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Addressing the Inpatient Penicillin Allergy: Implementing a Nurse-Driven Allergy Assessment Tool to Enhance Antimicrobial Stewardship.

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Addressing the Inpatient Penicillin Allergy: Implementing a Nurse-Driven Allergy Assessment Tool
to Enhance Antimicrobial Stewardship.

Submitted in Partial Fulfillment of the Requirements for the Degree of Doctor of Nursing
Practice at the University of Kentucky

By

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Louisville, KY

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Abstract

Background: In an acute care setting, more than half the inpatient population receives antibiotics. Approximately 10% of the general population reports an allergy to penicillin. It has been replicated in the literature with data that of those who report a penicillin allergy, up to 95% are incorrectly identified. When a patient is admitted to the hospital with a penicillin allergy on their electronic health record, they are at higher risk for adverse events such as a hospital acquired infection, the occurrence of an antibiotic resistant bacteria related to receiving broader therapy and increased healthcare utilization.

Purpose: The purpose of this project was to address the over reporting of penicillin allergies by creating a nurse driven protocol consisting of a focused allergy history assessment to help aid with risk stratification, future de-labeling and promotion of antimicrobial stewardship.

Methods: This was a quantitative quasi-experimental study utilizing a prospective and retrospective chart review. There was a two-group pre/post intervention in which patients with reported penicillin allergies were examined 3 months prior to intervention and 3 months post implementation of the nurse led allergy de-labeling protocol admitted to four adult Norton Healthcare inpatient hospitals (Norton Hospital Downtown, Norton Brownsboro, Norton Audubon and Norton Women's and Children).

Results: The number of patients from the pre-intervention group (n=8, 0.55%) to the post-intervention group (n=13, 0.88%) who were de-labeled increased by 62.5%. However, a chi-square statistical test was performed and revealed that there was no statistical significance (P = 0.28) in the rate of de-labeling. De-escalation occurred in 3 patients in pre versus 1 patient in post sample. Nursing documentation of patient interactions involving allergies resulted in 10 of

the 21 patients de-labeled in the pre- and post-intervention sample, 47.6%. The nurse driven protocol showed 76.9% compliance and had 1131 patient interactions out of 1472 patients admitted with penicillin allergies.

Conclusion: Although there was no statistical significance between pre- and post-group samples, with no active intervention it was nonetheless determined to be an improvement. Additionally, multidisciplinary education is needed for the healthcare team to enhance compliance and promote de-labeling . In addition, developing education for the patient when allergies are de-labeled and removed from the electronic health record. Nonetheless, the nurse driven tool was successful at filling the resource gap and gathering patient data when used correctly showing the potential it has in a multi-modal de-labeling approach within the multidisciplinary team upholding that nurses are essential to antimicrobial stewardship programs and their role within should be expanded.

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Dedication

To my wild and patient Caroline,

This was all for you. I know sometimes it seemed like you would never have your mommy back but finally, we made it. Now we can have this moment to celebrate, rest and enjoy this view together. Tink, mommy worked so hard to show you that no matter what happens in life or what obstacles may present themselves, you will always be bigger, stronger, and much more powerful than any goliath you may face. I will always be there to encourage you, lift you up, and help grip ahold of the weight you may bare to support and fight along with you whenever you need or even if you don't. I promise that you will never be made to go through anything alone, ever. Everything I've done the last few years including every decision I've made, every person I've walked away from, all the things I've ran towards and each sacrifice I've let go of was done to benefit you no matter the impact it had on me. You gave me the perseverance to continue when I wanted nothing more but to lay down and surrender. You are my greatest and most important 'why'. My hope for you is to one day when you're out in this intimidating world, you find your own 'why' and reason to not give up. You hold on tight to your truth, stand firm, don't sway and allow it to drive your own dreams, passions and goals to completion like you helped drive mine.

I also dedicate my work to the late memory of Mary Griffith, the first influential woman in my life that encouraged me to reach beyond my tangible grasp and showed me that the success I craved was attainable. I never dreamt I was capable of this until I met a woman of her caliber. Her voice softly saying, 'do well by doing good' will always echo in my head throughout my career and practice.

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Background

Problem Statement

In an acute care setting, more than half the inpatient population receives antibiotics. Approximately one fourth of patients report an allergy to an antimicrobial. Of the patients hospitalized, 10-15% have a reported beta lactam allergy (Blumenthal et al, 2017). These patients often times receive broader spectrum, less effective and sometimes more toxic antibiotics. Patients who have a reported beta lactam allergy and who are treated with a different class antibiotic have an increased risk of therapy failure and the occurrence of an adverse event (MacFadden et al., 2016). Previous data from outpatient and inpatient settings suggest that all patients who report a beta lactam allergy are not truly allergic to that class of antibiotic (Blumenthal et al, 2017). In fact, 95% of those who claim an allergy and are tested actually have no adverse effect or event and are found to actually tolerate penicillin and other related beta lactams, demonstrating the lack of detectable penicillin-specific IgE-mediated antibodies (Blumenthal et al, 2017). Furthermore, up to 80% of patients with a true beta lactam allergy lose their IgE antibody sensitivity after a decade (Chua et al, 2020).

When a patient suffers an adverse reaction to penicillin in childhood, there is often times an uncertain correlation between the underlying diagnosis and casual attribution of the penicillin administered, leading the physician to falsely label them allergic (Edwards & Aronson, 2000). A recent study found that primary care physicians (PCP) are the most likely to initially label a patient allergic to penicillin (Vyles et al., 2019). Once a patient is labeled “penicillin allergic,” patients often retain the label through adulthood (Vyles et al., 2019, Caubet et al., 2011). A

qualitative study from 2019 found that many PCPs knew that the documented allergies were incorrect but they were uncomfortable with using their clinical judgement to prescribe a penicillin or change the patient's health record in fear of a future anaphylactic reaction (Wanat et al., 2019). Because of this oversight, the Centers for Disease Control and Prevention and the Infectious Disease Society of America encourage thorough penicillin allergy history and evaluation outpatient and in an inpatient acute care setting (Blumenthal et al, 2017).

Consequences of problem

Alternative antibiotics used in the clinical setting of a penicillin allergic patient may be less efficacious and result in suboptimal outcomes (Stern et al., 2021, Trubiano et al., 2015, Trubiano et al., 2016). A providers mindful choice to avoid penicillin may also lead to the avoidance of other beta lactam therapy, especially cephalosporins (Macy & Blumenthal, 2018). For example, the aminoglycoside vancomycin is less effective against methicillin-sensitive *S aureus* (MRSA) bacteremia than nafcillin or the beta lactam cefazolin (Macy & Contreras, 2014).

Beta lactam antibiotics including cephalosporins like cefazolin are the mainstay of surgical antimicrobial prophylaxis (Bratzler et al., 2013). Although the occurrence of a true cross-reactive IgE-mediated response is very rare between a penicillin and cephalosporin, the American Society of Health-System Pharmacist clinical guideline indicates to avoid giving patients cephalosporins and carbapenems in the event of surgical prophylaxis if an IgE- mediated penicillin allergy is believed to have occurred or is documented (Bratzler et al., 2013). Therefore, patients with documented penicillin allergies often times receive less optimal alternative therapy with less efficacy, increased cost and adverse events with antimicrobials such as clindamycin, vancomycin,

or gentamycin, resulting in these patients being placed at an increased risk of surgical site infections (Blumenthal et al., 2018).

The chronic overuse of broader spectrum antibiotic therapy due to inappropriate allergy labels contributes to the growing incidence of antimicrobial resistance in the inpatient population. This has been a catalyst for increasing number of resistant organisms such as Methicillin-resistant *Staphylococcus aureus* (MRSA), Vancomycin-resistant *Enterococcus* (VRE) and *Clostridium difficile* infections for patients who report a beta lactam allergy (Chua et al, 2020, Macy & Contreras, 2014). A cohort study conducted by Macy & Contrearras (2014) compared antibiotic exposures and the prevalence rates of *Clostridium difficile*, MRSA, and VRE in patients with and without a penicillin allergy at hospital admission. After two years of observation the investigators concluded that patients labeled with a penicillin allergy were treated with significantly more fluoroquinolones, clindamycin and vancomycin ($p < 0.0001$) for each antibiotic compared with the control group. Penicillin allergic patients also had 23.4% more *C difficile*, 14.1% more MRSA, and 30.1% more VRE infections in comparison to the control group (Macy & Contreras, 2014).

Beta lactam allergies have also been associated with increased hospital length of stay, patient mortality and drug cost (Macy & Contreras, 2014, MacFadden et al., 2016). Studies have found that the prolongation of hospitalizations in these patients seem to be arbitrated by increased treatment failure from less effective, alternative antibiotics (Jeffres et al., 2016). Additionally, MacFadden et al. (2016) demonstrated that patients who did not receive the preferred beta lactam therapy as a consequence of an allergy label had greater risk for multiple unfavorable outcomes (aOR 3.18 95% CI 1.28-7.89). These adverse events, increased lengths of

stays, surgical site infections (SSIs) and treatment failures have shown to be amendable by removal of the penicillin allergy label (McDaniel et al., 2017).

Treatment failures related to decreased efficacy and the unintended adverse effects of alternative antimicrobials lead to increased cost to the patient and healthcare utilization. A study by Li and colleagues (2014) concluded that alternative antimicrobials were more expensive than if the patient could tolerate penicillin. Increased length of stays, SSIs, and treatment failures are all costly outcomes that are inflated in the context of the penicillin allergic patient. Inpatients with a listed penicillin allergy had direct drug costs ranging from no difference to \$609 per patient more than patients without a listed penicillin allergy (Macy & Contreras, 2014). A retrospective cohort study out of California found that patients also had an average 3-year total estimated additional healthcare expense of \$64.6 million (based on an average hospital day cost of \$2,123.56 in 2012) or about 9.5 times as much as penicillin allergy testing would have cost (Macy & Contreras, 2014). The removal of “penicillin allergy” from a patient’s medical record has been found to be extremely cost effective thus de-labeling of unnecessary penicillin allergies could be a monumental stride towards appropriate healthcare utilization to reduce cost while simultaneously protecting patients from adverse outcomes.

Current Evidence Based Interventions

Greater recognition of the consequences of the penicillin allergy has led to expanded efforts by hospitals and other healthcare organizations to develop processes by which patients can be de-labeled as a part of their antimicrobial stewardship initiatives. There are various methods to address inpatient beta lactam allergies. Previously, there has been routine penicillin skin testing with various success rates. Other organizations utilized routine allergy consultation,

with or without oral dose challenges and patient screenings performed by the pharmacist (Blumenthal et al, 2017). Blumenthal et al. (2015) reported a pharmacy-driven patient allergy history interview that revealed 65.6% of patients were switched to beta lactam antibiotics.

A systematic review and meta-analysis of 24 studies concluded that inpatient penicillin allergy testing is safe and effective in ruling out a penicillin allergy (Sacco et al., 2016) . The authors found that these patients should be evaluated and tested during their hospitalization given its benefit for patient outcomes and antimicrobial stewardship (Sacco et al., 2016). In an ideal world, every patient who has a penicillin allergy would be referred to an allergist for evaluation; however, the number of allergy specialist compared to the number of patients who report a penicillin allergy in the outpatient and inpatient setting is largely disproportional. Similarly, the availability of trained pharmacist to conduct focused interviews of patients admitted to the hospital documented to have a penicillin allergy proves to be the same. The ratio is extremely unbalanced. When considering the resource limitations, this approach becomes unrealistic and unattainable (Stern et al., 2021).

As mentioned, penicillin allergy de-labeling can take one of many forms. Evaluating the allergy by the details of the allergy history alone utilizing a point of care assessment tool for risk stratification could potentially de-label patients with non-immune mediated reactions which account for 20% of all penicillin allergies (Trubiano et al., 2015). By doing this, it targets patients with inaccurate allergy labels attached for reasons such as gastrointestinal symptoms or a family history. This approach also targets those where previous tolerance of a penicillin can be evaluated through a retrospective chart review. These proactive approaches require involvement of all members of the healthcare team. Therefore, to actively manage and evaluate

penicillin allergies, a proactive and collaborative approach is a necessity to prevent incorrect labeling as well as strategies to both assess and de-label patients.

Purpose of Proposed Project

The purpose of this project was to assist in addressing resource limitations associated with the evaluation of penicillin allergies by creating a nurse driven protocol consisting of a targeted allergy history assessment tool to help segment this large population with a risk stratification methodology to promote antimicrobial stewardship. This protocol could assist with identifying patients who may be eligible to be directly de-labeled of their penicillin allergy or undergo further investigation so challenge testing can be considered by an antimicrobial stewardship team in the future. Addressing the resource limitations could potentially allow patients to be de-labeled of this allergy more frequently leading to a reduction of potential future adverse events, occurrence of resistant bacteria and a decrease in overall healthcare utilization.

Objectives

1: Retrospective review of medical records prior to implementation of a nurse-driven protocol by examining:

- a. Number of appropriately de-labeled patients
- b. Number of patients receiving appropriately targeted antibiotics

2: Prospective review of medical records to determine success of allergy de-labeling following implementation of a nurse-driven protocol by examining:

- a. Compliance of complete admission screenings entered by nursing staff
 - b. Number of appropriately de-labeled patients
 - c. Number of patients receiving appropriately targeted antibiotics
3. Compare rates pre- and post-nurse-driven screening protocol of appropriate de-labeling and appropriate targeted antibiotic therapy in patients admitted with a beta lactam allergy at Norton Healthcare.

Theoretical Framework

This project consist of a quality improvement intervention. The PARIHS framework was used to guide this study. PARIHS stands for 'Promoting Action on Research Implementation in Health Services'. The PARIHS framework proposes three components (evidence, context, and facilitation); these factors are all related and work cohesively for successful implementation. The framework emerged from the following equation: $SI = f(E, C, F)$, where SI = successful implementation, E= evidence, C=context, F= facilitation and f= function of.

The first of the 3 components, evidence, is defined as knowledge that supports the effectiveness of the quality improvement intervention and is a combination of research, clinical expertise and patient choice. For each of these elements, a range from high evidence that supports effectiveness to low evidence to support effectiveness may be revealed. For successful implementation of evidence that supports the intervention a literature search was performed to find RCTs, systematic review and evidence-based guidelines to support high evidence. There was also high levels of consensus among clinicians acknowledging that mis-labeling patients as penicillin allergic is a problem in healthcare and there was a consistency of shared viewpoints

regarding the matter. Lastly, patient involvement in the de-labeling process with the allergy history assessments as well as the evidence to support the many benefits of de-labeling promoted a sense of partnership with patients.

The second component, context is defined as the environment or setting in which the intervention is being implemented. Context has been subdivided into three core elements on a range from low to high: an understanding of the prevailing culture, the nature of human relationships as summarized through leadership roles, and the organization's approach to routine monitoring of systems and services, measurement (Kitson et al., 1998). Using this ideology, Norton Healthcare was analyzed and found to be a high contextual environment as evidence by being a patient centered, learning environment with continuing education. Clear leadership and effective organizational structure that values its employees has been established with routine monitoring systems, audits and peer reviews.

The final element is facilitation. This is defined as the technique or process used by a person (i.e., the facilitator) to help others change their attitudes, skills, or behaviors and thereby improve the likelihood of success of the intervention (Kitson et al., 1998). Facilitators are seen as people who makes things easier, helps others towards achieving particular goals, encourage others, and promoting action. In the context of implementing research into practice, the facilitator's main job is to help people understand what they have to change and how they change it to achieve the desired outcome.

Successful implementation is dependent upon the relation between the nature of the evidence, the context in which the proposed change is to be implemented, and the mechanisms

by which the change is facilitated (Kitson et al., 1998). This doctoral project was built on evidence-based practice, emphasizes implementing the intervention and evaluation of the outcomes while utilizing this framework to drive it toward success.

Review of Literature

Methods of Search

Mis-labeled penicillin allergies currently account for an overwhelming 95% of the total number of penicillin allergic patients (Blumenthal et al, 2017). Alternative antibiotics used in the clinical setting of a penicillin allergic patient may be less efficacious and result in suboptimal outcomes (Stern et al., 2021, Trubiano et al., 2015, Trubiano et al., 2016). Therefore, the Centers for Disease Control and Prevention and the Infectious Disease Society of America encourages thorough penicillin allergy history and evaluation outpatient and in an inpatient acute care cite. The aim of this literature review is to support the implementation of a nurse driven protocol consisting of an allergy history assessment to help assist with risk stratification and promote antimicrobial stewardship in the inpatient population.

In the search for literature, CINAHL was used and the word search included: beta lactam allergy; Penicillin Allergy; intervention; evaluation; de-labeled. The search was restricted to full text, academic journals in which resulted in 43 studies. The titles and abstracts were reviewed for relevance, and those that included children or adolescents were excluded. In total there were 28 articles for full-text review.

Synthesis of Evidence

Adverse drug reactions affect 10-15% of all hospitalized patients and less than 10% of the general population (Blumenthal et al, 2017, Fazlollahi et al, 2017, Stern et al., 2021). The most common drug hypersensitivity identified is an allergy to beta lactam antibiotics or penicillin. Listed allergies to penicillin and other beta lactams is considered a public health problem if not 100% verified due to the limitations associated with appropriate drug selections and subsequent increased risk of frequent and longer hospitalization, antibiotic-resistant infections, medical cost and death (Fazlollahi et al, 2017, MacFadden et al., 2016, Stern et al., 2021, Trubiano et al., 2015, Trubiano et al., 2016). These allergy documentations are often inaccurate and more so reflect a common adverse drug reaction or intolerances including diarrhea, nausea, vomiting and headache as opposed to a true IgE-mediated response (Stern et al., 2021). A documented beta-lactam allergy increases the use of non-beta lactams such as vancomycin, fluoroquinolones and other aminoglycosides (Blumenthal et al., 2018). These alternative agents have been associated with increased cost to the patient, adverse drug events and reduced efficacy in certain clinical situations (Macy & Contreras, 2014, Krey et al, 2019, MacFadden et al., 2016). A population-based cohort study found that once a beta lactam allergy was recorded, there was a 14% increase in mortality risk for patients because they received less effective and/or more toxic antibiotics for subsequent infections (Blumenthal et al., 2019). The study concluded that the clinical outcomes for over 30 millions Americans with recorded beta lactam allergies may improve by proper beta lactam allergy verification and de-labeling. When evaluated properly, 95% of patients with recorded beta-lactam allergies were found to be not allergic (Blumenthal et al., 2019), (Stern et al., 2021). There are various methods to address inpatient beta lactam

allergies from the literature. Articles were discovered that discussed a nurse driven quality initiative intervention that did not show much success or difference in outcomes 3 months following implementation (Fabre et al. 2020). Although in the first 3 months there was no improvement, ongoing testing is needed to validate such findings.

Other organizations adapted a pharmacy-driven quality initiative with varying success rates. Previously, there has been routine penicillin skin testing. Other places utilized routine allergy consultation, with or without patient screening performed by pharmacist (Blumenthal et al, 2017). Some organizations have even targeted penicillin allergies only for inpatients with specific infections or those prescribed specific beta lactam alternative drug therapy such as Aztreonam (Azactam) (Blumenthal et al., 2017). One study concluded that multidisciplinary education coupled with pharmacy-led efforts and proper documentation of allergy reaction type by nursing to confront the challenge of beta lactam allergies among hospitalized patients actually increased the number of patients that transitioned from non-beta lactam therapy to beta lactam therapy while inpatient (Krey et al., 2019). A pilot study evaluated the effect of pharmacist driven allergy interview. Thirty-two patients were interviewed who had a documented beta lactam allergy. Out of the 32 patients, one-half were found to have reactions consistent with type 1 hypersensitivity and through a thorough medication history, it was found that these patients have received and tolerated more than 1 dose of a previous beta lactam persuading the providers to switch them from a non-beta lactam antibiotic to a more appropriate therapy option with a beta lactam in 26 of the patients interviewed (Sigona et al., 2016). It was concluded that a pharmacist-driven beta lactam allergy interview was effective in switching eligible patients to cephalosporin, carbapenem, or penicillin therapy and identifying

discrepancies between electronic health record (EHR) documented allergies and confirmed allergies (Blumenthal et al., 2015). Also, the pharmacists' antimicrobial recommendations were well received by medical providers, and all patients tolerated the prescribed beta lactam thereafter (Sigona et al., 2016). One healthcare system adapted a test dose challenge to verify true allergies. The outcome from this retrospective study increased beta lactam use by 80% across 5 acute care hospitals in one healthcare system (Blumenthal et al., 2019).

After verification of the existence or not of the allergy, the next step in prescribing beta lactam therapy becomes updating the electronic health record. Beta lactam allergy relabeling in the EHR resulted in a significant increase in the percentage of beta lactam antibiotics prescribed when the allergy label was removed or updated appropriately (Stern et al., 2021, Gaberine et al., 2020). By de-labeling and updating the EHR judiciously, this will enable the optimization of future treatment options with first-line therapy and decrease the risk associated with prescribed non-beta lactams (Shaw et al., 2020).

Identification of Knowledge Gap

In the clinical setting, there is currently no defined procedure or multidisciplinary process for identifying and evaluating the authenticity of penicillin allergies even though there is an overwhelming amount of evidence to support such. The purpose of this literature review was to show that the implementation of a multidisciplinary evidence-based tool to evaluate penicillin allergies improves patient outcomes and healthcare spending. The intent is to implement a collaborative, nurse-driven protocol containing an allergy history assessment by utilizing risk stratification to assist with future evaluation, de-labeling and promote antimicrobial stewardship. This project could potentially to reduce the redundancy of falsely reported penicillin allergies

and diminish the overall use of less efficacious therapy thus decreasing the suboptimal consequences that follow, improving healthcare utilization and optimizing patient outcomes.

Methods

Project Design

This project utilized a retrospective view into prospective quantitative quasi-experimental design utilizing an in-person encounter and/or an electronic health record review of patients who meet inclusion criteria. A two-group pre- and post-intervention sample type was used. If included in the prospective sample, patients had a penicillin allergy, admitted to an inpatient bed and were interviewed face-to-face through the admitting nurse or via family member regarding penicillin allergy reaction history and the answers were recorded in the electronic medical record with an assessment tool specifically designed with this study in mind. The project also involved a retrospective electronic health record review of patients who met inclusion criteria. The pre-intervention period was October 1st, 2021 to December 31st, 2021. The post-intervention sample was collected between January 11th, 2022 through March 31st, 2022. It was expected that patients who were admitted to the hospital with a penicillin drug allergy, through the admission and evaluation process, that at least 90% will have been interviewed with the penicillin allergy screen in the prospective sample.

Setting

Agency Description. Norton Healthcare not-for-profit hospital and health care system and now has five adult acute care hospitals and one pediatric hospital. The hospitals provide inpatient and outpatient general care as well as specialty care including heart, neuroscience, cancer,

orthopedic, women's and pediatric services and serves over 600,000 patients annually. A strong research program provides access to clinical trials in a multitude of areas. The mission and purpose of Norton Healthcare is to provide quality healthcare to all those that they serve in a manner that responds to the needs of their community and honor's their faith heritage. The vision of this organization is to be the region's most comprehensive, strongest and preferred health care organization, setting the standard for quality and caring. At Norton Healthcare, the values they hold are respect every person, set the standard for quality and caring, continually improve care and service, demonstrate stewardship of resources, accept accountability of results and succeed with integrity. This project is aligned with the mission to provide quality healthcare, Norton's vision for setting the standard for quality and the values of continually to improve the care delivered to the patients it serves while demonstrating stewardship of resources.

Stakeholders. For this project, several stakeholders were involved. First, the DNP project will consisted of Dr. Sheila Melander, the chair, Dr. Jacob Higgins, committee member, Dr. Matthew Song, the clinical mentor and Dr. Amanda Wiggins, the statistician. In addition, The Norton Research office had a vested interest in the care of patients participating in clinical research coordinated with Norton Healthcare. At the clinical sites, various hospital directors agreed to support the project implementation as well as the nursing educators helped to disseminate the project information to target nursing staff and providers. Nurses were key participants in completing the nurse driven protocol. Lastly, but most importantly, the patients were stakeholders. The patients with a reported penicillin allergy are also considered to be main stakeholders of this study given they are ultimately going to benefit the most from having improved outcomes overall.

Site Specific Facilitators and Barriers. There were several facilitators of completing this project successfully at Norton Healthcare including leadership and administrative buy-in, ensuring that the mission, vision and values of Norton aligned with the projects aims, and the availability and willingness to participate from the bedside staff and providers. The main barriers to implementation were turnover, employee burnout, reluctance to participate from staff, continuity of the study post implementation, as well as continued momentum and compliance. To overcome these barriers, timely and repeated follow-ups with study personnel, re-education, quality improvement, as well as the antimicrobial stewardship team were considered for implementation and evaluation. Ample educational material were prepared and dispersed to the providers and bedside staff prior and post implementation.

Sample

The sample consisted of adult inpatients who had a penicillin allergy documented on their electronic health record age 18-99. A sample was collected pre-intervention during the months of October 1, 2021 to December 31st, 2021. A sample was also be collected post implementation of the quality improvement intervention during the dates of January 11th, 2022 to March 31st , 2022. Inclusion criteria were patients who had 1) a recorded penicillin allergy, 2) 18 years or older with decision making capabilities or a Power of Attorney/appointed health surrogate, and 3) admitted to an inpatient bed. Exclusion criteria were 1) no documented penicillin allergy 2) followed by hospice not seeking curative care, 3) patients who are not in the general inpatient areas such as OB, Psych, Endoscopy and surgery.

A sample of 1,456 patients met inclusion criteria from October 1st, 2021 to December 31, 2021 and a sample of 1,472 met criteria from January 11th, 2022 to March 31st, 2022 during the post implementation period of the intervention to Norton Healthcare.

Procedure

IRB Approval. Prior to the study, University of Kentucky's Institutional Review Board (IRB) approval was obtained (eIRB #70486) and approval to conduct the study at Norton Healthcare from the Norton Research Office (NRO) was obtained. Informed consent was waived for this study. The first component of data collection was a retrospective chart review and the second component was a prospective chart review. The healthcare system's research IT department compiled a list of medical records meeting inclusion criteria from the system's electronic database within the defined timeframes and was then handed over to the primary investigator.

Norton Healthcare Approval. After gaining authorization to carry out the study from the NRO, the primary investigator (PI) then sought permission to begin the planning phase at Norton Downtown Hospital from the chief nursing officer (CNO). At the conclusion of the proposed project presentation, the CNO favored the project idea and requested that it instead be implemented at the system level. The PI then met with the Norton Healthcare system directors and educators during an operations meeting. In congruence with the CNO, system leaders favored the proposed project and gave approval to implement system wide.

Study Intervention. The idea of the nurse-driven protocol was developed based on an integrative literature review to find affordable, collaborative, practical and effective interventions to address this large population of patients who have the label of being penicillin allergic. The goal of the

study team was to ensure the allergy and reaction history on every patient admitted to Norton Healthcare with a penicillin allergy was obtained and to have the answers readily available to the clinicians while not adding to the nurses already heavy workload.

To do this, the PI and an Infectious Disease (ID) pharmacist who is a member of Norton's Antimicrobial Stewardship Program, worked together over the course of several months. The ID pharmacist, who is the subject matter expert on antimicrobial stewardship and penicillin allergies, constructed 8 specific allergy history questions (Appendix A) relating to penicillin to help differentiate between a true IgE-mediated response and an adverse side effect to penicillin. Any one of the 8 questions and their answers could potentially assist in leading providers into making a more informed decision.

The two members of the study team also had several meetings with the Clinical Informatics Manager of Norton Healthcare to work in collaboration with building the protocol into the electronic charting system that Norton utilizes called EPIC. During these collaborative interactions, one of the jobs of the PI was to act as the nurse champion and to find a solution to the proposed problem of not adding to the nurses workload and ensuring the nurses had to take no additional steps to complete the questions. By doing this, optimistically, it would promote compliance from the nurse stakeholders while also guaranteeing an effortless and practical transition into the implementation of the intervention. The solution was placing this intervention strategically into the nursing required admission documentation (RAD) inside of the admission navigator.

The nursing RAD is a list of 26 information gathering points that a nurse must document on when a patient is admitted to the hospital. These points includes a patient's past medical and

social history as well as verification of a patient's allergies or acknowledgement of no known allergies. Prior to the intervention, when verifying a patient's allergies on admission, a nurse had to confirm or deny the existence of the allergies listed or update the EHR with a new allergy the patient may report. After a discussion between the study team, it was decided and agreed upon to build the study intervention into the RAD after the patients allergy verification making it the 27th point of every patient for the nurse to document on.

In addition, the study team also worked in collaboration with the Clinical Informatics Manager to determine how and where they placed the answers to the questions so that the answers could both be easily accessible, viewed and documented on if needed by multiple disciplines to meet all workflows involved in the patients care. After some discussion, the answers were built into the patients storyboard and designed where if someone was to hover over a patient's allergies and the patient was allergic to penicillin, the answers would be revealed without ever leaving the patients summary page.

The intervention was inclusive of the bedside nurse whose role was to interview the patient with the aforementioned constructed 8 question intervention (Appendix A) while documenting the answers appropriately in the EHR on admission to the inpatient setting using the nursing admission navigator.

The procedure will be as follows:

1. After verifying the patients allergies, the nurse will move forward to the next section of the navigator titled "PCN Allergy Questions".
2. One question will be displayed asking if the patient has a penicillin allergy. If the patient has a penicillin allergy, the nurse must select 'yes'.

3. When yes is selected, the remaining list of the 8 research driven questions will be revealed and cascade down.
4. The nurse will ask the patient the questions and record the answers appropriately in the EHR.
5. If the patient does not have a penicillin allergy, the nurse will select 'No' and no questions will cascade.
6. Once the questions are answered or the nurse selects 'No', the nurse can move forward to the next section of the navigator. The intervention is complete.

The patients penicillin allergy and the answers to the 8 questions regarding their reaction only went under review by the provider or pharmacist if clinically indicated.

During the time frame of data collection and thereafter, education was provided to the bedside nurse and providers regarding penicillin drug allergies and evidence to support de-labeling. Nurses were also given education on where to locate the tool in the EHR, indications for use, and how to complete it. Additionally, providers were delivered separate education on how to access the answers and resources on next steps. The ID pharmacist participating in the study made the ID pharmacists at the other 3 adult hospitals aware of the intervention and how to utilize it.

Demographic measures. For this study, patient's sex, infection, previous recorded allergy reactions, previous received antibiotics, allergy reaction comment and deletion comment were obtained by chart review.

Data collection. Retrospective and prospective data collection for this study began with the admission process and EPIC audits/reports on those who have beta-lactam allergies admitted to inpatient daily during the aforementioned dates. Prospective data collection, post intervention was followed by the nurses reviewing the allergies during the admission process with a constructed penicillin allergy history screening tool and the clinicians updating the EHR if indicated. At the conclusion of the data period, a data request was obtained through the information technology department of Norton Healthcare. All data was recorded on an excel spreadsheet and then transferred to SPSS, a data analysis software.

Data Analysis. Descriptive statistics were used when describing the pre- and post-intervention samples. Analysis was tailored to the three main objectives of this doctoral project. After the main objectives were collected and analyzed, additional themes that arose from the data collected were analyzed further. The chi-square test of association was used to examine differences in rate of patients who were de-labeled of the penicillin allergy pre-intervention versus post-intervention. P-values less than 0.05 were considered significant.

Timeline of Project. This doctoral project was completed within a 6-month time frame. Pre-implementation and retrospective data collection from Norton Healthcare began October 1st, 2021 and concluded December 31st, 2021. Post-implementation and prospective data collection began January 11th and concluded March 31st, 2022. System education was sent to providers and nurses at the beginning of January 2022.

Results

The pre-intervention sample population was 1456 patients. Of this sample, 1164 had no change to allergy status. However, 292 had at least one documentation event after admission

with 8 patients who had penicillin removed from their electronic health record. Upon chart review, all 8 patients had true de-labeling occur. Of these 8 patients, 62.5% were females with the average age being 57.4 years old. Discontinuation reasons consisted of allergy being miscategorized in 62.5% of patients, erroneous entry for 25% and clinically insignificant in 12.5%.

The post-intervention sample was 1472 patients. Of the post-intervention group, 1229 patients had no change to allergy status or documentation of allergy while 243 patients had at least one documentation event after admission and 16 of these patients had the penicillin allergy removed from their electronic health record. After a thorough chart review, it was found that there were 3 cases where de-labeling did not actually occur. The majority of these patient were females, 76.9% (n=10) with the mean age of 54.8 years old. Reasons for removal included clinically insignificant 76.9% (n=10), erroneous entry 7.7% (n=1), and entry miscategorized 15.4% (n=2).

Therefore, the number of patients from the pre-intervention group (n=8, 0.55%) to the post-intervention group (n=13, 0.88%) who were de-labeled increased by 62.5%. However, a chi-square statistical test was performed and revealed that there was no statistical significance (P = 0.28) in the rate of de-labeling.

	Pre-intervention (n = 1456)	Post-intervention (n = 1472)	<i>p</i>
Allergy removed	8 (0.55 %)	13 (0.88 %)	(0.28)
Allergy not removed	1448 (99.5%)	1459 (99.12%)	

Retrospective into Prospective Data Collection

A chart review was performed of those who were de-labeled in both the pre-intervention and post intervention sample. In the retrospective sample (Appendix B), seven of the eight

patients had the penicillin allergy removed from their EHR and received antibiotics with 85.7 % (n=6) receiving penicillin or another beta lactam/beta lactamase inhibitor. Nearly 43% (n= 3) of patients received one or more type of a first or second generation cephalosporin with 2 patients overlapping and received a derivative of penicillin in addition to a first and/or second generation cephalosporin.

Of the post intervention sample (Appendix C), 62.5 % (n=10) received antibiotics. Penicillin and beta lactams were administered to 30% (n=3) and first or second generation cephalosporins were given to 10% (n=1).

Nurse Driven Penicillin Allergy Navigator Data

There were 1131 interactions with the penicillin allergy navigator. Nurse compliance was 76.9% (n=1472). Of those screened, 51.5% (n=582) had complete documentation. Of the patients who the screening was attempted, 90.9% (n= 1028) answered yes to having an allergy while 8.5% (n= 6) answered no and 0.6% (n= 7) had no answer selected but did have further questions completed in the screening. Nearly 52% answered that their reaction was greater than 10 years ago, 14.5% answered their reaction was less than 10 years ago. When asked if the reaction happened after the first dose 27.6% answered yes and 5.8% indicated no. Nine and a half percent stated their reactions started after several doses and 17.8% stated it did not occur. Study participants were asked if their reaction required hospital or ED care and 17.2% said yes and 19.9% said no. Six and a half percent of people reported needing treatment with epinephrine while 21.4% denied. When asked if they had taken Amoxicillin since reaction without issue, 108 patients said yes and 148 said no. When they were then asked if they have taken Keflex without issues since, 124 said yes and 107 said no (Table 1.).

Discussion

Retrospective and Prospective Rate of De-labeling

In this project, there was not an intervention put into place that proactively sought out patients to de-label. Therefore, even though the absolute values were low, there was nearly a 63% increase from the pre to post intervention groups for patients who were de-identified as penicillin allergic (0.55% vs 0.88%, $p = 0.28$). Given the similar size of the sample groups and previous de-labeling patterns within the system, it was determined that this was an improvement, however not statistically significant. Additionally, there was no way of knowing for certain if the nurse-driven assessment was the reason for the increase for the de-labeling or if this was simply by chance.

Retrospective Chart Review

The retrospective chart review revealed multiple themes. The breakdown of each individual de-labeling cases can be found in Appendix B. First, nurses were the primary discipline to remove the allergy from the EHR in 5 out of the 8 cases identified, however not on admission to the hospital. In two of the patient cases, the allergy was removed by an infectious disease physician while reviewing allergies and previous tolerated medications when deciding antimicrobial choices.

This review also supported that updating the chart timely and providing adequate education to the patient until learning is achieved regarding their allergies and removal is essential for the healthcare process. In one case of de-labeling in the retrospective group, a patient had a known MSSA infection with a penicillin allergy documented in 2012 (Appendix B.6). The allergy history events show that this patient's allergy to penicillin was re-added twice and

removed three times over the span of five months by multiple different disciplines, inpatient and outpatient, on the healthcare team. An inpatient pharmacist attached the comment “Tolerates Nafcillin” after the patient tolerated a Nafcillin graded dose challenge led by infectious disease while admitted with MSSA bacteremia. However, the allergy was not removed from the chart until nearly a month later by another inpatient pharmacist. A primary care provider (PCP) read and removed the allergy in the same day nearly two months following when the patient was seen for outpatient follow-up. Thus, it could be the case that the PCP saw the comment from the IP pharmacist attached to the allergy, therefore it was removed again. In the coming months, the patient was readmitted with recurrent MSSA bacteremia where the allergy was re-added by the nurse on admission. The patient was placed on empiric IV Cefepime and Vancomycin for initial treatment. The allergy went under review by the ID physician, removed for the third time and the patient was de-escalated to first line therapy with IV Nafcillin. The allergy being re-added by the PCP and a nurse leads one to believe that this patient may still be reporting that they have a penicillin allergy. This brings into question whether or not the patient was made aware that their allergy had been disproven and removed from their health record or if the patient understood what tolerating the Nafcillin graded dose challenge meant during their initial admission. This supports the notion that patient education in the event of allergy de-labeling is crucial.

Secondly, 4 cases were identified to have been de-escalated from broader spectrum therapies and switched to first line treatment with a first generation cephalosporin or beta-lactam (Appendix B.1, B.6, B.7, B.8) In 3 of the 4 cases of appropriate antibiotic administration, de-escalation only occurred only after the penicillin allergy was disproven or removed via chart

review. Also, a chart review of previous tolerated medications and reactions was documented to have occurred at some compacity and played a role in 4 of the 8 patients de-labeled proving that a multimodal approach via patient interview, thorough chart review and appropriate documentation is essential for de-labeling (Appendix B.1, B.2, B.6, B.8), (Stern et al., 2021, Gaberine et al., 2020, Shaw et al., 2020).

Lastly, 3 of the 8 cases of de-labeling was initiated and ultimately occurred because of the nurses discovery with their patient questions and appropriate documentation when verifying allergies (Appendix B.2, B.3, B.7) The first of the three involved an erroneous entry (Appendix B.7). The nurse noted in the chart, “Caregiver states was a mistake when entered” and removed the allergy from the EHR. Patient was initially started on empiric coverage for HCAP with a third generation cephalosporin and azithromycin. Upon review, the ID pharmacists recommended to de-escalate the patient to ampicillin-sulbactam in which the provider accepted the recommendation.

The second de-labeling initiated from a nurse inquiring about what type of reaction the patient had when exposed to a penicillin (Appendix B.3). The nurse documented dermatitis and the allergy occurred in the patients childhood. Some months later this patient had a complicated hospital course involving multiple surgeries and an intrabdominal abscess. The patient underwent an ampicillin dose challenge which was well-tolerated thus the allergy was removed by the nurse. To finish, a patient had a penicillin allergy noted with the reaction of hives occurring in childhood. On a subsequent admission, a nurse removed the allergy after noting that the patient had taken penicillin and amoxicillin since with no adverse events (Appendix B.2).

These cases highlight the invaluable role at the bedside the nurse plays and their ability to use clinical judgement.

Prospective Chart Review

The prospective chart review revealed multiple themes as well (Appendix C). First, there was a more multidisciplinary involvement in the de-labeling process involving the pharmacists, nurses and providers. Pharmacists were actively involved in 5 of the patient cases where de-labeling occurred compared to 2 in the pre-intervention sample. Their involvement included antibiotic recommendations for de-escalation, graded dose challenges, removal of allergies and updating allergy comments.

During the chart reviews, it was found that 10 of the nurse driven penicillin allergy history screens were used correctly, 3 were not and 3 were not able to be reviewed. Two patients received a graded dose challenge while one was directly in result of the nurse screening tool and the patient was ultimately de-labeled of their allergy. In an interesting scenario, a nurse added a penicillin allergy to the patients' medical record and moved forward to the nurse-driven tool to inquire deeper about the patient's reaction to penicillin (Appendix C.7). This nurse then asked the patient the first three questions before returning to the allergy tab to delete the penicillin allergy that the nurse just added, marking it an erroneous entry. It is uncertain to know, but the allergy history questions may have prevented this patient from being labeled with a penicillin allergy. In another situation, a nurse was verifying allergies with a patient and their family member who denied the patient of having the penicillin allergy (Appendix C.4). The nurse entered a comment attached to the allergy and stated "Father at bedside said he does not believe patient has this allergy, " then removed the allergy from the EHR. The nurse went

forward to the allergy questions, selected no and enter a comment that stated, “Father denied history.” This nurse completed the screen and allergy verification appropriately.

In all three cases where the screen was not completed correctly, additionally, these cases were situations where true de-labeling did not occur. For instance, during admission, a nurse re-added a penicillin allergy to a patient's record with the patient reaction comment of, “Pt reported, not sure but ‘could kill me’”. Upon review by the ID pharmacist, the allergy was removed due to the fact that it originally was removed on 6/30/2021 concluding that it was erroneously re-entered back by the nurse. It's safe to assume during the admission process when the nurse was verifying allergies, the patient may have stated they had a penicillin allergy and requested it to be added back to their medical record. If this did occur, again, it supports that patients need thorough education and to be informed when their allergies are disproven and removed from their medical records.

Another interesting situation that was discovered was a patient was admitted after experiencing hypoxia and suspected anaphylactic shock after receiving their first dose of amoxicillin outpatient. The allergy to amoxicillin and penicillin was added to the EHR on admission day (1/10/2021) by the pharmacist. Two days after admission the nurse removed the penicillin allergy after speaking with the attending provider and commented, “Spoke with Dr. and patient has received amoxicillin and penicillin several times in his life.” Even though the nurse removed the penicillin allergy, the allergy to amoxicillin remained on the EHR with the comment added from the pharmacist, “PCN anaphylaxis entered for hypoxia while patient was exposed to PCN-agent. Per Dr., patient confirmed he has taken amoxicillin/Augmentin multiple times in the past without issue. Provider believes multiple other medical issues could

have contributed to episode of hypoxia (CHF EF =20, COVID pneumonia) and this is an unproved PCN allergy.” As a result, this patient was not truly de-labeled of the penicillin allergy and would more than likely benefit from undergoing further review.

In this sample, there was 1 case of antibiotic de-escalation from piperacillin/tazobactam to Amoxicillin-clavulanate in a patient who was found to have an intraabdominal abscess (Appendix C.1). In 7 of the de-labeled patients, it was documented that the patient had received penicillin or a derivative since initial reaction through a chart review or patient interview (Appendix C.1, C.2, C.3, C.5, C.6, C.8, C.13) .

In 7 of the 13 patients with the allergy removed in this sample, again de-labeling was initiated and ultimately occurred because of the nurses discovery with their patient questions and documentation when verifying allergies (Appendix C.1, C.3, C.4, C.6, C.7, C.8, C.12). For example, a nurse removed an allergy on 3/23/22 after recognizing the patient was not allergic to penicillin following reviewing the allergy comment left by a previous nurse added on 6/18/2014 stating, “Takes amoxicillin without issue”. Thus, the nurse recognized that this patient was not allergic to penicillin and removed the allergy marking it as miscategorized. Comments left by nurses upon allergy verification were found in to 10 of the 21 de-labeling events in the overall study, or 47.6%. This is nearly half of those who were de-labeled demonstrating that the nurses job at the bedside is pivotal in de-labeling these patients and promoting antimicrobial stewardship.

There were also missed opportunities of timely de-labeling present throughout both samples. In the pre-intervention group, there were 2 missed opportunities to remove the allergy (Appendix B.6, B.8). In both cases, the allergy was updated that the patient tolerated a similar

agent that disproved the allergy existed from an ID physician and a pharmacist. However, the allergy was not removed from the EHR until later. In the post-intervention sample, there were 3 patient cases where de-labeling could have occurred sooner and 6 missed opportunities total (Appendix C.1, C.3, C.6). One patient review revealed 3 missed opportunities for de-labeling over the span of 4 years. Shaw et al. (2020) emphasized the importance of de-labeling and updating the EHR timely to ensure the optimization of future treatment options with first-line therapy and decrease the risk associated with prescribed non-beta lactams

Patients with a penicillin allergy also have higher likelihoods of developing hospital acquired infections (HAIs) (Chua et al, 2020). Of those de-labeled pre- and post-intervention, 7 patients total had a current or history of an HAI such as C diff, VRE, CRE and/or MRSA supporting the literature that these patients are at higher risk for adverse events and outcomes thus the manner in which we need to be de-labeling patients should be pro-active, not re-active.

Nurse Driven Penicillin Allergy History Navigator

Even though compliance to the nurse-driven navigator was not 100%, nurses were still able to gather valuable data on patients admitted with a penicillin allergy at a rate that a pharmacist or a physician could not. A main goal of the study team was to fill the gap of resource limitations associated with penicillin allergy de-labeling and transform it into a collaborative approach by utilizing nurses. In a nearly a 3-month period, nurses completed 1,131 focused patient interviews involving penicillin allergies (Table 1). Future studies would have to be completed to determine. The question then becomes 'is quality more important over quantity'. Yes, nurses interacted with the navigator 1 131 times, however, how many of these times are actually influential in penicillin allergy de-labeling. It is uncertain to know if the physician or

pharmacists were the one conducting the interviews, if they would have received different answers.

Each question was selected to carefully assess a patient's history to identify potential risk, the first step in allergy de-labeling. Chua et al. (2020) conclude that over 80% of patients lose their sensitivity to the penicillin allergy after a decade. The navigator collected that 587 patients stated that their reaction was greater than 10 years prior. Using this benchmark, this could very well mean these patients have a lower risk for having a response if exposed to a penicillin.

When asked if patients have received amoxicillin since initial reaction without issue, 108 patients answered yes. In the retrospective and prospective chart reviews above, patients were de-labeled by reviewing previous medications and verifying this alone. A question about cephalexin was asked, a first generation cephalosporin. One-hundred and twenty-four patients answered yes that they have received this medication since their initial reaction. Typically, patients who have a true penicillin allergy cannot receive first or second generation cephalosporins due to very low but present risk of cross-reactivity. These patients are more likely to receive third and fourth generation class therapy. The relevance of this question becomes if a person can tolerate a first generation cephalosporin like cephalexin, which cross chains are almost identical to that of a penicillin, then they also, almost all the time, can tolerate penicillin.

Next, a question was asked to assess whether a true IgE-mediated response occurred. The question read, 'Did your reaction happen after the first dose', 312 patients answered yes while 66 patients answered no. A true IgE-mediated response typically happens within 15 minutes of being exposed to the allergen, however, not always. A second question was asked, did your reaction happen after several doses. This question was used because sometimes a IgE-

mediated response does not occur until the second exposure when the body has created the IgE-antibodies and is exposed to the allergen again. Interestingly, 107 patients answered yes that their reaction happened after several doses and 201 patients replied no.

A question to assess the type of reaction they had was asked by the nurse (Table 1.) . Some of the answers do not imply a IgE mediated response. Of those interview, 24 patients reported a non-itching rash and 33 patients answered yes to nausea, vomiting and diarrhea. These reactions historically are intolerances and adverse reactions to the antibiotics, not an allergic reaction.

By using the answers to these questions, the nurse was able to collect data on a large sample of patients that provided insight to the clinicians on the risk value associated with the patient and their potential reaction to receiving a penicillin. This tool also was able to gather this data on over 75% of patients who were admitted to Norton with penicillin allergies during the specified time frames far surpassing previous efficiency. Further integration of this tool into practice with enhanced teaching for the nurses could have a major impact on outcomes both short term and long term.

Next Steps

This tool is now being used as a standard of practice at Norton Healthcare. The outcomes and rate of de-labeling will be followed as it is further integrated into practice. Furthermore, new ideas developed following this project will be presented to the stakeholders.

Implications for Future Practice

The implications for future practice are boundless. First are the implications involving an antimicrobial stewardship program (ASP). In a formal ASP, the recognized major stakeholders

include the pharmacy, an infectious disease physician, infection prevention personnel, epidemiology or microbiology professionals, and administrative support. By nature, antimicrobial stewardship is multidisciplinary and interesting enough, the only gear that seems to be missing from this clinical machine are nurses. When in actuality, it is the nurse that is the connection between these disciplines and the patient.

Nurses already contribute to the goals of ASPs effectively in our daily nursing practice. For instance, when cultures are ordered or when a standing protocol is in place, early collection of specimens are almost always collected by the nurse. Many of these test have nursing standing orders attached and allows the nurse to use their clinical expertise and judgement to initiate. Furthermore, it is the nurse who often times recognizes the first signs of infection to initiate the order and bring them to the attention of the provider. As highlighted, the nurses role in documentation and verification of allergies in our daily practice aligns with that of ASPs. Many daily activities of the nurses overlap with those of the traditional ASP stakeholders. Therefore, a future implication of practice could be finally recognizing the nurse as a valuable member of the ASP organizational chart and creating a nurse champion to truly make it multidisciplinary, effective, efficient and safe for patient care.

A second implication involving the ASP is implementing routine utilization of an Allergist – Immunologist (AI) for inpatients on a needs-base only such as those identified to be high risk of a reaction by this tool or if not enough information can be provided from the EHR or patient interview to make a determination. This nurse-driven protocol was able to collect allergy histories on patients and the answers could be used to evaluate the potential risk of mild to severe type 1 IgE-mediated reactions if re-exposed. By utilizing the nurses routine position in

patient care to collect this history instead of the AI, it potentially saves time allowing the AI to be more productive and review more patients. The AI could review the answers along with the medical record and only interview the patient if needed to make an informed recommendation on how to proceed with allergy testing. Similar to staff nurses, AIs are often overlooked but nonetheless an invaluable asset to ASPs. In this implication, the tool not only assists in valuable data collection but also assisting in appropriate allocation of resources.

Another major implication for future practice with this tool is expanding it to other areas of the hospital and community. This nurse-driven protocol was only used in the acute general inpatient setting meaning it excluded all outpatient services such as pre-admission testing (PAT), immediate care centers and primary care offices. It also excluded areas in the hospital such as endoscopy, interventional cardiology/Cath lab, pre-op, labor and delivery, mother/baby and surgery. Surgery areas in particular would benefit from utilizing this tool considering first generation cephalosporins are first line therapy in surgery prophylaxis to decrease SSIs. Including this tool as a part of a patient's PATs and based on their answers, placing a referral for an oral dose challenge, skin test or directly de-labeling prior to surgery, could lead to an overall the decrease in adverse events such as SSIs, reduced cost and optimizing patient surgical outcomes. However, when expanding to other areas, a facilitator is recommended to educate and drive the protocol to enhance compliance.

The opportunities with education also come with no limits. The need for education was a theme in the chart reviews and well as when reviewing navigator data. Educating the nurse stakeholders, as the hub of communication between the interdisciplinary team, to know the difference between an adverse effect verses a true IgE- mediated response such as a

maculopapular rash versus hives and cross-reactivity agents enhances the nurses ability to advocate, explore the reaction history more in depth and document appropriately. It is in a nurses daily workflow to verify and acknowledge medication allergies, and yet we are the discipline that are educated the least about them. It is essential for optimizing patient care to educate nurses about medication allergies, what true allergies entail and how to differentiate between the two. If a guideline or reference can be created and placed within the protocol along with ample education delivered, the bedside nurse could make an informed decision regarding whether there is enough information gathered for the allergy to be reviewed for removal. If so, the nurse could proactively initiate and send a pharmacy consult to review the allergy, and if in congruence with the nurses judgement, the allergy could possibly be removed by the pharmacist or could go under further review.

Educating the patient as the key stakeholder is also a future implication for practice. Patients should be educated regarding the penicillin allergy, be adequately informed when it is determined to no longer be clinically significant and the evidence to support such determination be explained to them until adequate knowledge has been achieved. There were multiple instances where a patient was de-labeled of the penicillin allergy, discharged home and on a subsequent admission the allergy was added back on the patients request. The need for education among the patients is arguably the most important because they are the ones who have the most autonomy over their own healthcare. Thus, it is crucial to educate them when an allergy has been disproved and is removed.

As stated previously, a medication allergy verification is collected on admission to the hospital by the nurse. This is already a function of ASP and is accepted widely as the nurses

responsibility. Furthermore, this study's nurse driven protocol to assess a patient's penicillin allergy history is a function that aligns with the goals of the ASP. If a penicillin allergy has been documented, the subsequent consequences are routinely linked to the members of the ASP team including pharmacy, microbiology, infectious disease, and fiscally to the hospital administration. A future nursing implication could be to also assess a patient's medication history and have this built into this tool. This will pull the history of medication usage from the EHR into the protocol for the nurse to review all potential cross-related antibiotics that the patient may have had received. This could become a worthwhile element in the event of penicillin allergy verification and a mode to assist in de-labeling.

Another implication is utilization of this tool and the data gathered in collaboration with the multidisciplinary team, ample educational, physical resources and providing available personnel, to work together to implement a proactive interventional multi-modal approach led by the ASP involving penicillin skin testing and/or challenge dosing to de-label the low-risk patients identified as penicillin allergic.

The tool is multifaceted, it has both a short-term impact and can influence long-term outcomes. The final future nursing implication is to follow and track these outcomes over time to measure the influence of this nurse driven tool in this patient population and healthcare system. These outcomes include overall healthcare utilization, readmission rates, hospital acquired infections, the occurrence of resistant bacteria, rate of de-labeling, antimicrobial use and following the trend of each hospital's antibiograms.

Limitations

Throughout implementation of this quality improvement intervention, many limitations presented themselves. First, due to the overwhelming size of this project and the location of multiple sites, it was difficult to facilitate compliance without having a focused facilitator at each site overseeing and performing feedback audits. Additionally, when dealing with multiple sites, dispersing the education and assessing for achieved learning outcomes of what is being asked of nurses or the need for further teaching was impossible to measure. Nurse turnover and burnout proved to have its impact on compliance secondary to the overwhelming staffing ratios with their patient loads in addition to the interchange of travel nurses that may not have received the initial or follow up education.

Also, the primary investigator was informed that in the middle of post-intervention time frame, one of the four ID pharmacists left their position at the hospital and the responsibility of that hospital was being spilt between 2 of the other ID pharmacist in addition to their own increasing their workload.

Time limitations also came about. To brainstorm ideas, present the idea, gain support, develop a plan of action, and collaborate with multiple disciplines to build this protocol into the EHR to become system wide took nearly eight months delaying the start of the project and limited the prospective time frame, thus not allowing for an equal time of three months for retrospective and prospective data collection. Lastly, data extraction was a limitation due to the multitude of ways a penicillin could be stored in the EHR and the ability to extract the sample.

Conclusion

To summarize, a nurse-driven protocol was designed, built into the EHR, and implemented across Norton Healthcare covering 1,607 beds. The assessment was used by every nurse working in the inpatient area and reviewed by members of the multidisciplinary team. This was achieved by gaining support from the systems administration, collaborative efforts with the multidisciplinary team and acquiring interdisciplinary buy-in. It is worth mentioning that this is no longer a pilot study but is now a standard of practice. The nurse allergy assessment continues after this study has concluded.

Although it is impossible to know if patients were de-labeled from the assessment alone, this study exemplified what successful collaboration within a multidisciplinary team to solve a problem could do. The ability of the nurse to assess the allergy history of patients allergic to penicillin at the rate they did far surpasses the ability of a single pharmacist or physician. The next steps towards success would be further educating the nurses and working closely with Norton's ASP to improve this tool, the functionality and to unlock the nurses potential while defining and expanding their role within an antimicrobial stewardship program.

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Table 1. Nurse Driven Penicillin Allergy Navigator Data

Question	(n=1131)
Penicillin Allergy?	<ul style="list-style-type: none"> • Yes- 90.9% (1028) • No- 8.5% (96) • NULL- 0.6% (7)
When was your reaction?	<ul style="list-style-type: none"> • Greater than 10 years ago- 51.9% (587) • Less than 10 years ago- 14.5% (164) • NULL- 33.6% (380)
Did your reaction happen after the first dose?	<ul style="list-style-type: none"> • Yes-27.6% (312) • No- 5.8% (66) • Do not Know- 32.1% (363) • NULL- 34.5% (390)
Did your reaction happen after several doses?	<ul style="list-style-type: none"> • Yes- 9.5% (107) • No – 17.8% (201) • Do not know- 36.9% (416) • NULL- 36% (407)
Did your reaction require ED or Hospital Care to treat your reaction?	<ul style="list-style-type: none"> • Yes- 17.2 (194) • No- 19.9% (225) • Do not know 27.9% (315) • NULL- 35.1% (397)
Did your reaction require treatment with epinephrine?	<ul style="list-style-type: none"> • Yes- 6.5% (74) • No- 21.4% (242) • Do not know- 36.4% (412) • NULL- 35.6% (403)
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	<ul style="list-style-type: none"> • Yes- 9.5% (108) • No- 13.1% (148) • Do not know- 36.2% (409) • NULL- 34.5% (390) • Have not taken since- 6.7% (76)
Have you taken cephalexin (KEFLEX) without issue since?	<ul style="list-style-type: none"> • Yes- 11% (124) • No- 9.5% (107) • Do not know 39.3% (444) • NULL- 34.8% (394) • Have not taken since- 5.5% (62)
Reaction?	<p>(Most Prevalent selections, not all inclusive)</p> <ul style="list-style-type: none"> • Selections including <u>Anaphylaxis</u>- 11.5% (123) • Hives- 16.4% (186) • Hives, Itching rash- 2.7% (30) • Itching Rash- 11.6% (131) • Lip Swelling- 1.9% (22) • Nausea, vomiting or diarrhea- 2.9% (33) • Non-itching Rash- 2.1% (24) • Shortness of Breath- 2.4% (27) • NULL- 29.9% (338)

Appendix A. Focused Allergy History Questionnaire

1. Penicillin allergy?
 - a) Yes b) No

2. What was your reaction? (select all that apply)
 - b) Other b) Anaphylaxis c) Shortness of Breath d) Diarrhea
 - e) Itching f) Photosensitivity g) Nausea and Vomiting h) nausea only
 - i) Swelling j) Anxiety k) Palpitations l) Dermatitis m) Rash n) Tinnitus
 - o) GI Bleeding p) Hemorrhagic Stroke q) GI Intolerance r) Cough
 - s) Headache t) Dizziness u) Hallucinations v) Fever w) Wheezing
 - x) Runny Nose y) Angioedema

3. When was your reaction?
 - c) Less than 10 years ago b) Greater than 10 years ago

4. Did your reaction happen after the first dose?
 - d) Yes b) No c) Do not know

5. Did your reaction happen after several doses?
 - e) Yes b) No c) Do not know

6. Did your reaction require ED or hospital care to treat your reaction?
 - f) Yes b) No c) Do not know

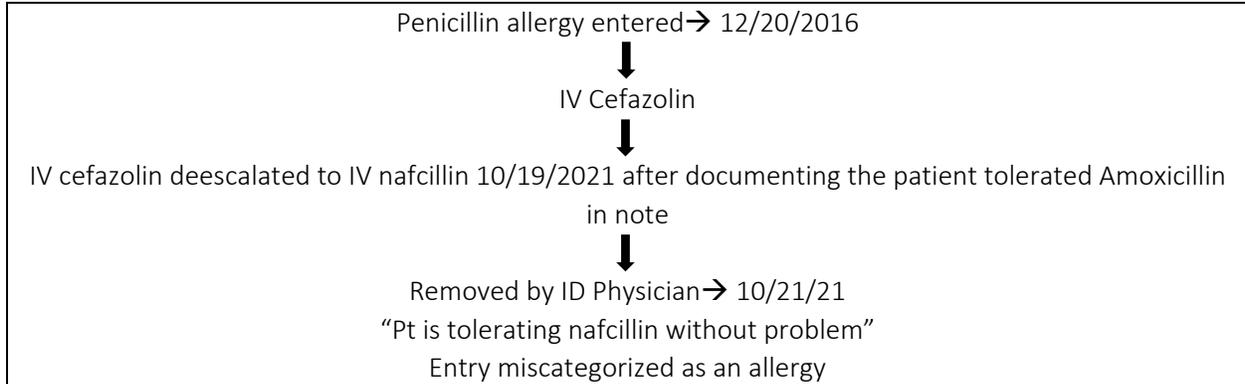
7. Did your reaction require treatment with epinephrine?
 - g) Yes b) No c) Do not know

8. Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) with no issue since?
 - h) Yes b) No c) Do not know

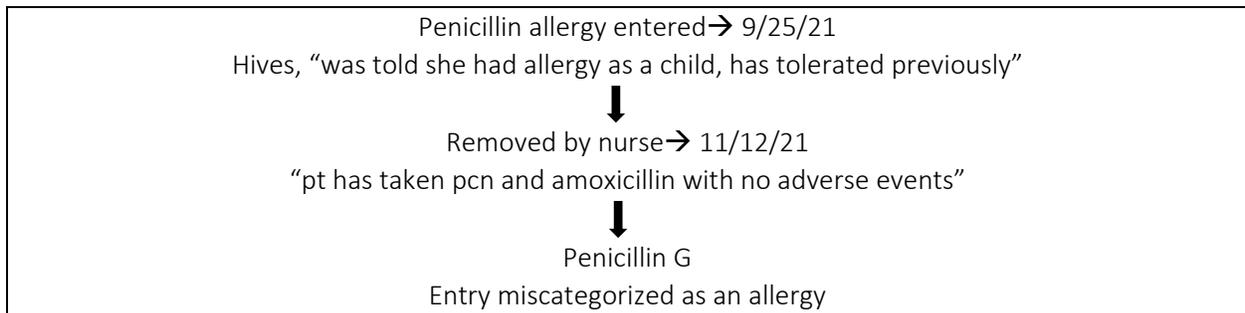
9. Have you taken cephalexin (Keflex) with no issue since?
 - i) Yes b) No c) Do not know

Appendix B. Retrospective Chart Review

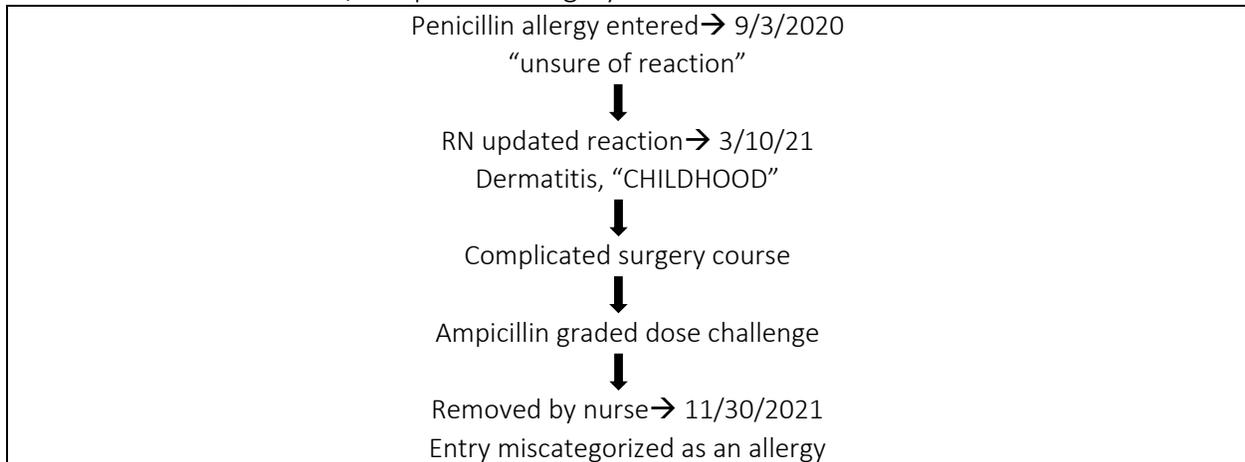
B.1 Patient 1. TV MSSA Endocarditis



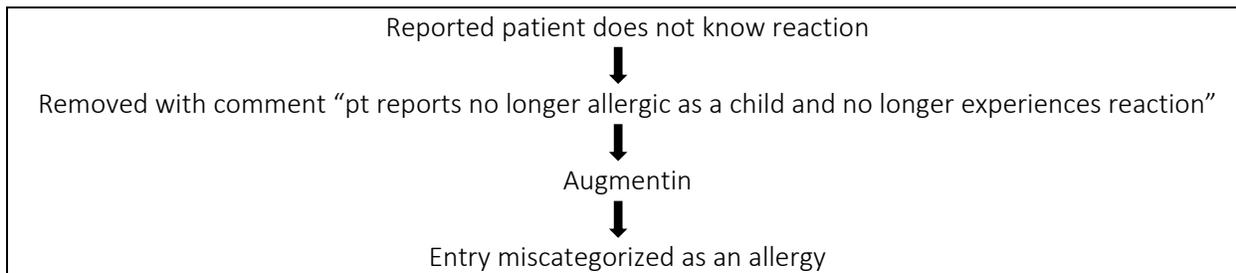
B.2 Patient 2. GBS



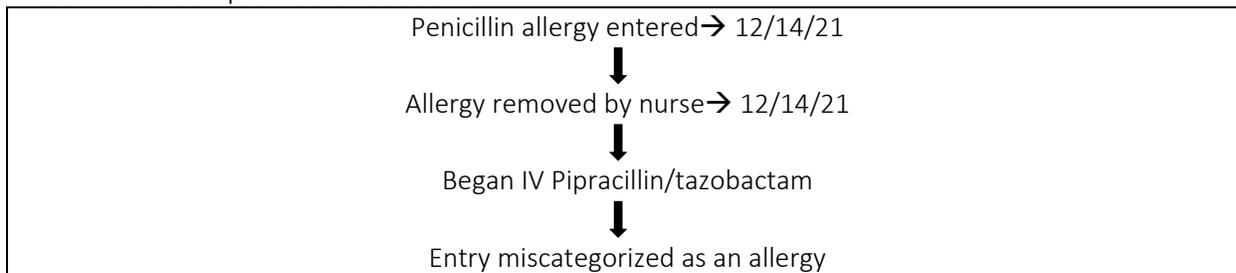
B.3 Patient 3. RUQ abscess/complicated surgery course



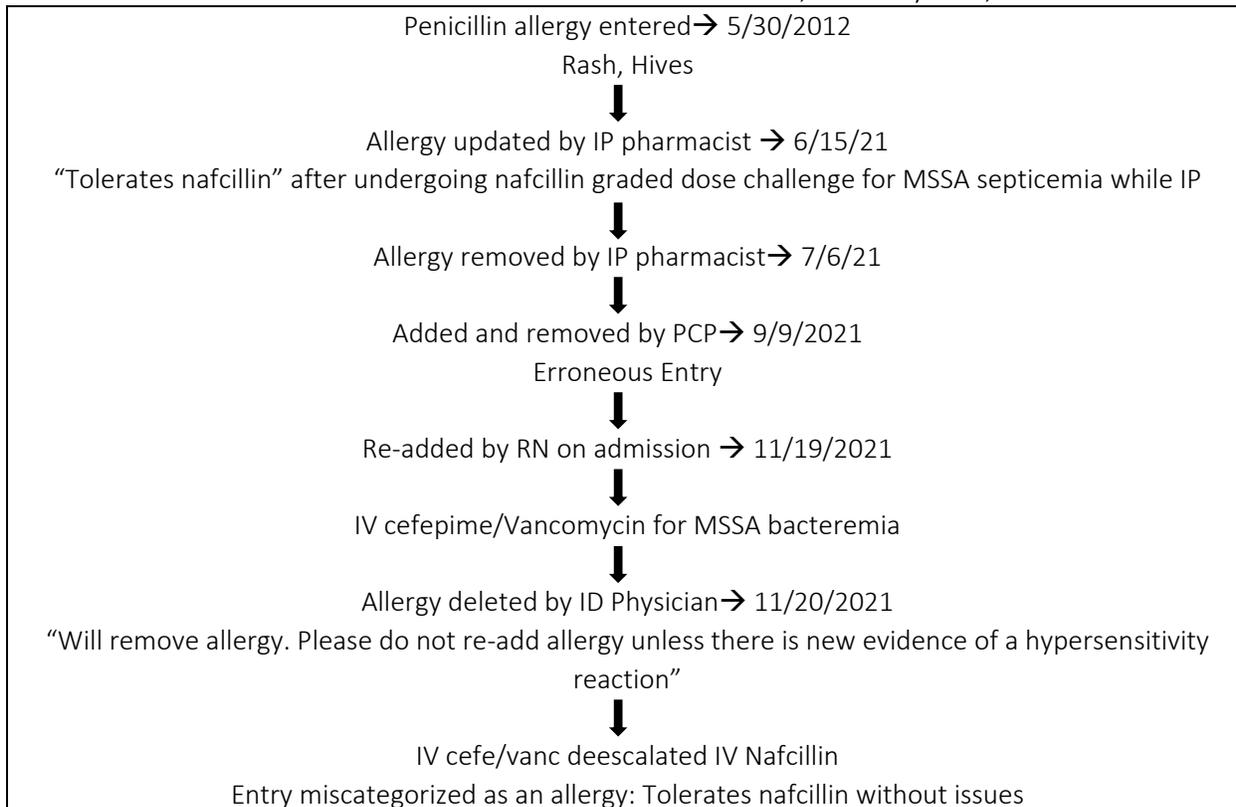
B.4 Patient 4. Unknown



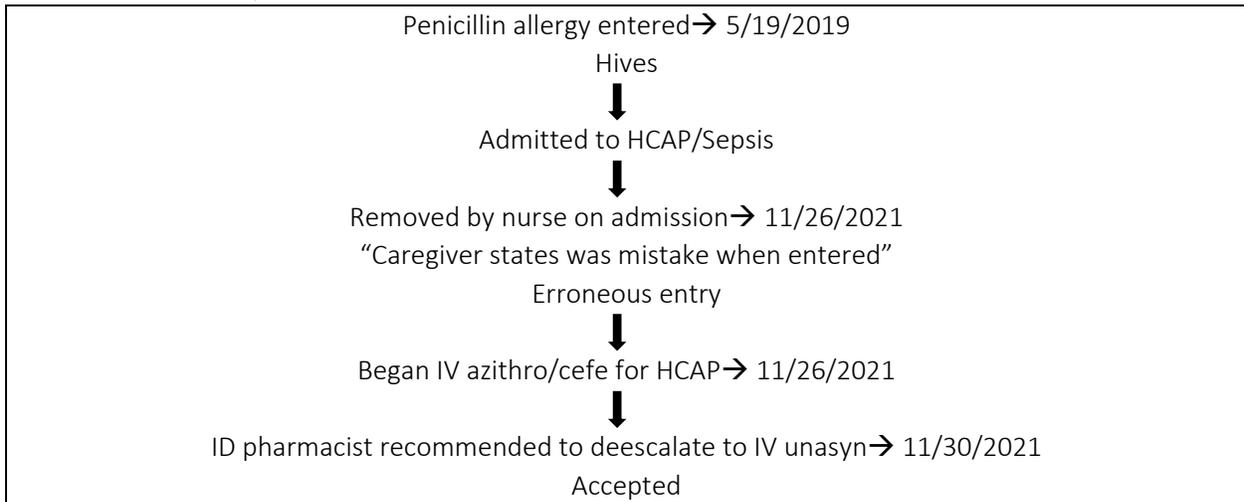
B.5 Patient 5. Suspected DM foot OM



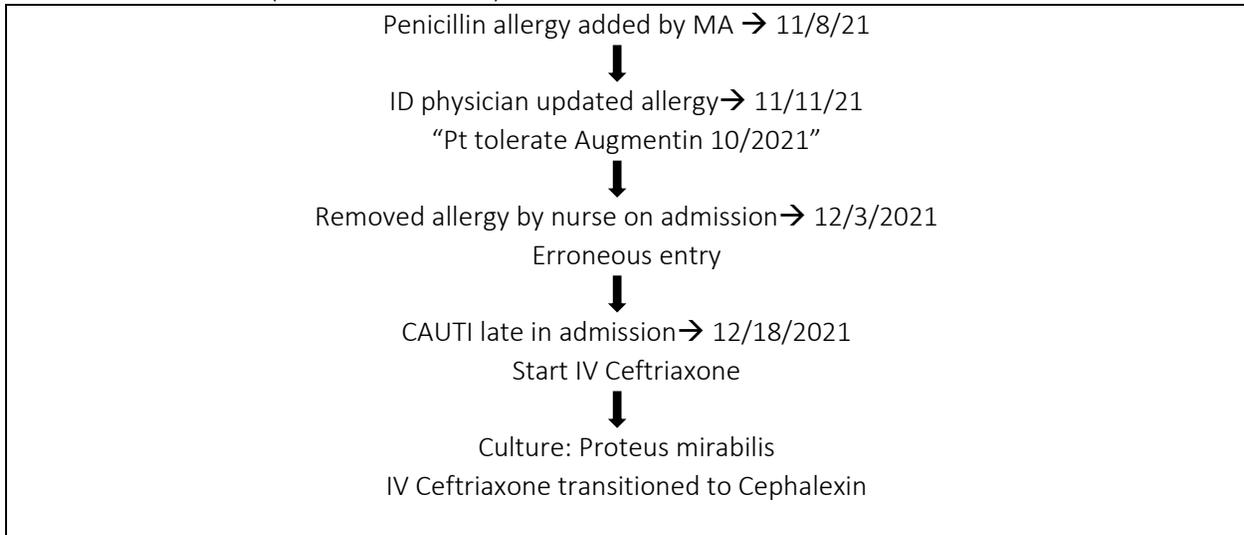
B.6 Patient 6. Recurrent MSSA bacteremia with lumbar discitis, osteomyelitis, intradiscal abscess



B.7 Patient 7. HCAP, Intrabdominal abscess

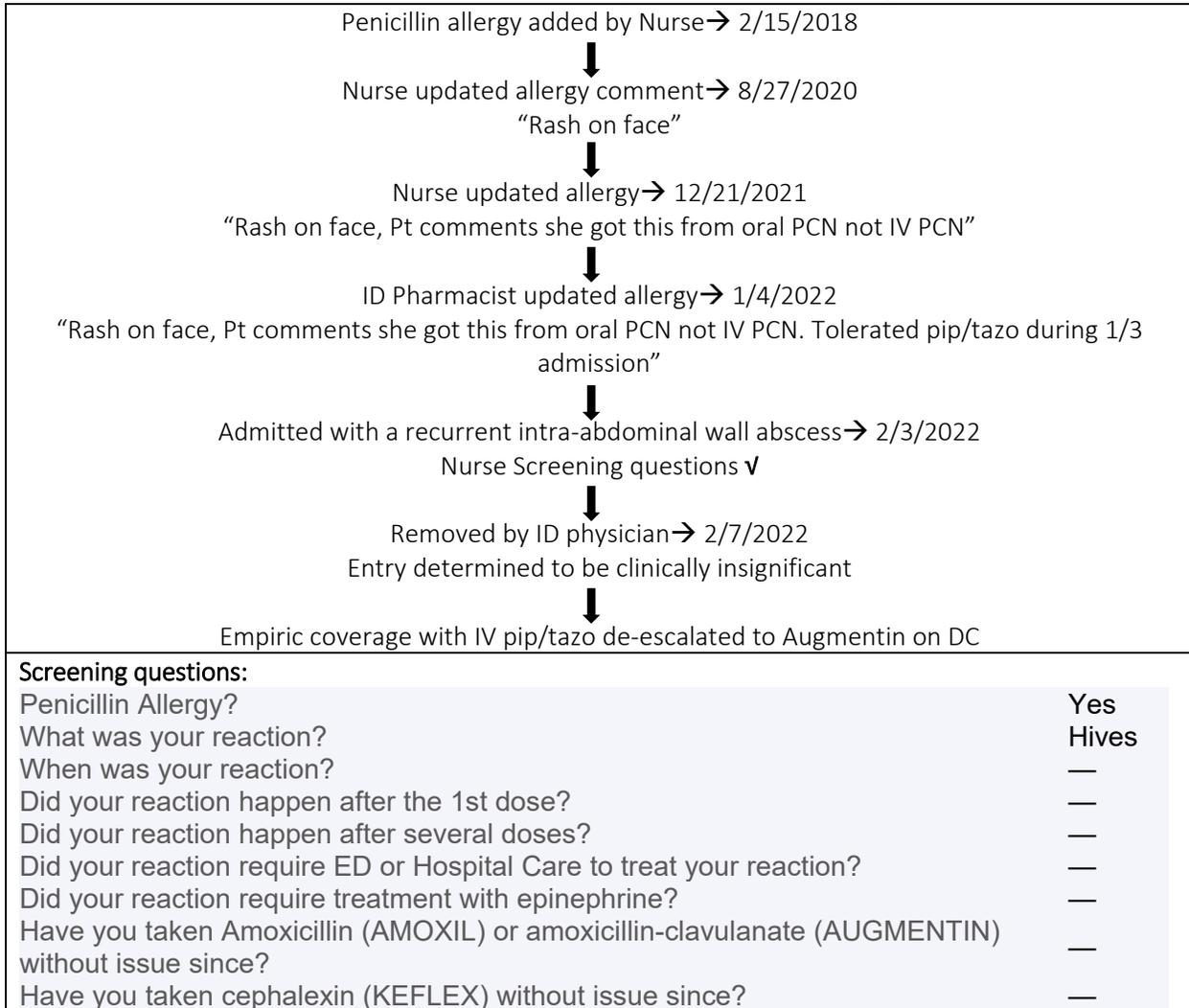


B.8 Patient 8. CAUTI (late in admission)

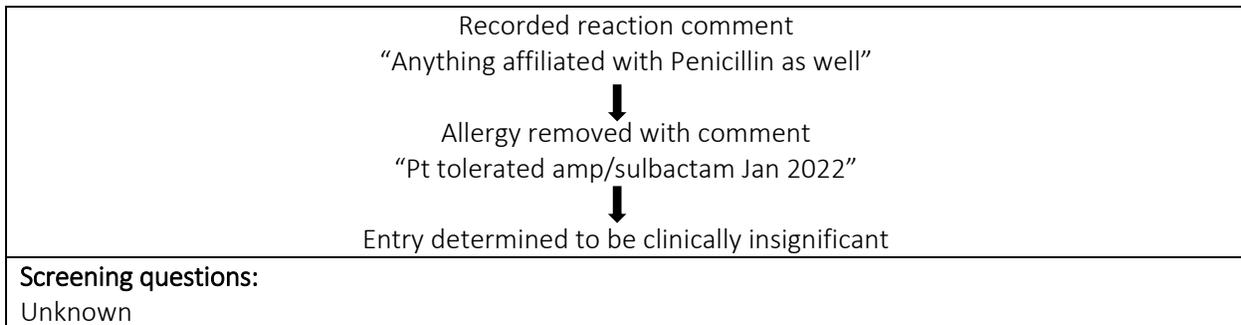


Appendix C. Prospective Chart Review

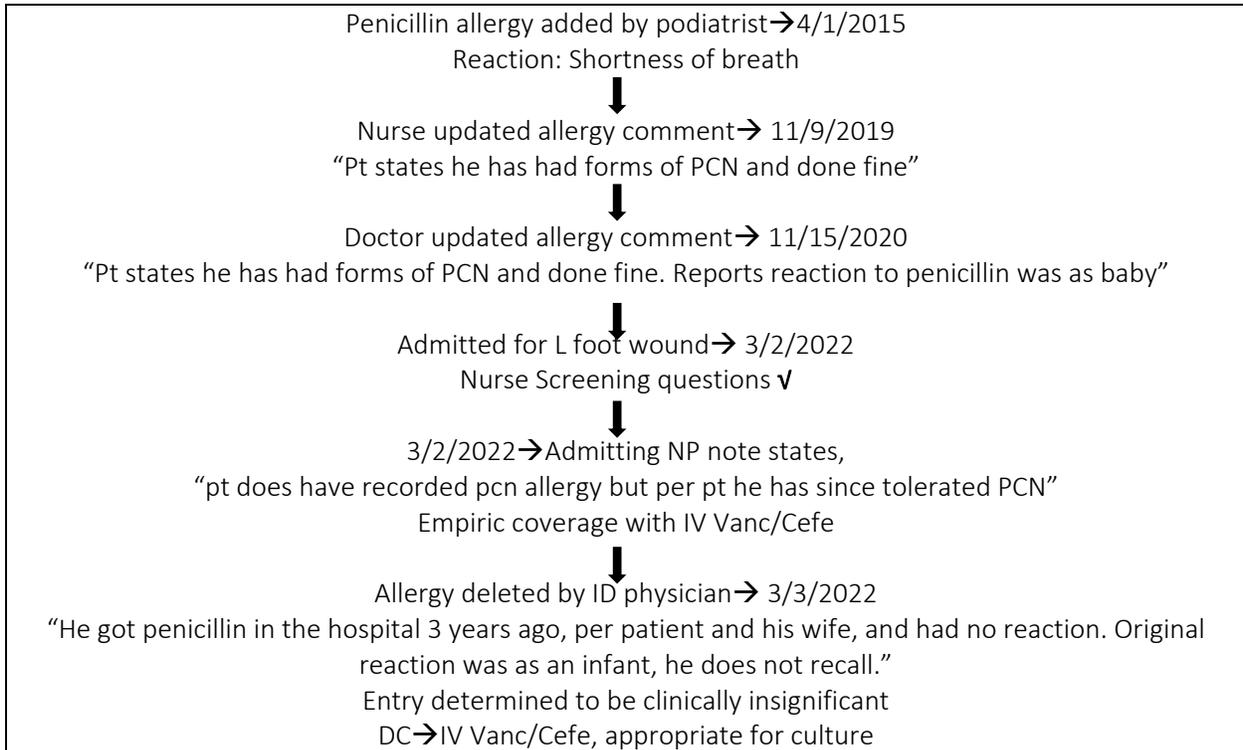
C.1 Patient 1. Persistent intra-abdominal abscess 2/2 Chrons Disease, sepsis



C.2 Patient 2. Unknown

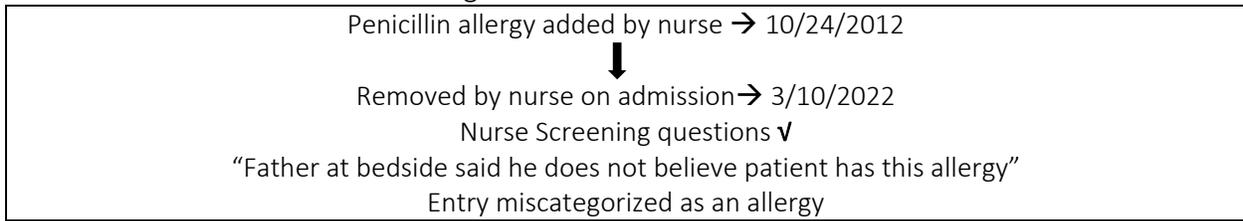


C.3 Patient 3. Diabetic OM



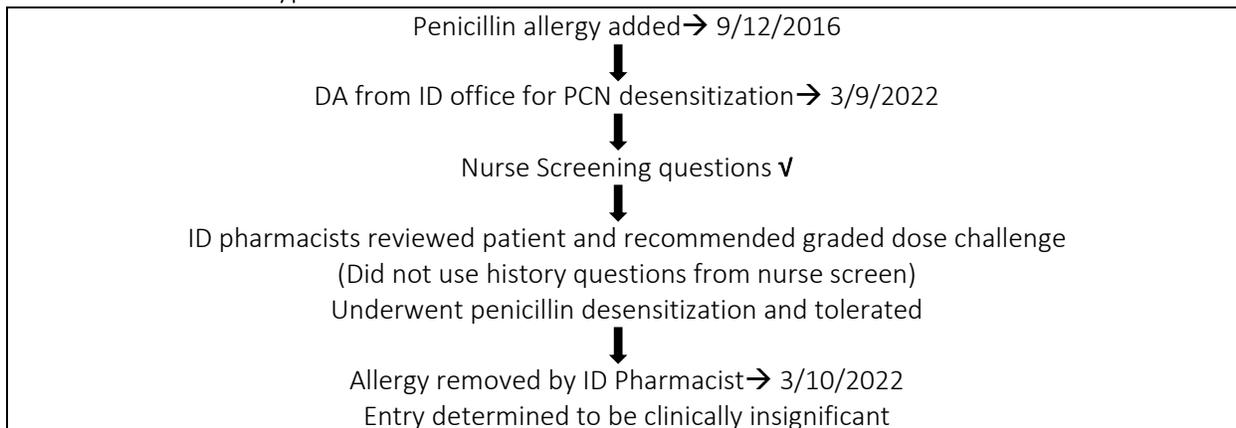
Screening questions:	
Penicillin Allergy?	Yes
What was your reaction?	Anaphylaxis
When was your reaction?	Greater than 10 years ago
Did your reaction happen after the 1st dose?	Yes
Did your reaction happen after several doses?	No
Did your reaction require ED or Hospital Care to treat your reaction?	Do not know
Did your reaction require treatment with epinephrine?	Do not know
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	Do not know
Have you taken cephalexin (KEFLEX) without issue since?	Do not know

C.4 Patient 4. Intracranial hemorrhage



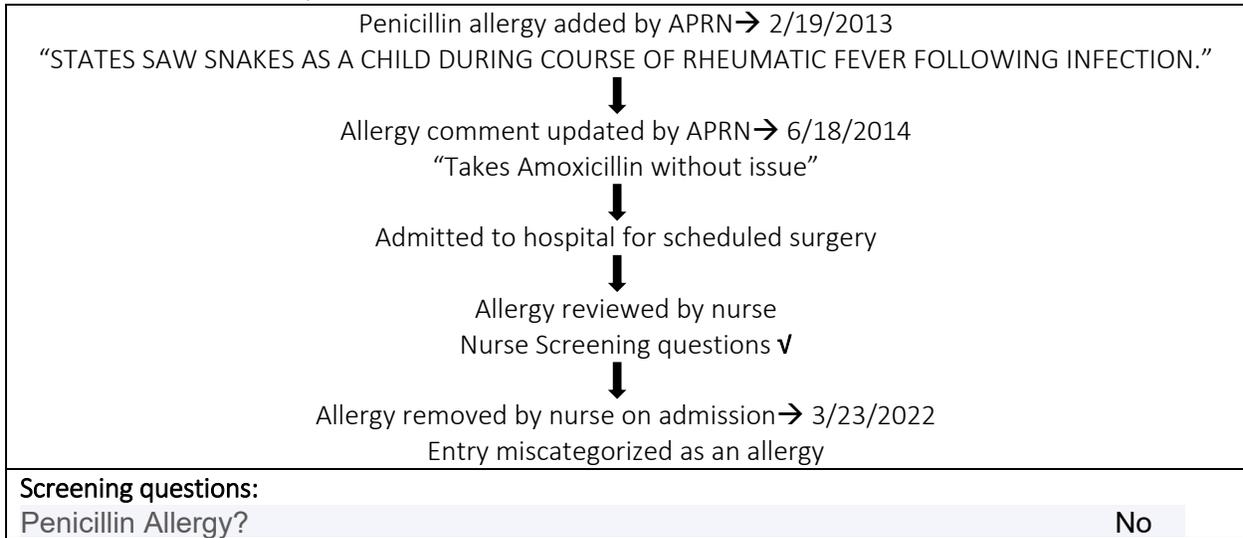
Screening questions:	
Penicillin Allergy?	No. The comment is according to father NKA.

C.5 Patient 5. Neurosyphilis

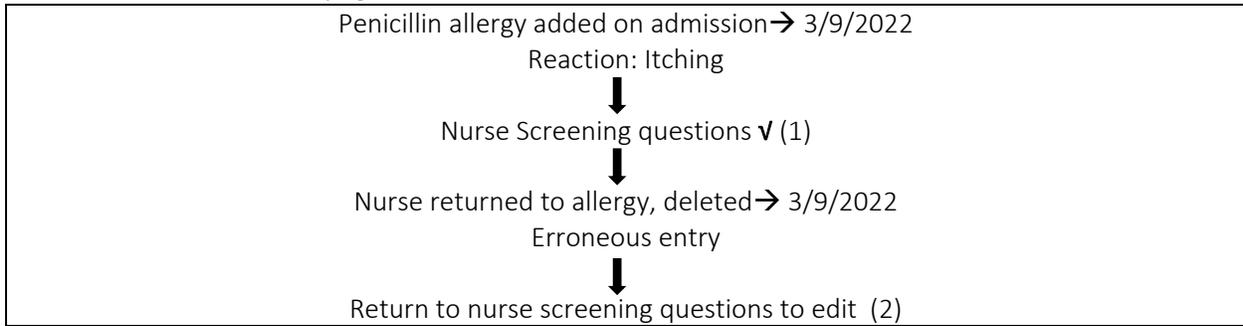


Screening questions:	
Penicillin Allergy?	Yes
What was your reaction?	—
When was your reaction?	Less than 10 years ago
Did your reaction happen after the 1st dose?	Do not know
Did your reaction happen after several doses?	Do not know
Did your reaction require ED or Hospital Care to treat your reaction?	Do not know
Did your reaction require treatment with epinephrine?	Do not know
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	Yes
Have you taken cephalexin (KEFLEX) without issue since?	Yes

C.6 Patient 6. Cervical Spinal Stenosis



C.7 Patient 7. Acute Pharyngitis



Screening questions:

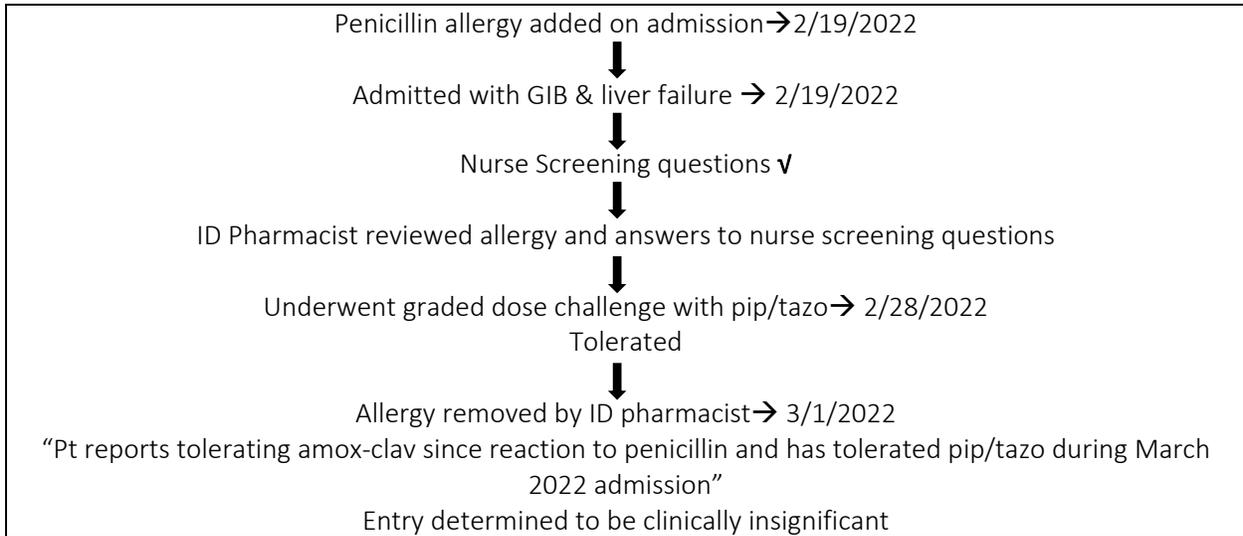
(1)

Penicillin Allergy?	Yes
What was your reaction?	Itching rash
When was your reaction?	Less than 10 years ago
Did your reaction happen after the 1st dose?	
Did your reaction happen after several doses?	
Did your reaction require ED or Hospital Care to treat your reaction?	
Did your reaction require treatment with epinephrine?	
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	
Have you taken cephalexin (KEFLEX) without issue since?	

(2)

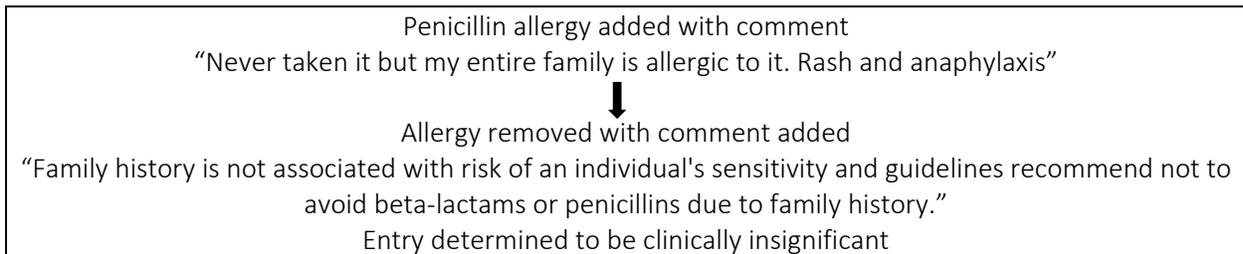
Penicillin Allergy?	No
What was your reaction?	—
When was your reaction?	—
Did your reaction happen after the 1st dose?	—
Did your reaction happen after several doses?	—
Did your reaction require ED or Hospital Care to treat your reaction?	—
Did your reaction require treatment with epinephrine?	—
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	—
Have you taken cephalexin (KEFLEX) without issue since?	—

C.8 Patient 8. GIB



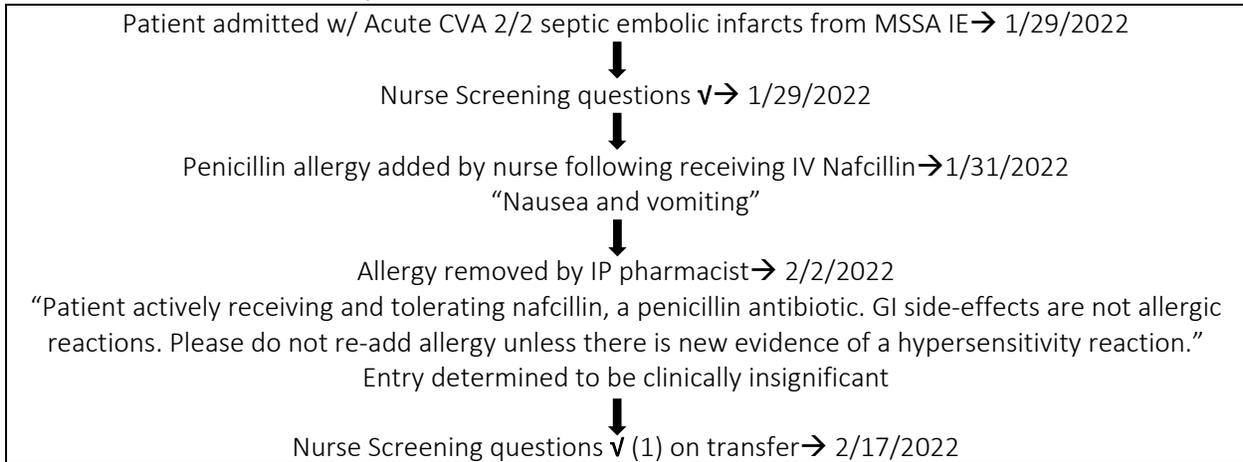
Screening questions:		
Penicillin Allergy?	Yes	No
What was your reaction?	—	—
When was your reaction?	Greater than 10 years ago	—
Did your reaction happen after the 1st dose?	No	—
Did your reaction happen after several doses?	Do not know	—
Did your reaction require ED or Hospital Care to treat your reaction?	No	—
Did your reaction require treatment with epinephrine?	No	—
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	Yes	—
Have you taken cephalexin (KEFLEX) without issue since?	Yes	—

C.9 Patient 9. Unknown



Screening questions:		
Unknown		

C.10 Patient 10. MSSA IE, Septic embolic infarcts

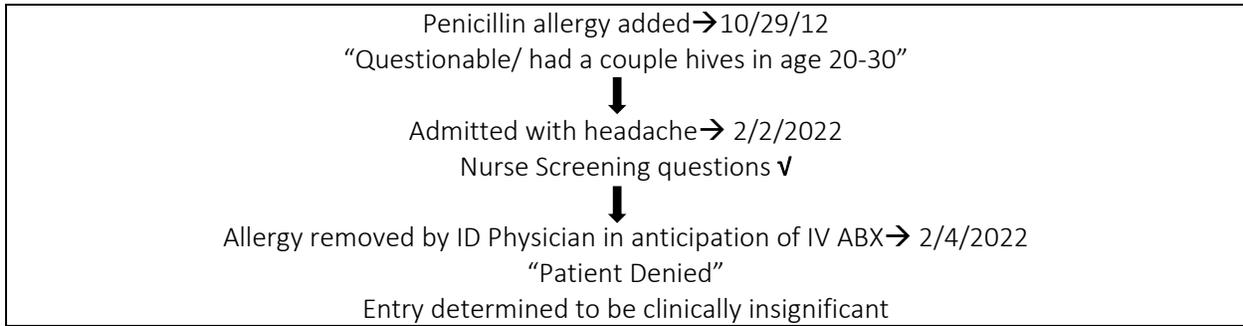


Screening questions:

Penicillin Allergy?	Yes
What was your reaction?	Nausea, Vomiting, or Diarrhea
When was your reaction?	Greater than 10 years ago
Did your reaction happen after the 1st dose?	Do not know
Did your reaction happen after several doses?	No
Did your reaction require ED or Hospital Care to treat your reaction?	No
Did your reaction require treatment with epinephrine?	No
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	No
Have you taken cephalexin (KEFLEX) without issue since?	No

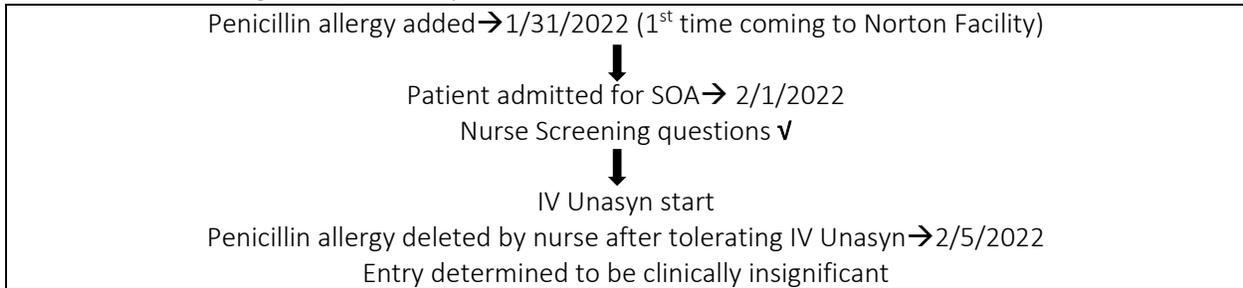
The allergy was not actually added until 2 days following admission. However, the nurse answered yes on the screening tool on admission to having a penicillin allergy.

C.11 Patient 11. Brain Metastases



Screening questions:	
Penicillin Allergy?	Yes
What was your reaction?	None of the Above, Please Specify
When was your reaction?	Greater than 10 years ago
Did your reaction happen after the 1st dose?	Do not know
Did your reaction happen after several doses?	Do not know
Did your reaction require ED or Hospital Care to treat your reaction?	Do not know
Did your reaction require treatment with epinephrine?	Do not know
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?	Do not know
Have you taken cephalexin (KEFLEX) without issue since?	Do not know

C.12 Patient 12 Lung mass/ Cavitory PNA



Screening questions:		Yes	No
Penicillin Allergy?		—	—
What was your reaction?		—	—
When was your reaction?	Greater than 10 years ago	—	—
Did your reaction happen after the 1st dose?		Do not know	—
Did your reaction happen after several doses?		Do not know	—
Did your reaction require ED or Hospital Care to treat your reaction?		—	—
Did your reaction require treatment with epinephrine?		Do not know	—
Have you taken Amoxicillin (AMOXIL) or amoxicillin-clavulanate (AUGMENTIN) without issue since?		Do not know	—
Have you taken cephalexin (KEFLEX) without issue since?		Do not know	—

C.13 Patient 13. Unknown

<p>Penicillin allergy added</p> <p>↓</p> <p>Allergy removed with comment added “Tolerating ampicillin/sulbactam without issue Feb 2022” Entry determined to be clinically insignificant</p>
<p>Screening questions: Unknown</p>