

RESEARCH ARTICLE

A Multidisciplinary Quality Improvement Initiative to Facilitate Penicillin Allergy Delabeling Among Hospitalized Pediatric Patients

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ABSTRACT

BACKGROUND: Penicillin allergy is reported in up to 10% of the general population; however, >90% of patients reporting an allergy are tolerant. Patients labeled as penicillin allergic have longer hospital stays, increased exposure to suboptimal antibiotics, and an increased risk of methicillin-resistant *Staphylococcus aureus* and *Clostridioides difficile*. The primary aim with our quality improvement initiative was to increase penicillin allergy delabeling to at least 10% among all hospitalized pediatric patients reporting a penicillin allergy with efforts directed toward patients determined to be low risk for true allergic reaction.

METHODS: Our quality improvement project included several interventions: the development of a multidisciplinary clinical care pathway to identify eligible patients, workflow optimization to support delabeling, an educational intervention, and participation in our institution's quality improvement incentive program. Our interventions were targeted to facilitate appropriate delabeling by the primary hospital medicine team. Statistical process control charts were used to assess the impact of this intervention pre- and postpathway implementation.

RESULTS: After implementation of the clinical pathway, the percentage of patients admitted to hospital medicine delabeled of their penicillin allergy by discharge increased to 11.7%. More than one-half of those delabeled (51.2%) received a penicillin-based antimicrobial at time of discharge. There have been no adverse events or allergic reactions requiring emergency medication administration since pathway implementation.

CONCLUSIONS: Our quality improvement initiative successfully increased the rate of penicillin allergy delabeling among low-risk hospitalized pediatric patients, allowing for increased use of optimal antibiotics.

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Dr Bauer was responsible for the development and implementation of the clinical care pathway, data collection, and drafting and reviewing the manuscript; Ms MacBrayne, Ms Stein, Drs Searns, Hicks, Sarin, Lin, and Duffey, Mr Rannie, Ms Wickstrom, and Drs Yang, Bajaj, and Carel were responsible for development and implementation of the clinical care pathway, data collection, and review and revisions of the manuscript; and all authors approved the final manuscript as submitted.

Penicillin allergy is reported in up to 10% of the general population; however, >90% of patients reporting such an allergy can tolerate penicillin-based antimicrobial agents without incident; true penicillin-induced anaphylaxis is exceedingly rare.¹ Penicillin allergy labels are linked to increased health care costs by way of longer hospital stays, increased exposure to suboptimal antibiotics,² and increased risk of methicillin-resistant *Staphylococcus aureus* and *Clostridioides difficile*.³ Thus, identifying children burdened with a penicillin allergy for whom that inappropriate label can be safely and confidently removed has the potential to improve patient care.

Skin testing for penicillin allergies can be used to rule out immunoglobulin E (IgE)-mediated reactions; however, recent findings reveal that, among low-risk patients who are unlikely to have an IgE-mediated allergy on the basis of clinical history, skin testing can safely be deferred while proceeding directly to an oral provocation challenge.⁴⁻⁶ This cultural shift has helped develop penicillin allergy delabeling clinical pathways that empower pediatricians to identify low-risk patients for penicillin allergy delabeling without the need for skin testing or subspecialty consultation.^{7,8} The aim with this quality improvement initiative was to increase the rate of penicillin allergy delabeling by day of discharge among low-risk patients admitted to our pediatric hospital medicine service. All patients, not just those who required antimicrobial therapy, were eligible for our penicillin allergy delabeling clinical pathway. Additionally, to preserve hospital resources, with our quality improvement project, we aimed to facilitate delabeling by the primary hospital medicine team instead of pediatric allergy and immunology subspecialists.

METHODS

Context

This quality improvement project occurred at a 400+ bed freestanding quaternary care children's hospital in the western United States. Our multidisciplinary team included members from allergy and immunology, antimicrobial stewardship, pediatric

hospital medicine, pediatric infectious diseases, and inpatient nursing leadership. Review of patients admitted to our hospitalist medicine service from January 1, 2017, through December 30, 2017, indicated that 6.5% of all patients admitted were labeled as penicillin allergic during our baseline time period. Only 2.0% (9 patients total) who reported a penicillin allergy were delabeled during this period, indicating a tremendous opportunity for improvement.

Interventions

To address our aim of increasing penicillin allergy delabeling among hospitalized pediatric patients, our project included the development of a clinical care pathway, workflow optimization to support delabeling, an educational intervention among pediatric residents and pediatric hospital medicine providers, and participation in our institution's quality improvement incentive program, all of which are discussed in more detail below.

Clinical Care Pathway

Our clinical care pathway on penicillin allergy delabeling provided an evidence-based guide to assist hospital medicine physicians in identifying and delabeling inappropriate penicillin allergies among low-risk patients (Fig 1). The pathway includes guidance for frontline providers to obtain comprehensive allergy history to risk stratify patients into 4 risk categories: no increased risk, low risk, moderate risk, and high risk (Fig 2). Patients avoiding penicillin-based antimicrobial agents solely because of a family member with a penicillin allergy and patients who had tolerated penicillin since their initial reaction are determined to be at no increased risk¹ of true penicillin allergy and are delabeled with family education alone. For moderate- and high-risk patients for whom the clinical history is more suggestive of a true IgE-mediated drug allergy or severe cutaneous adverse drug reaction, our pathway recommends formal evaluation through the allergy and immunology consultation service should future penicillin therapy be desired.

We defined low-risk patients as those who have delayed onset (>24 hours after the first dose) of nonprogressive symptoms

(such as gastrointestinal symptoms or rash) as candidates for a single dose oral provocation challenge. Exclusion criteria for oral provocation challenge included patients currently on antihistamines that might blunt a reaction, patients not taking anything by mouth, patients reporting vomiting >1 time in the last 24 hours, or patients having concerning respiratory symptoms, critical illness, or presence of a rash currently. Although other published pathways have categorized patients with a history of an urticarial rash as moderate risk,⁸ existing pediatric evidence has revealed that history of an urticarial rash is not an increased risk factor for a true IgE-mediated penicillin allergy,⁴ and thus we categorized delayed onset of urticarial rash alone in the low-risk group. Additionally, although graded oral provocation challenges have often been used,⁷⁻⁹ these have not been revealed to provide any safety benefit because reactions overall are rare and typically mild.^{5,6} Thus, our pathway used single dose oral amoxicillin challenges (45 mg/kg per dose, maximum 1000 mg) before a 60-minute observation period. This quality improvement initiative was approved by the Organizational Research Risk and Quality Improvement Review Panel, and this pathway underwent formal review and approval by our institutional clinical care guideline and measures review committee and our pharmacy and therapeutics committee. The full pathway is externally available.¹⁰

Although our institution does have allergy and immunology consultative services, because 1 purpose of this quality improvement project was to preserve hospital resources, patients at low or no increased risk were delabeled on the basis of clinical decision-making of the hospital medicine team through use of the clinical care pathway. Our quality improvement team was available for any questions from the primary medical team but was not involved in clinical decision-making, consent for oral provocation challenge, or in-person consultation with eligible patients unless requested by the treating team. Our clinical pathway additionally included a patient education handout to help facilitate the discussion between the primary team and

PENICILLIN ALLERGY DELABELING

ALGORITHM

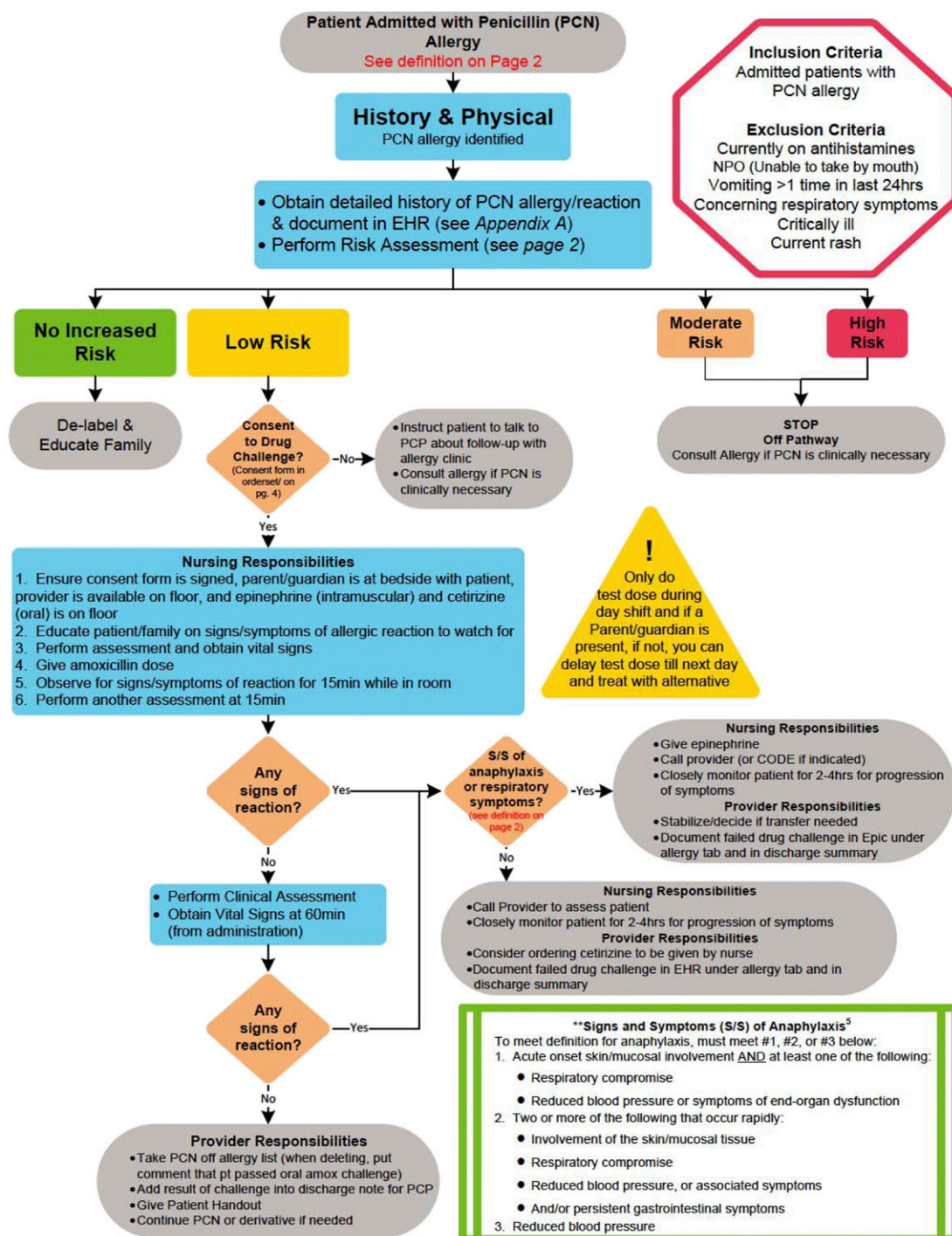


FIGURE 1 Penicillin allergy delabeling clinical care pathway algorithm. NPO, nothing by mouth; PCP, primary care physician.

No Increased Risk

(Can simply de-label patient, no drug challenge needed)

- Avoidance based on family history alone
- Has tolerated PCN since concerning incident without reaction

Low Risk

(Could consider oral challenge)

- Delayed onset (greater than 24 hours after first dose) onset of isolated, non-progressive symptoms (such as gastrointestinal symptoms or rash/hives alone)

Moderate Risk

(Allergy consult needed if PCN desired based on primary team and ID consult for possible skin testing and/or desensitization)

NOT To be given without Allergy and Infectious Disease input

- Unknown Clinical History
- Symptoms concerning for anaphylaxis
- Any symptoms requiring hospitalization
- Immediate symptoms (less than 24 hours after first dose of PCN)
- Progressive/worsening symptoms (within 60 minutes of dose)
- Reaction to intravenous/intramuscular formulation (within 60 minutes of dose)
- Primarily nasogastric tube (NG), gastric tube (GT), or jejunostomy tube (JT)

High risk

(PCN should be avoided. Skin prick testing and desensitization not recommended)

- Serious Cutaneous or Systemic Adverse Reactions concerning for but not limited to:
- Stevens-Johnson Syndrome (SJS) or Toxic Epidermal Necrolysis (TEN)
- Drug reaction with eosinophilia and systemic symptoms (DRESS)
- Acute Interstitial Nephritis (AIN)
- Serum Sickness

FIGURE 2 Risk stratification by clinical history to identify patients who were candidates for penicillin allergy delabeling. ID, infectious disease.

families on the risks versus benefits of penicillin delabeling. All admitted patients with a penicillin allergy label were candidates for delabeling, regardless of whether they required an antibiotic during admission.

Workflow Optimization

Once a patient was determined to be low risk and eligible for an oral challenge by the primary team, delabeling was offered to parents and caregivers with consent obtained. An order set in the electronic medical record (EMR) was implemented that included orders for patient monitoring by bedside nurses (which are described in

more detail below), the dose of oral amoxicillin for provocation challenge, and rescue medications (ie, intramuscular epinephrine and oral cetirizine), which were required to be at the bedside before administration of amoxicillin. A physician or advanced practice provider needed to be present on the floor as well as a parent or caregiver at the bedside for the duration of the procedure. Sixty minutes after administration of amoxicillin, an EMR alert would appear on the patient's chart asking the primary team to document the outcome of the provocation challenge and automatically adding a statement for

whether the patient passed their oral provocation challenge to the discharge summary. If the patient passed their challenge, this EMR alert would also direct providers to remove the penicillin allergy from the patient's medical record.

Oral provocation challenges were done on the inpatient floor with a standard nursing ratio of 1:4. Nursing was responsible for administering the dose and remaining in the room for the initial 15 minutes after administration, with a clinical assessment at 15 minutes and a final assessment including vital signs at the end of the 60-minute observation period. Caregivers at

the bedside were instructed to notify nursing for any changes or concerns outside the specified nursing assessments. Nursing leadership was involved early in creation of the pathway and was instrumental in development of the monitoring procedure. For example, the recommendation of the nurse being present at bedside for the first 15 minutes is not required in oral provocation challenges for allergic purposes; however, nursing leadership felt that mirroring the current protocol for blood transfusion monitoring, which has a similar process, would allow for ease of use and buy-in among nurses.

To encourage delabeling, our quality improvement team developed a list in the EMR of patients currently admitted to the hospital medicine service with a penicillin allergy listed. The penicillin delabeling pathway committee members were not involved in clinical decision-making or specific recommendations for eligible patients. However, committee members did review patients admitted to our hospital medicine service with a history of penicillin allergy Monday through Friday using a daily report in our EMR. On the basis of chart review of the documented allergy history and a patient's symptoms while admitted, pathway committee members would identify patients who might be categorized as no increased risk or low risk (Fig 2). A secure message would be sent through the EMR for these patients to the frontline medical provider (typically a pediatric resident) to remind them of the pathway and suggest discussing the patient's history of penicillin allergy on rounds that morning.

Educational Intervention

Because the culture at our institution and many others is to strictly avoid medications to which a patient is reportedly allergic, there was a significant educational component to our quality improvement project. A large part of our success was through including stakeholders in patient safety, hospital medicine, and pharmacy in the development of the pathway. After this, educational sessions were held with nursing, hospital medicine, infectious diseases, pediatric housestaff, and advanced practice providers. These all

emphasized the problem of inappropriate penicillin allergies and its prevalence at our institution. Our education also focused on the low-risk nature of penicillin allergy delabeling and the significant clinical benefits to our patients.

Participation in Quality Improvement Incentive Program

Our institution offers a quality improvement incentive to pediatric residents in the form of a small annual monetary bonus for achieving benchmarks in quality improvement, with typically 3 to 4 projects chosen each academic year. A part of our success can be attributed to our participation in this program. Because the baseline rate of delabeling was ~2.0%, residents received a financial incentive at the end of the academic year if the rate of delabeling was consistently >4.0% and a larger financial incentive if it was consistently >6.0%. As an additional incentive, our clinical pathway committee gave additional recognition to providers in the form of a gift bag anytime a patient was delabeled on their medical team.

Study of the Interventions

We developed a statistical process control (SPC) *P* chart using QI Charts version 2.0.23 (Scoville Associates, Raleigh-Durham, NC) to assess the impact of this intervention pre- and postimplementation of our clinical care pathway. Our SPC *P* chart (Fig 3) calculated the percentage of patients reporting a penicillin allergy at time of admission to the hospital medicine service who had this allergy removed by day of discharge. This was our primary outcome. Data were collected by using time stamps for the allergy tab in our EMR. We performed a retrospective review of these data using a 20% randomly assigned subset of these patients to evaluate data quality. After the penicillin allergy delabeling clinical pathway was implemented in April 2019, the committee continues to prospectively collect data over 12 months on percentage of penicillin-allergic patients delabeled by day of discharge and determines if these patients were at no increased risk (delabeled via education alone) or low risk (delabeled via oral provocation challenge).

Measures

We continue to assess several measures for this project. Our primary outcome measure is removal of penicillin allergy by day of discharge. We assess the reliability of this measure by retrospective chart review for any patient flagged as having their allergy removed. Additional process measures include the number of eligible patients, number of patients excluded, number of patients consented, number of patients who received an oral provocation test dose, and number of patients delabeled by using our EMR order set. Our balancing measure is number of patients undergoing oral amoxicillin challenge who require emergency medication administration (epinephrine or cetirizine) for concern of allergic reaction after oral provocation challenge.

Analysis

Standard SPC chart rules for determining special cause variation were used as evidence of improvement in our rate of penicillin allergy delabeling.¹¹ (Fig 3).

RESULTS

Of the 701 patients who reported a penicillin allergy at the time of admission over the 12-month period after pathway implementation, 82 (11.7%) had their penicillin allergy removed (Fig 3).^{12,13} Special cause variation was seen from the month before pathway implementation (March 2019) for 9 consecutive points above the mean. Inclusion of the month before implementation in the special cause variation was likely due to educational interventions already underway. Among the 82 delabeled patients, 31 (37.8%) were found to be at no increased risk the basis of clinical history and were delabeled without oral provocation challenge. The remaining 51 delabeled patients (62.2%) were in the low-risk category and were delabeled after successfully completing a single dose oral amoxicillin challenge (Fig 4).

There were no significant adverse events, and no patients required treatment with intramuscular epinephrine or oral antihistamines. All delabeled patients passed their oral provocation challenge without any reaction. One patient, who was

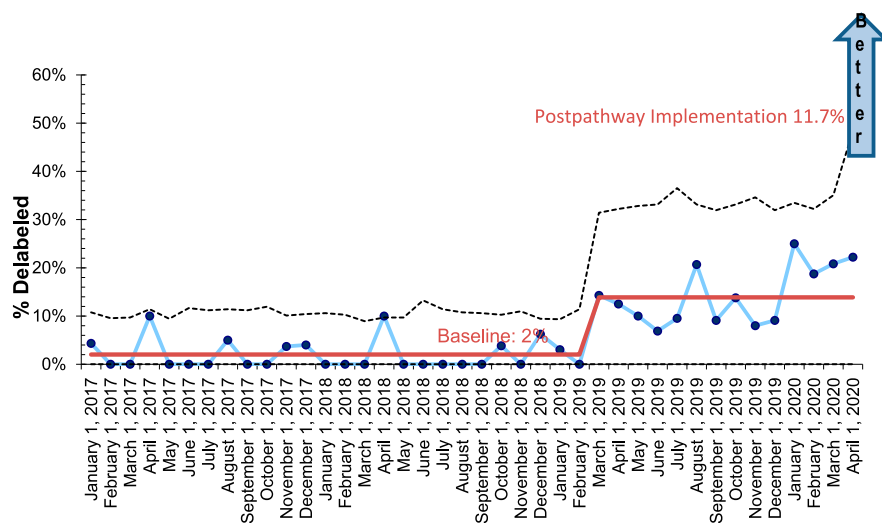


FIGURE 3 Control chart demonstrating percentage of patients with penicillin allergy admitted who were delabeled (y axis) each month (x axis) with our clinical pathway being implemented on April 1, 2019. The dotted line represents the upper control limit. Special cause variation was recognized starting March 1, 2019, for 8 consecutive points above the centerline.

not delabeled, had a delayed and nonbothersome rash that was determined to be equivocal and did not require intervention; this patient was scheduled for a repeat drug challenge in the outpatient setting, which has yet to be completed. Of the 82 patients who were delabeled, 56 (68.3%) patients were discharged on an antimicrobial to treat a presumed infection. Of the 56 patients requiring an antimicrobial, 42 (75.0%) were discharged on penicillin or amoxicillin (Fig 4).

Follow-up on delabeled patients was performed through review of the EMR at 1, 3, and 6 months postdischarge to assess for

“relabeling” of a penicillin allergy. Chart review identified 1 patient who was relabeled after discharge as penicillin allergic, although there was no documented reason in the EMR for any new symptoms, concerns, or return visits for penicillin-allergic reactions.

DISCUSSION

Our multidisciplinary quality improvement project successfully increased penicillin allergy delabeling among hospitalized children without the need for subspecialty consultation. Using available evidence for pediatric penicillin allergies, we developed

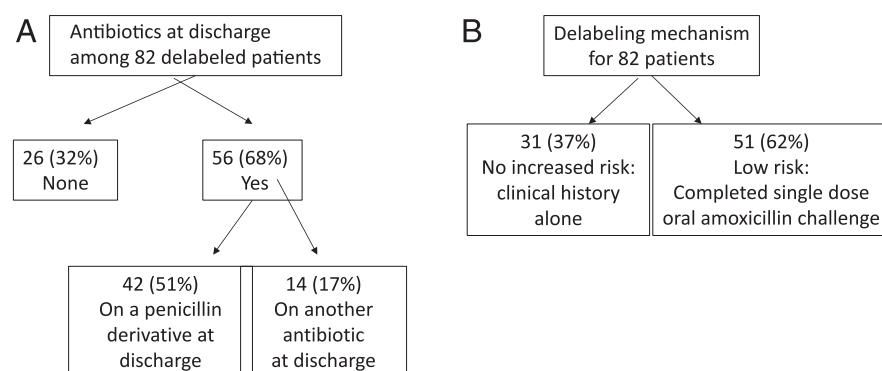


FIGURE 4 Flowchart depicting receipt of antibiotics for patients who were delabeled on discharge (A) and mechanism by which patients were delabeled (B).

an effective clinical pathway that did not require any preceding skin testing or graded oral drug challenges. When paired with a risk assessment tool, our pathway has proven to be a safe and effective strategy to delabel patients of inappropriate penicillin allergies. We met our primary aim of increasing the rate of penicillin allergy delabeling to at least 10% of all hospitalized patients reporting a penicillin allergy immediately after our pathway was implemented. Were it not for this quality improvement initiative, many of these patients would have continued to carry this inappropriate label, leading to suboptimal antibiotic use and associated morbidity.¹ Furthermore, 51.2% (42 of 82 patients) of patients who were delabeled received penicillin for treatment of presumed infection, indicating that delabeling in these 42 patients prevented unnecessarily broad, less effective, riskier, or more expensive second-line antimicrobial agents.

Although we quickly met our primary aim for this quality improvement initiative, there are ongoing opportunities to continue increasing our rate of penicillin allergy delabeling. Of the 701 total patients admitted to the pediatric hospital medicine service with a penicillin allergy after pathway implementation, 619 (88.3%) were not delabeled of their allergy. Some of these patients, of course, are likely to have clinically significant true allergies to penicillin and would be in the moderate or high-risk category on the basis of our clinical pathway risk assessment tool. However, we know that >90% of patients reporting a penicillin allergy can tolerate penicillin without incident, meaning there is ongoing room for improvement. Many of these patients were ineligible for the pathway because of concomitant use of antihistamines or existing symptoms that might be mistaken for allergic reaction, such as wheeze, rash, or vomiting. Unfortunately, because information in the allergy tab is typically not comprehensive enough to perform a thorough risk assessment, it is not possible to determine what proportion of patients could have been delabeled, a limitation that is discussed below. Our next immediate goal is to increase delabeling among hospitalized

pediatric patients to 15% through continuation of our current efforts and additional process refinement. One barrier we have identified is that occasionally an eligible patient is not approached for delabeling because the primary team thinks only patients who require treatment with penicillin during their admission are eligible for delabeling. Therefore, ongoing efforts to educate frontline providers about the pathway will be needed to continue to address barriers and improve our rate of penicillin allergy delabeling. Our long-term goal is to expand our quality improvement initiative to additional inpatient services (ie, subspecialty and surgical services), outpatient specialty clinics, ambulatory surgical procedures, and, eventually, community pediatric practices.

There are several key attributes we believe contributed to the success of this quality improvement initiative. Early in the process of pathway development, we recognized that frontline providers, namely bedside nurses and pediatric residents, were going to be key stakeholders crucial to the success of our pathway. Bedside nurses review allergic history for all patients at time of admission for documentation in the EMR and therefore have the potential to play a critical role in identifying eligible patients early in their hospital stay. To encourage uptake of this pathway among nurses, the nursing leadership was engaged early in pathway development to design our process in a way that would be best for patient care and safety without being too burdensome for nurses on a busy inpatient unit. In addition, getting early success from the pediatric residents who are the frontline providers for hospital medicine service at our institution was crucial. We employed several education sessions during resident training in which we shared our local data alongside published evidence for pediatric penicillin allergy delabeling to highlight an opportunity for improvement at our institution. By having our pathway selected as one of the annual financial incentives for resident quality improvement metrics, this also greatly impacted early uptake of our penicillin allergy delabeling pathway soon after implementation. In fact, because our education of frontline providers began

before the pathway was formally implemented, we think this led to special cause variation for an increase in penicillin allergy delabeling the month before pathway implementation (Fig 3). In addition, we found that by sending secure messages to pediatric residents caring for patients who might be eligible for delabeling, this simple “nudge” helped to keep our improvements sustainable and maintain a high level of awareness for our clinical pathway.

This study has several limitations. First, not all patients with a penicillin allergy were approached because many patients had concurrent clinical conditions that excluded them from oral provocation challenge on the basis of pathway recommendations. However, we feel this would be the case at any institution and reflects true clinical practice because delabeling all hospitalized patients is unlikely to be feasible or clinically appropriate. Additionally, given the limited clinical history in our EMR's allergy documentation section, it is not possible to retrospectively determine which patients would have been eligible for delabeling but were not approached by the team or had families who were not receptive to discussing penicillin allergy delabeling. More specific information in the allergy history documentation could have allowed us to recognize additional barriers to our pathway and identify interventions to improve our rate of penicillin allergy delabeling. Last, our follow-up on patients after delabeling was via chart review available in our EMR. Therefore, it is possible patients developed symptoms concerning for a penicillin allergy after discharge or had the allergy resurrected at outside institutions.

Despite these limitations, our data reveal successful implementation of our clinical pathway to delabel inappropriate penicillin allergies. Requiring allergy and immunology subspecialty consultation for every hospitalized penicillin-allergic patient would be an irresponsible and unsustainable use of hospital resources. Thus, the aim with our quality improvement project was to increase penicillin allergy delabeling by using a strategy that empowers the primary

hospital medicine team to identify patients, determine their risk of clinically significant penicillin allergy on the basis of history, and then to safely delabel patients of inappropriate penicillin allergies. Because we have quickly met our primary aim and sustained our penicillin delabeling rate since pathway implementation, we feel this quality improvement initiative presents a sustainable solution that preserves hospital resources.

CONCLUSIONS

Our multidisciplinary quality improvement project provided a safe and effective method for hospital medicine providers to delabel low-risk hospitalized pediatric patients without the need for subspecialty consultation. The early success of this quality improvement project can help guide other institutions in clinical pathway development aimed at identifying patients with inappropriate penicillin allergies to safely determine if that label can be removed in a controlled environment.

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