

**Description of a pharmacist-managed/administered penicillin allergy skin testing service
at a community hospital**

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Purpose. To describe how a pharmacist-managed and pharmacist-administered penicillin allergy skin testing (PAST) service was incorporated into an antimicrobial stewardship program at a community hospital.

Methods. A pharmacist-managed/administered PAST service was initiated in October 2015.

Patients 18 years of age or older were considered for PAST if they had a reported history of a type I or unknown type of allergic reaction to penicillin that occurred more than 5 years previously. Patients with a vague allergy history were considered for PAST if the provider was uncomfortable prescribing a preferred β -lactam out of concern for penicillin allergy. Patients were excluded if they were pregnant, had a history of a non-type I allergic reaction, or recently received antihistamines. The primary outcome was the percentage of patients who underwent PAST and were subsequently transitioned to a preferred β -lactam.

Results. PAST was initiated in 90 patients from October 2015 to December 2019. Eighty-five out of 90 patients (94%) completed PAST. Seventy-six out of 90 patients (84.4%) who underwent PAST were transitioned to a preferred β -lactam. The most commonly administered antibiotics prior to PAST were vancomycin, cefepime, and metronidazole. The most commonly used antibiotics after PAST were penicillin, piperacillin/tazobactam, and ampicillin/sulbactam. Among the 90 patients who underwent PAST, alternative antibiotics were avoided for a total of 1,568 days, with a median of 11 days (interquartile range, 6-18 days) avoided per patient.

Conclusion. Incorporating a pharmacist-managed/administered PAST service into a community hospital's antimicrobial stewardship program can improve the utilization of preferred antimicrobial therapy and help avoid use of more toxic, costly antimicrobials.

Keywords: hospitals, community; penicillins; pharmacists; skin tests

Alternative antimicrobial therapy in patients with reported penicillin allergies has been a concern for the profession of pharmacy and antimicrobial stewardship programs for decades. Despite thousands of medication approvals since the early 1940s, penicillin allergy remains the most widely self-proclaimed medication allergy. Approximately 30 million people in the United States (roughly 10% of the population) report a penicillin allergy.^{1,2} However, the majority of those reports of penicillin allergy are not accurate, as published data show that over 90% of patients who report penicillin allergy test negative upon penicillin allergy skin testing (PAST).³

The Infectious Diseases Society of America recently published an antimicrobial stewardship guideline that highlights the need to clarify and delabel penicillin allergies due to the risks of using alternative antibiotics.⁴ Patients with reported penicillin allergies have been shown to be at higher risk for surgical site infections and to have higher rates of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridioides difficile* infection.^{5,6} One way to avoid these poor outcomes is to delabel false penicillin allergies. There are multiple strategies described in the literature as being effective methods of penicillin allergy delabeling. A thorough and accurate allergy history is the cornerstone of this process, and many times is the only step required to appropriately delabel a penicillin allergy. Other strategies include direct oral challenge, graded challenge, desensitization, and PAST.⁷

PAST has been shown to safely and effectively rule out a penicillin allergy in patients with reported type I, or immunoglobulin E (IgE)–mediated, allergic reactions to penicillin (ie, anaphylaxis, urticaria, and angioedema) in both the inpatient and outpatient settings. Various inpatient PAST models have been previously described, including models deploying

clinicians such as allergists, infectious diseases fellows, nurses, physicians, and pharmacists.⁸⁻¹⁶ A recent review in *AJHP* summarized these models and provides a framework for pharmacists to implement a PAST service.¹⁷

Over recent years, there has been an increased number of publications describing pharmacists' role in PAST in healthcare systems. The majority of this literature has emerged from large university-affiliated teaching hospitals, with a limited number of studies describing a pharmacist-administered PAST service.¹¹⁻¹⁶ The study reported here describes the framework and results of implementing a pharmacist-managed and pharmacist-administered PAST service as part of a long-standing antimicrobial stewardship program in a community hospital.

Methods

A single-center observational cohort study was conducted at Munson Medical Center (MMC) in Traverse City, MI, and was initiated as a postgraduate year 2 (PGY2) infectious diseases (ID) pharmacy resident research project, with direction and oversight provided by an ID pharmacist at MMC. MMC is a 440-bed community teaching hospital with a postgraduate year 1 (PGY1) pharmacy residency program and a postgraduate year 2 (PGY2) ID residency program. At the time of the study there were 4 ID physicians and 2 ID nurse practitioners on staff at MMC. Allergists from community clinics were consulted as needed. Due to limited allergy specialist availability within the hospital, the ID and pharmacy departments collaborated to initiate a pharmacist-managed/administered PAST service, with the ID pharmacist and PGY2 ID pharmacy resident being accountable for the development, management, and administration of the PAST service. The study was reviewed and approved by the MMC institutional review board.

PAST training, competency, and service development. Initial training was performed by the manufacturer of benzylpenicilloyl polylysine (Pre-Pen, ALK-Abello) in August 2015. Subsequent training was performed by the ID pharmacist on an annual basis in July and included training 5 PGY1 pharmacy residents and 1 PGY2 ID resident. Starting in September 2019, the annual training program changed to incorporate the Penicillin Allergy Assessment and Skin Testing Certificate program, which includes 11 hours of didactic webinars and 4 hours of live demonstration, for a total of 15 hours of continuing education intended for all licensed healthcare practitioners.¹⁸ To maintain competency after the initial training, 2 penicillin allergy skin tests must be completed per year by each individual certified to perform PAST.

Protocol development started in January 2015, with PAST training occurring in August 2015 and the first PAST taking place in October 2015. The original PAST protocol approved by the MMC pharmacy and therapeutics committee restricted PAST ordering to the 4 ID physicians then practicing at MMC. This restriction was required in order to ensure that the initial demand did not exceed the resources available to fulfill PAST requests. Several months after the service went live, the PAST team became more comfortable with the process and the additional workload, and the ordering restriction was removed to allow all providers to request PAST. The hours of operation for the service were Monday through Friday, 7:00 AM to 3:30 PM.

Inclusion and exclusion criteria. Hospitalized patients 18 years of age or older were considered for PAST if they had a self-reported or documented history of an IgE-mediated reaction (ie, anaphylaxis, bronchospasm, urticaria, or angioedema) or unknown type of allergic reaction to penicillin that occurred more than 5 years prior to the current admission. Patients with a vague allergy history were considered for PAST if the provider was

uncomfortable prescribing the preferred β -lactam (Of note, as the years progressed, direct oral challenges were conducted more frequently for patients with low-risk allergy histories as further literature was published and providers became more comfortable challenging patients with remote, vague allergy histories.) Given limited personnel availability to perform PAST, testing of patients who were currently receiving a non-formulary-preferred antibiotic for an active infection for which a β -lactam antibiotic was preferred (eg, a patient receiving vancomycin for ampicillin-susceptible enterococcal endocarditis) were considered the highest priority. Patients were excluded if they were pregnant; had a history of a non-type I allergic reaction (eg, Stevens-Johnson syndrome, toxic epidermal necrolysis, glomerulonephritis, gastrointestinal intolerance); or had received either a first-generation histamine H₁ receptor antagonist (eg, diphenhydramine) in the past 24 hours or a second-generation H₁ receptor antagonist (eg, loratadine, fexofenadine, cetirizine) in the past 5 days and did not have a wheal of ≥ 3 mm in response to a histamine scratch test. Neutropenia (defined as an absolute neutrophil count of <500) was part of the original exclusion criteria but later removed after publication of safety and efficacy data on use of PAST in neutropenic patients.¹⁹

The PAST process. Patients were identified as candidates for PAST either through a formal request by a provider (usually via a phone call to the ID pharmacist) or through the prospective audit and feedback process performed by the antimicrobial stewardship team Monday through Friday from 7 AM to 3:30 PM. After a request was received, the first step was to perform a thorough allergy history and update the allergy documentation field in the electronic medical record (EMR) with those results. In many cases, PAST can be avoided by obtaining an accurate allergy history and investigating what agents a patient has tolerated in the past. After it is determined that the patient meets the criteria for PAST, the ID

pharmacist or a pharmacy resident performed the steps outlined in Table 1. This entire process took around 2 to 2.5 hours once the team was comfortable compounding the products, performing PAST, and documenting and sharing the results.

Primary and secondary outcomes. The primary study outcome was defined as the percentage of patients who started PAST and were transitioned to a preferred β -lactam. Secondary outcomes included the tolerability of PAST, the tolerability of an oral or intravenous (IV) challenge after a negative PAST result, days of alternative antibiotic therapy avoided, and the number of patients relabeled as having a penicillin allergy after a negative PAST result. The calculation for days of alternative antibiotic therapy avoided was defined as the number of calendar days after PAST on which a preferred β -lactam was administered instead of an alternative antibiotic. For example, if a patient with *Enterococcus faecalis* bacteremia had a negative PAST result on day 4 of vancomycin therapy and were transitioned to ampicillin or penicillin for the remaining 24 days of antibiotic therapy, the total days of alternative antibiotic therapy avoided would be 24. The total days of alternative antibiotic therapy avoided was further broken down into inpatient and outpatient days. In the example above, if the patient had remained an inpatient for 4 days after PAST while receiving the preferred β -lactam and was subsequently discharged to receive 20 days of the preferred antibiotic, the inpatient days of alternative antibiotic avoided would have been 4 and outpatient days avoided would have been 20.

Statistical analysis. Descriptive statistics were performed for primary and secondary outcomes. Medians were used for data that were not normally distributed.

Results

From October 2015 to December 2019, PAST was initiated in 90 patients, 44 (48.9%) of whom were tested either partially or completely by a pharmacy resident (a PGY1 or PGY2 ID resident) at MMC. Of those 90 patients, 3 patients did not have a histamine response, 2 patients had an ambiguous scratch test result, and the remaining 85 patients completed the PAST protocol. Of the 85 patients who completed PAST, all were negative and tolerated testing; however, 1 patient developed a rash 24 hours after substitution of piperacillin/tazobactam for cefepime was initiated. The patient's reported historical reaction was immediate development of hives in response to amoxicillin administration, which had occurred more than 20 years previously. The rash that occurred after the negative PAST result was determined to be a non-type I reaction. The rash slowly resolved after a switch from piperacillin/tazobactam back to cefepime. All other patients who completed PAST tolerated at least 1 dose of a penicillin antibiotic, resulting in a calculated negative predictive value (NPV) for PAST of 98.8%.

Demographics of patients who started PAST are summarized in Table 2. Their average age was 62 years, with females making up 61% of that group. In the majority of cases ($n = 77$ [86%]), skin tests were performed on an inpatient general medical floor, with 13 (14%) occurring in an intensive care unit setting and 2 (2%) performed on patients receiving mechanical ventilation. Fifty-one percent of patients reported hives ($n = 28$) or rash ($n = 18$) as prior penicillin reactions, with the majority (84%) of patients reporting a reaction more than 20 years ago. As stated previously, patients with a reported rash were skin tested more frequently early on in the development of the PAST service, with direct oral challenges becoming more common as literature increased on this topic and providers

became more comfortable. The most common infectious diagnoses were bacteremia (24%), skin and soft tissue infections (16%), and intraabdominal infections (14%). The organisms most frequently recovered were *Enterococcus* species (32%), *Streptococcus* species (22%), and Enterobacteriaceae (17%).

Of the 90 patients who started PAST, 76 (84.4%) were transitioned to preferred β -lactam therapy. In cases where PAST plus stewardship intervention facilitated a change in antibiotic therapy ($n = 76$), the antibiotics most commonly used prior to PAST were vancomycin, cefepime, and metronidazole (Figure 1A). The antibiotics most commonly used after PAST were penicillin, piperacillin/tazobactam, and ampicillin/sulbactam (Figure 1B); the pharmacist administering PAST not only recommended use of these antibiotics to the attending physician or ID consultant but also assisted with entering the orders into the EMR, which helped to avert phone calls about EMR allergy alerts from pharmacists not involved in the PAST program. In the 90 patients who started PAST, alternative antibiotics were avoided for a total of 1,568 days, with a median (interquartile range [IQR]) of 11 (6-18) days for each patient. Full details of days of alternative antibiotic therapy avoided can be found in Table 3.

Lastly, in an analysis conducted 30 days after 90 patients had started PAST, the proportion of patients with a negative PAST result who were relabeled as having a penicillin allergy in the allergy documentation field of the EMR was 13% (11 out of 85).

Discussion

Our results are consistent with previously published studies showing high tolerability and accuracy of PAST and an NPV of 98.8%. Not surprisingly, many of our patients reported having experienced a reaction to penicillin more than 20 years ago, with hives and rash as the most commonly reported reactions. A common clinical scenario encountered was *Streptococcus* or *Enterococcus* bacteremia with associated bone/joint involvement or endocarditis. These infections are typically treated for 4 weeks or longer, which explains the longer duration of alternative antibiotics avoided in patients with those infection types (Table 3). PAST was also prioritized specifically for these patients so that a definitive infection could be identified and a prolonged duration of alternative antibiotic therapy avoided. A lower priority was assigned to patients without an active infection and patients with an infection that could be safely treated with the preferred antibiotic(s) without performing PAST.

Multiple PAST models have been previously described, many of which included multidisciplinary collaboration including pharmacists, nurses, allergists, and ID fellows. Information describing a pharmacist-managed/administered model is limited but growing.¹¹⁻¹⁶ A report by Wall et al¹¹ published in 2004 was one of the first to describe a pharmacist-administered skin testing service. More recently, Englert and Weeks¹⁵ published results of a pilot study of a pharmacist-driven PAST program for adult patients prescribed alternative antibiotics in a community hospital setting. After screening 87 patients, 23 patients were initiated on skin testing, with 22 patients completing PAST. Similar to our study, that study found a high rate of patient transition to a preferred β -lactam (68%).

Griffith et al¹⁶ recently published a detailed description of a pharmacist- and pharmacy trainee-administered penicillin allergy assessment and skin testing service in South Carolina. That study was notable for multiple novelties, including involvement by not only pharmacy residents but also pharmacy students as key members of the penicillin allergy assessment and skin testing service. Pharmacists were not authorized to perform penicillin skin testing in South Carolina at the time of study initiation, and the investigators highlighted the extensive process they underwent to obtain approval of pharmacist-administered PAST from the state board of pharmacy (BOP). State BOP approval is a major limiting factor for pharmacy departments and antimicrobial stewardship programs interested in initiating a PAST service. A previously published list of each state's BOP ruling on this matter can be referenced for those seeking this information.¹⁷

The resources available to develop and maintain a new pharmacy service are limited in many community hospitals; however, we have been able to sustain our PAST service for over 4 years by being selective in who receives PAST, involving our pharmacy residents in roughly half of skin tests, and maintaining a strong collaboration with ID physicians, the hospitalist service, and outpatient allergists. Overall, the provider and patient feedback from this service have been overwhelmingly positive. Providers are unanimously supportive of this service because it alleviates one of the most common barriers to selecting appropriate antimicrobial therapy. For patients, a negative PAST result is frequently the best news they hear while in the hospital. Also, patients are rarely hesitant to participate once they hear the rationale behind performing PAST and the risks of continuing use of alternative antibiotics such as vancomycin, fluoroquinolones, clindamycin, and carbapenems.

Our study had several limitations. First, because there was no comparator group of patients without a penicillin allergy, to compare patient outcomes (eg, antibiotic-related

adverse reactions, readmission rates, 30-day mortality, *C. difficile* infections) and cost of antibiotic therapy. Without a comparator group, antibiotic cost avoidance is difficult to measure, mainly because patients typically receive 2 or 3 different antibiotics during the course of a hospital stay. It becomes very challenging to predict what antibiotics might be prescribed after PAST is performed, especially if PAST is conducted early on in the course of therapy. Second, we had a relatively low number of patients, given the PAST model and inclusion criteria used. In the future, we hope to scale this service so that it can impact all patients with a documented penicillin allergy, even if an active infection is not identified. Third, we did not keep track of the total number of penicillin allergy assessment requests throughout the study, so we do not have an accurate number for the percentage of requests that resulted in PAST. This shortcoming was realized after the PAST service had already been started; however, we predict that around 25% of penicillin allergy assessment requests resulted in PAST.

The “penicillin allergy” label was initially removed from the EMR of the 85 patients who completed PAST. Of those 85 patients, 11 (12.9%) were relabeled as allergic when an audit was performed 30 days after the last patient was tested. Our process for removing a notation of penicillin allergy from the EMR includes documenting negative PAST results in the allergy field and canceling the notation. In such cases we currently do not enter a placeholder notation (eg, “negative penicillin allergy skin test” in the allergy field; however, the rate of notations of allergy being inappropriately added back into the EMR is concerning and warrants efforts to determine the most effective method for preventing incorrect relabeling of patients as penicillin allergic. Other programs in which such placeholder notations are used have reported excellent success in limiting improper relabeling.^{15,16}

One of the challenges that still exists is pharmacists billing for this service in the inpatient setting. The cost of PAST and the time required to complete it are not billed separately but rather are incorporated into the diagnosis-related group (DRG) reimbursement scheme; however, this may change if the pharmacy profession's provider status initiatives are successful.

Since initiation of this inpatient pharmacist-managed/administered PAST service, 2 additional branches have been created in the outpatient setting. First, the 3 obstetrics/gynecology provider groups in our community now refer pregnant women with reported severe penicillin allergies to 2 outpatient allergists who perform an allergy history and PAST if indicated. The goal is to delabel penicillin allergies in this population prior to determination of their group B *Streptococcus* (GBS) colonization status and provide preferred penicillin prophylaxis prior to delivery for those women who test positive for GBS colonization. The second branch of the original inpatient PAST service was established in the outpatient infusion clinic across the street from the hospital, which is affiliated with Munson Healthcare. This PAST service is managed by 4 board-certified oncology pharmacists and a PGY2 oncology pharmacy resident and will be administered by an infusion clinic nurse or oncology pharmacist. The initial goal is to assess penicillin allergies and perform PAST, if indicated, in patients with gynecologic cancers prior to their primary surgery so that they can receive appropriate surgical antibiotic prophylaxis with cefazolin plus metronidazole instead of clindamycin and gentamicin. This pilot project may be extended to other presurgical services, depending on its success and resources available.

Conclusion

Penicillin and penicillin derivatives are often considered the antibiotics of choice for many common infections. In patients with a history of penicillin allergy, alternative agents are commonly used to treat these infections, which may lead to increased adverse reactions, resistance, and more expensive therapy. We have shown that initiation of a pharmacist-managed/administered PAST program in a community hospital can lead to beneficial outcomes in penicillin allergy delabeling and promoting the use of optimal first-line antibiotic therapy.

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Figure 1. Most commonly used antibiotics before (A) and after (B) penicillin allergy skin testing (PAST) in cases in which PAST plus pharmacist intervention facilitated a change in antibiotic therapy ($n = 76$). Pip/tazo indicates piperacillin/tazobactam; amp/sulb, ampicillin/sulbactam.

Key Points

- Approximately 30 million people in the United States report penicillin allergies, including up to 15% to 20% of hospitalized patients.
- Although not commonly available at community hospitals, penicillin allergy skin testing is an important tool used by antimicrobial stewardship teams to optimize antibiotic therapy in patients with purported penicillin allergies.
- A pharmacist-managed/administered penicillin allergy skin testing service in a community teaching hospital is a viable tool used to delabel penicillin allergies and optimize the use of preferred β -lactam antimicrobial regimens.

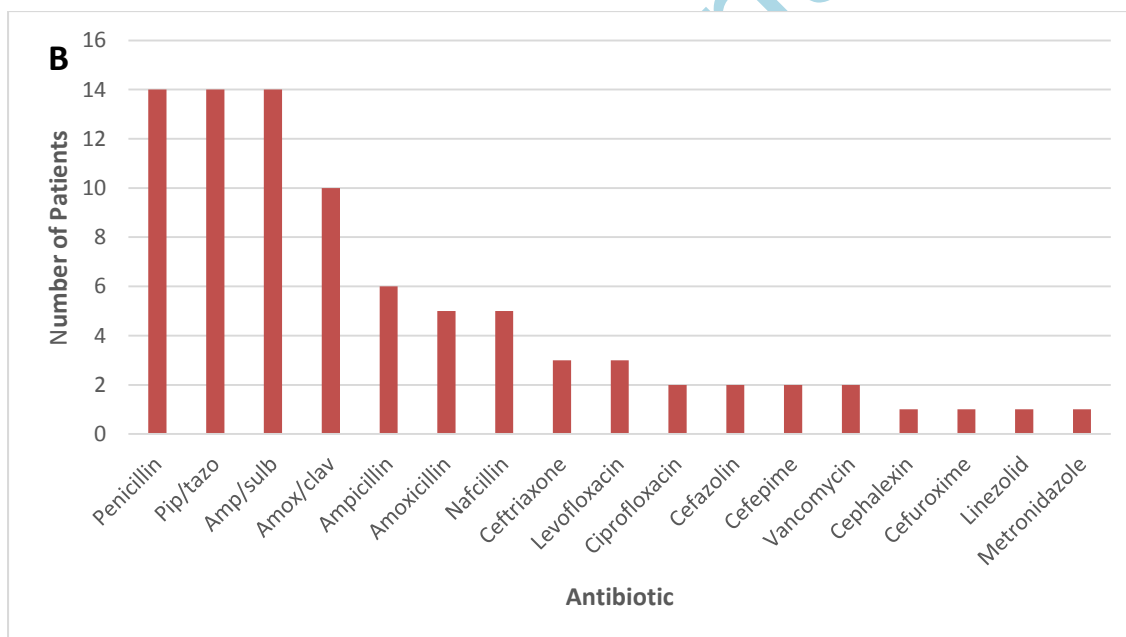
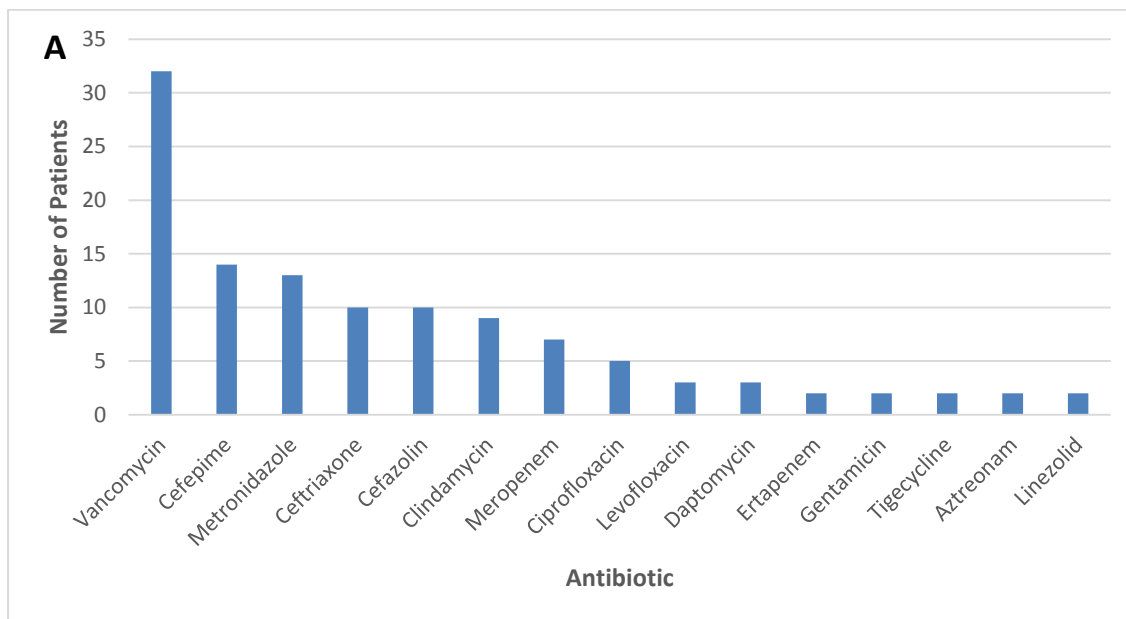


Table 1. Demographics of Patients Initiated on PAST ($n = 90$)

	No. (%) ^a
Female	55 (61)
Age, mean (SD), y	61.9 (17.3)
Age range, y	27-91
Hospital location	
General medical	77 (86)
Intensive care unit	13 (14)
Mechanically ventilated	2 (2)
Reported prior reaction to penicillin	
Hives	28 (31)
Rash	18 (20)
Unknown	14 (16)
Swelling	10 (11)
Anaphylaxis	9 (10)
Bronchospasm	6 (7)
Angioedema	3 (3)
Itching	2 (2)
Time since reported prior reaction	
More than 20 years	76 (84)
10–20 years	10 (11)
5–10 years	4 (4)
Primary infectious diagnosis	
Bacteremia	22 (24)
SSTI	14 (16)
Intraabdominal	13 (14)
Bone/joint infection	11 (12)
Dental abscess	10 (11)
Pneumonia	7 (8)
UTI	6 (7)
Endocarditis	3 (3)
Neutropenic fever	3 (3)
Empyema	1 (1)
Bacteria isolated	
<i>Enterococcus</i> spp	29 (32)
None	23 (26)
<i>Streptococcus</i> spp	20 (22)
Enterobacteriaceae	15 (17)
Gram-negative anaerobes	14 (16)
Gram-positive anaerobes	7 (8)
MSSA	7 (8)
Other <i>Staphylococcus</i> spp	5 (6)
Coagulase-negative <i>Staphylococcus</i> spp	2 (2)
<i>Pseudomonas aeruginosa</i>	2 (2)
Other aerobic gram-negative rods	2 (2)

Abbreviations: PAST, penicillin allergy skin testing; SSTI, skin and soft tissue infection; UTI, urinary tract infection; MSSA, methicillin-susceptible *Staphylococcus aureus*.

^aAll data are number (percentage) of patients unless otherwise indicated.

Table 2. Days of Alternative Antibiotic Therapy Avoided in Patients Who Underwent PAST, by Infectious Diagnosis^a

	Total Antibiotic Therapy Duration, Median (IQR), d	Days of Alternative Antibiotic Therapy Avoided, Median (IQR)			Total No. Days of Alternative Antibiotic Therapy Avoided
		Total Days	Inpatient Days	Outpatient Days	
All patients (<i>n</i> = 90)	14 (10-28)	11 (6-18)	3 (1-5)	8 (0-12)	1,568
Bacteremia (<i>n</i> = 22)	16	12	3	9	380
SSTI (<i>n</i> = 14)	14.5	11	3.5	9	298
Intraabdominal infection (<i>n</i> = 13)	15.5	12.5	6	7	156
Bone/joint infection (<i>n</i> = 11)	42	38	3	32	439
Dental abscess (<i>n</i> = 10)	12	11	1	9	146
Pneumonia (<i>n</i> = 7)	8	2	2	0	20
UTI (<i>n</i> = 6)	10	0	0	0	14
Endocarditis (<i>n</i> = 3)	42	35	5	30	82
Neutropenic fever (<i>n</i> = 3)	16	13	13	0	28
Empyema (<i>n</i> = 1)	43	5	5	0	5

Abbreviations: IQR, interquartile range; PAST, penicillin allergy skin testing; SSTI, skin and skin structure infection; UTI, urinary tract infection.

^aDays of alternative antibiotic avoided defined as number of days after PAST on which an alternative antibiotic was replaced by a preferred β -lactam.