Penicillin allergy de-labeling: Adaptation of risk stratification tool for patients and families

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To the Editor,

Penicillin allergy is a common drug allergy diagnosis reported in 10% of the population . However, over 90% of patients are found to be non-allergic upon allergist assessment . This discrepancy is often due to misclassification of symptoms in patients who receive penicillin-based antibiotics . Erroneous penicillin allergy labeling is a public health problem associated with use of alternative antibiotics that are generally less effective, more toxic, or more costly .

We previously developed and validated a decision support tool to assess penicillin allergy risk. It has been adapted into a mobile version that can be administered by various healthcare professionals. The goal of this study is to adapt the existing mobile tool into a patient-friendly version and validate it against the gold standard (allergist) assessment. If effective, this will empower lay individuals to conduct their own assessments and gain knowledge about levels of allergy risk. With this knowledge, patients can better advocate for themselves, potentially increasing efficiency of healthcare visits and reducing wait times for subspecialist assessments.

Between April and September 2023, 127 pediatric patients ages 6 months to 17 years and pregnant adults referred to the BC Children's and Women's Hospital for assessment of penicillin allergy were invited to use the patient tool to complete a self-assessment, resulting in the assignment of a risk category: (1) allergic; (2) high risk, possible allergy; (3) low risk, unlikely to be allergic; and (4) not allergic. Informed consent was obtained. 84 patients completed the self-assessment prior to their appointments and at their appointments the allergist conducted an assessment using the validated tool. Construct validity (ability of the patient tool to measure penicillin allergy risk) was captured by comparing the patient-oriented tool and the allergist assessment using intra-class correlation (ICC), where ICC = 0 (no agreement) to 1 (excellent agreement).

The primary outcome was the reliability of the patient tool to measure penicillin allergy risk compared with the gold standard allergist assessment. The secondary outcomes were to monitor potential safety risks and determine patient satisfaction with the tool.

The patient tool and allergist assessment demonstrated agreement in 57/84 (67.9%, Figure 1) assessments. Of these, 45/57 (78.9%) patients were stratified as low risk or not allergic by both the patient and the allergist. 33 of these 45 patients have undergone an oral penicillin challenge; 33/33 (100%) passed, de-labeling the allergy.

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Figure 1: Risk stratification by patient tool compared to allergist assessment

Agreement	Patient tool stratified to higher risk category than allergist assessment	Patient tool stratified to lower risk category than allergist assessment
57/84 (67.9%) 95% CI [56.7%,77.4%]	22/84 (26.2%)	5/84 (6.0%)
Safe = 94%	Safe = 94%	Safety risk = 6%
ICC = 0.618, 95% CI [0.40,0.76], p < 0.001	ICC = 0.618, 95% CI [0.40,0.76], p < 0.001	ICC = 0.618, 95% CI [0.40,0.76], p < 0.001

In 22/84 (26.2%) assessments, the patient tool determined a higher risk category than the allergist. This was primarily due to differences in perceived timing and description of symptoms when completing the patient tool compared to what was reported to the allergist.

Of the five patients stratified to a lower risk category using the patient tool (Figure 1), one responded to the self-assessment accounting for an initial exposure with mild symptoms, whereas the allergist accounted for a second exposure with more concerning symptoms. The other four patients misread the first question and incorrectly indicated that they had never taken a penicillin-based antibiotic so were miscategorized as not allergic.

Figure 2 details the results of the satisfaction survey.

Figure 2: Results of satisfaction survey completed by patients

	This patient tool was easy to use	The questions were easy to understand	Friends & family wo
Agree	53/62 (85.5%)	50/61 (82.0%)	44/62 (71.0%)
Neutral	4/62 (6.5%)	4/61 (6.6%)	14/62 (22.6%)
Disagree	5/62 (8.1%)	7/61 (11.5%)	4/62 (6.5%)

Percentages may not sum to 100 due to rounding.

The patient-friendly version of the validated assessment tool demonstrates good ability to determine risk of penicillin allergy based on agreement with the allergist assessment. It offers potential to empower patients to assess their risk of penicillin allergy and advocate in their care. To mitigate the safety risk in the small minority of patients and increase agreement and accessibility, we will improve readability and flow of the tool based on feedback received. This study provides proof of concept for a patient-driven tool; future work will involve a larger study with patients from community and hospital settings.

REFERENCES

AUTHORS

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AUTHOR CONTRIBUTIONS

Simonne L. Horwitz contributed to data analysis and interpretation and writing of the manuscript.

Ye Shen contributed to data analysis and interpretation and editing of the manuscript.

Stephanie C. Erdle contributed to data collection and editing of the manuscript.

Chelsea Elwood contributed to data collection.

Raymond Mak contributed to data collection and editing of the manuscript.

John Jacob contributed to study design and editing of the manuscript.

Tiffany Wong contributed to study design, data collection and study execution, editing of the manuscript, and supervision.

ETHICS APPROVAL

This study is classified as a Quality Improvement (QI) study and therefore does not fall within the scope of Research Ethics Board review.

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CONFLICTS OF INTEREST

Dr. Tiffany Wong is the faculty lead of the Doctors of BC Spreading Quality Improvement program.