antibiotic allergy, against their other allergies. This may be viewed as a coping strategy. Elsewhere, coping has been qualitatively described by families whose children have other confirmed allergic diseases.^{16,17} In the present study, children were inappropriately diagnosed with antibiotic allergy. Although these families were relieved to have been delabelled, the impact of having coped with many years with an allergy that their child did, in fact, not have—was still fresh in their minds.

The sequelae of events that resulted in a diagnosis of antibiotic allergy, with all children in our study, began with a red, raised rash, but rarely any further investigations. Whereas antibiotic allergy may present with a cutaneous manifestation and necessitate withdrawal,¹⁸ infants and children develop rash for a multitude of other reasons, including rarely related Immunoglobulin E-mediated allergic conditions,¹⁰ as well as viruses¹⁹ and infections.²⁰ Macular/popular rashes in childhood are often harmless and are commonly attributed to viral infections.²¹ However, viral infections can trigger and may be the main aetiological agent in acute or chronic urticaria, which resolves upon healing or controlling the viral infection.²² In some circumstances, parents advocated strongly for a referral to an allergist for follow up testing. However, this

was infrequently offered to parents by the physician who made the initial diagnosis. In Manitoba, access to an allergist requires a referral from a primary care physician or specialist. This “gate-keeping” approach may have reduced parental willingness to push for an allergist assessment. Elsewhere, it has been described that parents who found physicians to be inflexible or who were dissatisfied with one physician's opinion were more likely to seek a second opinion.²³

Medical testing can incite anxiety. Families in our study spoke at length of the importance of receiving correct and candid information and having the opportunity to ask questions, prior to consenting to go forth with a GOC.

As has been previously described in the food allergy literature, parents do not expect certainty from physicians, but prefer those who recognize parents' concerns and propose appropriate management.²³ Thus, while decisions to proceed with a GOC are ultimately up to the patient and his/her family, it behoves any physician who wishes to provide this option to a patient to explain the risks and benefits, and to comprehensively address concerns prior to, and during a GOC.

The delabelling of an antibiotic allergy brought understandable relief, but also raised questions as to what caused the initial “reaction.” Given the time elapse from initial reaction to the present study, it is impossible to confirm what caused the initial reaction. Of note, many childhood rashes are associated with urticaria and have a duration of 1-2 days, to several weeks or months.²⁴ In contrast, true antibiotic allergy is associated with immediate (<1 hour) reactions, including urticaria.²⁵

Families described quick and uninvestigated diagnoses as reckless. Some parents described how other healthcare providers were sceptical of the diagnosis, resulting in substantial stress for the parents. Whereas a misdiagnosis creates unnecessary emotional and financial burden for a family, it also warrants mention that penicillin allergy testing at time of initial suspicion is cost-effective to the healthcare system. In a recent economic evaluation study, cost savings were identified across countries, for both inpatients and outpatients (average \$657 USD and \$2746 USD, respectively).²⁶ Moreover, those patients who are misdiagnosed are often prescribed second-line agents, which may contribute to antibiotic resistance and poorer outcomes.⁷ Yet, even though children were misdiagnosed, parents whose children had other allergies, specifically to foods, underscored how penicillin allergy was perceived as having considerably less burden than food allergy. Families recalled how they had coped, through downward comparison, with the label of being antibiotic allergic, and other confirmed diagnoses.

In summary, we identified four major themes in our qualitative investigation in to families' perceptions of undergoing a GOC: A red, raised rash results in a quick diagnosis despite a lack of testing; sensitive care allays concerns; delabelling brings relief, but also mystery and calls for proper diagnoses; and quick diagnoses are reckless, but manageable through downward comparisons.

Qualitative methods are ideal to understand whether families are willing to alter their acceptance of antibiotics once their child has

been delabelled. To our knowledge, this is the first study in which the perceptions of antibiotic allergy delabelling have been described. Through the voices of those with lived experience, families articulated how the experience of being delabelled through a GOC will impact antibiotic-related decisions, including the reintroduction of first-line antibiotics, in the future. Heeding patients' voices and their descriptions of important healthcare priorities are essential to effectuate positive change in health care, health outcomes, and health policy, and align with the Canadian Institutes of Health Research mandate for patient-oriented health care.²⁷

We acknowledge the limitations of this study, including the inclusion of families from only a single site. Whereas this may limit the transferability of findings to other urban centres, the decision to purposively recruit from Winnipeg only was made for practical reasons. We also acknowledge that the majority of interviews were conducted over the phone, thereby removing the possibility to account for body language. Our initial intent was to perform all interviews in person. However, at the request of families, we received an amendment to our ethical approval to conduct interviews by phone.

In conclusion, families with a child previously labelled as being “antibiotic allergic,” but who has subsequently been delabelled, described how a rash always contributed to the initial diagnosis, although other investigations were rarely performed, that trust in the physician was essential, that delabelling brought both relief and mystery, and that rushed diagnoses ought to be considered reckless. These findings underscore the importance of a careful physical examination and clinical history of the patient, but also an ongoing dialogue to support families, both of which would ideally begin at the time of initial investigation.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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