

Project Lead/Key Contact
<ul style="list-style-type: none"> • <i>Lindsey Gouker MD, Medical Director UNC Pre-Procedure Services</i> • <i>Lindsey_Gouker@med.unc.edu</i> • 303-885-1340
Why are you interested in the Improvement Scholars Program?
<p>The ISP provides a unique opportunity of support, guidance, and mentorship in the design and implementation of an inter-departmental quality improvement project. While I have led departmental and small-scale interdepartmental QI projects, this program would allow me to expand my influence on a larger scale. I would gain not only additional QI experience and knowledge but additional leadership experience that will be critical to my advancement in the world of QI. The guidance and support from experienced clinical improvement leaders that is afforded through the ISP, along with the assistance of an IHQI project manager will be instrumental in the success of this project.</p>
Problem Statement: What is the problem you are looking to solve?
<ul style="list-style-type: none"> • <i>What is the problem?</i> Penicillin (PCN) de-labeling is not easily accessible to UNC pre-procedural patients. • <i>What happens?</i> Patients who would benefit from PCN allergy assessment and oral challenge de-labeling ahead of an upcoming procedure cannot access this procedure easily within UNC Medical Center/Health. Often their PCN allergy goes unassessed, resulting in 2nd line antibiotic administration, which in turn can lead to increased cost to the system, sub-optimal surgical-site infection (SSI) prevention/treatment, and increases in multi-drug resistant (MDR) secondary infections. • <i>When does it happen?</i> Patients with a PCN allergy label are encountered daily within the UNC Pre-Procedure Services (PPS) Clinic. • <i>How often/how much?</i> Approximately 15% of UNC Health patients report a PCN allergy, but <1% are true allergies to PCN. The American Academy of Allergy, Asthma, and Immunology (AAAAI) recommends all patients with a history of PCN allergy undergo an evaluation of their allergy history and indicated testing. • <i>To whom (which patients and or providers) does it happen?</i> Patients with a PCN-allergy label and an upcoming procedure being evaluated in the PPS Clinic.
Suggested Solution: Offer PCN allergy-labeled patients assessments via screening +/- oral challenge in the UNC Health Pre-Procedure Services clinic.

<p>Importance Statement: Why is this project important?</p> <ul style="list-style-type: none"> • <i>How will the improvement benefit patients?</i> Unverified PCN allergy labels result in increased surgical site infection rates, increased secondary infections due to the use of alternative antibiotics, and increased healthcare costs. Given the low rate of true PCN allergy, performing assessments ahead of an upcoming surgery will allow for 1st line perioperative antibiotic use in most procedural patients, reducing perioperative complications outlined above. Additionally, removing an inaccurate PCN allergy label has been shown to improve future outcomes of care and reduce lifetime health care costs. De-labeling a patient has immediate benefits as it relates to a scheduled procedure but also lifetime benefits in the form of reduced healthcare costs and complications from alternative antibiotic use. • <i>What is the potential downside of this effort for patients?</i> (1) Risk of inducing an allergic reaction with oral challenge in patients with a true PCN allergy. This risk can be significantly mitigated with the use of validated screening assessments and protocols available via collaboration with our UNC Allergy/Immunology colleagues (Dr. Millie Kwan) who perform these same assessments and indicated testing in their outpatient clinic in Easttown and via resources available from the AAAAI. (2) PCN de-labeling is a billable procedure, so patients may incur costs related to their insurance coverage. • <i>What background information (data/analysis/literature) supports the choice of this effort?</i> The true rate of PCN allergy in general population is <1%, despite self-reporting rates of 10-15%. Patients with a history of PCN allergy are more likely to be treated with less effective and more toxic antibiotics, which results in increased SSI rates, increased secondary MDR bacterial infections (C.Diff, VRE, MRSA), and longer hospital stays (Blumenthal et al, Clin In Dis, 2018; Blumenthal et al BMJ 2018, Macy et al J Allergy Clin Immunol 2014). PCN allergy de-labeling has been shown to have a favorable cost-benefit ratio via cost-savings and better outcomes for patients (E. Macy and Y Shu, J allergy Clin Immunol 2017). Finally, the AAAAI issued the following position statement in 2022: “Efforts to de-label can and should be performed by all clinicians, especially for those with low-risk histories...The AAAAI encourages widespread and routine PCN allergy evaluations, which are integral for successful antibiotic stewardship.” PCN de-labeling is safe to be done in an outpatient setting with validated screening tools and safety protocols while improving patient outcomes and reducing health care costs. • <i>What area or organizational goals does this project align with/support?</i> 1. Patient harm reduction 2. Outpatient care improvement • <i>How has this problem been addressed successfully at UNC or elsewhere?</i> PCN allergy assessment and de-labeling with oral challenge is only currently available through the UNC Dept of Allergy/Immunology.
<p>Project Scope</p> <p>In Scope:</p> <ul style="list-style-type: none"> • <i>What is the specific patient population your project will impact?</i> Pre-procedural patients with a documented PCN allergy presenting to UNC PPS. • <i>How many patients are in the population?</i> ~30/week • <i>In what setting(s) would this problem be addressed?</i> PPS clinic (hospital-based outpatient clinic) <p>Out of Scope:</p> <ul style="list-style-type: none"> • Non-PCN allergic patients presenting to PPS clinic

Measures: (Process, Balancing, Structure)							
Please describe the anticipated outcome measure(s), 2-3 process measures, and one balancing measure. Please do not include more than 5 measures total.							
Measure Name	Measure Type	Measure Calculation	Measure Exclusion	Data Source	Baseline	Goal	Collection Frequency
PCN-allergic patients approached	Process	PCN patients approached/Total PCN allergy patients		Epic Smartphrase report	0%	80%	Q week
PCN allergic patient challenges completed	Outcome	PCN patients challenged/Total PCN allergy patients		Epic Smartphrase report	0%	50%	Q month
Antibiotic Stewardship	Outcome	% of surgical patients receiving 1 st line antibiotics perioperatively		Pharmacy audits via Epic reports	TBD	TBD	Q month
Adverse Events	Balancing	Adverse reactions to oral antibiotic challenge requiring medical management	Determined to be unrelated to antibiotic administration	Epic Smartphrase report	0%	<1%	Q week
Root Cause Analysis							
<ul style="list-style-type: none"> What do you think are the underlying causes of the problem? There are many financial and social barriers that limit access to allergists to assist in assessment of allergy validity and indicated testing and thus, allergy labels, once applied, are very difficult to remove. Why do you think the problem is happening? PCN and PCN-derivatives are common antibiotics used during childhood and young adulthood and are often accompanied by a variety of non-immune side-effects that are mislabeled as allergies. Their common use and general misunderstanding of allergy symptoms leads to inappropriate allergy-labeling. Additionally, there is limited ability to nuance allergy and side-effect labels within the EMR, and a fear of an avoidable adverse outcome as it relates to a medication allergy, both of which influence patients and clinicians to retain allergy labels. 							

Ideas for Improvement	
<ul style="list-style-type: none"> <i>What ideas do you have for changes that will result in improvement?</i> PPS will screen PCN-allergic patients seen in the PPS clinic ahead of an upcoming procedure and offer indicated oral antibiotic challenges with protocols established by UNC A/I colleagues in efforts to de-label PCN-allergic patients. This will result in both short-term gain in the form of improved perioperative antibiotic stewardship during their upcoming procedure and long-term gain in the form of lifetime healthcare-associated cost-savings and better patient outcomes. 	
Risks and Opportunities	
<ul style="list-style-type: none"> <i>What factors do you anticipate will foster improvement?</i> (1) Cohesive, consistent, and collaborative group of nurses, physicians, and ancillary staff in PPS (2) Strong desire within PPS staff to contribute to UNC Health patient outcomes via patient-centered opportunities during our encounters (3) Patients are desiring of procedures and often willing to engage in opportunities for improved health unique to the periprocedural time frame that they may not otherwise engage. <i>What are the major challenges you anticipate?</i> (1) Patients are often attached to their allergy labels and may fear harm with removal of the allergy (2) Patients may fear additional out-of-pocket costs for the testing (3) PPS staff may have reservations about the risk of an allergic reaction in the PPS clinic. 	
Stakeholders and Project Team Members	
<ul style="list-style-type: none"> <i>Who are the key stakeholders in your system and processes?</i> (1) PCN-allergy labeled patients (2) Surgeons/Proceduralists (3) PPS Staff (4) A/I colleagues (Dr. Kwan) (5) Pharmacists <i>Who are the key project team leaders to design and implement change?</i> Dr. Lindsey Gouker, Susan Hayek RN, Lindsay Daniels and/or another "to be determined" pharmacy subject matter expert 	
Name	Role
Ted Sakai, Greg Balfanz	<i>Sponsor(s)</i>
Lindsey Gouker	<i>Team Lead</i>
Mildred Kwan, Lindsay Daniels	<i>Subject Matter Expert(s)</i>
Nathan Woody	<i>Data Lead</i>
Susan Hayek	<i>Clinical Site Manager</i>
Impact on the Quintuple Aim	
<ul style="list-style-type: none"> <i>Improved health:</i> PCN allergy labels increase perioperative complications and lifetime health care costs and are notoriously inaccurate in >90% of those who carry the label. De-labeling will result in improved health and outcomes of our patients. <i>Enhanced patient experience:</i> This process is patient-centered in that it will allow patients to safely access a service that will improve their health and perioperative outcomes without having to travel to another clinic for a separate appointment. <i>Enhanced clinician and staff experience:</i> Leading a patient-centered initiative that has demonstrated safety in similar environments and has been shown to meaningfully impact health outcomes is professionally rewarding for PPS staff. Successful de-labeling will remove a clinical challenge that many clinicians face at the bedside: giving desired 1st line antibiotics or risk of an avoidable adverse reaction. De-labeling PCN allergies allows more clinicians to give 1st line antibiotics without fear of an avoidable adverse reaction. <i>Health equity:</i> Access to A/I services can be limited by institutional, social, and economic barriers. By offering this service embedded within another patient encounter in the PPS clinic, we are increasing access to care and equity while decreasing demand of an already limited A/I service. 	

<ul style="list-style-type: none"> • <i>Reduced costs:</i> Evidence shows that inaccurate PCN allergy labels, present in >90% of those who carry such designation, increase healthcare costs related to loss of antibiotic stewardship, increased rates of infections, and management of side-effects. De-labeling patients will reduce healthcare costs and improve patient outcomes.
<p>Sustainment Plan</p> <ul style="list-style-type: none"> • <i>What ideas do you have for sustaining the improvement?</i> Given the small, consistent, and engaged staff at PPS, this new process will be designed with the intention to incorporate the screening as part of every PCN-allergic patient encounter, which will reinforce its integration as routine for all patient encounters. • <i>How do you see the work you start with IHQI's support continuing?</i> While I feel I have a sound concept and have already established collaboration with other engaged SMEs within UNC Health, I foresee IHQI support helping me translate my process improvement from concept to reality by using guiding principles of Quality Improvement to give my project the best chance at success and sustainability. Once the process is successful within the PPS clinic, I foresee using our success, with the help of IHQI, to potentially expand it beyond the PPS clinic to other disciplines within UNC Health.
<p>Carolina Quality Tools</p> <p><i>How will Carolina Quality tools (Just Culture, SAFE reporting, TeamSTEPPS, huddles, and visual management boards) be used to support the work? Although use of these tools is not required, applications including them will be strengthened.</i></p> <p>A completely new process in the PPS clinic will require productive teamwork to be successful. To promote this productive teamwork, I will utilize time during our daily huddles to discuss PCN allergy delabeling process during the critical phases of project inception and initiation to seek feedback and inform PDSA cycles. With new processes that involve potential patient safety concerns, Team STEPPS will be utilized to help all members of the team to feel empowered to recognize and address any safety concerns and ultimately feel comfortable that the final process implemented upholds patient safety and centeredness.</p>
<p>References</p> <ul style="list-style-type: none"> • Sponsor: letter attached from Dr. Ted Sakai-Dept Chair, UNC Dept of Anesthesiology • Sponsor: (no letter, verbal agreement) Greg Balfanz-Vice Chair of Patient Safety and Quality Improvement, UNC Dept of Anesthesiology

April 2, 2025

Improvement Scholars Program Committee
Institute for Healthcare Quality Improvement
University of North Carolina at Chapel Hill

RE: Dr. Lindsay Gouker's application to the Improvement Scholars Program at UNC's Institute for Healthcare Quality Improvement (IHQI)

Dear Members of the Improvement Scholars Program Committee,

It is with great enthusiasm that I write to support Dr. Lindsay Gouker's application to the Improvement Scholars Program at UNC's Institute for Healthcare Quality Improvement (IHQI). Dr. Gouker is an exceptional clinician, educator, and leader whose dedication to advancing patient care through evidence-based, system-level improvements makes her an ideal candidate for this program.

As an Assistant Professor in the Department of Anesthesiology and the Medical Director of Preprocedure Services at UNC Medical Center, Dr. Gouker has demonstrated a consistent and passionate commitment to quality improvement, education, and patient safety. Her prior experience includes leading and contributing to a number of impactful QI initiatives, including optimizing perioperative antibiotic administration for patients with penicillin allergies and reducing the environmental impact of anesthetic practices. Her scholarship, including multiple presentations at the American Society of Anesthesiologists Annual Meeting, reflects a thoughtful, data-driven approach to improving clinical care.

Dr. Gouker has submitted a compelling concept proposal to develop a sustainable process for **penicillin-allergy delabeling** through oral antibiotic challenges in the Preprocedure Services (PPS) clinic. This initiative directly addresses a known barrier to optimal antibiotic stewardship and perioperative care and has the potential to significantly improve patient outcomes and resource utilization.

The Improvement Scholars Program is a structured, experiential learning program where participants learn clinical improvement leadership by proposing, designing, and leading a project with guidance and support from experienced clinical improvement leaders. Participants receive training, mentorship, and the dedicated support of an IHQI Faculty Coach and Project Manager for 12 months. I am confident that Dr. Gouker will fully engage with and contribute to the program, bringing her strong clinical insight, academic rigor, and collaborative spirit.

In support of this endeavor, I am pleased to confirm that Dr. Gouker will be granted protected time to dedicate to the proposed quality improvement project. Our department fully supports her participation in the Improvement Scholars Program and is committed to facilitating her ongoing development as a clinical improvement leader.

Thank you for considering Dr. Gouker's application. Please do not hesitate to contact me should you need any further information.

Sincerely,

A handwritten signature in blue ink that reads "Tetsuro Sakai". The signature is written in a cursive, flowing style.

Tetsuro (Ted) Sakai, MD, PhD, MHA, FASA
Professor and Chair,
Department of Anesthesiology
University of North Carolina at Chapel Hill