DEVELOPING AND IMPLEMENTING A FORMAL PREGNANCY SCREENING POLICY PRIOR TO SYSTEMIC CANCER TREATMENT: A QUALITY IMPROVEMENT PROJECT

by

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ABSTRACT

Background: Systemic anticancer therapies are essential to cancer treatment but pose significant teratogenic risks when administered during pregnancy, particularly during the first trimester. Pregnancy screening prior to systemic therapy remains inconsistent nationwide, with reported screening rates as low as 17–20%. In June 2025, the Quality Oncology Practice Initiative (QOPI) introduced standards requiring formal pregnancy screening policies and documentation before initiation of systemic therapy.

Local Problem: This QOPI-certified cancer center lacked a formal pregnancy screening policy, increasing the risk of an adverse event.

Purpose: This quality improvement project aimed to implement a standardized pregnancy screening policy and achieve 100% compliance among patients of childbearing potential aged 18–50 receiving systemic cancer therapy at a comprehensive cancer center in south-central Montana.

Methods/Intervention: Guided by the Plan–Do–Study–Act framework, a pregnancy screening policy was integrated into electronic health record workflows including modifying treatment plans and infusion checklists, creating standing orders, and standardizing documentation. Staff and provider education and multidisciplinary collaboration supported workflow refinement. Weekly retrospective chart audits monitored compliance for patients receiving intravenous, subcutaneous, or oral systemic cancer therapy over 7 weeks.

Results: At baseline, no eligible patients had documented pregnancy screenings (0%). After three PDSA cycles, missed screenings decreased from 100% (0) to 59% (24/41) among eligible infusion patients and from 100% (0) to 65% (11/17) among eligible oral therapy patients.

Conclusion: Standardized pregnancy screening improved compliance with QOPI standards, but workflow barriers remain. Ongoing audit, education, and process refinement are required to sustain safe patient care.

CHAPTER ONE

REVIEW OF THE LITERATURE

Introduction

With permission from advising faculty, the following review of literature is a continuation of unpublished work presented in *Before the first dose: Preventing patient harm by standardizing pregnancy testing prior to chemotherapy* (Bosket, 2025).

Cytotoxic chemotherapy, targeted therapy, immunotherapy, and hormonal therapy are collectively referred to as systemic therapy, anticancer therapy, or antineoplastic therapy (Sylva & Ahmed, 2024). While being the cornerstone of cancer treatment, systemic therapy poses significant risks to a pregnant woman and the fetus, particularly during the first trimester of pregnancy (Shah et al., 2023). Chemotherapy targets all rapidly dividing cells, amplifying the risk of teratogenic effects in a developing fetus (van Gerwen et al., 2021). Targeted therapy and immunotherapy also disrupt vital processes of fetal growth (Wolters et al., 2021). Exposure to such agents in the first trimester is known to lead to miscarriage and anomalies of organs and limbs (van Gerwen et al., 2021; Wolters et al., 2021). Likewise, Danet et al. (2018) report facial malformations, central nervous system (CNS), and cardiac defects along with myelosuppression, infection, and hemorrhage in the first trimester. Exposure to systemic therapy in the second and third trimesters affects the nervous, skeletal, and renal system development. Even if no congenital abnormalities occur, exposure to systemic therapy causes intrauterine growth restriction and decreases amniotic fluid which contributes to preterm birth (Danet et al., 2018).

Despite known pregnancy dangers, national oncology organizations such as the American Society of Clinical Oncology (ASCO), the National Comprehensive Cancer Network (NCCN), and the Oncology Nursing Society (ONS) have historically failed to issue guidelines for routine pregnancy testing prior to chemotherapy administration (Gustafson et al., 2018; AHRQ, 2023). As a result, cancer centers across the country lack uniform approaches to pregnancy screening (Gustafson et al., 2018). While some cancer centers have written internal facility policies, Jangles et al. (2018) found that thirty percent of surveyed cancer organizations failed to have a pregnancy screening policy. The absence of a standardized pregnancy screening policy reflects a critical gap in both ethical standards and clinical practice, ultimately placing patients at increased risk. However, as of June 2025, ASCO's Quality Oncology Practice Initiative (QOPI) released new certification standards regarding pregnancy screening. The new standards require a policy addressing pregnancy testing and documentation for all routes of treatment administration prior to initiating therapy and prior to each regimen change (Association for Clinical Oncology, 2025). To maintain QOPI certification, this cancer center in south-central Montana must develop and implement a formal policy regarding pregnancy testing and documentation.

Background

Although pregnancy with cancer occurs infrequently, with an incidence of 0.1–0.2% (Jangels et al., 2018), Gustafson et al. (2018) maintain that the administration of chemotherapy to a pregnant person should be a "never" event thus justifying a universal approach to prevent potential catastrophic harm. In addition, Britton (2017) found that many patients either did not receive contraceptive counseling or received inadequate counseling from their oncology team. The combination of high-risk drug administration and insufficient patient education significantly

elevates the risk of harm and emphasizes the need for confirmation of pregnancy status prior to receiving chemotherapy.

Oncology professionals rely on national organizations such as ASCO, NCCN, and ONS to lead the profession in research, treatment, education, advocacy, and policy. The evidence-based guidelines promote high-quality patient care to improve patient outcomes (ASCO, 2025; NCCN, 2025; ONS, 2025). For decades, these national oncology organizations have acknowledged the teratogenic risks of antineoplastic therapy by publishing literature highlighting the risks of chemotherapy to pregnant persons and fetuses (Gustafson et al., 2018; AHRQ, 2023). Despite this awareness, no formal guidelines existed for pregnancy screening. The lack of guidelines produced variability across institutions, with many institutions lacking any policy (Gustafson et al., 2018).

New standards released by QOPI in June 2025 provide structured guidance for cancer centers to model formal pregnancy screening policies and procedures. This change provides direction for QOPI certified cancer centers to ensure patient safety with consistent screening practices. To maintain QOPI certification, this cancer center in south-central Montana must comply with new standard 3.1 regarding pregnancy screening. Failure to establish a policy not only puts the cancer center at risk for losing QOPI certification but, more importantly, places patients of childbearing potential at risk for a catastrophic adverse event. Therefore, this scoping review aims to synthesize research regarding pregnancy testing prior to systemic cancer treatment, how to improve policy compliance, and utilization of serum vs urine pregnancy testing.

Methods

Search Strategies

This scoping review was prepared utilizing the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA). A PRISMA flow diagram is provided in Appendix A. A literature synthesis review of the databases Web of Science and CatSearch along with searching Google Scholar was conducted from June 19-22, 2025 using the following terms: “pregnancy,” “pregnancy testing,” “pregnancy screening,” “urine,” “serum,” “standardized,” “cancer,” “chemotherapy,” “policy,” and “quality improvement.”

Eligibility — Inclusion and Exclusion Criteria

Articles were included if they were (1) published between 2015-2025, (2) peer reviewed, (3) open-access, (4) full text, (5) focused on patients over 18 years of age, and (6) abstracts of quality improvement projects initiating pregnancy screening prior to systemic therapy. Articles were excluded if they were (1) published outside the timeframe, (2) focused on patients less than 18 receiving systemic therapy, (3) not available in full text, (4) concentrated on one specific systemic cancer therapy, and (5) focused on pregnancy screening prior to radiation therapy.

Results

The initial search consists of 979 articles. After evaluation, using the inclusion and exclusion criteria, 13 articles are included in the scoping review. Three sources are abstracts of quality improvement projects presented at ASCO. Two abstracts present the data that led to a quality improvement project and one abstract presents the use of an EHR to increase compliance

with pregnancy screening policy. Two sources are cohort studies which evaluated pregnant women who received chemotherapy and adverse outcomes. Two sources are a retrospective observational study which evaluated the frequency of pregnancy screening prior to systemic cancer treatment. One source is a systematic review on the prevalence of contraception counseling and use as well as unintended pregnancy and abortion. One source is a descriptive, prospective study on the pregnancies of women exposed to antineoplastic agents. Two sources are policy development articles urging the development of pregnancy screening standards. One source is descriptive review on the management of pregnancies while having cancer. One source is an educational summary stating the superiority of serum over urine specimens for pregnancy screening.

Table 1. Summary of Sources in the Scoping Review

Author(s)	Year	Study Type	Description / Focus
Berger et al.	2019	QI Abstract (ASCO)	Quality improvement project on pregnancy testing before chemotherapy.
Rogers et al.	2017	QI Abstract (ASCO)	Quality improvement project on pregnancy testing before chemotherapy.
Shah et al.	2023	QI Abstract (ASCO)	Utilization of an EHR to increase compliance.
van Gerwen et al.	2021	Cohort Study	Evaluated pregnant women who received chemotherapy and adverse fetal outcomes.
Metcalfe et al.	2025	Cohort Study	Examined maternal and neonatal outcomes following chemotherapy exposure during pregnancy.
Chadwick et al.	2021	Retrospective Observational Study	Assessed the frequency of pregnancy screening prior to systemic cancer treatment.
Hu et al.	2019	Retrospective Observational Study	Evaluated institutional compliance with pregnancy screening protocols before chemotherapy.

Table 1. Summary of Sources in the Scoping Review continued

Authors(s)	Year	Study Type	Description/Focus
Britton	2017	Systematic Review	Investigated contraception counseling, use, unintended pregnancy, and abortion.
Danet et al.	2018	Descriptive Prospective Study	Followed pregnancies of women exposed to antineoplastic agents.
Gustafson et al.	2018	Policy Development Article	Advocated for creation of standardized pregnancy screening guidelines.
Jagel et al.	2018	Policy Development Article	Advocated for creation of standardized pregnancy screening guidelines.
Wolters et al.	2021	Descriptive Review	Discussed management of pregnancies concurrent with cancer diagnosis.
Betz & Fane	2025	Educational Summary	Compared serum vs. urine testing for pregnancy screening.

Note. This table summarizes the 13 sources included in the scoping review, organized by author, year, and study type to demonstrate the range of literature informing the analysis.

The literature on the effects of antineoplastic therapy during pregnancy indicates that significant fetal harm may occur in all three trimesters, with the highest risk of severe effects occurring during the first trimester (van Gerwen et al., 2021; Danet et al., 2018; Gustafson et al., 2018; Shah et al., 2023; Wolters et al., 2021). Chemotherapy's method of action targets rapidly dividing cells, including those of a developing fetus (Danet et al., 2021). Targeted therapy and immunotherapy interfere with essential proteins to fetal development (Wolters et al., 2021). Systemic therapy administered before conception may induce spontaneous abortion and cause severe fetal anomalies, including organ, limb, CNS, cardiac, and facial defects (van Gerwen et al., 2021; Danet et al., 2018; Gustafson et al., 2018; Wolters et al., 2021), at rates reaching 10-20% (van Gerwen et al., 2021; Danet et al., 2018). Women who received chemotherapy were twice as likely to experience neonatal morbidity or mortality events compared to those who did

not receive chemotherapy (Metcalfe et al., 2025). Thus, researchers recommend delaying chemotherapy until after 12-14 weeks gestation to avoid such serious adverse events (van Gerwen et al., 2021; Wolters et al., 2021). Risks shift towards the nervous system and skeleton in the second trimester. Furthermore, exposure in the third trimester increases the risk of renal defects, restricted uterine growth, low amniotic fluid, and preterm birth (Danet et al., 2018). Providers discuss with the patient medical termination of a pregnancy if chemotherapy cannot be delayed (Danet et al., 2018).

Patient behavior, along with provider and patient misconceptions around fertility and contraception, contributes to the risk of pregnancy during chemotherapy and raises ethical concerns. Approximately half of pregnancies in the United States occur unintentionally, leaving the opportunity for pregnancy to occur before a cancer diagnosis (Hu et al., 2016; Britton, 2017). In addition, the incidence of pregnancy coinciding with a cancer diagnosis increases as more women delay having children until later age (Wolters et al., 2021). However, multiple studies report pregnancy testing only occurred 17-20% of the time prior to initiating systemic therapy (Chadwick et al., 2024; Hu et al., 2016). One patient unknowingly received chemotherapy while pregnant due to providers attributing her symptoms to side effects of treatment (Chadwick et al., 2024). Additionally, patients assume antineoplastic therapy causes infertility or assume amenorrhea means infertility and stop using contraception despite remaining sexually active (Britton, 2017; Berger et al., 2019). Furthermore, providers remain inconsistent regarding contraception counseling and documentation (Britton, 2017; Chadwick et al., 2024).

The literature highlights gaps and variability in pregnancy screening practices. Despite pregnancy testing being a longstanding requirement in specialties such as surgery and radiology

to mitigate fetal risk, QOPI only recently implemented comparable guidelines for oncology (Gustafson et al., 2018; Association of Clinical Oncology, 2025). Up until June 2025, leading national organizations such as ASCO, ONS, and NCCN lacked consistent recommendations (Gustafson et al., 2018; AHRQ, 2023). While ASCO promoted pregnancy screening, no formal guidelines addressed timing, frequency, or testing method (Rogers et al., 2017). Thus, only 30% of NCCN institutions reported having a policy for pregnancy screening (Jangles et al., 2018; Gustafson et al., 2018). Consequently, pregnancy screening policies not only varied among institutions (Jangles et al., 2018; Gustafson et al., 2018), but also suffered from poor compliance, where they do exist (Berger et al, 2019).

Multiple authors advocate for formal guidelines regarding pregnancy screening prior to chemotherapy to reduce patient harm and ill effects to the developing fetus (Gustafson et al., 2018; AHRQ, 2023; Rogers et al., 2017; Jangles et al., 2018; Berger et al., 2019). The literature supports pregnancy screening in adult persons of childbearing potential (POCP). This includes female patients aged 18-55; excluding those with a history of hysterectomy, oophorectomy, or an absence of menses for twelve consecutive months (Rogers et al., 2017; Shah et al., 2023; Chadwick et al., 2024; Gustafson et al., 2019). Some evidence supports stopping pregnancy screening at age 50 due to no pregnancies found in women >50 years old in an audit of >1,000 pregnancy tests (Gustafson et al., 2019). Serum pregnancy testing is recommended, as it is more sensitive and can detect pregnancy 7-9 days after conception (Gustafson et al., 2019; Betz & Fane, 2025). Research recommends screening POCP 7-14 days prior to initiating systemic therapy (Gustafson et al., 2019; Berger et al., 2019; Rogers et al., 2017; Shah et al., 2023). There is no consensus for subsequent screening. However, it is recommended to ask POCP before each

treatment whether pregnancy is possible, and to test individual patients if a pregnancy risk is identified (Gustafson et al., 2019; Berger et al., 2019). Additionally, the authors recommend incorporating pregnancy testing into prompts, order sets, and hard stops in the EHR (Gustafson et al., 2018; Jangles et al., 2018; Shah et al., 2023). Organizations utilizing EHR alerts and hard stops report improved pregnancy screening compliance, with evidence demonstrating up to a 76% increase in compliance (Jangles et al., 2018; Shah et al., 2023).

Discussion and Conclusion

This scoping review reinforces the need for an organizational policy in alignment with QOPI 2025 standards for routine pregnancy screening prior the antineoplastic therapy. Available research demonstrates the substantial risks anticancer therapy poses to pregnant patients and fetuses, particularly during the first trimester when teratogenic effects can result in irreversible harm. The literature supports standardized pregnancy testing for all patients of childbearing potential aged 18-50 prior to antineoplastic therapy. Best practice includes utilization of serum pregnancy testing within 7-14 days prior to initiation of systemic therapy, EHR systems for ordering, and completing checklists to improve compliance.

There are limitations to this scoping review largely due to a history of no national oncology guidelines. Because pregnancy screening standards are new to oncology, much of the literature focuses on adverse events and gaps in care rather than providing evidence based best practices. Most of the studies are retrospective, observational or descriptive articles which exhibit less strength of evidence compared to a randomized controlled trial. In addition, three of the sources, although appearing in a peer reviewed oncology journal, are quality improvement

abstracts rather than full articles. Lastly, the variety of articles makes it difficult to directly compare findings.

Evidence in this review answers why and when pregnancy testing should be performed, who should be screened, by what method, and how to increase policy compliance. The literature does not clearly define when to repeat pregnancy screening with ongoing treatment, how to integrate pregnancy screening protocols within clinic workflows, or patient preferences regarding pregnancy screening. Proceeding with this QI project is in alignment with the new QOPI 3.1 standard for QOPI certified cancer centers and removes avoidable harm to patients. Despite limited high-level evidence, severe patient safety implications justify action.

CHAPTER TWO

QUALITY IMPROVEMENT PROPOSAL

Introduction

Systemic, anticancer, or antineoplastic therapies, including cytotoxic chemotherapy, targeted therapy, immunotherapy, and hormonal therapy are essential to cancer treatment (Sylva & Ahmed, 2024). Exposure to these treatment modalities pose significant risks during pregnancy such as congenital anomalies, miscarriage, intrauterine growth restriction, and preterm birth (Shah et al., 2023; van Gerwen et al., 2021; Wolters et al., 2021; Danet et al., 2018). Historically, major oncology organizations such as ASCO, NCCN, and ONS issued general warnings regarding these risks, but lacked formal pregnancy screening guidelines prior to systemic therapy (Gustafson et al., 2018; AHRQ, 2023). The absence of universal standards created wide variability in screening practices and compromised patient safety (Gustafson et al., 2018; Jangles et al., 2018). In June 2025, QOPI released updated standards requiring certified cancer centers to establish a formal pregnancy screening policy and documentation. Standard 1.3 calls for a formal pregnancy screening policy for patients of childbearing potential at minimum prior to the initiation of all forms of systemic therapy and prior to each regimen change (Association of Clinical Oncology, 2025). Compliance with the new standard is vital to maintaining QOPI certification and preventing catastrophic harm to patients.

Problem and Specific Aim Statement

The absence of national oncology standards for pregnancy screening reflects a critical gap in clinical practice that places patients of childbearing potential receiving systemic therapy at increased risk for an adverse event. New QOPI standard 1.3 rectifies this gap in care. The site for this quality improvement (QI) project does not have a formal policy regarding pregnancy testing and has not been conducting pregnancy screening. The aim of this quality improvement project is to strengthen clinical practice by introducing a standardized pregnancy screening policy and achieving 100 percent adherence to QOPI Standard 1.3 among patients of childbearing potential aged 18 to 50 within 7 weeks. Implementation of the QI project is essential to enhancing patient safety and maintaining QOPI certification.

SMART Goals

In alignment with enhancing patient safety and complying with QOPI standards, the cancer center aims to (1) draft new pregnancy screening policy and revise standing orders policy to include serum and urine pregnancy tests, (2) provide provider and staff education and implement policy driven procedures, and (3) 100% compliance regarding pregnancy screening in patients of childbearing potential aged 18-50 prior to systemic therapy.

Table 2. SMART Goals

<table>
<tr><td colspan="3">SMART Goal #1: Policy Development

By 12/1/25, draft a pregnancy screening policy, revise the standing orders policy, and obtain department approvals.</td></tr>
<tr><td colspan="3">Description of strategies to be utilized to accomplish SMART goal including resources.

• Draft a standardized pregnancy screening policy for patients of childbearing potential aged 18-50 in alignment with QOPI standard 1.3.
• Revise the standing orders policy to include serum pregnancy and urine pregnancy tests.</td></tr>
<tr><td>Data to be collected</td><td>Method of collection and who is responsible</td><td>Planned data analysis</td></tr>
<tr><td>• Documentation of completion and approval for both policies</td><td>• Quality manager is responsible for ensuring policy approval and documentation for the pregnancy screening policy
• Infusion manager is responsible for ensuring policy approval and documentation for the standing orders policy</td><td>• Policy completion: yes or no
• Policy approval: yes or no</td></tr>
<tr><td colspan="3">SMART Goal #2: Procedure Implementation

Within 28 days of facility PEC approval, implement standardized pregnancy screening procedure including staff education, workflow implementation, and documentation; achieving 100% staff training completion rate among providers and nurses in the cancer center.</td></tr>
<tr><td colspan="3">Description of strategies to be utilized to accomplish SMART goal including resources.

• Provide provider and staff education on policy, ordering, documentation, and IT changes
• Implement pregnancy screening policy for patients of childbearing potential
• Implement pregnancy test verification documentation by infusion nurses or oral oncology pharmacists prior to administration of treatment</td></tr>
<tr><td>Data to be collected</td><td>Method of collection and who is responsible</td><td>Planned data analysis</td></tr>
</table>

Table 2. SMART Goals continued

• Documentation of education • Go-live date	• Quality manager, DNP student, and department leads will collect provider and staff signatures on attendance sheets for education documentation	• List all providers and staff on a roster and check off the names of providers and staff who have completed education • Bar graph comparing number of providers and staff with the number who have completed education
SMART Goal #3: Compliance Achievement By March 2026, achieve and sustain 100% compliance regarding pregnancy screening in all patients of childbearing potential aged 18-50 prior to systemic therapy, as measured by weekly chart audits over the 2-3 month implementation period.		
Description of strategies to be utilized to accomplish SMART goal including resources • Weekly random sampling of charts from patients of childbearing potential • Record data on a secure Excel spreadsheet • Identify and rectify barriers to compliance • Conduct reeducation as appropriate		
Data to be collected	Method of collection and who is responsible	Planned data analysis
• Number of patients sampled • Number serum pregnancy results • Number of default urine pregnancy results • Number of missed pregnancy screenings • Feedback on workflow challenges	• DNP student and quality manager will collect and enter data on privately shared spreadsheet • DNP student and quality manager will collect feedback comments	• Quantitative data using descriptive statistics • Pregnancy screening data displayed using a pie chart • Qualitative analysis of feedback for ongoing refinement

Organizational Microsystem Assessment

This QI project takes place at a comprehensive community owned cancer center located in south-central Montana that offers radiation, palliative care, medical oncology, gynecological oncology, high risk breast, research, navigation, and infusion services for the adult population. The cancer center is in a large city hub and serves a predominantly rural region of the state, as well as parts of the Dakotas and Wyoming. Approximately 500 patients receive treatment each month, including approximately 40 female patients aged 18-50. The cancer center currently does not have a pregnancy screening policy. The baseline data shows zero patients of childbearing potential being screened for pregnancy prior to systemic therapy. Cancer center leadership takes pride in the facilities multiple patient care certifications and is committed to maintaining QOPI certification. Stakeholders for the QI implementation include the medical director, cancer center quality manager, managers of infusion center, medical oncology, and gynecologic oncology, and department leads in information technology (IT) and oral pharmacy.

Plan-Do-Study-Act Process

The Plan-Do-Study-Act (PDSA) is the ideal model for this QI project due to providing a structured and cyclical approach to testing and implementing a change. PDSA uses data to drive decision-making for future cycles, allowing for assessment, refinement, and optimalization (Ogrinc et al., 2022).

Plan: The DNP student reached out to the cancer center's quality manager to ask whether there were any QI projects that could benefit from their assistance. The quality manager suggested assistance in developing a formal pregnancy screening policy and procedure. The

student and quality manager started by meeting on a weekly basis to conduct need assessments, gather background information, and plan the agenda for stakeholder meetings. Stakeholders gave valuable feedback regarding proposed intervention feasibility.

Do: First, the quality manager will write a pregnancy screening policy. The infusion manager will revise the standing order policy to include serum and urine pregnancy tests. The IT nurse will revise quick orders, pretreatment plans, PowerPlans, and the infusion center preadministration checklist. The medical oncology clinical coordinator will revise the paper lab order sheet to include serum pregnancy testing. After staff education, the providers will order serum pregnancy screening per policy. The infusion nurses will verify pregnancy test results prior to administrating systemic therapy for patients receiving IV therapy and the oral oncology pharmacists (pharmacists who specialize in dispensing and monitoring patients receiving oral cancer therapy) will verify results prior to oral therapy. Infusion nurses and oral oncology pharmacists will order urine pregnancy screening if serum pregnancy screening results are not available. Data will be collected from a random sample of patients who received treatment during the implementation phase. Quantitative data will be collected and assessed by the number of patients of childbearing potential who received therapy, how many had a serum pregnancy test, how many defaulted to a urine pregnancy test, and how many pregnancy screenings were missed.

Study: The student will continue to meet with the quality manager on a weekly basis to review quantitative data from the previous week. Compliance data will be presented monthly in the cancer center department huddles.

Act: The enacted interventions will be adjusted, adapted, or abandoned per stakeholder feedback for the next PDSA cycle.

Methods

Implementation Summary

This QI project takes place at a comprehensive cancer center in south-central Montana in the medical oncology, gynecology oncology, oral pharmacy, and infusion center departments. The objective is to implement a formal policy and procedure for pregnancy screening patients of childbearing potential aged 18-50 prior to systemic therapy; excluding patients with documented hysterectomy, oophorectomy, or absence of menses for 12 months without clinical intervention. Providers will begin ordering serum pregnancy tests on the same schedule as the pretreatment laboratory assessments prior to systemic therapy. Infusion nurses or oral oncology pharmacists will verify serum results prior to approval or administration of systemic therapy. If a serum pregnancy result is missing, the infusion nurses and oral oncology pharmacists will order a default urine pregnancy test and review results prior to treatment. Compliance is monitored weekly with random patient sampling and reviewed at provider and nursing staff huddles monthly. The proposed implementation is scheduled to begin in mid-December 2025, following approval from the MSU Committee and Institutional Review Board (IRB), and the facility's Privacy and Exemption Committee (PEC).

Timeline

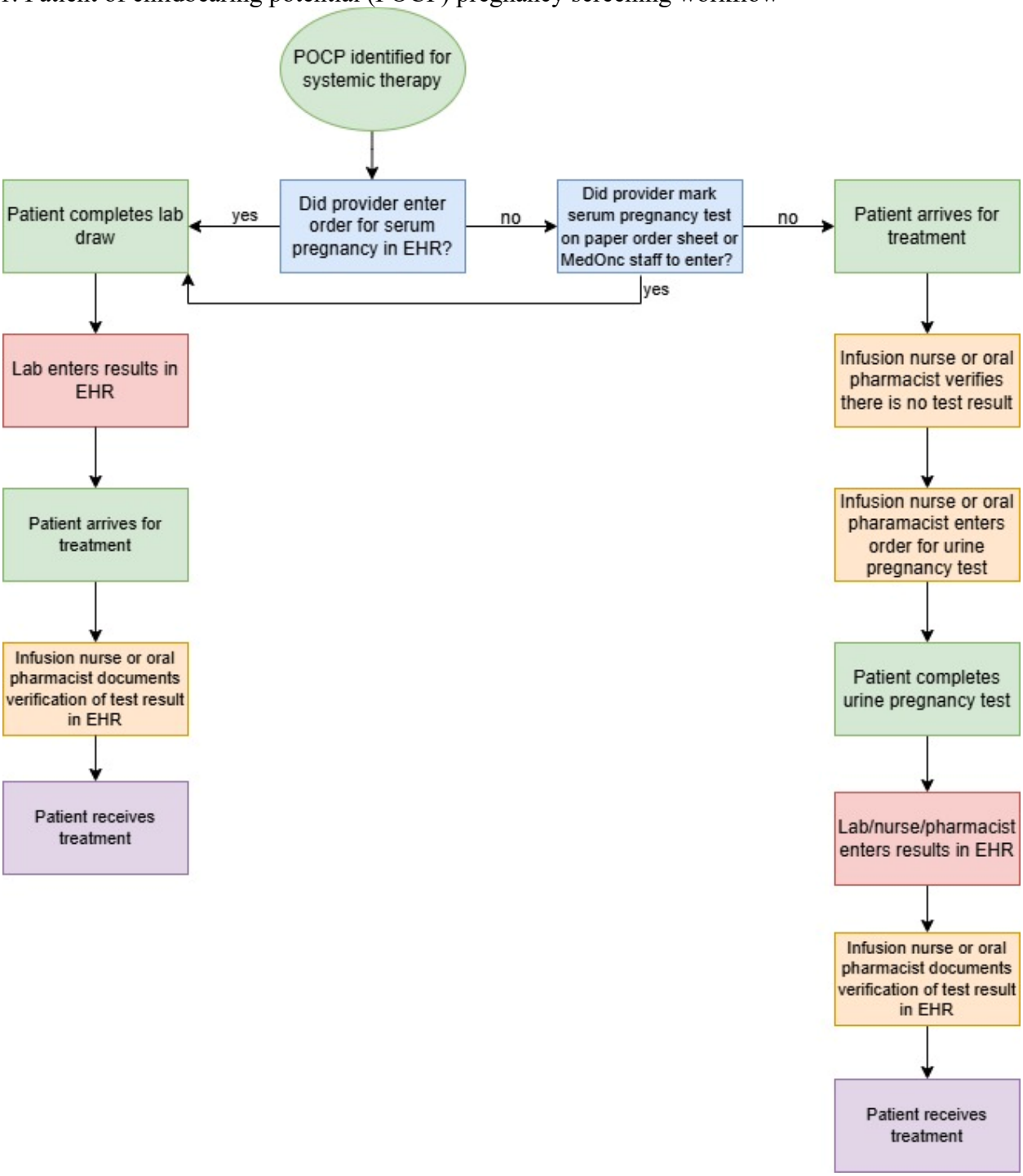
- August-November 2025: Weekly site assessment meetings, stakeholder meetings, drafting of policy, and EHR build.
- November 2025: By 11/23/25, submit IRB draft to Topaz.
- December 2025: By 12/3/25, submit to facility's PEC.
- December 2025: 12/17/25, present at PEC meeting.
- January 2026: Staff education. Go-live after PEC approval.
- January 2026-February 2026: Data collection and evaluation.
- April 2026: Results review and dissemination.

Budget

This QI project is expected to incur minimal costs. Staff time for policy writing and revision, IT enhancement requests, and staff education are covered by department operational budgets. Policy writing and revision is estimated to take two to four hours. IT enhancement requests are estimated to take 40 hours, utilizing one to three person teams. Education will take place at regularly scheduled staff meetings and huddles, totaling approximately two hours.

New Process

Figure 1. Patient of childbearing potential (POCP) pregnancy screening workflow



Education

Staff education includes providing rationale for the QI project by reviewing the new QOPI standard. Education for providers includes when and where to order serum pregnancy tests in the EHR or on the paper form. Education for infusion nurses and oral oncology pharmacists includes how and where to document verification of test results. Infusion nurses and oral oncology pharmacists will also be educated on how to order urine pregnancy tests if there is no serum pregnancy test result. Medical oncology and gynecological oncology staff will be trained in the new process for awareness. Training will occur at provider meetings, staff huddles, and job aids.

Strengths, Weaknesses, Opportunities, Threats (SWOT)

Table 3. SWOT Analysis of Pregnancy Screening Policy QI Implementation

Strengths	**Weaknesses**
• Strong leadership support • Motivated stakeholders • QOPI standard as framework • Dedicated cancer center quality manager	• Limited time • IT resources
Opportunities	**Threats**
• Enhanced patient safety • Model for future QI projects • Model for pregnancy screening QI projects in associated cancer centers	• Provider and staff resistance to workflow change • Existing problem with providers entering lab orders in EHR • Serum pregnancy test requires collection in red tube, cannot be added on to purple or green tubes • Need for ongoing compliance monitoring

Threat mitigation strategies include close stakeholder involvement, clear communication, frequent reeducation, and responding to feedback.

Evaluation and Analysis

This QI intervention will be evaluated by the DNP student and quality manager through retrospective weekly chart audits of random patient samples. Quantitative data will be collected from December, or at least by January, through March of the implementation period. Data collected from patient charts are (1) Number of serum pregnancy tests ordered, (2) Number of urine pregnancy tests ordered, and (3) Number of missed pregnancy tests. Data analysis for compliance will be completed weekly. The results, represented in a pie chart, will be reported out to staff monthly at provider meetings and staff huddles. Data will be entered on a shared Excel spreadsheet between the DNP student and the quality manager. Descriptive statistics will be used to evaluate the frequency of serum pregnancy tests, urine pregnancy tests, and missed pregnancy tests.

Safety and Confidentiality

This QI project will enhance patient safety and will not pose an increased risk to patients. The serum pregnancy tests will be collected along with labs required for treatment monitoring. Urine pregnancy tests are not invasive and do not pose an increased risk. Patient information on the Excel spreadsheet will be de-identified and stored in a private TEAMs group between the DNP student and the quality manager. The DNP student presented this QI initiative to the Performance Improvement Office (PIO) at the project site. PIO decided this project does not

require PIO oversight. Before implementation, the project requires approval from Montana State University IRB and the facility's PEC.

Conclusion

The absence of a formal pregnancy screening policy prior to systemic cancer therapy represents a significant gap in both patient safety and compliance with the new 2025 QOPI Standard 1.3. This QI project seeks to address this gap by developing a standardized pregnancy screening policy for patients of childbearing potential aged 18–50. After close collaboration with the stakeholder team, this QI project proceeded using the PDSA framework.

Interventions include drafting the pregnancy screening policy, revising standing orders, updating EHR PowerPlans, and integrating pregnancy screening into workflows. Staff education sessions and stakeholder feedback ensure communication and sustainability. The project will launch following Montana State University IRB and facility PEC approval. Data gathering will take place over 7 weeks.

SMART goal targets 100% policy compliance. Data will be collected weekly and analyzed for number of serum pregnancy test results, number of default urine pregnancy test results, and number of missed pregnancy screenings. Quantitative results will be analyzed using descriptive statistics and displayed using a pie chart. Compliance updates will be communicated through provider meetings and staff huddles.

This QI project aims to use evidence-based practice, interdisciplinary collaboration, and data analysis to enhance patient safety and maintain QOPI certification.

CHAPTER THREE

QUALITY IMPROVEMENT MANUSCRIPT

Contribution of Authors and Co-Authors

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☒ Prepared for submission to a peer-reviewed journal
☐ Officially submitted to a peer-reviewed journal
☐ Accepted by a peer-reviewed journal
☐ Published in a peer-reviewed journal

Clinical Problem

Systemic anticancer therapies, including chemotherapy, targeted therapy, immunotherapy, and hormonal therapy, are foundational to cancer treatment but pose substantial risks when administered during pregnancy. Exposure to antineoplastic agents can result in miscarriage, congenital malformations, intrauterine growth restriction, and preterm birth, with the most severe teratogenic effects occurring during the first trimester (Danet et al., 2018; Shah et al., 2023; van Gerwen et al., 2021; Wolters et al., 2021). These therapies target rapidly dividing cells and critical molecular pathways essential to fetal development, leading to irreversible harm to the central nervous, cardiac, skeletal, hematologic, and renal systems (Danet et al., 2018; Wolters et al., 2021).

Although cancer during pregnancy is rare, occurring in approximately 0.1–0.2% of pregnancies, the administration of chemotherapy to a pregnant patient is considered a "never event" due to the catastrophic potential for fetal harm (Gustafson et al., 2018; Jangles et al., 2018). Gaps in pregnancy screening prior to systemic therapy persist on a national level. Studies demonstrate that pregnancy testing occurs in only 17–20% of patients of childbearing potential prior to starting systemic cancer treatment (Chadwick et al., 2024; Hu et al., 2016). Considering nearly half of pregnancies in the United States are unintended and misconceptions of patients and providers regarding fertility and amenorrhea during cancer treatment, there is a possibility of unrecognized pregnancy at treatment initiation (Britton, 2017; Berger et al., 2019). In addition, individuals delaying childbearing and the increasing incidence of cancer among younger individuals has increased the potential of overlap between pregnancy and a cancer diagnosis (Gustafson et al., 2018; Jangles et al., 2018).

Historically, major oncology organizations such as the American Society of Clinical Oncology (ASCO), National Comprehensive Cancer Network (NCCN), and Oncology Nursing Society (ONS) have acknowledged the teratogenic risks of systemic anticancer therapy, but formal guidance regarding pregnancy screening prior to initiation of treatment has been limited (AHRQ, 2023; Gustafson et al., 2018). In the absence of national standards, institutional practices have varied, with approximately 30% of oncology centers lacking a formal pregnancy screening policy (Jangles et al., 2018). In June 2025, the Quality Oncology Practice Initiative (QOPI), ASCO's practice certification program, introduced standards requiring a formal pregnancy screening policy and documentation prior to initiation of systemic therapy and regimen changes (Association of Clinical Oncology, 2025).

The comprehensive cancer center in south-central Montana lacked a formal pregnancy screening policy. Development of such a screening policy was needed to improve patient safety, reduce avoidable harm, and align with QOPI standards.

Review of the Literature

The literature demonstrates that exposure to systemic anticancer therapy during pregnancy is associated with significant fetal morbidity and mortality across all trimesters, with the highest risk occurring during the first trimester (Danet et al., 2018; van Gerwen et al., 2021). Outcomes include miscarriage, major congenital anomalies affecting the central nervous system (CNS) and cardiovascular system, facial malformations, myelosuppression, hemorrhage, and infection (Danet et al., 2018). Chemotherapy administered in later trimesters carries risks of neurodevelopmental injury, skeletal abnormalities, renal dysfunction, intrauterine growth restriction, and preterm birth (Danet et al., 2018; Wolters et al., 2021).

Despite these risks, pregnancy screening practices remain inconsistent. Multiple studies document low screening rates prior to initiation of systemic therapy as well as inconsistent documentation when screening was performed (Chadwick et al., 2024; Hu et al., 2016). Contributing factors include inadequate contraceptive counseling, provider assumptions regarding infertility, and patient misinterpretation of amenorrhea as infertility (Britton, 2017; Berger et al., 2019). Evidence supports routine pregnancy screening in persons of childbearing potential aged 18–50, excluding those with documented hysterectomy, bilateral oophorectomy, or menopause defined as 12 months of amenorrhea without intervention (Gustafson et al., 2019; Shah et al., 2023).

Serum pregnancy testing is recommended over urine testing due to greater sensitivity and reliability for early detection within 7 days of conception (Betz & Fane, 2025; Gustafson et al., 2019). Recommendations support pregnancy testing within 7–14 days prior to the initiation of systemic therapy. Although evidence is lacking regarding how often to repeat testing, some authors recommend pregnancy screening prior to regimen changes and, in some cases, before each treatment cycle (Berger et al., 2019; Rogers et al., 2017).

Studies further demonstrate that embedding pregnancy screening into the electronic health record (EHR) workflows through prompts, order sets, and hard stops can improve compliance up to 76% (Jangles et al., 2018; Shah et al., 2023). The literature strongly supports implementation of standardized pregnancy screening policies to prevent an adverse event.

Conceptual Framework

This quality improvement (QI) project was guided by the Plan-Do-Study-Act (PDSA) framework. PDSA framework was selected because it provides a structured, cyclical approach to

data assessment, process refinement, and resource optimization while also supporting implementation and continuous refinement using real-time data and stakeholder feedback (Ogrinc et al., 2022). During the Plan phase, needs assessments, stakeholder input, and workflow analysis informed policy development and EHR modifications. The Do phase focused on publication of the written policy, revision of standing orders to include serum and urine pregnancy testing, and updates to treatment plans and checklists. Additionally, this phase included obtaining approval to perform urine pregnancy testing in the infusion center, securing pregnancy tests and serum lab tubes, and providing staff education and competency training. The Study phase involved weekly chart audits and data review to assess compliance and identify gaps. Finally, the Act phase supported continuous refinement of processes and workflows based on data evaluation and staff feedback, supporting sustainability, patient safety, and alignment with QOPI standards.

Aims / Purpose of the Project

The purpose of this QI project was to enhance patient safety and align the facility practice with the 2025 QOPI guidelines. The primary aim was to implement a standardized pregnancy screening policy, with a project goal of achieving 100% compliance with QOPI Standard 1.3 among patients of childbearing potential aged 18–50 years receiving systemic cancer treatment within 7 weeks of implementation.

Methods

Context

The QI project was conducted at a comprehensive, community-owned cancer center in south-central Montana that serves a predominantly rural population across Montana, Wyoming, and the Dakotas. The cancer center provides medical oncology, gynecologic oncology, infusion services, oral oncology pharmacy, radiation oncology, and palliative care. Approximately 500 patients receive treatment monthly, including an estimated 40 patients of childbearing potential aged 18-50 years. Prior to this project, the facility did not have a formal pregnancy screening policy or routine screening practices. Leadership's commitment to patient safety and maintenance of QOPI certification supported implementation.

Interventions: Phase I

The QI Phase I intervention focused on writing and implementing of a formal pregnancy screening policy for patients of childbearing potential aged 18–50 years prior to systemic cancer therapy. For patients receiving treatment in the infusion center, a negative pregnancy test result was required prior to initiating treatment and before subsequent cycles within 7 days of therapy. For patients receiving oral oncolytic treatment, a negative pregnancy test result was required within 30 days prior to treatment initiation, allowing time for completion of prior authorization, and was repeated when patients returned for reassessment. Providers ordered serum pregnancy tests with standard pretreatment laboratory studies. Infusion nurses and oral oncology pharmacists verified pregnancy test results prior to therapy administration. When serum results were unavailable, a default urine pregnancy test was used as an alternative. The intervention

included revisions to standing orders, PowerPlans, quick orders, the infusion preadministration checklist, and paper laboratory requisitions. Comprehensive staff education was completed by the Doctorate of Nursing Practice (DNP) student and department stakeholders.

Three weeks after project initiation, a stakeholder meeting was held on 1/23/26 to review preliminary findings and assess early outcomes. At that time, data revealed that 80% (8/10) of eligible infusion center patients had not undergone pregnancy screening. Follow-up documentation audits identified a workflow-related gap within the infusion preinfusion checklist that required modification. Initially, the negative pregnancy test confirmation field was triggered only when the "Chemo/Bio patient" option was selected as "Yes." This workflow captured therapies documented by treatment cycles but excluded therapies documented as individual treatments. As a result, maintenance immunotherapies and hormonal therapies were unintentionally excluded from the pregnancy screening workflow. To address this gap, stakeholders agreed to revise the checklist so that the negative pregnancy test confirmation field was triggered when "Chemo/Bio patient" was marked "Yes" or "No", ensuring inclusion of all relevant systemic therapies.

To further strengthen compliance, stakeholders agreed that infusion pharmacists would assist with identifying missing pregnancy test results. Because pharmacists routinely review laboratory results prior to nursing review, they would notify infusion nurses when a serum pregnancy test was not resulted. The infusion nurse would then determine whether a urine pregnancy test was appropriate. Stakeholders also discussed adding a mandatory dropdown field requiring justification when "Not Applicable (NA)" was selected for pregnancy test confirmation, with the goal of preventing inappropriate use. The infusion manager decided

against this addition, citing concerns that pregnancy screening already represented a substantial workflow change for staff.

In contrast to infusion patients, chart audits demonstrated that 100% (3/3) of oral oncology patients had not undergone pregnancy screening. In response, the oral oncology stakeholder reinforced the pregnancy screening policy and workflow during the subsequent oral oncology staff meeting. Additionally, because no serum pregnancy tests had been ordered by providers during the initial evaluation period, the DNP student reinforced provider education by distributing an email that included current audit data and reminders regarding the requirement to order serum pregnancy testing according to policy.

The QI project was implemented at the organization's main campus; however, changes to the PowerPlans and preinfusion checklist also affected seven affiliated outreach sites that utilize the main campus's EHR. Although these outreach sites are not included in QOPI certification and operate under independent policies, infusion representatives from these locations were invited to participate in future stakeholder meetings to promote awareness and alignment. The information technology (IT) stakeholder also notified these sites of the upcoming EHR changes prior to go-live.

Patient education emerged as an additional area of concern. Stakeholders disagreed regarding whether formal patient education was necessary and which discipline should be responsible for providing it. The provider stakeholder indicated that informing patients that pregnancy screening was a new institutional policy would be sufficient, however, in practice this communication was inconsistent. Infusion nurses and oral oncology pharmacists also reported discomfort initiating discussions about pregnancy screening and explaining the rationale for the

policy. To address this barrier, stakeholders discussed creating a standardized education script to support staff in delivering consistent patient education.

Interventions: Phase II

At the stakeholder meeting on 2/19/26, the provider stakeholder reported earlier that week she had reinforced the pregnancy screening policy and the preferred use of serum pregnancy testing during a provider meeting. She also emphasized the importance of documenting childbearing status and pregnancy screening requirements within the assessment and plan section of the visit note. This guidance was reportedly well received by providers.

During the discussion, stakeholders agreed that the policy should first be introduced and explained to patients in person by their provider to support patient understanding and trust. As a result, oral oncology pharmacists agreed to temporarily defer pregnancy screening for established patients who were not yet aware of the policy change until the patient's next in-person provider visit, rather than addressing the change by phone.

Following the implementation of workflow modifications identified at the 1/23/26 stakeholder meeting, data from go-live through 1/23/26 were compared with data from 1/26/26 to 2/19/26. Among infusion center patients, the missed pregnancy screenings decreased by 24%, from 80% (8/10) to 56% (14/25), with an overall missed screening rate to date of 63% (22/35). Among oral oncology patients, the missed pregnancy screening rate decreased by 33%, from 100% (3/3) to 67% (6/9), with an overall to date missed screening rate of 75% (9/12). These improvements were largely attributed to infusion nurses and oral oncology pharmacists proactively ordering pregnancy screening, demonstrating the positive impact of multidisciplinary engagement and workflow integration on patient safety outcomes.

Audits of verification documentation in the infusion setting continued to reveal inappropriate selection of “NA” for pregnancy test confirmation. However, verification documentation in oral oncology showed great improvement. An IT request to link a “No” response for pregnancy screening confirmation to an automatic order for a urine pregnancy test remained pending IT leadership approval. As part of the sustainability plan, the infusion team agreed to assume responsibility for ongoing chart audits. The DNP student also agreed to create a chart audit job aid. In addition, the DNP student drafted a patient-facing pregnancy screening policy notification for review by the quality manager and provider stakeholder.

Interventions: Phase III

During the final week of data collection, overall pregnancy screening compliance remained below goal of 100%. Among eligible infusion center patients, 33% (2/6) were not screened, However, this still reflected a 10% improvement in compliance as compared with the previous PDSA cycle. Across the full 7-week data collection period, 59% (24/41) of eligible patients were not screened, resulting in an overall compliance rate of 41%.

Among eligible oral oncology patients, 40% (2/5) were not screened, which also reflected a 10% improvement in compliance compared with the previous PDSA cycle. Across the 7-week period, 65% (11/17) of patients were not screened, yielding an overall compliance rate of 35%.

In addition to the standard weekly compliance audit, the final week of data collection included a review of provider documentation following education delivered at the prior week’s provider meeting. This audit evaluated whether pregnancy screening was documented within the assessment and plan of the progress note. Of the 8 patients seen prior to treatment, 4 patients

(50%) had documentation indicating that pregnancy screening was incorporated into the provider's assessment and plan.

The sustainability plan includes staff from infusion, oral pharmacy, and inpatient cancer care. The team members will use the job aid created by the DNP student to perform monthly audits.

Measures

Policy compliance was measured through weekly retrospective chart audits of eligible patients receiving either IV, subcutaneous, or oral oncology systemic treatment. Data collected included the number of infusion patients sampled, the number of patients who met eligibility criteria, the number of serum pregnancy tests ordered, the number of default urine pregnancy tests ordered, the number of missed pregnancy test screenings, and the number of positive tests. Patients receiving IV and subcutaneous treatment were tracked separately from patients receiving oral oncology treatment. Weekly chart audit data was reported as the number of missed tests. Percent of weekly and overall missed tests was calculated by dividing number of missed tests by number of eligible patients. Overall compliance was calculated by dividing the number of eligible patients by the total number of eligible patients.

Results

At baseline, no eligible patients had documented pregnancy screenings (0%). During implementation, compliance steadily increased following EHR integration and staff education. The number of screenings ordered by infusion or pharmacy staff slightly outnumbered those ordered by providers (13 versus 10).

At three weeks post-implementation, 80% (8/10) of eligible infusion center patients and 100% (3/3) of eligible oral oncology patients had not undergone pregnancy screening. In response, workflow modifications to the preinfusion checklist were implemented and provider and staff education was reinforced.

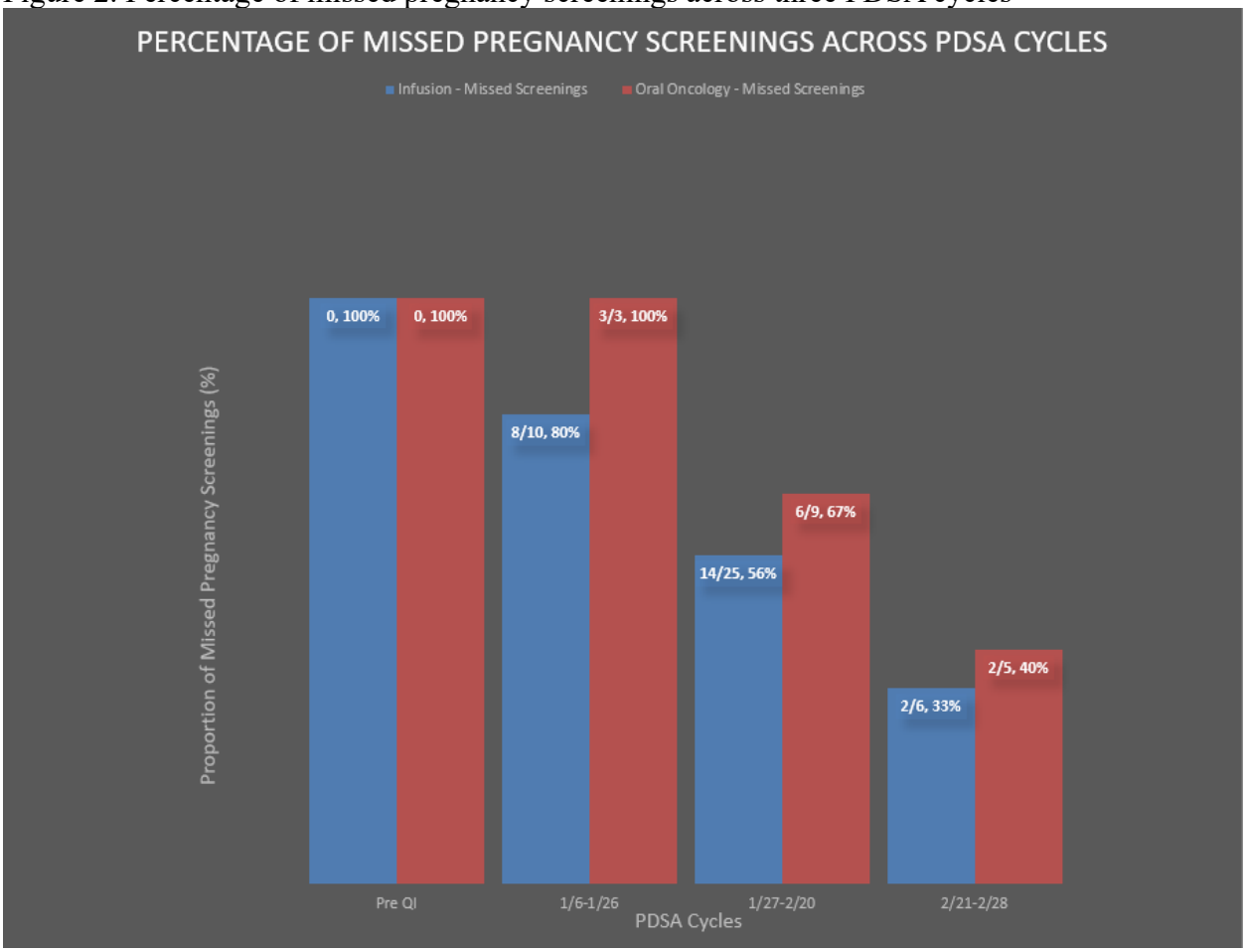
Following Phase I and II interventions, missed screenings among eligible infusion patients decreased from 80% (8/10) to 56% (14/25), representing a 24-percentage-point improvement. Missed screenings among eligible oral oncology patients decreased from 100% (3/3) to 67% (6/9), representing a 33-percentage-point improvement. These improvements appeared to be associated with weekly reporting of chart audit findings to the infusion and oral pharmacy stakeholders, reinforcement of staff education, and proactive identification and ordering of pregnancy tests by infusion nurses and oral oncology pharmacists.

During the final week of data collection (Phase III), 33% (2/6) of eligible infusion patients were not screened, reflecting a 10% improvement from the previous PDSA cycle. Over the full 7-week period, infusion compliance was 41% (17/41). Fifty-nine percent (24/41) of eligible patients had missed screenings. During the final week of data collection, 40% (2/5) of eligible oral oncology patients had missed screenings, also reflecting a 10% improvement from the previous PDSA cycle. Over the 7-week period, oral oncology compliance was 35% (6/17). Sixty-five percent (11/17) of eligible patients had missed screenings.

A focused audit of provider documentation during final week demonstrated that 50% (4/8) of eligible patients had pregnancy screening addressed within the assessment and plan following reinforced provider education. Data showed zero positive pregnancy tests in either group. One patient refused testing. Despite measurable improvement, compliance remained

below the institutional goal of 100%, indicating ongoing workflow and documentation challenges.

Figure 2. Percentage of missed pregnancy screenings across three PDSA cycles



Discussion

The QI project demonstrated that implementation of a standardized pregnancy screening policy supported by EHR integration and interdisciplinary collaboration can improve patient safety and compliance with QOPI quality standards. Findings align with prior literature showing that system-level interventions, particularly EHR prompts and hard stops, significantly enhance

adherence to safety practices (Jangles et al., 2018; Shah et al., 2023). The intervention reduced variability in practice and mitigated the risk of an adverse event. Over the 7-week implementation period, missed pregnancy screenings decreased from 100% (0) to 59% (24/41) among eligible infusion patients and from 100% (0) to 65% (11/17) among eligible oral therapy patients, reflecting meaningful improvement from baseline pregnancy screenings of 0%.

Limitations

Several limitations affected project implementation and outcomes. Operational challenges included resistance to workflow changes, which contributed to inconsistent ordering practices and inaccurate or incomplete documentation. Despite strong stakeholder engagement, modifying established workflows proved challenging. Staff-related limitations included provider shortages and high clinical workloads that further limited compliance. Additionally, the primary provider stakeholder was on leave for three months during the planning and early implementation phases, limiting both provider stakeholder input and critical provider-level reinforcement Design limitations that influenced the findings include the relatively short evaluation period, which restricted the ability to assess sustained practice change. Finally, the single-site, rural setting may limit generalizability to larger oncology practices with different patient populations, resources and workflow structures.

Recommendations

Healthcare organizations should adopt standardized pregnancy screening policies for patients of childbearing potential receiving systemic cancer therapy. Integration into EHR workflows, routine staff education, and ongoing audit-and-feedback processes are recommended

to sustain compliance. Earlier and more consistent engagement of frontline staff, along with clearer delineation of workflow expectations at the outset, may have reduced variability and accelerated compliance. Sustainability plan should include ongoing monthly audits and feedback, routine staff and provider reminders and reeducation, and a copy of the policy at every workstation for easy reference. Future research should explore optimal rescreening intervals and patient perspectives on screening practices.

Conclusion

This quality improvement project addressed a critical patient safety gap by implementing an evidence-based pregnancy screening policy aligned with QOPI 2025 standards. Over the 7-week implementation period, missed screenings decreased from 100% (0) to 59% (24/41) among eligible infusion patients and from 100% (0) to 65% (11/17) among eligible oral therapy patients, with corresponding improved provider documentation following targeted education. These findings demonstrate system-level interventions such as EHR integration can improve compliance with safety practices. Although the project did not achieve the institutional goal of 100% compliance, findings demonstrated that the project enhanced safety, reduced practice variability, and supported institutional certification requirements. Continued efforts on audit feedback, provider engagement, and workflow optimization will be necessary to sustain these practice changes over time. Overall, this project underscores that standardized pregnancy screening is a high-impact patient safety intervention that safeguards patients of childbearing potential against preventable harm while receiving oncology care.

CHAPTER FOUR

ADVANCED NURSING ESSENTIALS REFLECTION

Introduction

The Mark and Robyn Jones College of Nursing Doctor of Nursing Practice program at Montana State University prepares advanced practice nurses to translate evidence into practice, lead quality improvement initiatives, and improve patient safety through systems-level change. The Advanced Nursing Essentials, as outlined by the American Association of Colleges of Nursing (AACN), provide a framework for developing the knowledge, skills, and competencies required for this role (AACN, 2021). This reflection examines the application of selected AACN Domains to a quality improvement project focused on implementing pregnancy screening for patients of childbearing potential prior to receiving systemic cancer treatment. The project addressed a critical patient safety gap in oncology care by integrating evidence-based practice, ethical principles, informatics, interdisciplinary collaboration, and person-centered care. The doctor of nursing practice (DNP) student demonstrated the essential role of advanced nursing practice in improving clinical outcomes and protecting vulnerable patient populations.

Domain 1: Knowledge of Nursing Practice

The DNP student applied Domain 1, Knowledge of Nursing Practice, to this quality improvement QI by integrating and translating nursing science and utilizing evidence-based practice to initiate pregnancy screening prior to cancer treatment (AACN, 2021). The QI project combines nursing clinical expertise and patient-centered care to address a patient safety gap for patients of childbearing potential receiving systemic therapy. Knowledge of the natural sciences,

such as pathophysiology and pharmacology, and of ethical principles from the liberal arts helped guide complex planning and implementation decisions. Previous coursework in Evidence-Based Practice, Advanced Health Assessment, and Ethics, Law, and Policy laid the foundation for critical appraisal and synthesis of the literature and applying the evidence to solve this clinical problem. The DNP student learned in Evidence-Based Practice the hierarchy of levels of evidence and practiced critically appraising publications for strength and reliability of evidence. The DNP student developed a strong understanding of the hierarchy of evidence and refined skills in critically appraising the quality, strength, and reliability of research. As a result, systematic reviews and meta-analyses were prioritized to inform the QI project due to their high level of evidence, while expert opinion was used sparingly and only when higher-level evidence was limited, ensuring that practice decisions were grounded in the most rigorous and credible data available.

Domain 2: Person-Centered Care

Domain 2, Person-Centered Care, focuses on practicing individualized, holistic, and evidence-based care (AACN, 2021). The DNP student drew on prior coursework in Ethics, Law, and Policy; Advanced Nursing Leadership; and Program Planning and Evaluation: Outcomes and Quality Improvement to lead the QI project and collaborate with stakeholders in drafting the pregnancy screening policy. The resulting policy incorporated evidence-based interventions to ensure the safety of patients of childbearing potential during cancer treatment. As part of the coursework for Vulnerability and Healthcare in Diverse Communities, the DNP student completed 45 clinical hours at the Community Crisis Center and the Amyotrophic Lateral Sclerosis (ALS) clinic, gaining direct experience with patients with complex medical, social, and

psychosocial needs. These experiences instilled a strong sense of responsibility in the DNP student to advocate for vulnerable populations and prevent devastating adverse outcomes. Pregnancy screening in patients of childbearing potential exemplifies this commitment to advocacy, equity, and patient safety by proactively implementing safeguards that prevent devastating adverse outcomes in this vulnerable population.

Domain 4: Scholarship for the Nursing Discipline

This QI project exemplifies Domain 4, Scholarship for the Nursing Discipline, through the synthesis of literature, application of guidelines and evidence-based practice, and dissemination of data to improve patient safety (AACN, 2021). Courses such as Evidence-Based Practice and Scholarly Project Seminar prepared the DNP student to complete a literature search of scholarly sources and complete a synthesis of the literature to address the critical gap at this oncology practice. Coursework in Design of Healthcare Systems was essential to developing and implementing the pregnancy screening policy, standardizing procedures, and implementing new workflows across multiple cancer center departments. Applying these systems-based skills, the DNP student created a patient-visit flowchart that delineates the pregnancy screening process, defines staff roles, and promotes consistency, efficiency, and accountability in clinical practice. Lastly, Statistical Applications provided the foundation required for collecting quality data and translating the results to demonstrate the impact of this change on patient care. Analysis of this information will guide future decision-making, workflow refinement, and sustainability of the process.

Domain 6: Interpersonal Partnerships

Domain 6, Interpersonal Partnerships, was required for coordinated collaboration among the stakeholders and the success of the QI project (AACN, 2021). Courses such as Evidence-Based Practice, Healthcare Informatics, and Vulnerability and Healthcare in Diverse Communities were foundational in learning how to work in a group to successfully accomplish a task. The group assignments in these courses honed accountability, communication, flexibility, and patience needed for successful interpersonal partnerships. The DNP student facilitated consistent and structured stakeholder engagement by scheduling monthly stakeholder meetings, distributing agendas in advance, and sending post-meeting summary communications, while accommodating multiple provider schedules and following up on requests. Individual meetings were conducted with information technology (IT) personnel and oral oncology pharmacists to clarify workflows and operational processes, and weekly meetings with the facility advisor ensured ongoing guidance and alignment. In addition, the DNP student provided individualized education to 16 physicians and advanced practice providers, followed by a summary of the education sessions that incorporated provider feedback to the providers and stakeholders. To support transparency and sustain engagement, the DNP student distributed weekly data updates on pregnancy screening performance. Through strong collaborative engagement, the stakeholder team strengthened patient safety and ensured compliance with national quality standards.

Domain 8: Informatics and Healthcare Technologies

The DNP student applied Domain 8, Informatics and Healthcare, through IT and electronic health record (EHR) integration to support safe and efficient cancer care. The

Healthcare Informatics course provided a foundational competency in informatics processes used to update order sets and nursing pretreatment checklists. Understanding how informatics influences workflows enabled the QI project to move smoothly into implementation and to support best practices. For this QI project, IT and EHR integration played a critical role in enhancing patient safety and workflow efficiency by modifying oncology PowerPlans and incorporating verification documentation into the infusion nursing pre-infusion checklist. The DNP student collaborated closely with IT specialists to ensure that these electronic modifications accurately reflected the updated pregnancy screening policy and aligned with clinical workflows. Multiple Plan-Do-Study-Act (PDSA) cycles were conducted to test, refine, and optimize the integrations, addressing usability issues, minimizing workflow disruptions, and ensuring that the documentation process was both efficient and reliable for staff. These iterative improvements helped create a standardized workflow that supported consistent screening, reduced the risk of errors, and reinforced best practices across the oncology care team.

Project Impact

This Advanced Nursing Essentials reflection demonstrates how integration of the AACN Domains, developed through the DNP program curriculum, supported the successful design, implementation, and evaluation of a QI project focused on pregnancy screening for patients of childbearing potential receiving systemic cancer treatment. Application of evidence-based practice, ethical decision-making, statistical analysis, informatics integration, healthcare systems design, and nursing leadership resulted in meaningful improvements in patient safety for this vulnerable population. These domains highlight the role of the FNP (family nurse practitioner)-

DNP prepared nurse as a clinical leader capable of advancing high-quality, patient-centered care through systematic quality improvement initiatives.

Prior to this project, the DNP student often experienced frustration with the slow pace of change and the recurrence of unresolved issues within the practice setting. This quality improvement experience illuminated both the complexity and scope of meaningful change, while providing essential lessons to carry forward into future initiatives. Earlier and more consistent engagement of frontline staff, along with clearer delineation of workflow expectations at the outset, may have reduced variability and accelerated compliance. The leadership skills developed and confidence gained through leading this QI project have been invaluable in preparing the DNP student for a future role as a professional medical provider.

Stakeholder engagement throughout the project presented several leadership challenges, particularly when addressing resistance to change and competing clinical priorities. Notable learning moments occurred during provider education and concerns about eligibility criteria, workflow burden, and role responsibility. Navigating these conversations required active listening, flexibility, and clear communication of patient safety goals. These experiences again strengthened the DNP student's leadership capacity and honed soft skills that are translatable to the FNP role of navigating conversations with colleagues and directing patient care.

The QI project significantly enhanced the DNP student's confidence and competence in applying quality improvement methodology. While familiar with Plan-Do-Study-Act (PDSA) cycles prior to this project, hands-on application deepened understanding of their value in real-world settings. Data collection and analysis emphasized process improvement takes time while

also underscoring the critical importance of detailed, accurate documentation and timely order entry in the FNP role to support safe, high-quality patient care.

In the transition to the FNP role, this project underscores that sustainable change in clinical practice requires more than strong evidence and a goal. Change also depends on ongoing patient and staff education, continuous feedback loops, visible leadership, and flexibility. This QI experience shaped the DNP student's professional role as an FNP through approaching clinical problems with a systems-focused, data-driven, and patient-centered perspective. The leadership skills and quality improvement expertise developed through this project will directly translate to the DNP student's future FNP practice by supporting safe clinical decision-making, efficient care delivery, and problem solving to improve patient outcomes.

Conclusion

This Advanced Nursing Essentials reflection highlights how the integration of AACN Domains, learned through DNP program curriculum, supported the successful design, implementation, and evaluation of the QI project focused on pregnancy screening in patients of childbearing potential receiving systemic cancer treatment. Application of evidence-based practice, ethical decision-making, statistical methods, informatics integration, healthcare design, and nursing leadership created meaningful and sustainable changes for this vulnerable population. These domains demonstrate the role of a DNP-prepared nurse as a clinically educated leader who can advance high-quality patient-centered care through quality improvement initiatives.

This QI project significantly influenced the DNP student's approach to clinical practice by reinforcing the importance of proactively identifying patient safety gaps and designing evidence-based interventions to address them. The DNP student developed leadership skills in stakeholder engagement, conflict resolution, and interdisciplinary collaboration, learning to navigate differing opinions and professional schedules while maintaining project momentum. The experience strengthened the DNP student's ability to apply quality improvement methodology, including PDSA cycles and data-driven decision-making, to evaluate processes and implement sustainable change. The DNP student also gained valuable insight into managing resistance to change, communicating effectively across multiple disciplines, and leveraging informatics to optimize clinical workflows. These skills and lessons will inform the DNP student's future role as an FNP, enabling leadership of initiatives that improve patient outcomes, enhance system efficiency, and support a culture of continuous quality improvement.

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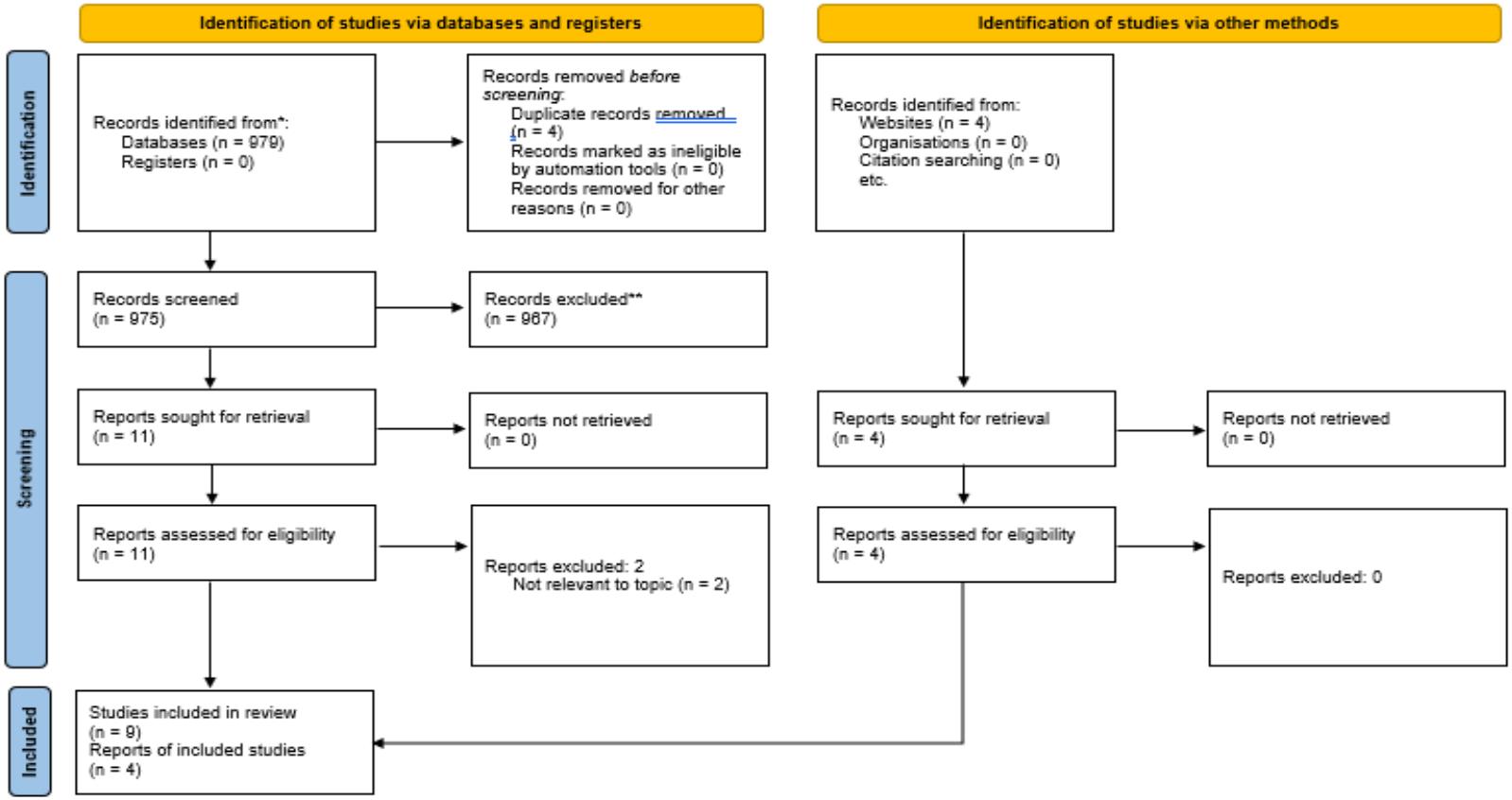
APPENDICES

APPENDIX A

PRISMA

PRISMA 2020 flow diagram for new systematic reviews which included searches of databases, registers and other sources



*Consider, if feasible to do so, reporting the number of records identified from each database or register searched (rather than the total number across all databases/registers).
**If automation tools were used, indicate how many records were excluded by a human and how many were excluded by automation tools.

Source: Page MJ, et al. BMJ 2021;372:n71. doi: 10.1136/bmj.n71.