SHEA

Concise Communication

Evaluation of current practice for penicillin allergy labeling using the PEN-FAST tool

Mary Beth Foran DNP, FNP[1] ⬤, Anastasia Brown MD[2], Julie A. Thompson PhD[1], Timothy Schwob MD[2],
Blanca Iris Padilla FNP, PhD[1] ⬤ and Margaret A. Bush PhD, RPh[1] ⬤

[1]Duke University, School of Nursing, Durham, NC, USA and [2]Independent Scholar

Abstract

Inaccurate penicillin allergy labeling may deter healthcare providers from initiating appropriate therapy and contribute to antibiotic resistance. In a rural urgent care setting, the current practice of penicillin allergy labeling was evaluated using the PEN-FAST tool. The results confirm opportunity to further evaluate and improve current practice for allergy assessment.

(Received 3 May 2024; accepted 11 July 2024)

Introduction

Though 10% of the population is reportedly allergic to penicillin, >90% of those may tolerate penicillin without significant hypersensitivity reactions.[1] Penicillin allergy labels may lead to increased use of broad spectrum antibiotics and higher risk of antibiotic resistance, suboptimal treatment plans, and adverse outcomes such as *Clostridium difficile* and increased prevalence of Methicillin-resistant *Staphylococcus aureus*.[2] Most penicillin allergy evaluations are performed by allergists in the United States. This impacts individuals with limited accessibility to specialized clinicians or insurance coverage.[3] Although true hypersensitivity reaction to penicillin does not discriminate, improper penicillin allergy labeling has been shown to differ by race, leading to potential inequity within health care.[3]

Investigating a label of penicillin allergy can be performed in primary care settings. Use of an assessment tool to better risk-stratify and properly identify such patients is essential in efforts to promote antibiotic stewardship and achieve superior patient outcomes. The validated PEN-FAST tool helps providers assess penicillin allergy and provides risk-stratification of individuals for a hypersensitivity reaction.[4,5] The PEN-FAST tool helps identify those who can complete direct oral drug challenge rather than skin testing.[5] A score of < 3 is associated with a high negative predictive value of 96%, which can be interpreted as a low-risk penicillin allergy resulting in eligibility for a direct oral challenge test.[4,5] Successful risk stratification with the PEN-FAST tool followed by formal skin testing resulted in 85% of penicillin allergy labeling being removed.[4]

This quality improvement (QI) project was conducted in an urgent care setting located in the Appalachian region of the US.

Corresponding author: Mary Beth Foran; Emails: Marybeth.foran@duke.edu, marybethforan@outlook.com

Current practice for allergy labeling within the electronic medical record (EMR) relies upon an accurate history as reported by the patient during triage and documented in the EMR by a staff nurse. Retrospectively, over a 2-month period all patient encounters for a single provider were reviewed to assess baseline penicillin allergy rate per the EMR. Of the 224 encounters, 45 (20.1%) were labeled with a penicillin allergy in the EMR, reflecting a higher rate than the likely 1% of the general population that is actually allergic to penicillin.[6]

The purpose of the QI project was to evaluate the current practice of penicillin allergy determination by comparing the existing medical record to PEN-FAST method. This provides an evidence- based assessment of current practice and feasibility for a future practice change, to improve penicillin allergy labeling. The results can be used to engage future quality improvement efforts in antibiotic stewardship.

Methods

Comparison of PEN-FAST to the patient's EMR was used to characterize the prevalence of potential over-labeling of penicillin allergies. Collection of penicillin allergy label status in the EMR with current standard practice methods was compared with allergy risk derived from use of the PEN-FAST tool.

Patients with a reported penicillin allergy in their EMR were identified and the PEN-FAST tool was prospectively applied to determine the percentage that would be potentially labeled as allergic to penicillin using a systematic approach. This QI project was formally evaluated using a quality improvement checklist and determined not to be human subjects' research.

Setting and participants

The project took place in an urgent care setting in the Appalachian region of the United States, during the period of July 2023–

Table 1. Rates of penicillin (PCN) allergy label with and without PEN-FAST

Age (years) Median (Range)	Number of patients (N)	PCN-allergy label per EMR, n (%)	PCN-allergy label per PEN-FAST, n (%)	Baseline EMR vs PEN-FAST *P*-value[a]
36 (18–89)	151	24 (15.9)	3 (2.0)	<.001

[a]McNemar *t* test.

December 2023. The EMR for patients aged 18 years and older were reviewed.

Data collection

Over a 2-month period, patients with documented penicillin allergy in the EMR were prospectively administered the PEN-FAST survey tool by the same provider. The rates of penicillin allergy were calculated and compared. The project was limited to determination and comparison of allergy label rates by EMR versus the PEN-FAST risk determination tool. Information gathered was used to evaluate current practice for penicillin-allergy labeling and was not used for clinical decision making nor changes to the medical record.

Evaluation tool and measurement

The PEN-FAST tool evaluates the reported allergy, duration since most recent noted reaction, type of reaction (anaphylaxis or angioedema), presence of severe cutaneous reaction, and type of treatment required in response to the reaction.[4,7] The risk stratification is categorized on a scale of 0-5, with low to no risk (0-2), moderate risk (3), and high risk (4-5) of hypersensitivity reaction to penicillin. The PEN-FAST assessment takes approximately 4 minutes to administer.[8]

For purposes of this QI project, "potential mis-labeling" of a penicillin allergy was defined as a score of < 3.

Analysis

A McNemar test in IBM SPSS version 28 was used to compare the EMR and PEN-FAST rates of penicillin allergy label. The level of significance was set apriori at 0.05. Additionally, descriptive statistics (n, %) are provided for the breakdown of PEN-FAST risk score categories.

Results

Of the 151 patients, 24 (15.9%) were listed with an allergy in the EMR, although only three patients (2%) had PEN-FAST scores of 3 or greater, *P* <.001, revealing a statistically significant difference in penicillin allergy label when using PEN-FAST risk stratification relative to using the EMR label (Table 1).

Use of the PEN-FAST tool illustrated that of the 24 patients labeled as allergic in the EMR, 87.5% (21 of 24) were potentially mislabeled, as they had scores of < 3 on PEN-FAST. Implementation of the PEN-FAST tool resulted in the following risk-stratification results: (148/151) 98% in low or no risk; (2/151) 1.3% in moderate risk; (1/151) 0.7% in high risk (Figure 1); 3/151 (2%) when moderate- and high-risk categories are combined.

Discussion

Accurate penicillin allergy status is important in urgent care because of the high rate of antibiotic prescribing in this outpatient setting. In this QI project PEN-FAST provided a systematic
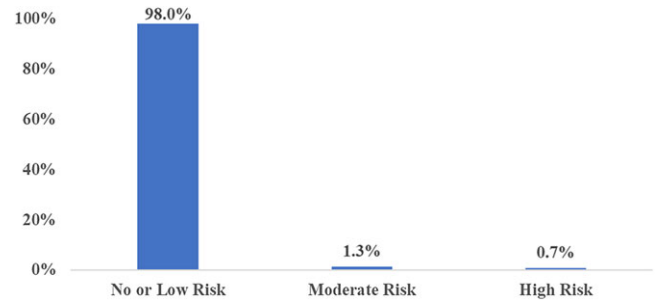

Figure 1. PEN-FAST categories: 98% in low or no risk; 1.3% in moderate risk; 0.7% in high risk (2% for moderate and high risk combined).

method for evaluating the current practice of documenting penicillin allergy status in a rural urgent care setting. Potential penicillin-allergy rates were significantly reduced based on the PEN-FAST risk stratification method compared with the existing EMR method. PEN-FAST is a simple, effective clinical decision tool for triaging staff and providers to implement and provides a consistent format for assessing penicillin allergy risk status. It can easily be added to the EMR and takes approximately 4 minutes to administer.[8] Limitations of the existing practice include poor documentation and limited, accurate history as reported by the patient(s). The PEN-FAST tool provides a consistent, structured set of questions for obtaining relevant characteristics of prior allergy and a validated method for assessing risk. However, it is important to note that the PEN-FAST score distinguishes between different levels of risk and can identify when direct oral challenge may be appropriate, however it cannot be used alone to de-label a penicillin allergy.

Far too often healthcare staff continue the same methodological approach due to comfort and ease, believing there is no need for improvement. Approaching a practice change by way of an evidence-based evaluation tool can demonstrate a change is needed and enables buy in and engagement throughout the change process. Results from this project demonstrate that use of a validated allergy risk stratification tool can be useful in the urgent care setting to assess current practices for penicillin allergy labeling. Implementation of such a tool in practice should be considered to further antibiotic stewardship efforts.

Competing interests. All authors report no conflicts of interest relevant to this article.

References

1. Is it really a penicillin allergy? Centers for Disease Control and Prevention website. https://www.cdc.gov/antibiotic-use/community/pdfs/penicillin-factsheet.pdf. Published 2017. Accessed April 27, 2024.
2. Olans RD, Olans RN, Marfatia R, Angoff GH. Inaccurate penicillin allergy labeling, the electronic health record, and adverse outcomes of care. *Jt Comm J Qual and Patient Saf* 2022;48:552–558.

3. Arasaratnam RJ, Chow TG, Liu AY, Khan DA, Blumenthal KG, Wurcel AG. Penicillin allergy evaluation and health equity: a call to action. *J Allergy Clin Immunol Pract* 2023;11:422–428.

4. Trubiano JA, Vogrin S, Chua KYL, *et al.* Development and validation of a penicillin allergy clinical decision rule. *JAMA Intern Med* 2020;180:745–752.

5. Mabilat C, Gros MF, Van Belkum A, *et al.* Improving antimicrobial stewardship with penicillin allergy testing: a review of current practices and unmet needs. *JAC-Antimicrob Resist* 2022;4:dlac116.

6. Trubiano JA, Adkinson NF, Phillips EJ. Penicillin allergy is not necessarily forever. *JAMA* 2017;318:82–83.

7. Copaescu AM, Vogrin S, Shand G, Ben-Shoshan M, Trubiano JA. Validation of the PEN-FAST score in a pediatric population. *JAMA Netw Open* 2022;5: e2233703.

8. Satwinder SK, Adams DT, Parker B. Implementation of the PEN-FAST Penicillin allergy screening tool in the emergency department during medication reconciliation. *Open Forum Infect. Dis* 2021;8:S137–S138.