Proposal Format and Length (by invitation only, due to Arianna Keil by February 3, 2023).
If you are invited to submit a full proposal, please address the items below. Format proposals using 11-point font, 1-inch margins and single-spaced text. Please limit responses to items #2-#17 to a maximum of 8 pages.

1. Project Lead/Key Contact (name, email & phone number)
    1. Sean Gaffney, MD M.Ed. – Project Co-Lead, sgaffney@med.unc.edu 330-592-5611
    2. Vineeta Rao, CPP – Project Co-Lead, vineeta.rao@unchealth.unc.edu 317-224-7252

2. Why are you interested in participating in the Improvement Scholars Program?

Sean Gaffney: I am the new Medical Director of the Outpatient Oncology Palliative Care (OOPC) clinic. In this new role, I am looking forward to improving our current care-delivery model and expanding access to our services. Prior to this appointment, I primarily engaged with quality improvement through the lens of medical education as I have background as a former high school teacher and a Master's degree in Education. While I believe that education is a vital aspect of improving patient care, I am aware that education alone is ineffective. Thus, it is essential to develop skills in other methods of quality improvement, particularly as I grow in this leadership role. With that in mind, I would be thrilled to join the IHQI Scholars Program where I will have the opportunity to 'learn by doing' and to benefit from the expertise of quality improvement specialists throughout our institution. If selected for this program, I would welcome the periodic learning sessions and monthly mentorship as I know these lessons will be immediately applicable in my role as Medical Director and will also give me the tools needed to translate our quality improvement work into publishable material that can be shared with our peer institutions.

Vineeta Rao: Quality improvement is a passion of mine because it connects me to the patient – once a problem is identified, my goal as a clinician is to create a sustainable solution that will improve care for not just one but many patients across our system. What gives me the most fulfilment in my work as a clinician is to see the direct impact of care in my patient's lives. I see the investment in QI as an opportunity to multiply my impact as a clinician, by creating system processes that maximize the benefits that each individual patient will receive for their care and to ensure their care is thoughtful, consistent, and equitable. Since beginning in my pharmacist role in the Outpatient Oncology Palliative Care team, I have seen the growing need to be thoughtful and consistent with opioid prescribing and risk mitigation strategies, as the opioid crisis continues to ravage our nation and a growing number of patients with concurrent substance use disorders struggle with cancer-related pain. I am confident that establishing consistent and standard practices for opioid safety in our clinic will enable each clinician to spend more time with the patient and to focus on the heart of palliative care – supporting each individual coping with advanced illness and maximizing their quality of life. By participating in the Scholars Program, I hope to gain time-management, multidisciplinary teamwork, and presentation and publication skills to balance quality improvement project management with my daily role as a clinician, so that I am better equipped to identify care gaps and to create and implement sustainable solutions to improve care. Having additional mentorship through the IHQI will also provide experience and perspective to create a more sustainable and highly impactive change within in our clinic.

3. **Which UNC Health improvement priority will your project address?**

By employing a standardized approach to opioid risk mitigation, that is multi-disciplinary and pharmacist-led, we endeavor to address two main improvement priorities, and two minor improvement priorities. First, this approach will improve health equity. It is well documented that pain in minority populations is mischaracterized and undertreated, and that historically under-represented populations receive differential care based on perceptions of opioid risk.[1–3] We want to ensure that we are providing safe access to opioids to all patients regardless of race, ethnicity or prior substance use history. Without a standardized approach to opioid risk mitigation, we risk allowing implicit biases to inform our decisions about when to prescribe opioids and when to increase monitoring for opioid misuse. Second, this initiative aligns with preventing patient harm and reducing mortality by cultivating a culture of safe opioid prescribing and by standardizing care for patients who receive opioid medication prescriptions. Finally, while not the primary improvement targets of this initiative, this project will occur in the outpatient setting and we anticipate that this approach will support the improvement priorities of "outpatient care improvement" and "patient experience promotion."

4. **What is the problem or gap in quality you seek to improve?**

The quality gap we are trying to improve is two-fold. First, there is a prevalence of under treatment of cancer-related pain, with an estimated 1/3 of cancer patients not receiving adequate analgesia and this is thought to disproportionately impact underrepresented individuals.[2,4] Inadequate analgesia not only increases a patient's suffering but negatively impacts functional status and ability to cope with serious illness[5]. Uncontrolled pain is correlated with increased presentation to the ED and subsequent hospital admission.[6]

Second, while opioids may be essential treatment for cancer-related pain, there continues to be a public health crisis related to opioid misuse. In 2019, there were nearly 50,000 opioid overdose deaths in the United States.[7] Overdose is just one of several risks associated with opioids. Appropriately, similar guidelines have been developed by the Centers for Disease Control and Prevention (CDC), the American Society of Clinical Oncology (ASCO) and the American Pain Society underscoring the importance of an opioid risk mitigation strategy for all patient receiving opioid prescriptions.[5,8,9] Each of these guidelines embraces a "universal precautions" strategy, which includes appropriate pain assessment, , risk evaluation for opioid misuse, informed consent with patient-provider agreement, frequent re-assessment of risk/benefits, and routine monitoring, often with urine drug screens.[10]

While these guidelines exist, they have primarily been focused on non-cancer patients with chronic pain requiring long-term opioid use, with few examples of how to successfully implement these guidelines in the cancer population. At present, there is no standardized approach for opioid risk mitigation for oncology patients at UNC receiving opioids for cancer-related pain. With no standardized protocol to reduce opioid misuse, any effort to address these complicated issues end up being provider specific. This is not only confusing for patients but also makes it more likely that implicit bias may be impacting decisions about who is monitored for opioid misuse and who is denied access to critical medication for cancer-related pain. Our over-arching objective is to develop a multi-disciplinary, standardized approach to opioid risk mitigation to address this two-fold problem.

5. **Describe the patient population affected, scope, and impact of the problem (1 page)**

What is the specific patient population your project will impact?

The target population for our project will be all cancer patients at UNC receiving opioids for cancer-related pain through the outpatient oncology palliative care (OOPC) clinic. In the future, we plan to expand this quality improvement process to include all cancer patients at UNC receiving opioid therapy, regardless of whether it is through the OOPC clinic.

How many patients are in the population?

Historically, the OOPC clinic sees ~500 new patients per year, with over 1800 unique visits. While not all of our patients require opioids for cancer-related pain, we prescribe opioids for at least 85% of our patients.

How frequently does the problem occur?

Nationally, it is estimated that the prevalence of opioid use disorder is 8% in patients with chronic, cancer-related pain[11], and over 20% of oncology patients are believed to be at risk for nonmedical opioid use[12]. As there has been a national push to reduce adverse events related to opioid use, there has also been an overcorrection in some practices that is impacting the ability for cancer patients to safely receive first-line opioid medications for moderate to severe cancer-related pain.[5] At UNC, the extent of the problem is unclear as there has not been a uniform approach to screening and identifying patients at increased risk for non-medical opioid use or OUD in the cancer population. Given that UNC serves a higher percentage of underrepresented groups, it is likely that the problem is more prevalent amongst the population of patients cared for at the Cancer Hospital compared to national averages.

What is the impact of the problem?

As discussed in detail above, the impact of the problem is two-fold, causing under treatment of pain for many cancer patients, while continuing the risk of opioid misuse and abuse by a subset of cancer patients. Under treatment of pain not only results in unnecessary suffering and decline in functional ability, it also has systematically impacted underrepresented communities with greater frequency. The consequences of opioid misuse and abuse are well-documented in the medical literature and the lay press. Prescribing opioids with a universally applied opioid risk mitigation plan matches best practices under current guidelines; it also has the potential to improve cancer pain management while reducing risk of opioid misuse and abuse.

6. **What do you think are the underlying causes of the problem? Why do you think the problem is happening?**

For decades, "cancer pain" has been considered an alternative category exempt from the same opioid prescribing restrictions applied to other categories of pain. Most pain management guidelines, including the recently updated guidelines from the Centers for Disease Control and Prevention (CDC) published in November 2022[9], exclude the management of cancer-related pain from recommendations regarding the limited use of opioid doses and duration for chronic pain (defined as pain persisting for longer than three months). While it is appropriate to categorize cancer-related pain as unique, due to the often quickly changing nature of pain directly related to a potentially rapidly changing disease, this separate categorization may have contributed to the underlying thought that patients with cancer pain are not at risk for substance use disorders.[11] As cancer care has vastly improved in the past decades, new treatment modalities have allowed patients to live longer with a diagnosis of advanced cancer with a high quality of life. Every decision a clinician and patient make is based on an assessment of the risk of an intervention compared to its benefit. For a patient with an end-stage disease and limited life of months, the risk and benefit ratio may differ significantly from a patient who has a prognosis of decades. For the patient with a prognosis of months, the long-term adverse effects of medications like opioids may not be nearly as high of a risk when compared to the benefit of function, pain relief, and quality of life they

receive from the medication. However, the converse is also true – that a patient with a cancer diagnosis with a prognosis of years is not immune to the adverse effects and risk of dependence that can occur with opioid therapy.

Compared to the chronic pain setting, there have not been standard policies regarding opioid prescribing and risk mitigation in the oncology setting where patients' disease course may fluctuate rapidly. The lack of standard policies can introduce clinician bias, as it is left to the individual clinician's subjective perception of risk to order a urine drug screen, prescribe naloxone, or complete a signed patient-provide pain agreement. Implementing standard practices for these risk mitigation steps can minimize clinician bias and provide equitable care for all patients receiving opioids.

7. **What is the history of improvement or attempted improvement at UNC Health? What work will your proposed improvement build on?**

In other outpatient settings where pain medications are frequently prescribed, such as the UNC Hospital Pain Management Center, standard practices are in place for opioid risk mitigation. In this clinic, patient sign pain agreement yearly and agreements are updated by nursing staff. Prompts such as placing a "miscellaneous nursing order" are utilized to communicate needs for updates to staff. Progress notes are used to track urine drug screens and pain agreement updated dates. Urine drug screens are updated at least yearly for stable, low-moderate risk patients or more frequently if there are aberrancies or a patient is moderate-high risk. Most providers prescribe nasal naloxone for patients prescribed oral morphine equivalent (OME) of 50 or greater, if they have a comorbid condition that increases risk of respiratory depression, if they are also prescribed benzodiazepines or other sedating medications or if there are children or other concerning people present in the home. Clinic pharmacist (CPP) keeps track of the last prescribed dates of naloxone in the patient's progress note and reorders a prescription every 2 years. Clinic also performs pill counts to monitor medication use. Patients are instructed to bring all remaining pills or empty bottles/boxes if they are out of medication and our nurses perform pill counts when rooming the patient. The pill count is documented in the patient chart by the nurse and we use this as part of our clinical assessment of the patient. The pain clinic follows the UNC policy for "Management and Monitoring of Controlled Substances in Outpatient Care Setting". If changing opioids or the patient is no longer taking them and has pills leftover, clinic staff will destroy them in clinic per the policy.

Our proposed improvement will build upon these risk mitigation steps taken by other UNC outpatient clinics by establishing a workflow process to ensure risk mitigation steps of routine naloxone prescribing, urine drug screens, and signed pain agreements in the outpatient oncology palliative care clinic.

8. **Please complete the "Measures Table". Please describe the anticipated outcome measure(s), 2-3 process measures, and one balancing measure. Please do not include more than 5 measures total.**

Our primary objective with this intervention is to ensure that all patients receiving opioid medications are being properly educated on the risks associated with opioids and are aware of the universal strategies our clinic will be employing to ensure opioid risk mitigation. To that end, our primary outcome will be whether patients have reviewed and signed our patient-provider opioid agreement which both reviews the risk associated with opioid use and reviews our monitoring policies. The patient-centered goal behind this primary outcome is to reduce and avoid opioid-related adverse events. Given that aim, our secondary measure will be to track opioid-related adverse events, with a specific focus on evidence of non-medical opioid use and ED/Hospital presentations for opioid-related complications.

We will track two process measures to help ensure we are implementing the monitoring steps of patient-provider opioid agreement. First, we will track whether or not a patient has been prescribed naloxone. As noted above, the more naloxone available at home or in a community, the better the likelihood of averting opioid overdose and death.[13] Second, we will measure urine drug screen performed within 3 months of establishing care with our team. The literature suggests that universal urine screening can help detect non-medical opioid use earlier, thereby allowing treatment plan adjustments or appropriate referral if substance use disorder determined to be present. [5]

Finally, while this intervention is designed to help reduce provider distress, we want to make sure that actually proves to be the case. Our balancing measure will be to survey the clinicians and staff in the OOPC clinic to elicit their feedback on how this intervention is impacting their daily workflow and overall sense of moral distress related to opioid prescribing.

Measure Name	Measure Type	Measure Calculation	Measure Exclusion	Data Source	Baseline	Goal	Collection Frequency
Primary: Signed Opioid Agreement for all OOPC patients receiving opioid prescriptions	**Outcome**	Numerator: Patients in OOPC clinic with signed opioid agreement documented in Epic Denominator: OOPC clinic patients receiving opioid prescription	OOPC clinic patients not receiving opioid prescription from OOPC provider	Epic media tab and OOPC provider notes	Not currently available	90%	Monthly
Secondary: Opioid Related Adverse Events (evidence of non-medical opioid use, ED/Hospital Admission for opioid related complication)	**Outcome**	Numerator: Patients in OOPC clinic with adverse opioid event Denominator: OOPC clinic patients receiving opioid prescription		Epic Chart Review	Unknown	<15%	Every 3 months
Percentage of OOPC clinic patients with Urine Drug Screen (UDS) in first three months	**Process**	Numerator: Patients in OOPC with documented UDS in first 3 months of establishing care Denominator: New OOPC clinic patients receiving opioid prescription	OOPC clinic patients not receiving opioid prescription from OOPC provider	Epic Results Section	Not currently known	75%	Monthly
Percentage of OOPC clinic patients prescribed Narcan	**Process**	Numerator: Patients in OOPC clinic with naloxone prescription Denominator: OOPC clinic patients receiving opioid prescription		Epic medication section	Not currently known	90%	Monthly
Provider Satisfaction with New Protocol	**Balancing**	Opioid Risk Mitigation Survey		Measurement Tool		>90% satisfaction	Every 3 months

9. **What ideas do you have for changes that will result in improvement? (1-2 pages)**

The current guidelines-supported strategy for opioid risk mitigation is to employ a "Universal Precautions" strategy with each patient that requires opioid therapy to manage long-term pain. While each set of guidelines interprets universal precautions slightly differently, the general themes include appropriate pain assessment, risk evaluation for opioid misuse, informed consent with patient-provider agreement, frequent re-assessment of pain and risks/benefits ongoing opioid therapy, and routine monitoring, often with urine drug screens. If aberrant behavior is identified or substance use disorder is diagnosed, this should be addressed transparently with patient and additional support should be provided.

While this approach is rational and has been successful utilized in the non-cancer pain population, it is challenging to implement, particularly in the oncology context. In the OOPC clinic, past attempts have been made to employ universal precautions, most notably a patient-provider opioid agreement was developed several years ago and is intermittently utilized. Overall, however, these efforts have fallen short and there remains no standardized approach to opioid risk mitigation for oncology patients at UNC. Part of the dilemma in the OOPC clinic is that pain management is only a small subset of our work within our broader efforts to accompany patients and families coping with serious illness. As a result, we find that time spent on opioid risk mitigation limits our ability to build trust/rapport, provide coping support, and assist patients with critical advance care planning needs.

To address this gap, we are aiming to launch a multi-disciplinary initiative to codify a consistent approach to universal precautions for all cancer patients receiving opioid medications for cancer-related pain. To develop a standardized process that will be sustainable, we will engage in an iterative process with a multi-disciplinary team. We will start with a pilot led by our clinical pharmacist colleagues with specialty-trained in palliative care, in collaboration with the nursing leadership and physician/APP providers in the OOPC clinic. Similar to the manner in which oncology pharmacists meet separately with patients to review the risks/benefits of chemotherapy, we plan to have palliative-care trained pharmacists have separate clinic visits with patients.

As our first test of change, we will focus on a subset of patients in the OOPC clinic. Our pilot will focus on new patients seen by project co-leader, Sean Gaffney, MD who sees ~15-20 new patients per month. During a patient's initial visit, pain will be assessed, opioid plan will be made, and provider will introduce a standardized clinic protocol to ensure that all patients *safely* have access to needed opioid medications. Patient will be informed that they will be scheduled for a separate visit (virtual or in-person) with our other project co-lead, Vineeta Rao, a clinical pharmacist. During this visit, the clinical pharmacist will review the risks/benefits of opioid therapy, establish expectations for opioid monitoring, and sign a patient-provider opioid agreement with each patient. In addition to this intervention, we will also keep a registry of each patient that is participating in this new, standardized protocol. For each patient, we will be tracking whether they have had their opioid safety visit, whether they signed an opioid agreement, whether they have an up-to-date naloxone prescription, whether they have had a urine drug-screen within the first 3 months of establishing care, whether they have displayed any behavior suggestive of non-medical opioid use (i.e. early refill request) and whether they have presented to ED or been admitted for opioid related, adverse event. Data collection and entry to the registry will be conducted on a continual basis with a plan for monthly review to ensure all data is collected through the EHR. Along with keeping this registry, we plan to meet 1-2x/month to review the registry, flag any patients that are not meeting the protocol objectives, complete a root-cause analysis of why they are not meeting the objectives, and then appropriately intervene.

By starting with this smaller-scale test of change, we will be able to address obstacles and improve our approach through multiple PDSA cycles. Once a uniform approach is solidified, the project will be expanded to include the other MDs and APPs in the OOPC clinic. To allow for this expansion, we anticipate that we will train other team members to lead dedicated opioid risk mitigation visits with patients. While the pharmacy department is appropriately situated to lead this effort, clinical pharmacists are a limited resource and we anticipate needing to cross-train nurses and providers to meet this need. Furthermore, at project onset, we will more heavily rely on chart review and manual input of registry data. With time and in collaboration with our embedded epic professionals, we hope to track this data more seamlessly through Epic in a manner that will allow the work of monitoring and intervening to occur more naturally in the normal work-flow of subsequent clinic visits.

10. **How has this problem has been addressed successfully elsewhere?**

In a 2020 article published in the Journal of General Internal Medicine, Seal et al. describe the impact of a quality improvement initiative implemented at the San Francisco VA Medical Center (SFVAMC) aimed at reducing opioid dose and mitigating opioid risk.[14] An interdisciplinary pain team (IPT) consisting of medical providers, psychologists, and pharmacists were embedded into primary care clinics within the SFVAMC campuses to address care based on a biopsychosocial model of pain care. In addition to improving pain control, this initiative sought to meet VA opioid safety initiative metrics of increasing urine drug screen monitoring, increasing naloxone kit distribution, and decreasing co-prescription of opioids and benzodiazepines. Visits were conducted virtually or in-person periodically over a 6-month

period (median of 4 visits in 6 months), and these visits focused on nonpharmacological, physical, and behavioral self-management strategies for pain control. Compared to a matched cohort of patients receiving usual primary care (UPC), 174 patients in the intervention group saw a significantly greater mean opioid reduction in Morphine Equivalent Daily Dose (MEDD) at 6 months (68.4 MMED in IPT group vs. 107.1 MMED in UPC group, $p = 0.03$). In addition, an uptake in opioid risk mitigation strategies was observed in the group receiving IPT care. Naloxone distribution increased from 38.1% to 71.4% in the IPT group after 6 months, and co-prescribing of benzodiazepines decreased from 16.3% to 10.9%. While differences exist between this non-cancer chronic pain population consisting exclusively of veterans compared to the OOPC clinic at UNC, this initiative sought to address risk mitigation through regular, targeted telehealth or in-person visits with multidisciplinary personnel in a similar manner to the QI initiative we propose and saw an improvement in adherence to VA national safety standards.

In 2020, Hellier et al. published a single-center retrospective cohort study describing a pharmacist-led monitoring of patients prescribed opioids for chronic non-cancer pain in an academic resident clinic.[15] The pharmacist's primary intervention was implementation of CDC guidelines for opioid monitoring and risk mitigation in patients with chronic non-malignant pain. Primary outcomes included creation of an annual patient provider agreement, annual urine drug screen, and quarterly review of a prescription drug monitoring program, and documentation of quarterly evaluation of opioid use. Compared to a control group of 100 patients who did not receive monitoring, the group receiving pharmacist-led monitoring of opioid risk mitigation (n=100) showed significant increase in patient provider agreement creation (28% vs 100%, $p < 0.001$), increase in UDS obtained (59.2% vs 90.6 %, $p < 0.001$), and quarterly review of prescription drug monitoring program (26% vs 70%, $p < 0.001$). This initiative demonstrates the impact a clinical pharmacist can have on opioid risk mitigation within a clinic.

As described in response to Question 7, within the UNC Health system, risk mitigation strategies that include a regular workflow for obtaining patient-provider agreements, urine drug screens, and naloxone prescriptions have been successfully implemented and primarily managed by a clinical pharmacist in the UNC Pain Management Center. These examples demonstrate effective efforts to address opioid safety and risk mitigation strategies within outpatient clinics and provide models of how an interdisciplinary team including a pharmacist can implement successful measures to that end. Helpful though these examples are, this quality improvement initiative differs significantly as this clinic serves exclusively oncology patients and seeks to address opioid safety in the context of cancer related pain.

11. **How will high performance management tools (Just Culture, SAFE reporting, team communication and teaming skills, huddles, and visual management boards) be used to support the work?**

The OOPC clinic already employs a weekly team huddle every Monday, in which we address system-based concerns and patient-specific issues as a multi-disciplinary team comprised of physicians/APPs, nurses, pharmacists, and clinic administrators. With the initiation of this improvement project, we will continue to utilize the weekly team huddle and dedicated a portion of each huddle to reviewing progress related to this project and troubleshooting any patient-specific issues.

A top priority for implementing this project is to contribute to a just culture. Right now, as a clinic, we carry the moral distress of trying to provide opioid medications to patients in need without a standardized approach to reducing opioid-related risks. In doing so, we are concerned that we are contributing to racial and health inequities as we know implicit bias likely informs decision-making in the absence of a just, standardized approach.

As part of the pilot phase of this intervention, the project co-leaders intend collaborate with the project manager and project sponsor to develop a visual management board prior to rolling out the intervention to the entire clinic.

12. **Please describe how your project addresses each of the 5 elements reflected in the** Quintuple Aim for Health Care Improvement.

Improved health – The entire purpose of this intervention is to ensure that patients with cancer-related pain have safe access to needed opioid medications. In doing so, we reduce suffering and improve functional status related to pain. Furthermore, by implementing a standardized opioid risk mitigation strategy, patients are educated from the start on the risks and benefits of opioids. Then, through protocolized monitoring, we will be able to identify nonmedical opioid use earlier, reduce opioid misuse, and assist patients with opioid use disorder with obtaining treatment earlier. Finally, our protocol will specifically ensure that all patients receiving opioids have access to naloxone which has been demonstrated to reduce opioid deaths in communities with adequate naloxone saturation.

Enhanced patient experience – This improvement project is specifically designed to enhance the patient experience. First, by creating a dedicated visit to review opioid risks and benefits, we are able to clearly set expectations for patients,

we are able to reduce fears related to opioid side effects, and we are able to establish that are clinic is built on a culture of transparency and safety. Second, by turning opioid risk mitigation into a multi-disciplinary endeavor, the palliative care provider will now be able to dedicated more time to the other needs of our patients and families, particularly related to coping with cancer.

Enhanced clinician and staff experience - One of the current challenges with opioid risk mitigation in the OOPC clinic is that the first visit is not the best suited time to review our clinic's opioid policy. For a palliative care provider in an oncology clinic, the first visit is ideally focused on conducting a full symptom review, building rapport by learning about a patient's background, and starting the conversation around prognostic awareness and advance care planning. Adding in opioid risk mitigation not only crowds out time but threatens to undercut rapport-building. At the same time, our OOPC providers report significant moral distress related to trying to implement opioid risk mitigation without a standardized process. Providers worry that they are either allowing implicit-bias to impact decision-making or worry that they are not providing adequate risk mitigation and thereby potentially causing harm to patients or unknowingly facilitating opioid diversion.

Health equity - The literature as captured the unfortunate truth that underrepresented populations frequently have pain mischaracterized and undertreated.1–3 As part of this initiative, we want to ensure that we are providing safe access to opioids to all patients regardless of background. By standardizing a universal approach to opioid risk mitigation, we aim to remove implicit bias from the decision-making process when it comes pain assessment, opioid prescribing and monitoring for nonmedical opioid use. Through this approach, we aim to increase access to needed opioid pain medications for historically underrepresented populations while also establishing necessary safeguards for patients at increased risk of opioid misuse, which is documented to be more prevalent in socio-economically disadvantaged populations.

Reduced costs - While cost reduction is not the explicit purpose of this intervention, we do expect to be cost neutral as we do not anticipate needing to hire any additional personnel to implement this intervention. Additionally, the literature does suggest that there may be cost reduction in several forms, including: 1) currently, significant staff time is devoted to early opioid refill requests. We anticipate this intervention will reduce early refill requests and allow staff time for other tasks. 2) By improving undertreatment and improving opioid safety, we hope to reduce ED and hospital admissions for uncontrolled pain and for adverse opioid events

13. **Please describe the support and engagement you have from leadership for the work you are proposing. Please indicate leaders with whom you have consulted about this proposal**. (1/2 page)

From the palliative care perspective, this project has been reviewed with Dr. Laura Hanson who is the Medical Director of UNC Palliative Care. Dr. Hanson was the first to suggest that we apply for the IHQI Scholars Program. She has offered her full support for the initiative and has volunteered to be the project sponsor. She has been a leader in the Department of Medicine for decades and has extensive research and quality improvement experience. Additionally, we have discussed this initiative with Melanie Kelly (RN/MSN) who is the Director of Palliative Care Services for the UNC Health System. She has pledged her full support for this initiative as well and believes it will be a helpful model that other palliative care clinics may be able to adopt across the system.

This project also has the backing of multiple levels of leadership within the Department of Pharmacy Services. Interim Assistant Director of Oncology Pharmacy Services, Nathan Barnes, has met with Vineeta Rao to discuss the purpose and design of this quality improvement project. As Vineeta's direct report, he has agreed to support the time commitment needed to implement this project and participate in the Scholar's Program and has committed to ensuring Vineeta will have adequate time to dedicate to it. Lead Clinical pharmacist of Outpatient Clinical Oncology Group, Jordan Miller, has already met with Vineeta separately to discuss the vision for this project, to provide helpful feedback on project design and outcomes, and has offered full support of her participation in the Scholar's Program including ensuring she has time dedicated to project activities. Before his transition out of his role in Fall 2022, former Director of Oncology Pharmacy Services Maurice Alexander also provided full support of the initiative, commenting that this QI project meets a nationally recognized need for equitable care by reducing clinician bias and ensuring standard practices for opioid risk mitigation.

14. **Who will comprise the project team?**

Sean Gaffney, MD, M.Ed.; Project Co-Lead: Sean is an Assistant Professor with the UNC Palliative Care Program within the Division of General Medicine and Clinical Epidemiology. He is the Medical Director of the OOPC clinic. Sean will be responsible for engaging with and coaching all of the staff in the OOPC clinic on how to implement this new

initiative. He will help analyze monthly data collection and conduct root-cause analysis for any patient that is not meeting the project objectives.

Vineeta Rao, CPP; Project Co-Lead: Vineeta is clinical pharmacist with specialty training in palliative care. She will be the primary representative from the pharmacy department. Vineeta is already embedded in the OOPC clinic and is involved in care for the entire clinic population. In her role, she is looking to increase her direct patient time and therefore will be the primary pharmacist conducting dedicated opioid risk mitigation appointments with each new patient. Along with pharmacy residents, Vineeta will help collect data monthly and flag any patients that are not meeting the targets of the universal precautions initiative

Jennifer Hanspal, RN, BSN, MS, OCN: Jennifer is the clinical nurse manager for the OOPC clinic. Previously, she worked as an Oncology Nurse Navigator with the Comprehensive Cancer Support Program and served on the UNC Cancer Survivorship Advisory Board and the UNC Oncology Patient Education Committee. Jennifer extensive experiencing in implementing new QI initiatives in the ambulatory setting.

Christine McGrath: Christine is an administrative specialist with UNC Health. She coordinates patient appointments for all patients in the OOPC Clinic. She will ensure that all patients have a dedicated appointment with our pharmacy team.

Melanie Kelly, RN, MSN, CHPN: Melanie is the Director for Palliative Care Services at UNC Health. Her leadership interest and roles have included system-level work to increase palliative care's reach and integrate palliative care principals through education and process changes. Melanie works regularly with other clinical leaders across the UNC Health System, including prior as a co-lead for the UNC Advance Care Planning Taskforce.

Kristen Bingham, PT, DPT: Kristen is an embedded Epic Professional at UNC who specializing in ambulatory workflows to promote optimization, standardization and end-user experience with Epic@UNC EMR. She is the primary Epic liaison for the OOPC Clinic and will help navigate data collection through the Epic EHR.

Laura C. Hanson, MD, MPH; Project Sponsor: Dr. Hanson will provide expertise in quality improvement methods and measurement. She is Professor of Geriatric Medicine and Medical Director of the UNC Palliative Care Program. She has extensive experience in quality improvement methods applied to palliative care, including CMS contractual work resulting in NQF-endorsed quality measures. She will be the project sponsor and provide regular guidance for how to improve our intervention and then turn this intervention into scholarly work.

15. **How will you ensure sufficient time to dedicate to the project over the scholar year?**
Sean Gaffney will see patients in this project as part of his routine clinical work. In addition to his clinical work, Sean has 0.1 FTE dedicated to his administrative role as the medical director of the OOPC clinic and this works fall within the purview of that role. In addition, Sean has 0.15 FTE dedicated to QI/Educational initiatives. For the duration of the IHQI Scholars Program, Sean will dedicate that 0.15 FTE to this project, which will easily allow for 4-8 hours per week.

Vineeta Rao will also see patients in this project as part of her routine clinical work. She has clinical time in the OOPC clinic at least 4 days per weeks and is currently looking to increase her direct patient interaction and views this initiative as the most appropriate use of her unique skillset. In addition, Vineeta has the full support of her supervisor to dedicate some of her administrative time to participating in data collection and monitoring our registry of patients to flag needed intervention.

16. **What factors do you anticipate will foster and hinder improvement? (1 page)**
There are several factors that will foster and support this improvement project. First, as discussed above, the current lack of a standardize approach to opioid risk mitigation is a source of significant moral distress for providers in the OOPC Clinic. As a result, there is significant demand for this intervention and we anticipate enthusiastic participation and feedback. Second, this intervention is intentionally multi-disciplinary. We believe in the strength of working in a team design and are confident our intervention will be improved by the diverse input of multiple team members. Third, we are employing an iterative process of implementation. By intentionally beginning with a smaller footprint, we ensure that we will quickly be able to adjust and enhance the intervention. Finally, this is not the first quality improvement initiative that the OOPC clinic and its staff have implemented. We are an embedded clinic within the cancer hospital, so we are accustom to working collaboratively and troubleshooting across a variety of clinic settings. This experience will prove critical as we roll out this intervention.

As with any intervention, we can also anticipate barriers to success. First, based on our initial review, the outcome data we are planning to track is not quickly identifiable in the EHR. We recognize that reviewing charts to gather outcome data

will be labor intensive and that the sustainability of this approach will need improved data collection mechanisms. Second, as currently conceived, we are planning on increasing patient-facing encounters. Based on our current staffing model, we believe we can meet this demand. However, we acknowledge that this might prevent scaling this model to all clinics, which is why we intend to develop a data registry that would allow pivoting towards more of a collaborative care model if necessary. Finally, this intervention has not had the luxury of being vetted by actual patients. We anticipate patients will appreciate increased clarity and transparency, but we may encounter unexpected patient feedback (i.e. resistance to monitoring intervention such as urine drug screen or dissatisfaction with having to sign an opioid agreement).

17. **What ideas do you have for sustaining the improvement? How do you see the work you start with IHQI's support continuing? (1/2 page)**

Given the current demand for a standardized approach to opioid risk mitigation, we are confident this approach will be readily adapted by the providers in our clinic, especially given our plans to incorporate their feedback throughout its implementation. Between the enthusiasm for a standardized approach to opioid risk mitigation and utilizing a multi-disciplinary team, we anticipate this protocol being naturally absorbed into the clinic culture for the enduring future.

Furthermore, our improvement project is intentionally iterative. After piloting this initiative with a subset of patients within the OOPC clinic, we will then experience scaling to the entire OOPC clinic. By building in the experience of scaling this model, we expect to learn critical lessons that will make us better prepared to help facilitate the expansion of this model to other ambulatory settings.

18. **Implementation Timeline (1 page)**

April 2023: Notification of Award

April- August 2023:

- IRB application
- Gather baseline data of current outcome measures (patient-provider opioid agreements, naloxone prescriptions, early refill requests)
- Work with Epic Professionals to upgrade outpatient dashboard
- Design opioid risk mitigation visit procedure
- Review and upgrade patient-provider opioid agreement
- Create opioid risk mitigation survey for provider/staff feedback from OOPC

Sept 1, 2023: Project Start

Sept-Oct 2023:

- Implement pilot of intervention with medical director and clinical pharmacist
- Monthly collection of measure data through chart review
- PDSA cycle on pilot intervention
- Develop visual management board in preparation for expansion from pilot phase to entire clinic

November-December 2023:

- collection of first quarter quality metrics
- root cause analysis of deviations from standardized protocol and adverse opioid events from quarter 1
- Update and training for all staff in OOPC Clinic
- Expand intervention to all OOPC providers by start of Cycle 2

January- Feb 2024:

- collection of second quarter quality metrics
- root cause analysis of deviations from standardized protocol and adverse opioid events from quarter 2
- refinement of standardized workflow with input from all OOPC providers during weekly team huddles
- Update visual management board

March-May 2024:

- collection of 3rd quarter quality metrics
- root cause analysis of deviations from standardized protocol and adverse opioid events from quarter 3
- Opioid Risk Mitigation survey given to providers/staff of OOPC Clinic

May-July 2024:

- collection of 4th quarter quality metrics
- root cause analysis of deviations from standardized protocol and adverse opioid events from quarter 4
- final reporting of project progress
- sustainability planning
    - Design education curriculum to teach other clinics

19. References

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20. Letters of Support: Two letters of support are required. One from the project sponsor (defined below) and one from your supervisor. Submit both letters with the application.

1. Project Sponsor (required letter of support, first of two)

The project sponsor (e.g., Division Chief, Service Leader, Department Chair, Nursing Supervisor, Vice President, etc.) has executive authority and provides liaison with other areas of the organization, serves as a link to senior management and the strategic aims of the organization, and provides resources and removes barriers on behalf of the team.

The Improvement Scholar and project team are accountable to the Project Sponsor for project results. The sponsor is not a day-to-day participant in team meetings and testing. The sponsor reviews the team's progress on a regular basis. The sponsor must meet at least quarterly with the project team.

The project sponsor's letter of support should describe his/her commitment to supporting change within the unit and working to facilitate changes outside the unit as needed.

2. Supervisor (required letter of support, second of two)

The supervisor's letter of support should describe his/her commitment to ensuring that the Improvement Scholar will have sufficient time to:

- Conduct the improvement project
- Attend IHQI meetings and just-in-time training (see page 1)