Pharmacist-Led Penicillin Allergy Assessment Program – A pilot Study

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Disclosures

- I have no actual or relevant financial conflicts of interest in relation to this presentation
- This research was IRB approved at St. Cloud Hospital

Abbreviations

- Avg = Average
- DC = Direct challenge
- PCN = Penicillin
- PST = Penicillin skin testing
- RCT = Randomized controlled trial
- SCH = St. Cloud Hospital

Objectives

- Describe the benefits of de-labeling penicillin allergies
- Identify the role a pharmacist can play in implementing a penicillin allergy assessment and de-labeling service in an inpatient setting

St. Cloud Hospital (SCH)

- Located in St. Cloud, MN
- 489 licensed beds

Background

- About 25% of patients report having at least one allergy to an antibiotic with penicillin allergy being the most common
- Patient-reported penicillin allergies are widely unverified and unquestioned when less than 5% are truly allergic
- These unverified allergy labels are associated with poor patient outcomes including increased outpatient mortality, longer hospital stays, inappropriate antibiotic prescribing, development of antibiotic-resistant infections, and increased healthcare costs

Current PCN De-labeling Practices

- Gold Standard: skin testing followed by oral challenge if negative
- Recent RCT supports use of direct oral challenge alone
- Literature has shown that 30-63% of patients can have allergy removed after interview and assessment of medical records alone

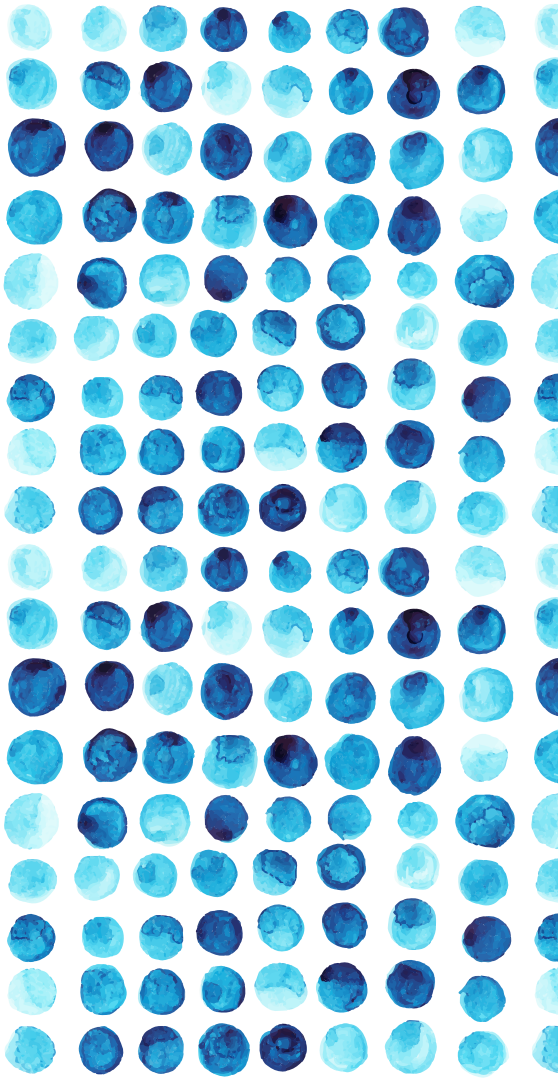
PALACE Randomized Clinical Trial

- Multicenter, parallel 2-arm noninferiority, international, open-label, randomized clinical trial
- Adult patients referred to an outpatient allergy clinic for a penicillin allergy history with a calculated PEN-FAST score < 3
- Objective: To determine whether a direct oral penicillin challenge is noninferior to the standard of care of penicillin skin testing followed by an oral challenge in patients with a low-risk penicillin allergy.
- Positive oral challenge occurred in 1/187 patients (0.5%) in the intervention group and 1/190 (0.5%) in the control group with an RD of 0.0084 pp (90% CI, -1.22 to 1.24 pp)

Study Purpose

To pilot pharmacist review and assessment for allergy de-labeling of inpatient units for patients with reported penicillin allergies at St. Cloud Hospital to determine the feasibility and potential clinical benefits of offering this service.

Methods



Study Design

- Single center, 5-week pilot
  - December 2023 to January 2024
- Included all non-pregnant adult patients admitted to St. Cloud Hospital
- Patient list generated each day utilizing Epic reporting system

Outcomes

- Primary:
  - Number of allergies removed
- Secondary:
  - Pharmacist time required to complete assessment
  - Average risk score of allergy
  - Number of recommendations accepted by providers

PEN	*Pe*nicillin allergy reported by patient	☐ *If yes, proceed with assessment*
F	*F*ive years or less since reaction[a]	☐ **2 points**
A	Anaphylaxis or angioedema	
	OR	☐ **2 points**
S	Severe cutaneous adverse reaction[b]	
T	*T*reatment required for reaction[a]	☐ **1 point**
		☐ **Total points**

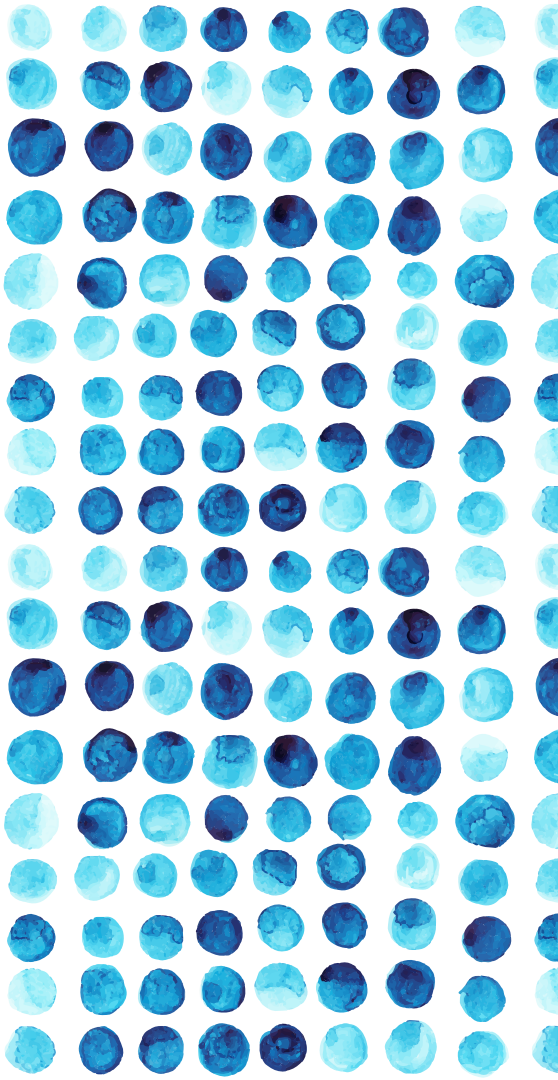
Interpretation

Points	
0	**Very low risk** of positive penicillin allergy test <1% (<1 in 100 patients reporting penicillin allergy)
1-2	**Low risk** of positive penicillin allergy test 5% (1 in 20 patients)
3	**Moderate risk** of positive penicillin allergy test 20% (1 in 5 patients)
4-5	**High risk** of positive penicillin allergy test 50% (1 in 2 patients)

Pharmacist Recommendations

- Non-immune-mediated reaction: Remove allergy
- 0-2: Direct oral challenge
- 3: Graded challenge/outpatient allergist
- 4-5: Leave allergy in place

Results

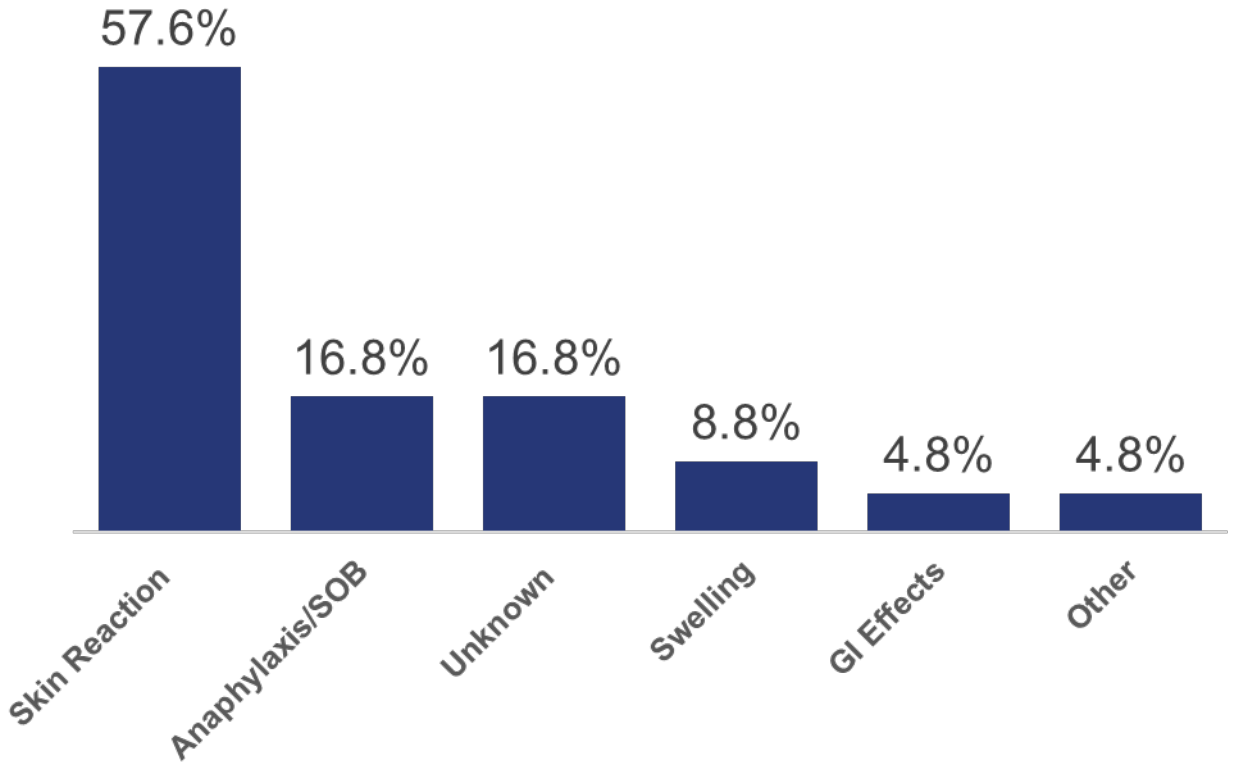


Patient Characteristics

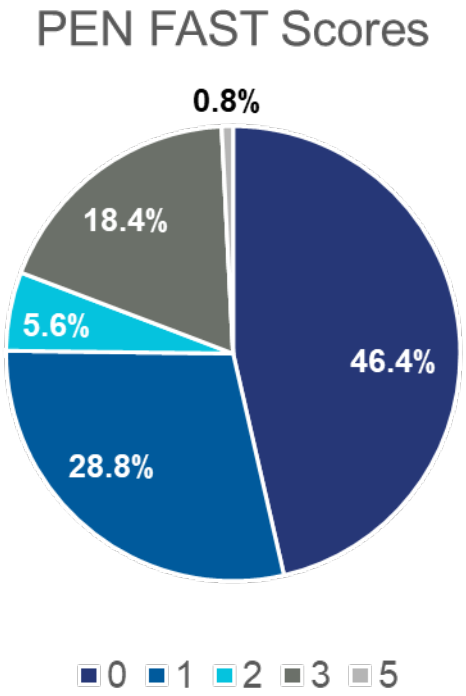
- 234 patients assessed, 125 included

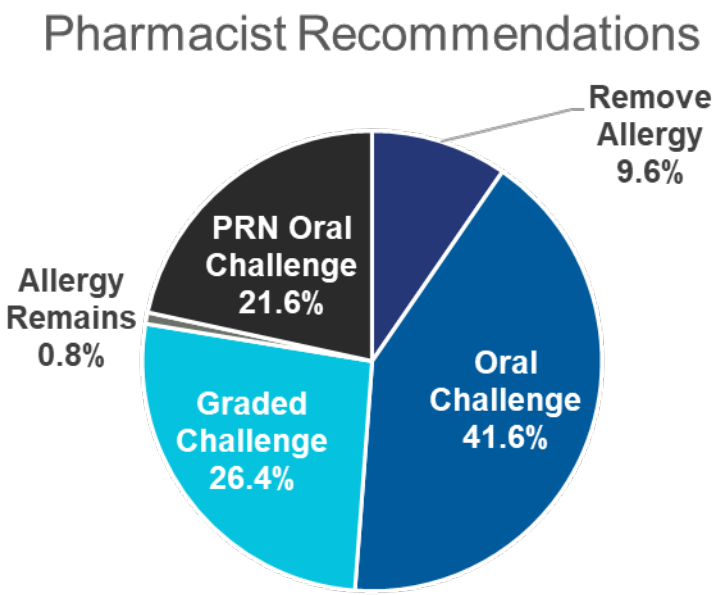
Study Population	
Age (mean) years	67.6 (22-98)
Female Gender, n %	73 (58.4%
Avg Census of PCN Allergies	24 (10-55)
Avg # Patients Seen per Day	11.7 (5-17)

Patient Reported Allergic Reactions



PEN-FAST Scores & Recommendations





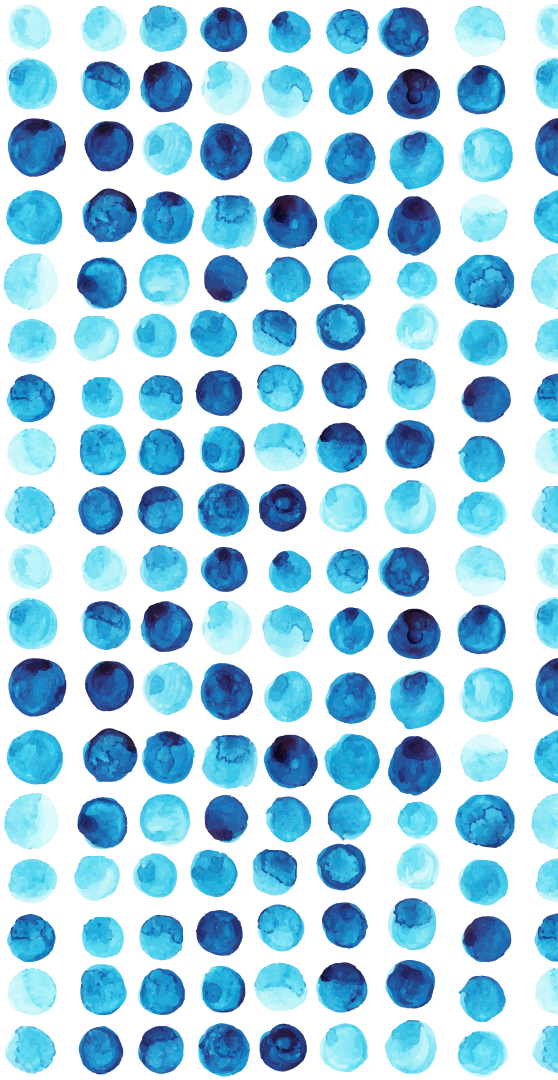
Primary & Secondary Outcomes

Outcomes	
Allergies Removed	**18 (14.4%)**
Recommendations Accepted	9 (17.3%)
Allergic Reactions w/Challenge	1 (12.5%)
Allergies Removed w/Interview Alone	**12 (67%)**

Secondary Outcomes (Feasibility)

Outcomes	
Average Time to Allergy Removal	18.1 hours
Average Pharmacist Time Spent Per Patient	17.2 min
Average # Patients Assessed Per Day	11.7

Discussion



Getting Provider Buy-In

- Sent out summary of project to hospitalist and intensivist teams before study began
- Answered all questions before study began
- Provided contact information for any questions that may come up

Provider Summary Layout

- Why?
- What?
- Who?
- When?
- Where?
- How will this affect you?
- How can you utilize this service to benefit your patients?
- Contact information

Provider Acceptance

- 9 (17.3%) of oral challenge recommendations accepted
  - Majority were hospitalists (89%)
- Received phone calls from providers with recommendations of patients to be included in the study
- When not accepted most providers did not leave a reason

Getting Patient Buy-In

- Explain the reasoning behind it
  - Facilitated through conversation with patient and completion of consent form
- Patients who are excited about removing the allergy can help prompt the provider as well
- 89% of patients agreed to direct oral challenge

Cost Savings

- Cost savings was not estimated in this study
- However, is another potential benefit that comes with PCN allergy de-labeling
- Less preferred regimens cost 1.82-2.58 times more than first-line beta-lactams

Cost Savings Studies

Study	Description	Savings
Jones et. al.	Quasi-experimental study comparing patients who completed PST with a matched control group	Average of **$353.03/patient**, and **$556.91/patient** for those who had an antimicrobial change
Harper et. al.	Multicenter, retrospective case series where pharmacist was asked to assess PCN allergy by physician with interview, PST, or amoxicillin challenge	Therapy adjusted in 80% of patients including switching from aztreonam which saved **$3,831.80/patient**
Sousa-Pinto et. al.	Economic evaluation study utilizing decision models to project economic impact of penicillin allergy testing	PST & DC: inpatient **$1444 and $256** outpatient Only DC: inpatient **$1343 and $417** outpatient Penicillin allergy testing found to be less costly in **78.8%** of simulations

Limitations

- Time constraints based on resident's schedule
- Many patients excluded due to being unable to remember reaction
- No outpatient follow-up

Conclusion & Next Steps

- Pharmacists can play a helpful role in penicillin allergy de-labeling with relatively minimal time commitment.
- Penicillin allergy assessments could easily be added to the current practice of pharmacist medication reconciliation at St. Cloud Hospital.

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