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PREGNANCY | Society for Maternal-Fetal Medicine

SMFM SPECIAL STATEMENT

Society for Maternal-Fetal Medicine Special Statement: Assessment and management of reported penicillin allergy in pregnancy

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Abstract

Approximately 8% of pregnant people report being allergic to penicillin, yet most of these patients are not truly allergic, either because their allergy has waned or was misdiagnosed in the first place. Penicillin allergy testing can distinguish those who are at risk for reaction to penicillin from those with no or minimal risk. Pregnant patients who report a penicillin allergy may need alternative antibiotics, which are more costly and less effective than first-line antibiotics and are associated with increased maternal risks. Identifying patients who can tolerate penicillin and other β-lactam antibiotics through testing contributes to antibiotic stewardship, improves health outcomes, and saves costs. This Special Statement describes the steps for obstetrical providers to develop a penicillin allergy testing program for pregnant people using a quality improvement framework and multidisciplinary collaboration. It describes in detail how to plan an effective program and provides sample documents that can be modified to support planning, implementation, and evaluation.

KEYWORDS

allergy, anaphylaxis, antibiotic stewardship, cost-effectiveness, delabeling, desensitization, healthcare costs, penicillin, penicillin allergy testing

1 | INTRODUCTION

Penicillin allergy is one of the most commonly reported allergies and is reported by approximately 8% of pregnant individuals [1–3]. The majority of these patients are not truly allergic—either because the initial reaction was misdiagnosed as an allergy or the allergy has waned over time [1, 2, 4, 5]. Understanding a patient's history of penicillin allergy becomes especially important in the pregnant population, given that β-lactam antibiotics are commonly necessary in pregnancy for prophylactic treatment of group B streptococcus (GBS), surgical site infection prophylaxis in cesarean delivery, or treatment of syphilis in pregnancy. Because of the high rates of penicillin tolerance in those with reported allergies, identifying pregnant individuals who would tolerate penicillin

and other β-lactam antibiotics is an important public health goal.

Penicillin allergy testing has been used as an antibiotic stewardship practice to reduce unnecessary alternative and broad-spectrum antibiotic use, and data support this practice in the obstetrical population. The American College of Obstetricians and Gynecologists (ACOG), with the support of the Society for Maternal-Fetal Medicine (SMFM), recommends obtaining a penicillin allergy history to identify those who may benefit from penicillin allergy testing, including those with histories suggestive of an immunoglobulin E (IgE)-mediated process or allergy of unknown severity. Multiple studies have demonstrated not only the safety of allergy testing but also the high rate of penicillin allergy delabeling and reduction of alternative agent use [4, 6–12]. Delabeling refers to the removal of a penicillin allergy label based on initial misclassification of the allergy or current evidence of tolerance to penicillin. Treatment with alternative antibiotics has been associated with higher costs; less efficacy; increased complications, including toxicity and antibiotic-associated infections; increased hospitalization time; and increased mortality [7, 13–15]. In the obstetrical population specifically, the use of alternative antibiotics in the setting of unconfirmed penicillin allergy has been associated with increased rates of post-cesarean wound complications, endometritis, and prolonged maternal and neonatal hospital admissions [16]. Penicillin allergy testing programs are integral to promoting antibiotic stewardship, optimizing antibiotic therapy, decreasing adverse outcomes, and reducing healthcare costs.

Despite the benefits of an obstetrical penicillin allergy testing program, developing such a program can be daunting. Obstetrical providers play an important role in identifying individuals with a penicillin allergy, performing a thorough history, and referring individuals who would benefit from penicillin allergy testing. Doing so requires both knowledge of penicillin allergy and the capacity to perform all these tasks in addition to the many other tasks required as part of traditional prenatal care. Allergists or other allied health professionals must have the bandwidth to evaluate pregnant patients who require penicillin allergy evaluation and testing in a timely manner and feel comfortable caring for these individuals during pregnancy. To ultimately accept penicillin allergy testing, pregnant individuals often require detailed counseling regarding the importance and safety of testing in pregnancy. Logistical considerations, including standardized referral processes, wait times for allergy appointments, and access to in-person allergist evaluation and testing—as well as insurance coverage of this testing—are important aspects in developing a program. For patients who ultimately undergo successful testing and allergy delabeling, processes to facilitate timely communication and implementation of this information into clinical practice are necessary.

This Special Statement describes quality improvement approaches to penicillin allergy evaluation and testing in pregnancy and outlines best practices for implementing an obstetrical penicillin allergy testing program. The goal of this Special Statement is to optimize screening and testing for penicillin allergy in pregnancy and reduce the need for second-line antibiotics. We propose the introduction of quality metrics that will enable institutions and other stakeholders to assess their baseline screening and allergy referral rates, evaluate equity of screening, monitor changes over time, and identify opportunities for improvement.

2 | DEVELOPING A PENICILLIN ALLERGY TESTING PROGRAM USING QUALITY IMPROVEMENT METHODOLOGY

A focus on integrated care coordination is important in cases of reported penicillin allergy to expedite the patient's access to penicillin allergy testing, desensitization if needed, and prophylaxis or treatment of infectious diseases. Given the prevalence of patients who will tolerate β-lactam antibiotics, developing a penicillin allergy testing program becomes an important first step. Key stakeholders and champions of the program will span disciplines including obstetrics, maternal-fetal medicine, allergy/immunology, pharmacy, infectious disease, and nursing, reflecting the leadership within these disciplines and the institution. Engaged and interested individuals are the foundation of the obstetrical penicillin allergy program. Additionally, regular multidisciplinary meetings, either in person or virtual, can ensure alignment of the treatment timelines and contingencies.

Once a multidisciplinary group has been organized, developing the obstetrical penicillin allergy program can begin. Education is a key first step in development. It should include the rationale behind penicillin allergy testing in pregnancy, key tenets of penicillin history-taking, penicillin allergy testing steps, and the safety of penicillin allergy testing in pregnancy. Obstetrical providers should be educated on counseling patients on these aspects of testing. Suggestions for dissemination of information include weekly institutional meetings, such as grand rounds; small group educational sessions with nurses and providers; and educational materials that can be reviewed independently.

The electronic medical record (EMR) can be used to develop assistive strategies to translate education into

TABLE 1 Important information to include in history-taking tools to assess penicillin allergy.

- Type of reaction (e.g., rash, hives, angioedema, anaphylaxis)
- Timing of the event in relation to antibiotic administration
- Date of the allergic reaction
- Did the patient require treatment for the reaction?
- Other allergies to assess the allergy risk profile and potential for cross-reactivity
- Previously administered antibiotics and the presence or absence of residual reactions

patient care, including assistance with history-taking. The PEN-FAST penicillin allergy history tool has been validated internally and externally and may be helpful in identifying individuals who are unlikely to have a true penicillin allergy [17]. This tool assigns various points for the following aspects of the patient's reported penicillin allergy: 5 years or less since the reaction; anaphylaxis or angioedema; severe cutaneous adverse reaction; and treatment required for reaction. Total points indicate the patient's actual risk level (very low, low, moderate, or high). PEN-FAST can be built into the EMR for patient evaluation and subsequent documentation purposes. Other tools to assist in taking the patient's history are available that can be adapted to fit individual institutional needs. See Table 1 for important patient history information to include in these tools. Once history-taking is complete, patients can be characterized as having absent risk, low risk, moderate-to-high risk, or severe non-IgE-mediated reactions. Patients with histories that are inconsistent with allergies should be counseled on the appropriateness of penicillin administration, and the purported allergy should be removed from the patient's EMR and documented. For individuals with moderate-to-high risk or unclear histories, referral for penicillin allergy testing is warranted. For those with non-IgE-mediated reactions, penicillin should be avoided. Patients should receive educational information on penicillin allergy, the implications of delabeling, and the testing process. Providers should document this counseling in addition to the plan surrounding the penicillin allergy in the EMR. See Table 2 for penicillin allergy symptoms and Figure 1 for the assessment, referral, and treatment process.

2.1 | Sample documentation

The following statement is an example that can be used in documentation to describe the rationale for penicillin allergy testing:

> Penicillin allergy is the most commonly reported drug allergy in the United States, with a reported prevalence of 10%. Studies suggest that most individuals who report a penicillin allergy are not truly allergic—either because the index reaction was not penicillin-related or the sensitization dissipated over time. A majority of patients will require antibiotics during pregnancy, of which β-lactams, namely penicillins and cephalosporins, are the most frequently indicated as first-line therapy. Unfortunately, being labeled with a penicillin allergy during pregnancy has been associated with maternal morbidity, including increased risk of cesarean delivery, postcesarean wound complications, and longer hospital stay; therefore, penicillin allergy evaluation in pregnancy is recommended. The patient [does/does not] agree to this evaluation.

2.2 | Referral process

Once the indication for penicillin allergy testing is identified, the obstetrical provider should refer the patient for specialized testing by a qualified healthcare provider, who may be in the field of allergy/immunology, pharmacy, infectious disease, or another specialty. The referral process may involve electronic consultation, outpatient appointments, or both, depending on the program, and may be facilitated by a standardized template that includes the patient's pregnancy status, due date, and pertinent allergy history. The referral process should also include a standardized pathway for expedited urgent referrals to an allergy/immunology specialist when penicillin skin testing or desensitization is indicated, such as in the treatment of syphilis. Receiving clinics that process these referrals may have different bandwidths for consultation. Because of the time-sensitive nature of penicillin allergy testing in pregnancy prior to the time of clinical relevance (e.g., when the patient may need β-lactam antibiotics in pregnancy or at the time of syphilis diagnosis), using pre-established blocks in the allergy clinic's schedule reserved for high-risk or time-sensitive cases may be prudent. Evaluating wait times and clinic structuring is imperative during the development phase of the referral process, as some practices with long wait times may hold clinic slots specifically for pregnant patients to allow for timely testing. The patient should be provided with comprehensive instructions and support regarding penicillin allergy testing and information about what to expect during the encounter. Automated reminders for appointments should be set to

TABLE 2 Penicillin allergy symptoms by risk level [18].

Risk level	Symptoms
Not at risk	• Headaches • Family history with *no personal history* of allergic reaction • Yeast infections • Previous tolerance of penicillin
Low risk	• Rash (nonspecific or maculopapular) • Isolated symptoms that are unlikely allergic (e.g., itching without rash, nausea, diarrhea) • Unknown reaction >10 years ago without features of an allergic (IgE-mediated) reaction[a]
Moderate-to-high risk	• Hypotension • Hives or urticaria • Vomiting • Respiratory distress • Angioedema or laryngeal edema • Anaphylaxis
Severe non-IgE-mediated[a] risk	• Stevens–Johnson syndrome • Delayed-onset cutaneous or systemic reaction (e.g., eosinophilia or drug-induced hypersensitivity syndrome) • Toxic epidermal necrolysis • End-organ dysfunction

Abbreviation: IgE, immunoglobulin E.

[a]Features of IgE-mediated reaction include cutaneous symptoms (itching, flushing, urticaria, angioedema) with the presence of additional organ system involvement, such as the respiratory (dyspnea, wheezing, bronchospasm, shortness of breath), cardiovascular (arrhythmia, syncope, chest tightness), or gastrointestinal (abdominal pain, nausea, vomiting, diarrhea) system.

prevent lapses in care continuity and to prevent missed opportunities for evaluation.

Following consultation, penicillin allergy testing can occur. Institutions should develop local protocols for penicillin allergy testing in pregnancy that include testing location and timing, with a pre-specified eligibility algorithm. Testing should be performed in facilities with well-trained personnel who are able to identify allergic reactions and who have medications, equipment, and support staff available to treat potentially serious reactions. Protocols for transportation in an emergency should be outlined in case the patient develops a significant reaction during the allergy testing. After testing, patients should receive education and counseling on monitoring for important symptoms and information on whom to contact should these symptoms arise.

Testing will identify patients who are still considered to be allergic to penicillin and should not receive β-lactams unless they undergo desensitization. A process should be developed for those who require desensitization. Desensitization is rarely required during pregnancy. However, if needed, it carries the potential for anaphylaxis and should therefore take place in the inpatient setting—typically an intensive care unit—to ensure appropriate staff and equipment are available for an emergency. Inpatient preparation could be streamlined by the development of an order set, created with input from those representing the disciplines of allergy, obstetrics, and critical care. The order set should include consultation requests for all specialties, a penicillin dosing algorithm, a description of the type and frequency of maternal and fetal vital signs, and as-necessary orders for medical interventions targeted at reversing allergic reactions. Clear criteria for monitoring patient responses during and after desensitization should be established with input from allergy specialists regarding appropriate monitoring and from obstetrical providers regarding monitoring fetal status if the patient's pregnancy is at a viable gestational age.

If testing shows the patient does not have a penicillin allergy, a process should be developed, followed, and documented for counseling the patient, removing the allergy label from the EMR (i.e., delabeling), and alerting the obstetrical provider. The EMR can be adapted using smart elements to standardize the documentation and potentially allow for electronic query of testing results.

The penicillin testing program should undergo quality monitoring and continuous improvement. Patient and provider feedback should be elicited to evaluate the process, using measurements such as time to treat, patient experience, and clinical outcomes. The protocols should be regularly reviewed and refined based on outcome data to reduce delays and optimize care pathways. Any adverse outcomes should be reviewed for deviations from the standard of care or for opportunities for process improvement. Table 3 outlines a sample penicillin allergy

TABLE 3 Developing a penicillin allergy testing program [17, 19–23].

Step	Description
Define the problem.	• Reported penicillin allergy is common, although most individuals are not truly allergic. • A reported penicillin allergy is associated with adverse outcomes in pregnancy. • Obstetrical providers lack education on penicillin allergy evaluation and management. • Systems to assess penicillin allergy are absent. • Processes to refer patients expeditiously to penicillin allergy testing are lacking. • Patients who are not appropriately delabeled of their penicillin allergy receive second-line agents that are less effective, often more costly, and associated with increased risks of adverse outcomes.
Assemble the team.	At different sites, teams may consist of some of the following individuals based on availability, resources, and needs of the institution: • Maternal-fetal medicine specialist • Obstetrician • Anesthesiologist • Allergist • Infectious disease specialist • Intensive care specialist • Nursing staff • Pharmacist
Describe the proposed model for allergy testing.	Allergy testing should be performed in a facility with well-trained personnel and medications to address possible serious reactions, which may be different at each institution: • Ambulatory setting • Labor and delivery triage • Inpatient setting

Determine and set the goals.	Sample goals using the SMARTIE framework
	• Specific:
	  ○ Implement routine penicillin allergy testing for all indicated pregnant individuals reporting a drug allergy within X months.
	• Measurable:
	  ○ Increase the percentage of pregnant individuals receiving appropriate antibiotics for GBS prophylaxis by X% within X months.
	  ○ Increase the percentage of pregnant individuals with penicillin allergy undergoing cesarean delivery receiving appropriate surgical prophylactic antibiotics by X% within X months.
	• Achievable:
	  ○ Train X% of the multidisciplinary team on the new allergy testing protocols within X months.
	• Relevant:
	  ○ Ensure X% of patients with a documented penicillin allergy are counseled and X% receive a referral to allergy within their prenatal care period.
	• Time-bound:
	  ○ Achieve full integration of the multidisciplinary model into both ambulatory and inpatient settings within X year(s).
	• Inclusive/equitable:
	  ○ Review the measurable outcomes by demographic information (race, ethnicity, insurance status, preferred language, etc.) to ensure that these initiatives are applied equitably.
	Sample goals using the RE-AIM framework
	• Reach:
	  ○ Proportion of pregnant patients offered allergy testing
	• Effectiveness:
	  ○ Proportion of those who undergo testing and have their penicillin allergy label changed in the EMR versus the rate of use of second-line antibiotics for GBS prophylaxis (with goal of decreasing over time)
	• Adoption:
	  ○ Description of providers offering allergy testing in different clinical settings
	• Implementation:
	  ○ Fidelity and cost of the program
	• Maintenance (conceptually at individual and organizational levels):
	  ○ Measures of success (and balancing measures)

(Continues)

TABLE 3 (Continued)

Step	Description

Implement the intervention [17, 19, 20].	The interventions to implement a penicillin allergy testing program are multifaceted.
	• Programmatic implementation components
	  ○ Identification of patients with reported penicillin allergy
	  ■ Query of EMR for patients with an active pregnancy episode and penicillin allergy recorded in the EMR
	  ■ Standardized assessment using a screening tool such as PEN-FAST at a prespecified time period in pregnancy—for example, the initial prenatal visit
	  ○ Assessment of individual's penicillin allergy history
	  ■ Provider or ancillary staff education on penicillin allergy and related history-taking
	  ■ Evidence-based decision tools, such as PEN-FAST, to assess for low- versus high-risk allergies, or history-taking tools [21–23]
	• Referral system for individuals who require allergist evaluation
	  ○ Consider a standardized electronic consultation system to initiate referral
	  ○ Consider initial telemedicine consultation
	  ○ Use referral template with notation of pregnancy and estimated due date
	  ○ Consider holding clinical appointments for penicillin allergy testing in pregnancy at institutions with prolonged wait times
	• Devise standard penicillin allergy testing protocol in pregnancy
	  ○ Skin testing
	  ○ Oral challenge
	  ○ Safety monitoring plan and standardized patient education on precautions
	• Devise standard desensitization protocol in pregnancy
	  ○ Develop ideal location with necessary support staff and proximity to necessary medications and interventions
	  ○ Develop an inpatient order set
	  ○ Outline appropriate fetal and maternal monitoring during desensitization and after
	• Incorporate findings into clinical care
	  ○ Standard removal of penicillin allergy for individuals who have been delabeled
	  ○ Documentation of counseling and communication with referring obstetrical provider
	  ○ Obstetrical provider to incorporate allergy delabeling by using β-lactam antibiotics as first-line treatment when indicated
	• Monitoring for adverse events
	  ○ Data gathering system on allergic reactions, both immediate and delayed
	  ○ Consider standard documentation in the allergy consultation note
	  ○ Data gathering if any delayed adverse outcomes were associated with the allergic reaction
	• PDSA cycles (brief, allergy-specific focus)
	• Additional considerations
	  ○ Referral of pregnant people with multiple antibiotic allergies for potential testing/resolution to increase antibiotic options if needed
	  ○ Referral for testing for NSAID allergy to reduce use of opiates postpartum and/or make available for preeclampsia prophylaxis

Establish quality metrics.	• Possible process measures
	  ○ Documentation of counseling for individuals with penicillin allergy (can use the EMR to create queried data)
	  ○ Rate of referrals to allergy specialists (number of individuals referred over total individuals with penicillin allergy)
	  ○ Rate of completed referrals to allergy specialists (number of individuals with completed referrals over the number of individuals referred)
	• Possible outcome measures
	  ○ Rate of penicillin allergy delabeling (number of patients delabeled over total patients referred for penicillin allergy testing)
	  ■ Can consider evaluating observed penicillin allergy delabeling over expected based on the literature
	  ○ Rates of second-line antibiotics use for GBS prophylaxis
	  ■ Consider evaluating this measure based on individuals who underwent penicillin allergy testing versus those who did not
	  ■ Consider evaluating appropriate second-line antibiotic use via the algorithm
	  ○ Rates of appropriate GBS evaluation in the setting of penicillin allergy (PCR test versus culture with sensitivities)
	• Possible balancing measures
	  ○ Cost considerations (calculate costs of the program versus cost savings)
	  ○ Adverse reactions

Abbreviations: EMR, electronic medical record; GBS, group B streptococcus; NSAID, nonsteroidal anti-inflammatory drug; PCR, polymerase chain reaction; PDSA, plan, do, study, act.

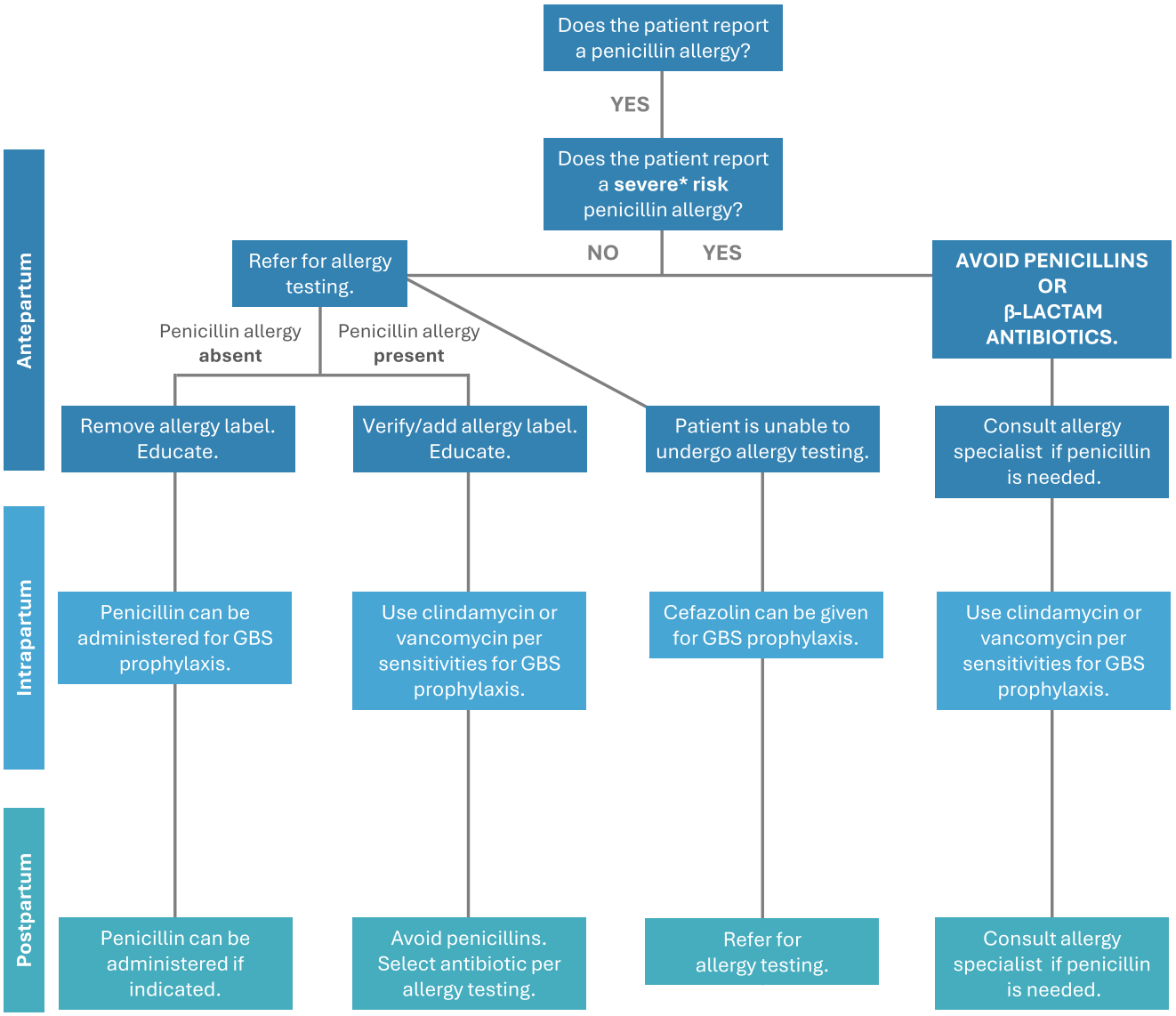

FIGURE 1 Flow chart of penicillin allergy assessment, referral, and treatment. *Severe risk is non-IgE-mediated. GBS, group B streptococcus; IgE, immunoglobulin E.

testing program, including key components, examples of quality improvement interventions, and quality metrics to consider. Plan-do-study-act (PDSA) cycles are necessary for continued refinement and should be planned during implementation of the penicillin testing program. See Figure 2 for a sample PDSA cycle.

3 | COST CONSIDERATIONS AND COST-EFFECTIVENESS/BUSINESS CASE

When developing a penicillin allergy testing program, it is important to consider cost and cost-effectiveness during implementation and beyond. Penicillin allergy testing in obstetrical care supports antibiotic stewardship, patient safety, and cost reduction, which aligns with precision medicine principles. Up to 95% of reported penicillin allergies are inaccurate or outdated [14], resulting in unnecessary use of second-line antibiotics, which incurs higher costs and increased maternal and neonatal complications [15]. According to modeling, testing can yield savings of $657 per inpatient and $2746 per outpatient [24]. ACOG endorses such testing to ensure safer antibiotic use during pregnancy [25].

Although initial investments in training, staff, equipment, and EMR tools are required, these costs are offset by long-term savings from reduced hospital stays, lower infection rates, and improved coordination of care [24]. Success metrics—such as delabeling rates and decreased second-line antibiotic use—demonstrate the value of testing programs and support national efforts to combat antimicrobial resistance [26].

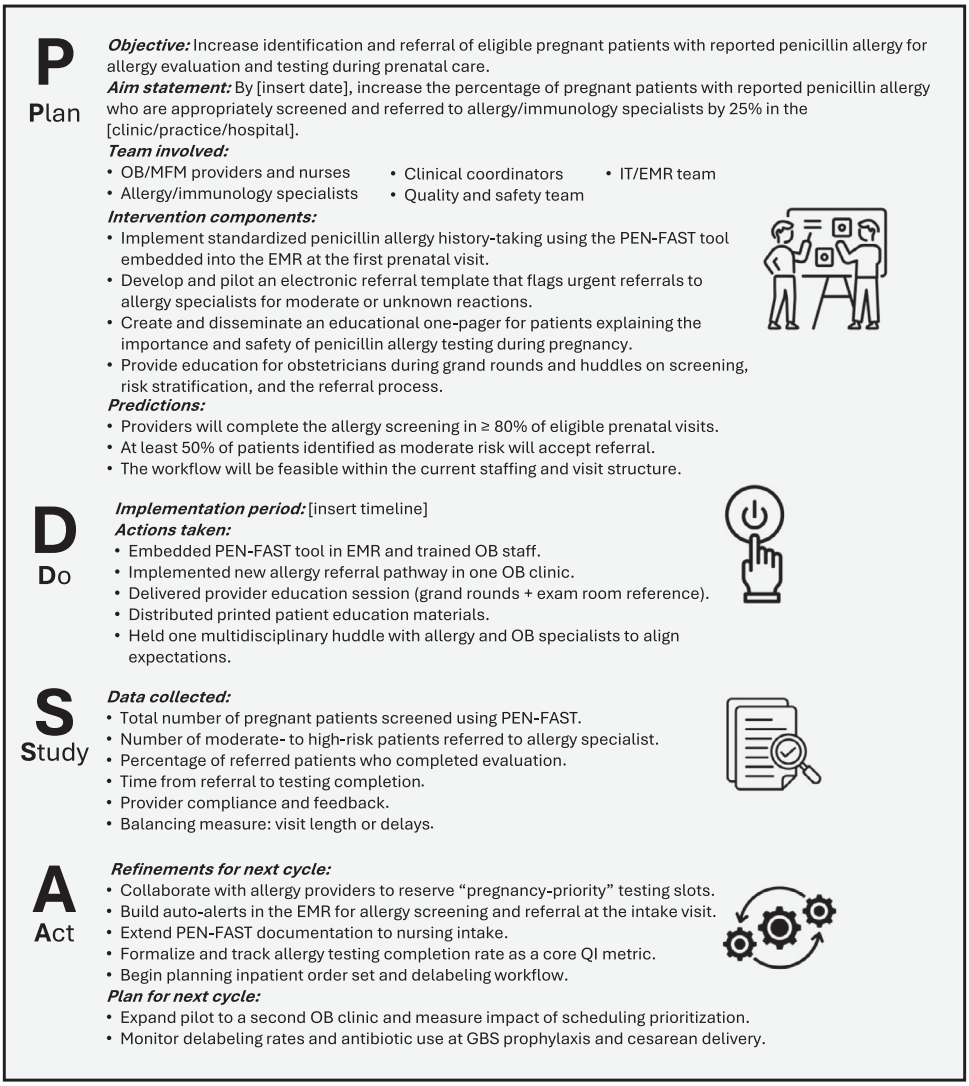

FIGURE 2 Sample plan-do-study-act (PDSA) cycle: Enhancing penicillin allergy screening and referral in prenatal care. EMR, electronic medical record; GBS, group B streptococcus; IT, information technology; MFM, maternal-fetal medicine; OB, obstetrics; QI, quality improvement

A sample financial model (see Figure 3) for a practice with 4000 annual deliveries (8% with reported penicillin allergies) projects direct costs of $328,400 and indirect costs of $20,000, with estimated annual savings of $345,600 from successful delabeling of 230 patients—achieving nearly a balance of costs and savings in year one and positioning the program for future gains.

Active involvement from an organization's financial stakeholders (e.g., chief financial officer, business manager) is essential for accurate cost-tracking, aligning expenses with institutional strategy, and validating cost-effectiveness. Close collaboration enables sustainable improvements by reducing reliance on broad-spectrum antibiotics, improving outcomes, and enhancing patient satisfaction.

3.1 | Creating a business plan for an obstetrical penicillin allergy testing program

Practices can develop a business plan for establishing a penicillin allergy testing program by adapting the model described in Figure 3 to their own obstetrical population. The business plan should first define the objectives of the program—for example, to identify and delabel penicillin allergies, thereby enhancing antibiotic stewardship, improving maternal and neonatal outcomes, and achieving cost savings. The business plan should describe the assumptions used to calculate the prevalence of penicillin allergy among the practice's population, projected uptake, success rate, and cost savings. It should define the

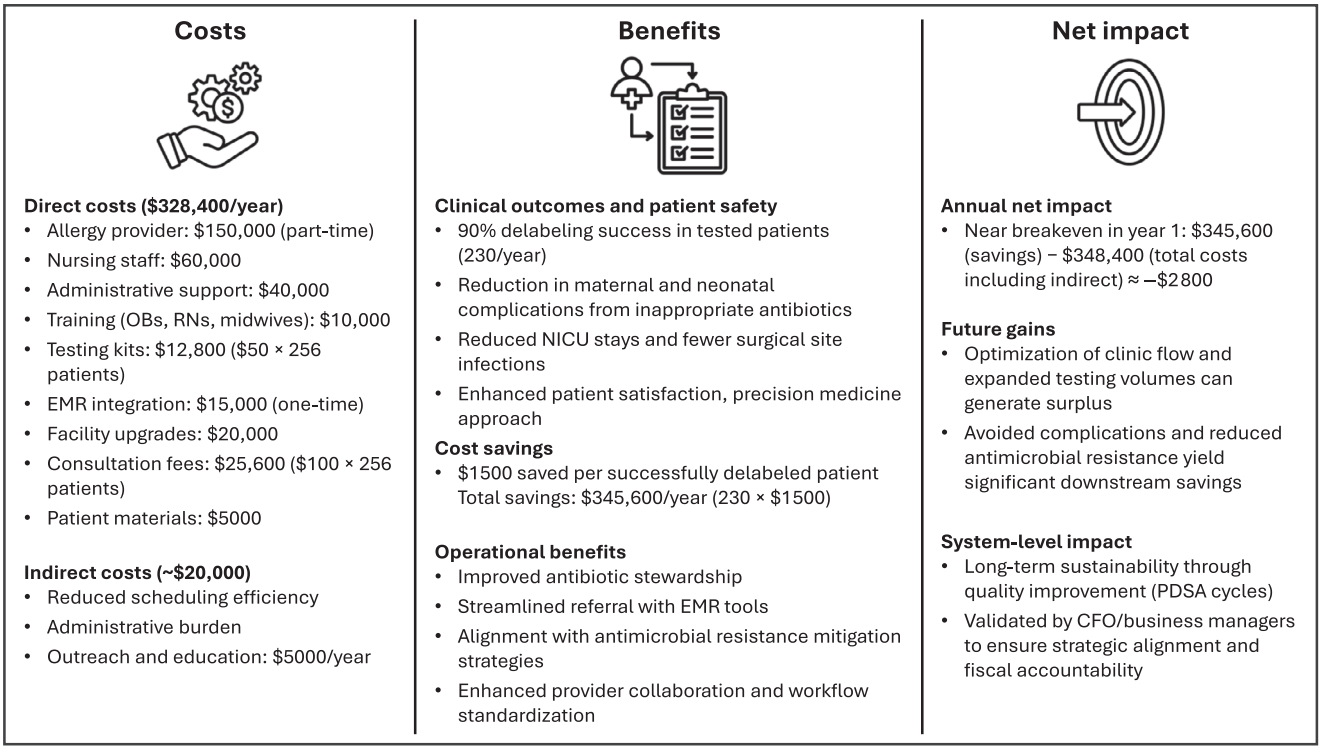

FIGURE 3 Hypothetical model of costs, benefits, and net impact of a penicillin allergy testing and desensitization program in a practice with 4000 deliveries per year [24]. CFO, chief financial officer; EMR, electronic medical record; NICU, neonatal intensive care unit; OB, obstetrician; PDSA, plan, do, study, act; RN, registered nurse

TABLE 4 Sample implementation timeline for establishing a penicillin allergy testing program.

Phase 1 (Months 1–3): Program planning, electronic medical record integration, training of medical staff, and patient education material development
Phase 2 (Months 4–6): Pilot testing program with a subset of patients and process adjustments based on feedback
Phase 3 (Months 7–12): Full-scale implementation, monitoring, and collection of initial outcome data
Ongoing: Continuous quality improvement cycles (plan-do-study-act) and annual reviews for cost and process optimization

components required for the initial investment. Finally, the business plan should include an implementation timeline (see Table 4).

4 | CONCLUSION

Reported penicillin allergy is common in pregnancy; however, most individuals do not have a true allergy. Penicillin allergy testing is crucial, as mislabeling can lead to less-effective, higher-risk, and more costly antibiotic use—potentially causing worse maternal and neonatal outcomes. Delabeling benefits patients by enabling safer use of first-line antibiotics and provides economic advantages by reducing unnecessary use of expensive alternatives, avoiding complications, and promoting optimal antibiotic stewardship. Leveraging quality frameworks for allergy identification, referral, and delabeling enables providers to standardize care, improve testing efficiency and efficacy, and track the impact of initiatives on optimizing patient outcomes.

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