

Implementation of a Pharmacist-Driven Detailed Penicillin Allergy Interview

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Abstract

Background: Self-reported penicillin allergies may be outdated or inaccurate, leading to the use of alternative antimicrobials that may be less effective, more toxic, and/or more expensive. Although penicillin skin tests can provide accurate assessments of penicillin allergies, these procedures are not feasible at all institutions. Another solution is to conduct a detailed penicillin allergy interview (DPAI), which can potentially lead to optimization of antimicrobial therapy. **Objective:** The purpose of this study was to assess the impact of a pharmacist-driven DPAI protocol. The primary objective was to measure the number of patients requiring a change to their allergy profile following DPAI. Secondary objectives included characterizing allergy profile updates and measuring the number of recommendations to switch to a β -lactam agent, provider acceptance rate, and patient tolerance. **Methods:** Standardized pharmacist-driven DPAIs were conducted prospectively on adult patients admitted with a documented penicillin allergy. The allergy profile within the electronic health record (EHR) was updated and a recommendation to switch to noncarbapenem β -lactam therapy was made when indicated by a decision algorithm. **Results:** A total of 175 (37.5%) patients received a DPAI. Of these, 133 (76.0%) required a change to their allergy profile. Additionally, 135 (77.1%) patients interviewed were on antimicrobial therapy, with 42 (31.1%) meeting criteria to switch to noncarbapenem β -lactam therapy; of which 31 (73.8%) patients were successfully transitioned, with no signs or symptoms of intolerance. **Conclusions and Relevance:** Implementation of pharmacist-driven DPAIs can provide updated and corrected allergy information within the EHR, allowing for de-escalation and/or optimization of antimicrobial therapy.

Keywords

penicillin allergy, β -lactam, antimicrobial, carbapenem, allergy interview

Background

Penicillin allergies are reported in approximately 10% of patients in the United States.^{1–4} These allergies can be outdated and/or inaccurate and may lead to inappropriate use of alternative antimicrobial agents that are potentially more expensive, less effective, and more toxic.^{3–12} In a retrospective matched cohort including more than 154 000 patients, there was an increase in the use of vancomycin, ciprofloxacin, and clindamycin observed in patients with reported penicillin allergies. These patients also had an increased prevalence of *Clostridioides difficile*, methicillin-resistant *Staphylococcus aureus* (MRSA), and vancomycin-resistant *Enterococcus* (VRE) infections, resulting in an increase in hospital length of stay and associated hospital costs.^{4,9} These findings emphasize the need for clarification of penicillin allergies in an attempt to de-escalate and/or optimize therapy. Furthermore, the Centers for Disease Control and Prevention (CDC) recognizes the impact that penicillin allergies can have on the selection of optimal antimicrobial

therapy. The CDC recommends using a systematic approach to the evaluation and diagnosis of penicillin allergies by health care professionals.^{13,14}

Up to 90% of patients with a documented history of a penicillin allergy are subsequently able to tolerate a β -lactam antimicrobial agent after formal allergy testing.^{15,16} In a retrospective study, patients with any severity of self-reported penicillin allergy who received cefepime, ceftioxin, ceftriaxone, cephalexin, or meropenem were analyzed for cross-reaction via chart review. The authors found that among 175 patients, only 10 patients (6%) experienced a subsequent allergic reaction after receiving at least 1 dose of the non-penicillin β -lactam, with only 1 patient experiencing an

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immediate type 1 hypersensitivity reaction.¹⁷ In a retrospective cohort study, patients were evaluated for adverse drug events after a test dose of a β -lactam antimicrobial was administered. The authors found that 7.5% of patients experienced an adverse drug event, and only 3.8% of those were considered a hypersensitivity reaction, indicating that providing test doses to patients with reported β -lactam allergies is safe.¹¹ The results of these studies suggest a low probability that a patient with a self-reported penicillin allergy will have a subsequent reaction to a cephalosporin or carbapenem. However, a prescriber may hesitate to prescribe a β -lactam antimicrobial for a patient if an IgE-mediated reaction is suspected. One method to confirm a documented IgE-mediated penicillin allergy is through penicillin skin testing (PST). The proportion of negative skin tests in patients with reported penicillin allergies in one study ranged from 79% to 100%, resulting in an increased use of penicillin and cephalosporin agents and a decreased use of vancomycin and fluoroquinolones.¹⁸

Although PST may provide an accurate assessment of penicillin allergies, it may not be feasible at all institutions because of lack of resources, time, and trained personnel to perform the procedure and interpret the results. Detailed patient interviews can be utilized as an alternative method to PST for clarification of documented penicillin allergies.^{10,12,19} It may take up to 60 minutes to fully complete a PST, whereas a detailed penicillin allergy interview (DPAI) may only take up to 5 minutes to complete. A retrospective study by Sigona et al²⁰ evaluated the impact of a pharmacist-driven β -lactam allergy interview and found that 65% of patients were able to be successfully transitioned to a β -lactam antimicrobial agent after the interview during their 7-month study period. In the case that a patient is unable to participate in an interview, chart review may also be an option. A multipronged interventional study utilizing a penicillin allergy screening tool consisting of chart review with or without patient interview resulted in a reduction in aztreonam duration of therapy in penicillin allergic patients.²¹ These 2 studies demonstrate the successful use of allergy assessments and interviews as a means to clarify a penicillin allergy, thus providing the health care field a practical tool to de-escalate and/or optimize antimicrobial therapy when PST may not be feasible.

At our institution, patients are frequently prescribed a non- β -lactam or a carbapenem antimicrobial agent if they have a documented penicillin allergy. Currently, there is no formal process to clarify penicillin allergies reported in the electronic health record (EHR). By implementing a pharmacist-driven DPAI, it is hypothesized that allergy profiles will be more accurate, allowing more patients to receive noncarbapenem β -lactam antimicrobials when appropriate. The purpose of this study was to assess the impact of a pharmacist-driven DPAI protocol.

Methods

Study Design, Setting, and Patient Population

This was a single-center, prospective evaluation assessing the impact of a pharmacist-driven DPAI at Cleveland Clinic Marymount Hospital, a 322-bed, acute-care, community hospital. Patients were included if they were 18 years of age and older and admitted with a documented penicillin allergy within the EHR between December 26, 2017, and March 26, 2018. This 3-month period was a pilot phase following implementation of the DPAI protocol at our institution. Patients were excluded if the DPAI was unable to be completed because of the inability to participate fully in the interview or absence of family member/power of attorney. Patients were also excluded if the interview was declined by the patient or if the patient was pregnant.

A list derived from the EHR, which populated patients admitted with a documented penicillin allergy in real time, was utilized to identify patients eligible for DPAI. Patients from this list were screened daily and interviewed by a member of the investigational team. The investigational team comprised the pharmacy resident and 2 clinical inpatient pharmacists. Patient interviews were prioritized based on current antimicrobial therapy. First priority was given to patients who were on aminoglycoside, carbapenem, clindamycin, fluoroquinolone, or aztreonam antimicrobial therapy. Second priority was given to patients who were on other antimicrobial therapy. Patients not on systemic antimicrobial therapy at the time of screening and those ordered 1-time preoperative antimicrobials were prioritized last.

A standardized questionnaire was utilized to conduct DPAs (Table 1). Information regarding previous tolerance to β -lactam antimicrobials was obtained from medication administration records within the EHR as well as patient report from the interview. The allergy section of the patient's EHR was updated according to the information obtained from the DPAI and chart review and a progress note was placed in the EHR detailing the interview. If a change in antimicrobial therapy was warranted, a recommendation was made to the prescribing service based on an intervention decision algorithm (Figure 1). Factors that guided recommendations included type and severity of the penicillin allergy, time frame of reaction, which antimicrobial the intolerance or adverse reaction was to, history of β -lactam tolerance, which antimicrobial the reported tolerance was to, current or previous culture and susceptibility data, indication for the antimicrobial, and the anticipated duration of therapy. This study was approved by the institutional review board.

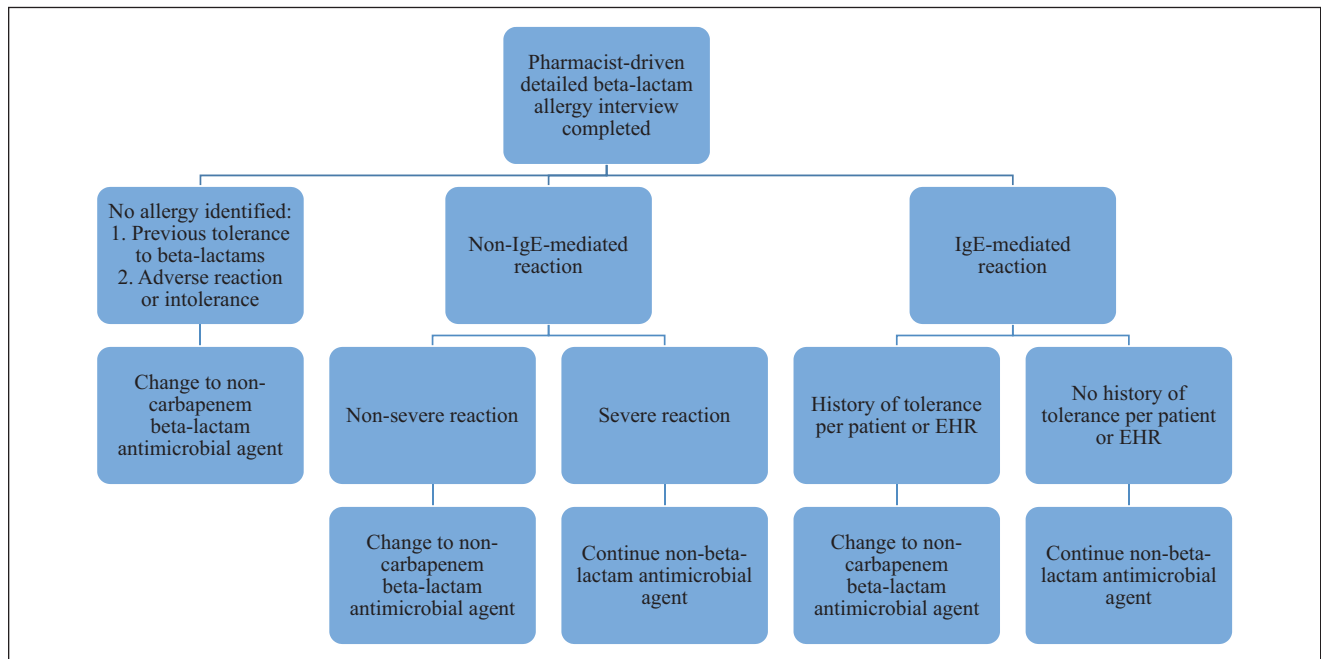
Study Outcomes

The primary objective of this study was to measure the number of patients requiring any change to their allergy

Table 1. Pharmacist-Driven Detailed Penicillin Allergy Interview Questionnaire.Standardized β -Lactam Allergy Interview Questionnaire

1. Are you currently pregnant?
2. What antibiotic allergies do you have?
 - a. What was the name of the antibiotic that you had a reaction to?
3. What was the reaction that occurred when you took that antibiotic?
 - a. Was the allergy limited to only GI intolerance (eg, nausea, vomiting, diarrhea)?
 - b. Did any of the following reactions occur?
 - i. Ulcers or lesions/sores in mouth?
 - ii. Scaling skin
 - iii. Blisters
 - iv. Eye involvement
 - v. Throat closing or facial swelling
 - vi. Stevens Johnson Syndrome, Toxic Epidermal Necrolysis, DRESS, vasculitis, serum sickness (eg, joint pain, arthritis reaction)
 - vii. Penicillin induced kidney or liver injury, hemolysis, low platelets
4. How soon after taking that antibiotic did the reaction occur?
5. How long ago did the reaction occur?
6. Have you ever taken a penicillin (eg, amoxicillin, amoxicillin/clavulanate, piperacillin/tazobactam) or cephalosporin (eg, cephalexin, cefuroxime, ceftriaxone) since that reaction?
 - a. Did you have any reactions to that medication?
7. Have you ever had a penicillin skin test?
 - a. What was the result of the test?

Abbreviations: DRESS, Drug Rash with Eosinophilia and Systemic Symptoms; GI, gastrointestinal.

**Figure 1.** Intervention decision algorithm based on DPAl.

Abbreviations: DPAl, detailed penicillin allergy interview; EHR, electronic health record.

profile within the EHR. Secondary objectives included characterizing the types of changes made to the allergy profile, describing the history of tolerance to β -lactam antimicrobials, measuring the time from admission to

DPAl, quantifying the number of eligible patients successfully transitioned to noncarbapenem β -lactam antimicrobial therapy, measuring the time from admission to implementation of the recommended antimicrobial, and

assessing the tolerance of the recommended antimicrobial. Changes to the allergy profile included the addition of a previous intolerance, a positive result from a PST, or history of tolerance (eg, uneventful receipt of a penicillin or cephalosporin antimicrobial), modification of the reaction or reaction type, or deletion of the allergy. Allergies were only deleted if requested by the patient. IgE-mediated reactions were defined as hives, itching, and anaphylactic type reactions. Nonsevere, non-IgE-mediated reactions were defined as contact dermatitis (rash). Severe, non-IgE-mediated reactions were defined as Stevens-Johnson syndrome, seizures, or other life-threatening reactions.

Statistical Analysis

Data analysis was performed using descriptive statistics. Outcomes were reported as mean $\pm$ SD, median $\pm$ interquartile range, or n and percentage.

Results

A total of 466 patients with a penicillin allergy documented within the EHR were admitted during the 3-month study period. DPAIs were attempted on 194 (41.6%) patients. A total of 19 patients were excluded (15 patients unable to participate, 3 patients declined interview, 1 pregnant patient), resulting in a total of 175 patients interviewed for this study.

Baseline Demographics

The average age of those interviewed was 65.4 ± 17.8 years, with 112 (64%) patients being female. History of a resistant microbe (eg, carbapenem-resistant *Enterobacteriaceae*, extended-spectrum β -lactamase, MRSA, or VRE) occurred in 14 (8%) patients (Table 2). A total of 140 (80%) patients reported that their initial reaction to penicillin or a penicillin-type antimicrobial occurred more than 10 years prior to the interview and 8 (4.6%) patients received PST prior to admission.

Outcomes

The most common reaction described by patients during DPAI was suggestive of an IgE-mediated reaction, which was self-reported in 76 (43.4%) patients. Nonsevere, non-IgE-mediated reactions were reported in 45 (25.7%) patients. It was determined that there was no true allergy for 23 (13.1%) patients. There were 29 (16.6%) patients who were unable to recall the details of their penicillin allergy. History of tolerance to β -lactam antimicrobials occurred in 102 (58.3%) patients (Table 3).

There were 133 (76%) patients who required a change to the allergy section in the EHR. The documentation of a previous tolerance or intolerance was added to the EHR in 58 (33.1%) patients and the reaction or reaction type was modified in 32 (18.3%) patients. Both the addition of a previous tolerance or intolerance and the reaction or reaction type

Table 2. Baseline Demographics.^a

Baseline Demographics	n = 175
Age, years (mean $\pm$ SD)	65.4 $\pm$ 17.8
Female	112 (64)
History of resistant microbe (MRSA, ESBL, CRE, VRE)	14 (8)
History of PST	8 (4.6)
On an antimicrobial at time of interview ^b	135 (77.1)
Antimicrobials at the Time of DPAI	n = 189
Carbapenem	15 (7.9)
Monobactam	8 (4.2)
Fluoroquinolone	57 (30.2)
Clindamycin	8 (4.2)
Vancomycin (intravenous therapy only)	28 (14.8)
Aminoglycoside	3 (1.6)
Penicillin	8 (4.2)
Cephalosporin	26 (13.8)
Tetracycline	14 (7.4)
Macrolide	14 (7.4)
Other	8 (4.2)

Abbreviations: MRSA, methicillin-resistant *Staphylococcus aureus*; ESBL, extended-spectrum β -lactamase; CRE, carbapenem-resistant *Enterobacteriaceae*; VRE, vancomycin-resistant *Enterococcus*; PST, penicillin skin testing; DPAI, detailed penicillin allergy interview.

^aAll variables are reported as n (%) unless specified otherwise.

^bPatients may have been on more than 1 antimicrobial at the time of the interview.

Table 3. Results.^a

Allergy Characteristics Based on DPAI (n = 175)	
Reaction type	
No allergy identified	23 (13.1)
Nonsevere, non-IgE-mediated reaction	45 (25.7)
IgE-mediated reaction	76 (43.4)
Severe, non-IgE-mediated reaction	2 (1.1)
Undetermined allergy type	29 (16.6)
Time since initial reported reaction	
Less than 10 years	20 (11.4)
Greater than 10 years	140 (80)
Unable to recall	15 (8.6)
History of tolerance to β -lactam since initial reported reaction	73 (42)
Allergy Profile-Related Interventions Following DPAI (n = 175)	
No changes	42 (24)
Addition of previous intolerance or tolerance	58 (33.1)
Modification of reaction or reaction type	32 (18.3)
Addition of previous intolerance or tolerance and modification of reaction or reaction type	41 (23.4)
Deletion of allergy	2 (1.1)
Antimicrobial Therapy-Related Interventions Following DPAI (n = 135) ^b	
Recommended change to noncarbapenem, β -lactam antimicrobial	42 (31.1)
Recommendation accepted by provider	31 (73.8)
Patient tolerated β -lactam	31 (100)
Change in therapy not indicated	93 (68.9)
Appropriate therapy	33 (35.5)
Current β -lactam therapy	22 (23.7)
IgE-mediated or non-IgE-mediated severe reaction	25 (26.9)
Nearing completion of antimicrobial course	4 (4.3)
Unknown reaction type or tolerance history	9 (9.7)

Abbreviation: DPAI, detailed penicillin allergy interview.

^aAll variables are reported as n (%).

^bData assessed only for patients who were initially on at least 1 antimicrobial during the time of DPAI.

were modified in 41 (23.4%) patients. In addition, 2 (1.1%) patients requested that the allergy be removed from their EHR after completion of the interview.

A total of 135 (77.1%) patients were on systemic antimicrobial therapy at the time of the DPAI. The 3 most common antimicrobial classes ordered were fluoroquinolones, intravenous vancomycin, and cephalosporins (Table 2). A change in antimicrobial therapy was recommended for 42 (31.1%) patients, with a provider acceptance rate of 73.8%. The most common reason for not recommending a change in therapy was that the patient was deemed to be on an appropriate treatment for their presumed disease state, which occurred in 32 (35.5%) patients (Table 3). All patients who received a recommended β -lactam antimicrobial tolerated the change without allergic or adverse reactions. The median time from admission to DPAI was 1 day (1-3 days) and median time from admission to initiation of recommended antimicrobial was 1 day (0.5-2 days).

Discussion

Inaccurate allergy histories within the EHR can lead to sub-optimal antimicrobial choices by providers. Our study demonstrates that implementation of a pharmacist-driven DPAI resulted in updated and more accurate allergy information within the EHR in 76% of interviewed patients.

Previous literature states that up to 90% of patients with reported penicillin allergies are able to tolerate β -lactam antimicrobials.^{15,16} In this study, 36% of patients were already prescribed a β -lactam antimicrobial, and were, therefore, not eligible for a switch to β -lactam therapy. Regardless, DPAs were completed for these patients to update the EHR in the event of a subsequent admission requiring antimicrobials. An additional 23% of eligible patients who were not on a β -lactam prior to DPAI were successfully transitioned to a β -lactam with no documentation of signs/symptoms of an intolerance or allergic reaction. This resulted in a total of 59.3% of patients on initial

antimicrobial therapy who were able to tolerate a β -lactam antimicrobial with a reported penicillin allergy in our study. There are a number of factors that may have contributed to a lower rate of transition to a β -lactam. First, there was a large proportion of patients with a self-reported IgE-mediated reaction in this cohort, especially hives. Without a documented history of tolerance to β -lactams, or delabeling of the allergy via PST, these patients would not have been eligible for a switch to β -lactam therapy through the interview process alone. A PST coupled with DPAI would have been beneficial in determining true IgE-mediated reactions in such patients. Additionally, PST would also have a role in those patients who could not recall their reaction. Finally, not all patients deemed eligible for a β -lactam antimicrobial per DPAI results were candidates for the switch. Examples of such patients include those who were nearing completion of therapy and those who were already on an appropriate antimicrobial agent based on the indication.

In previous studies evaluating penicillin allergy interviews, provider acceptance rate of switching to β -lactam therapy was found to be between 63% and 87%.^{20,22} In our study, provider acceptance rate was also high, demonstrating increased willingness from providers to prescribe β -lactams when there is adequate documentation available regarding the allergy. There were instances when providers elected to continue therapy with the initial non- β -lactam antimicrobial, despite the patient being eligible to switch to a β -lactam (eg, utilizing monotherapy with a respiratory fluoroquinolone for community-acquired pneumonia). Change to a β -lactam antimicrobial occurred in 4 patients (12.9%) prior to formal completion of the DPAI. This occurred because of documented history of tolerance to β -lactams within the EHR.

Although our study shares similarities with previous studies evaluating penicillin allergy interviews, a key difference includes an algorithmic approach to antimicrobial selection following DPAI, with a focus on noncarbapenem-based recommendations for eligible patients. The DPAI workflow prioritized patients based on presence and type of antimicrobial in order to identify patients who would benefit the greatest from β -lactam therapy. We also used a multipronged approach in clarifying allergy histories by combining historical EHR data as well as patient interview.

There are a few limitations to this study worth mentioning. One limitation is the low capture rate of DPAIs. During the study period, DPAIs were predominantly performed by the investigational team Monday through Friday between 07:00 and 18:00 hours. Patient fall outs occurred mostly as a result of patients being discharged prior to being interviewed. Because of this time constraint and pharmacist availability, DPAIs were prioritized based on type of antimicrobial therapy. This could have introduced selection bias, potentially leading to an increased number of

candidates for β -lactam therapy. Patients who were not on an antimicrobial at the time of screening were prioritized last for DPAI. These patients may have still benefited from DPAI because clarification of their allergy could have implications on antimicrobial selection during subsequent admissions. Because it can be challenging to rely on a patient's historical report of hives, attempts were made by the interviewers to differentiate between hives versus rash with the use of visual aids. Recommendation to switch to a β -lactam in eligible patients who were nearing completion of antimicrobial therapy was not attempted, mostly because of the inability to observe for tolerance prior to discharge. Finally, although we were able to reduce the number of patients on non- β -lactam therapy, we did not directly assess the impact of the intervention on other outcomes such as days of therapy, cost, length of hospital stay, and rates of *C. difficile*, MRSA, and VRE infections.

Potential improvements would be to expand the time period in which interviews are occurring and to train additional pharmacists on the DPAI workflow to improve the capture rate. As mentioned previously, there were a large number of patients with self-reported IgE-mediated reactions in our study. Although PST is infeasible at our institution due to the lack of an inpatient allergy service or trained personnel to perform the procedure, an outpatient consultation with Allergy or Infectious Diseases for PST could be recommended in such patients as a method for delabeling penicillin allergies.

Conclusion and Relevance

This study demonstrates that DPAI leads to a more thorough and descriptive penicillin allergy record in the EHR, allowing providers to choose the most optimal antimicrobial regimen. Clarification of penicillin allergies can also influence prescribing practices during future admissions, emergency or urgent care visits, or outpatient office visits. Although PST is the most optimal method for delabeling penicillin allergies, significant interventions are still possible with DPAI when PST is not feasible.

Authors' Note

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