Evaluation of a Presurgical Pregnancy Testing Protocol at an Ambulatory Surgery Center

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Purpose: *A presurgical pregnancy testing protocol is recommended to prevent the administration of surgery and anesthesia to women of childbearing years who present for surgery with an undetected pregnancy. It is important to determine the compliance, cost analysis, time required, and barriers to complete a presurgical pregnancy testing protocol.*
Design: *Postimplementation qualitative and quantitative evaluation of a presurgical pregnancy protocol.*
Methods: *A review of the patient's electronic medical record, survey of the nursing staff, and an administrative interview was conducted 1 year after implementation of the presurgical pregnancy protocol.*
Findings: *Overall presurgical pregnancy protocol compliance was 0.7%. The total labor and equipment costs were $19,033 to $30,202 per year. Nurses reported significant time- and patient-related barriers to execute the protocol.*
Conclusions: *A pregnancy testing protocol is a valuable safety measure that faces barriers, which can impede compliance. Through the use of simplified protocols, educational interventions for patients and providers, protocol compliance can be increased.*

Keywords: *pregnancy testing, hCG, anesthesia, protocol, preoperative, ambulatory surgery.*

APPROXIMATELY 40 MILLION PEOPLE per year receive anesthesia in the United States through general, regional, or monitored anesthesia care techniques. The rates of anesthesia complications vary by technique and include cardiac arrest, respiratory compromise, vascular injury, neurologic injury, lung and diaphragm injury, or medication toxicity.[1-4] Female patients at risk for pregnancy represent a particularly vulnerable subset of the anesthetic population.[5] Confirmation of a patient's pregnancy status is part of a comprehensive health-risk assessment for patients of childbearing age scheduled to receive anesthesia.[5] The process of pregnancy detection, especially for an early pregnancy, may be clinically challenging for providers to perform.[5,6]

Surgery and anesthesia, when administered to a pregnant woman, expose both the mother and the developing fetus to medical hazards, such as rapid shifts in CO_2, blood pressure, or sympathetic nervous system function. These alterations may result in fetal blood flow reductions.[5,7] The risk of negative pregnancy outcomes such as spontaneous abortion, premature labor, low

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birth weight, higher infant mortality, and fetal hydrocephalus are all increased by exposure to surgery and anesthesia.[5,6] In addition, surgical exposure to diagnostic radiation carries the risk of fetal intrauterine growth restriction, fetal mutation, and fetal demise.[8] Many of the medications commonly used by anesthesia providers during surgery are associated with teratogenic effects for a fetus in utero. Some specific examples of the teratogenicity of anesthesia drugs include benzodiazepines, which have been associated with cleft palate development, nitrous oxide, which has been associated with fetal DNA damage, and volatile gasses, propofol, and etomidate, which have been associated with fetal neurotoxic outcomes.[7,9,10] The adverse effects of these drugs include disruption of fetal organogenesis and suppression of fetal growth and brain development.[7,9]

Identification of women that present with an undetected pregnancy allows providers to limit the potential physiological and teratogenic dangers of anesthesia and surgery.[5] Point-of-care (POC) pregnancy testing protocols provide valuable information to identify pregnant females scheduled for elective surgical procedures.[5] The purpose of this quality improvement project was to evaluate a presurgical pregnancy testing protocol implemented in an ambulatory surgery center to determine institutional implications of the presurgical pregnancy testing protocol including compliance, cost analysis, workforce time effort, and barriers to complete the protocol.

Literature Review

Human chorionic gonadotropin (hCG) is a hormone that is directly associated with pregnancy. It is secreted early in pregnancy by the rapidly growing placental cells inside the uterus. hCG is detectable in blood 8 to 10 days after conception and in urine 9 to 14 days after conception.[11,12] POC urine hCG tests have been used routinely in the surgical arena. These tests have excellent reliability with 100% sensitivity and 99% specificity, a positive predictive value of more than 98% and a negative predictive value of more than 99%.[13-15] POC urine hCG tests yield results in approximately 7 minutes, compared with blood hCG tests, which require over an hour and can lead to potential surgical delays.[13,15] Furthermore, POC hCG tests are easy to use, noninvasive, and are recommended as a superior method for pregnancy detection.[11,13]

Presurgical testing is currently a controversial issue. There are concerns that practitioner reliance on unnecessary testing increases costs and does not decrease rates of complications.[16] Opponents of preoperative testing suggest instead that patient assessment and clinician evaluation of symptoms should be used to detect patient comorbidities.[17] However, in the case of pregnancy assessment, physical examination and historical information alone is inadequate to determine pregnancy status.[5,6] The routine questions used to determine pregnancy risk include the date of the patient's last menstrual period (LMP) and a history of the current method of birth control. However, inaccurately reported dates of menses, unrecognized ovulation changes, or imperfect birth control use often obscure interpretation of the patient's answers.[6] Inaccurate patient reporting in response to questioning can misrepresent the patient's risk for pregnancy. A urine pregnancy test yields valid and accurate information necessary to make informed medical decisions and decrease the woman's anesthesia risk.[5,6]

Preoperative pregnancy testing is supported by prominent national and international professional organizations. The American Society of Anesthesiologists and the British National Institute for Health and Care Excellence both have guidelines that support presurgical pregnancy testing with a protocol.[11,18] In addition, the Association for Nurse Anesthetists standards stipulate anesthetists have an obligation to thoroughly assess each patient and develop a specific anesthetic plan that is tailored to the medical risks for each patient. Considering these standards, presurgical pregnancy testing may be a vital assessment tool to assist anesthesia providers in developing a safe plan of care.[19] Hutzler et al[14] implemented a presurgery pregnancy testing protocol that yielded a positive pregnancy test rate of 0.15%. In a literature review, Maher and Mahabir[5] found support for the implementation of a presurgical pregnancy testing protocol across 14 different articles of 10,000 subjects, for a reported positive pregnancy test result rate ranging from 0.34% to 2.4%. This study supported

the need for an institutional-wide standard of care regarding presurgical pregnancy assessment and the need to have a reliable pregnancy testing protocol in place. As a result, Maher and Mahabir[5] proposed a recommendation for best practice that included day of surgery urine pregnancy testing for all patients who have menstruated during the year before their day of surgical admission.[5]

The aims of this quality improvement project were to evaluate the institutional implications of the presurgical pregnancy testing protocol including compliance, cost analysis, the time required to complete the protocol, and barriers to complete the protocol. The results of this project may be used to inform presurgical pregnancy testing protocols for other facilities.

Methods

Study Design, Sample, and Organizational Setting

This project was conducted in a same day ambulatory surgical center located in North Carolina. The center included eight operating rooms and treated over 6,000 patients in 2017. The inclusion criteria were female patients aged between 12 and 55 years, who were scheduled for an elective surgical case or procedure requiring anesthesia from July to November 2017. Females aged less than 12 years or those greater than 55 years were excluded from the study. To determine the workforce time requirement and the cost analysis of the presurgical pregnancy protocol, a second sample consisted of nurses and surgical administrators who worked in the surgical center and implemented the current presurgical pregnancy protocol.

Implementation

An institutional database query tool was used to identify 150 female patients who met inclusion criteria during the study time parameters of July to November 2017. For each patient identified, a chart review was performed via the electronic medical record to assess the presence of documentation required by the presurgical pregnancy protocol. Compliance for the presurgical pregnancy protocol was defined as the presence of documentation of all steps of the presurgical protocol. An online survey was distributed to the preoperative nurses responsible for implementation and documentation of the presurgical pregnancy protocol policy. Institutional surgical administrators were interviewed to provide information related to materials and labor costs associated with the implementation of the presurgical pregnancy protocol.

Data Collection

Data collection included demographic and protocol-related information. Demographic data included the patient's age and surgical type. Protocol-related information included (1) preanesthesia phone interview documentation on the inquiry of the possibility of pregnancy and the patient's LMP and (2) day of surgery inquiry of the possibility of pregnancy and the patient's LMP. Additional data collected included the documentation of the pregnancy test result and pregnancy test lot number with expiration date. If the patient was excluded from testing, evidence of the patient meeting protocol exclusion criteria was verified.

Perioperative nurses were recruited to complete the survey via a group e-mail sent by nursing administration. The e-mail contained a link, valid for one-time use. Responses to the survey were anonymous. The online nursing survey comprised two parts. Part 1 included questions regarding the time needed to complete the steps of the presurgical pregnancy protocol that take place on the day of surgery, and part 2 included free-text descriptions of nurse-reported barriers to complete the presurgical pregnancy protocol. Data were also collected regarding materials and labor costs associated with the implementation of the presurgical pregnancy protocol, which included nursing hourly wage, supply costs of POC pregnancy tests, and approximate number of pregnancy tests used per month.

Statistical Analysis

All numerical data were analyzed using SPSS Statistics Software version 23. Categorical data were analyzed for frequencies and percentages. Demographic data were analyzed using descriptive

statistics including means, standard deviation, and frequencies. Survey comments related to protocol implementation barriers were compiled and analyzed qualitatively for recurring concepts and themes. Data analysis related to cost was calculated using basic arithmetic functions.

Results

The descriptive statistics for females who were included in the presurgical pregnancy protocol are presented in Table 1. The mean patient age was 41.5 years. The primary procedures for which the patients presented included general surgery (25%), gynecologic surgery (19%), and pain procedures (17%).

Protocol Compliance

Compliance was reported for each step of the presurgical pregnancy testing protocol separately and as an overall rate. The compliance rates for the presurgical pregnancy protocol by step are reported in Table 2. The overall compliance of the presurgical protocol as determined by performing all six required steps was 0.7% (Figure 1). Compliance rates for steps 1 and 2, evidence of questioning regarding the possibility of pregnancy and the patients' LMP during their preanesthesia phone interview before surgery, were 21% and 37%, respectively. Compliance rates for steps 3 and 4, the inquiry of the possibility of pregnancy and the patients' LMP on the day of surgery, were 30% and 57%, respectively. We found 121 of the 150 (80%) female patient sample met the criteria to receive a presurgical pregnancy test. A pregnancy test (step 5) was appropriately administered to 64% of eligible patients and inappropriately withheld for 36% of patients (Table 2). Patients were appropriately excluded from the presurgical pregnancy protocol testing in 93% of cases. According to the protocol, step 6 required documentation of the pregnancy test lot number and expiration dates; this was completed at a rate of 52%. Figure 2 displays the overall compliance of the presurgical pregnancy protocol steps required on the day of surgery. All completed pregnancy tests yielded a negative result.

Nursing Workforce Assessment

Sixteen preoperative nurses completed the survey resulting in an 80% response rate (Table 3). Seventy-five percent of the respondents reported steps 1 to 4 of the presurgical pregnancy protocol took 0 to 2 minutes, 38% of the nurses reported step 5a took 3 to 5 minutes, 69% of nurses reported step 5b took 3 to 5 minutes, and 63% of nurses reported step 6 took 0 to 2 minutes to complete (Table 3). Qualitative data regarding patient-related, time-related, and equipment-related barriers to complete the presurgical pregnancy protocol were obtained via a free-text section included in the survey. The most common reported barriers to complete the protocol were increased difficulties and delays in obtaining presurgical urine samples and patient resistance to protocol-related requests. Other themes found in the data related to presurgical pregnancy testing barriers included nursing delays in entering test documentation, nursing delays related to entering electronic medical record orders, nurse staffing, and late patient arrivals.

Cost Analysis

A review of the Ambulatory Center's administrative report was used to analyze the equipment

Table 1. Descriptive Statistics of Female Patients Included in the Presurgical Pregnancy Protocol

Variable	
Age (y), Mean (SD)	41.5 (8.8)
Age categorical, n (%)	
20-30 y	19 (12.7)
31-40 y	47 (31.3)
41-50 y	57 (38)
51-55 y	27 (18)
Scheduled surgery or procedure, n (%)	
General	38 (25.3)
Gynecology	28 (18.7)
Pain/anesthesia	26 (17.3)
Orthopaedic	22 (14.7)
Plastic	9 (6.0)
Eye	9 (6.0)
Gastroenterology	9 (6.0)
Otolaryngology	8 (5.3)
Urology	1 (0.7)

Table 2. Presurgical Pregnancy Protocol Compliance Rates

Step	Compliance Measure	N	N (%)
1-6	Overall compliance	150	1 (0.7)
	Inquiry completed before the day of surgery		
1	Asked about last menstrual period		31 (20.7)
2	Asked about possibility of pregnancy		55 (36.7)
	Inquiry completed on the day of surgery		
3	Asked about last menstrual period		45 (30.0)
4	Asked about possibility of pregnancy		86 (57.3)
5	*Pregnancy test exclusion*		
	Testing not required (exclusion)		29 (19.3)
	Testing required (no exclusion)		121 (80.7)
5	*Pregnancy test inclusion*	121	
	Test not completed		44 (36.4)
	Test completed		77 (63.6)
6	*Pregnancy kit lot number and expiration date*	77	
	Not documented		37 (48.1)
	Documented		40 (51.9)

costs associated with implementation of POC presurgical pregnancy tests. The cost per box of pregnancy tests was $56.50. An average of six boxes was used per month resulting in a yearly equipment cost of $4,140. Complete labor costs associated with the pregnancy testing protocol were calculated through analysis of the survey data and the facility reported nursing hourly wage. The survey reported time to complete collection, processing, and documentation of the presurgical pregnancy protocol was 6 to 14 minutes, which resulted in a cost of $4.16 to

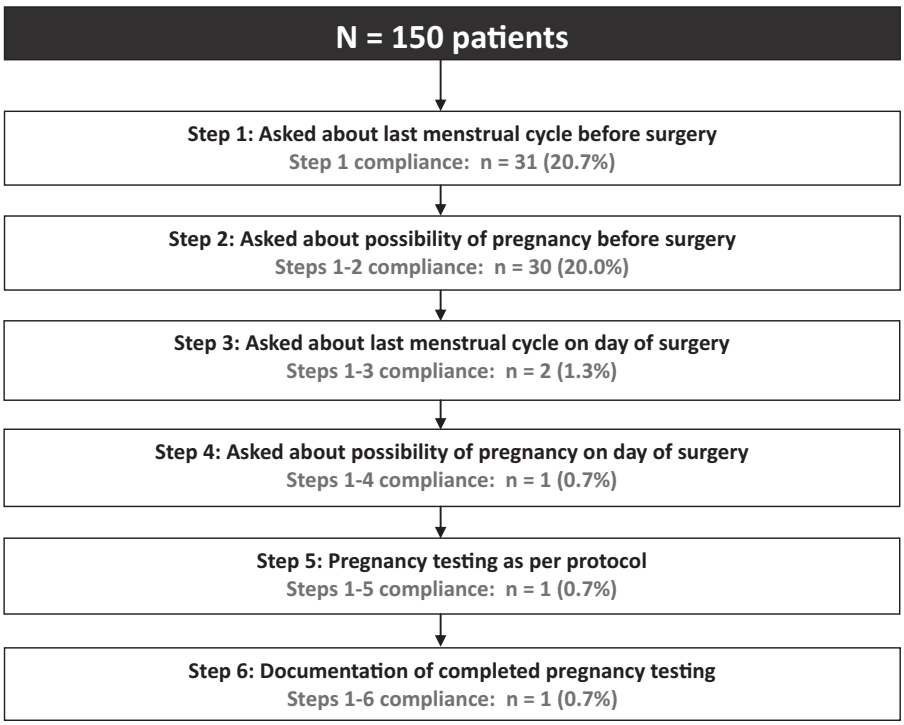

Figure 1. Overall compliance rate for steps 1 to 6.

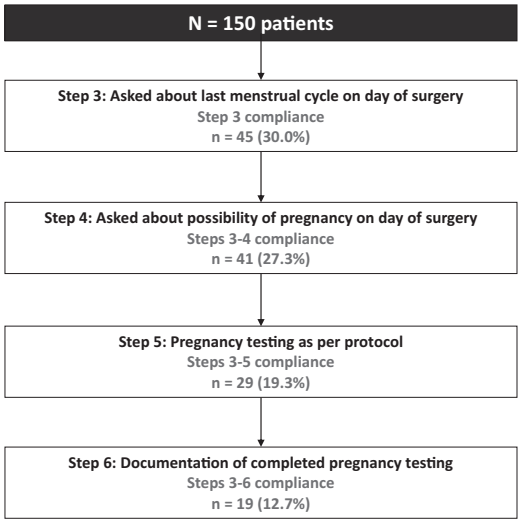

Figure 2. Compliance rate for steps required on the day of surgery only (steps 3 to 6).

$7.28 per test. In 2017, approximately 4,420 female patients who met the inclusion criteria presented for surgery resulting in nursing labor costs of $14,893 to $26,062 for the year. The cumulative yearly nursing labor and equipment cost was $19,033 to $30,202. The equipment costs associated with testing were not charged to the patient or the institution, nor were they reimbursed by an outside payer.

Discussion

The purpose of this project was to evaluate the institutional implications of the preoperative pregnancy testing protocol including compliance, cost analysis, the time required to complete the protocol, and barriers to complete the protocol. The issues of compliance with the presurgical pregnancy protocol, barriers to complete the protocol, and costs related to the protocol are important to address.

There are multiple reasons for low protocol compliance rates noted in the literature. As protocols introduce new practice changes, they require workflow interruptions, workflow delays, and task reprioritization.[20] These changes increase the risk of task priority conflicts, resulting in the omission of new protocol behaviors, thereby supporting noncompliance.[20] In addition, excessive protocol complexity can overwhelm or confuse clinicians, further preventing compliance.[21] Although the presurgical pregnancy testing protocol overall compliance was low, less than 1%, it is important to note the average individual compliance rate for the most critical steps of the protocol, steps 3 to 6 completed on the day of surgery, was 68%. Activity for protocol compliance in this study spanned many days. It required nursing staff to question the patient about the possibility of pregnancy and their LMP during their preanesthesia phone interview many days before the day of surgery. This requirement caused a time burden for staff, represented a workflow redundancy, fragmented presurgical care, and decreased the execution of the protocol overall. By simplifying the protocol and concentrating protocol activities to the day of surgery alone, compliance rates may increase.[21] If the protocol was simplified to include day of surgery activity (steps 3 to 6), the overall compliance rate improves 10-fold to 12.7% (Figure 2). There is support in the literature for

Table 3. Day of Surgery Presurgical Pregnancy Protocol Time Analysis (N = 16)

Step	Question	0-2 min n (%)	3-5 min n (%)	>5 min n (%)
3-4	What is the time required to ask the patient about the possibility of pregnancy and their last menstrual period?	12 (75.0)	4 (25.0)	0 (0.0)
5a	What is the time required to collect a urine sample?	5 (31.3)	6 (37.5)	5 (31.3)
5b	How much time is required to test urine?	4 (25.0)	11 (68.8)	1 (6.3)
6	How much time is needed to document test results?	10 (62.5)	5 (31.3)	1 (6.3)

educational interventions as a means of increasing protocol compliance. Provider education supplied in written, verbal, and electronic forms are shown to be effective methods for increasing protocol execution.[20,22,23] Protocol education should be clear, focus on the details of protocol content, and the anticipated positive patient effects for maximum clinician impact.[20]

The results of the nursing staff survey provided data on the significant time-related barriers to the protocol. The nurses reported the majority of time needed to perform protocol steps was spent in the collection and testing of urine samples. These steps of the protocol were often delayed because of the patient's inability to provide a urine sample at the appropriate time. The literature supports the use of instructional signs to facilitate patient participation in protocol activities.[22,23] Clear signage posted in the presurgical patient waiting area alerting female patients about the collection of a presurgical pregnancy urine sample before surgery may increase the patient required participation in the protocol and would help prevent delays after the registration process once the patient enters the presurgical holding unit on the day of surgery.[22,23]

The cost data obtained for the presurgical pregnancy protocol included information on the full labor requirements (including urine sample collection, processing, and documentation) to perform testing. Kahn et al[15] reported a partial labor cost of $2.53 per test, which closely mirrors the cost found in the present study facility of $1.56 to $2.60 per test. The overall presurgical pregnancy protocol costs to the facility of $19,033 to $30,202 may seem substantial, but surgery center administration must weigh this cost against the potential harm to the mother and fetus, the costs associated with surgical cancellations, and the medicolegal costs of complications from administering surgery and anesthesia to a pregnant patient.

Limitations

The database query used to obtain patient data could not sort pregnancy tests by result. This prevented a full evaluation of protocol compliance in the event of an unexpected positive pregnancy test. Next, the nursing survey regarding the time needed to complete the protocol omitted a minute interval choice. The addition of this interval would have created a more accurate depiction of the time requirements to complete the protocol. The nursing time required to ask protocol-related questions during the presurgical phone calls was excluded from the time survey, which prevented its inclusion in the cost analysis and protocol barrier analysis for activities that are executed before the day of surgery. In addition, this project was implemented as a single site evaluation of a presurgical testing protocol.

Conclusions

Patients that present to surgery with undetected pregnancies represent a population that is both difficult to diagnose and high risk. Implementing a POC pregnancy testing protocol for female surgical patients represents current best practice for preoperative screening. To our knowledge, this project is the first multisystem review of the literature, compliance, and financial implications of a presurgical pregnancy testing protocol as a patient safety measure. The results of this study revealed low protocol compliance, significant time- and patient-related barriers to protocol implementation, and protocol-associated labor costs are similar to those found in the literature. These findings and the solutions discussed can lead to increased compliance, decreased barriers to success, and point to the need for further educational, time, and cost saving interventions to increase pregnancy testing protocol effectiveness.

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