Duplicate Type and Screen Testing

Waste in the Clinical Laboratory

Margaret L. Compton, MD; Penny C. Szklarski, MLT; Garrett S. Booth, MD, MS

• ***Context.***—**In the United States, approximately $65 billion dollars is spent per year on clinical laboratory testing, of which 20% to 30% of all testing is deemed inappropriate. There have been multiple studies in the field of transfusion medicine regarding evidence-based transfusion practices, but limited data exist regarding inappropriate pretransfusion testing and its financial and clinical implications.**

Objective.—**To assess duplicative testing practices in the transfusion medicine service.**

Design.—**A 24-month retrospective review was performed at a 1025-bed tertiary care center, identifying all duplicate type and screen (TS) tests performed within 72 hours of the previous TS. Duplicative testing was classified as appropriate or inappropriate by predetermined criteria. The level of underordering was analyzed through a query of the electronic event reporting system. A cost analysis was performed to determine the financial impact of inappropriate duplicative TS.**

Results.—**The mean rate of inappropriate, duplicative TS orders was 4.13% (standard deviation ± 4.09%). Rates of inappropriate ordering ranged from 0.01% to 15.5% depending on the clinical service and did not correlate with volume of tests ordered. There were 8 reported cases of delayed blood delivery due to lack of a valid TS during the study period, demonstrating that underordering is also a harmful practice. The laboratory cost of inappropriate testing for the study period was $80,434, and phlebotomy costs were $45,469.**

Conclusions.—**Our study demonstrates that inappropriate TS ordering is costly, both financially and clinically. By evaluating the percentage of inappropriate TS tests by clinical services, we have identified services that may benefit from additional education and technologic intervention.**

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Laboratory testing is a fundamental part of the modern health care landscape, with an estimated 60% to 70% of medical decision making based on test results.[1] In the United States, approximately $65 billion dollars per year is spent on clinical laboratory testing.[2] It is estimated that between 20% to 30% of all tests are inappropriate, defined as any test for which the results are not likely to be medically necessary in the appropriate management of the patient's medical condition.[3–5] Inappropriate tests may fulfill this definition in several ways, including ordering a test despite a low pretest probability, using an unapproved or suboptimal test for a particular condition, errors in order entry, underordering, or retesting at an inappropriately short interval. Identifying and eliminating sources of waste within the clinical laboratory are important steps in addressing the increasing cost of health care.

Owing to the expense and potential morbidity associated with the administration of blood products, there are multiple studies within the field of transfusion medicine regarding resource utilization, in particular the analysis of appropriate hemoglobin thresholds for transfusion.[6–9] However, in addition to encouraging evidence-based transfusion practices, transfusion medicine services should also be aware of the potential for reducing inappropriate pretransfusion testing. AABB standards state that for patients who have received transfusions or who were pregnant in the 3 months preceding transfusion, or for patients with unknown history, an antibody screen should be performed within 3 days of transfusion.[10] Two determinations of the recipient's ABO group is required if a computer system is used as a method to detect ABO incompatibility. Repeated confirmatory type and screen (TS) testing is required in solid organ and hematopoietic stem cell transplant (Table 1). Beyond these clinical indications, repeated testing represents potential medical waste.

Besides the lack of a clinical benefit, duplicative TS testing has the potential to cause harm to both the hospital system and the individual patient. Duplicative testing is one of the 13 measures used by the Office of the Inspector General to assess for questionable billing practices; therefore, it is within the laboratory's best interest to identify and address sources of inappropriate testing to avoid potential legal repercussions.[11] With growing use of bundled payments, there is also a financial incentive for providers to avoid inappropriate tests, as there is no additional reimbursement

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From the Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center, Nashville, Tennessee.
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Reprints: Margaret L. Compton, MD, Vanderbilt University Medical Center, 1161 21st Ave S, MCN CC3322, Nashville, TN 37232-2561 (email: margaret.l.compton@vanderbilt.edu).

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Table 1. Clinical Scenarios Requiring Duplicate Type and Screen Testing

Duplicate Pretransfusion Testing Policies	
Organization	**Policy**
Organ Procurement and Transplantation Network (OPTN)	2.6.A. Deceased Donor Blood Type Determination: The host organ procurement organization (OPO) must ensure that each deceased donor's blood type is accurately determined by testing two donor blood samples prior to incision. 3.3.A. Blood Type Determination Before Registration on the Waiting List: Transplant programs must determine each candidate's blood type by testing at least two candidate blood samples prior to registration on the waiting list. Transplant programs must test at least two blood samples from two separate blood draws taken at two different times.[31]
Foundation for the Accreditation of Cellular Therapy (FACT)	B6.4.3. Allogeneic donors and allogeneic recipients shall be tested for ABO group and Rh type using two independently collected samples. Discrepancies shall be resolved and documented prior to issue of the cellular therapy product.[32]

despite increased costs related to staffing time of the phlebotomist and medical technologist, cost of the reagents and blood collection tube, and sample storage.[12] Lastly, excessive phlebotomy can lead to iatrogenic anemia,[13,14] which may be associated with increased morbidity and mortality in certain patient populations.[15]

We performed a 24-month retrospective review of all clinical laboratory specimens received at the Vanderbilt University Medical Center (VUMC; Nashville, Tennessee) Blood Bank to determine the extent of inappropriate samples received. We report on the level, frequency, and location of inappropriate TS samples from a large tertiary academic medical center and discuss potential actions to address inappropriate testing.

MATERIALS AND METHODS

A 24-month institutional review board–approved retrospective review of the electronic blood bank laboratory information system (LIS; SSC Soft Computer, Clearwater, Florida) was performed for 2013 and 2014 at a tertiary care center with 1025 licensed beds, 72 operating rooms, and with a volume of approximately 59 112 inpatient discharges, 1 834 856 ambulatory visits, and 118 590 emergency department visits in fiscal year 2014.[16] A computer-generated data collection was performed, identifying all duplicate TS tests received within 72 hours of the previously performed TS, samples designated as unacceptable for testing, and samples for which testing was deferred by the technologist, herein referred to as "hold" samples. Data were collected on the location where the test was ordered, the date and time of the current specimen, the date and time of the prior TS, and whether there was an indication for repeating the TS. All duplicate samples were classified as appropriate or inappropriate from predetermined criteria. Inappropriate duplicative samples were defined as repeated samples within 72 hours of first collection, excluding patients undergoing solid organ and hematopoietic stem cell transplant. We also excluded samples collected within 12 hours of TS expiration, as this period represented the maximum length of a nursing shift at our institution. Additional samples that were required for further blood bank testing, including transfusion reaction testing, adsorption studies, or further samples needed to characterize an antibody, were not counted as duplicate samples. The collected data were analyzed by 1 member of the team, and an independent audit of 10% was performed by the other 2 team members to ensure consistency and accuracy in coding of the duplicate samples. Statistical analysis was performed with a χ^2 method (Graph Pad Software, La Jolla, California).

In accordance with AABB *Standards for Blood Banks and Transfusion Services*, 30th edition,[10] samples collected for a TS require the name, medical record number, date of collection, and phlebotomist identification on the specimen. Upon receipt of a sample in the VUMC Blood Bank, specimens were evaluated for appropriate labeling of the sample, presence of a requisition form with an appropriate order, and sample quantity (Figure 1). Specimens not meeting the labeling requirements or samples with insufficient quantity for testing were defined as unacceptable samples and no testing was performed. Sufficient quantity for a standard TS is defined as 1 to 1.25 mL of whole blood, the amount required to perform forward and reverse typing for A, B, and D; a direct antiglobulin test for IgG; and a 2-cell antibody screen using an automated platform. If no test was ordered per the requisition the specimen was logged into the blood bank LIS as a hold and no testing was performed. If an order to transfuse is present without a TS order, the technologist notifies the clinical team. If a technologist identifies a duplicate order or the presence of a TS obtained within the prior 24 hours for the patient at the time of accessioning, the technologist may also log the test as a hold. However, placing a hold on the specimen is not mandated by our laboratory's standard of practice and therefore is at the technologist's discretion. Although hold samples and unacceptable samples represent an expenditure of staffing time and a quantity of iatrogenic blood loss, these categories were not tabulated as "inappropriate," as these samples did not necessarily reflect inappropriate ordering practices.

To assess for underordering, the Vanderbilt online incident reporting system was queried for the study period to identify any cases in which delivery of blood products was delayed. The reports were analyzed to assess if absence of TS testing played a role in the delay. A cost analysis was performed that included labor,[17–19] phlebotomy supplies, and clinical laboratory consumables.

RESULTS

A total of 123 517 TS samples were received by the VUMC Blood Bank in the 24-month study period, of which 6385 samples (5.1%) were duplicate orders. Of these, 2463 samples (2.0%) were deemed clinically appropriate for duplicative testing and 3922 samples (3.2%) were determined to be inappropriate as based on our predetermined criteria (Figure 2). An additional 1985 samples (1.6%) were held by the medical technologist, and 1706 samples (1.4%) were unacceptable for testing. Data were analyzed on a quarterly basis, and no seasonal variation in ordering practices was observed.

Inappropriately ordered specimens originated from multiple clinical services (Figure 3). Rates of inappropriate ordering ranged from 0.01% in the neonatal intensive care unit to 15.5% in the inpatient surgical units, with an overall combined mean rate of 4.13% (standard deviation ± 4.09%) for all clinical services. To assess if differences in ordering rates between clinical services were solely due to variation in test volume, a weighted "expected" rate of inappropriate ordering was calculated for each clinical service by using the average rate of inappropriate ordering across the institution and each clinical service's test volume. A χ^2 analysis

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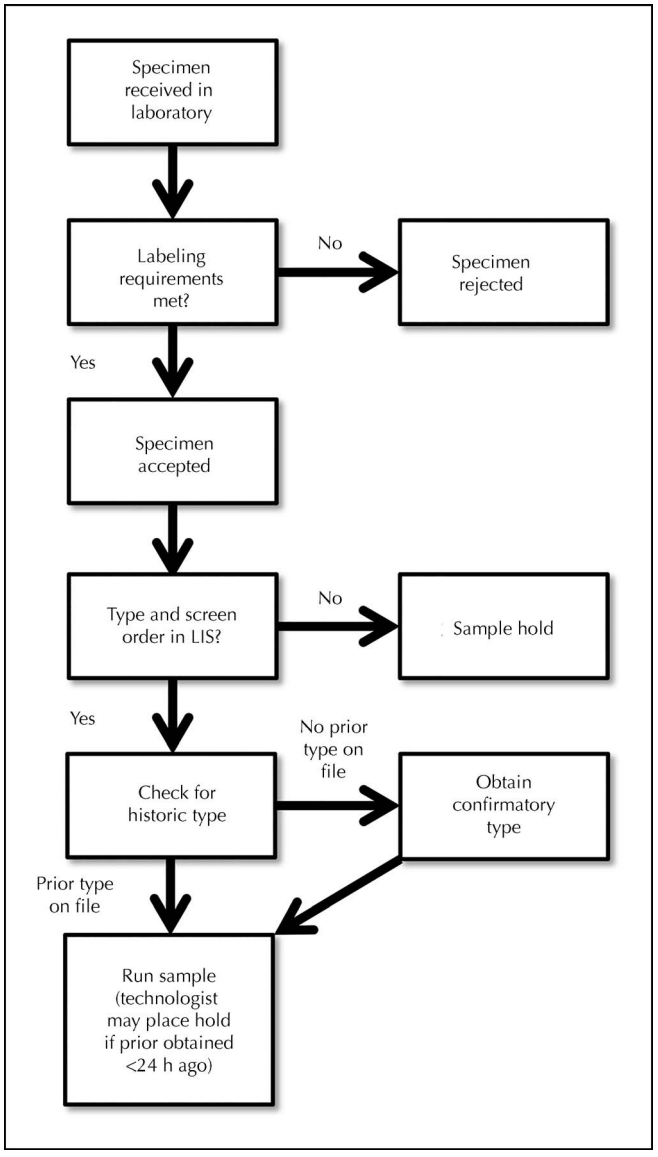

Figure 1. *Workflow diagram for specimens received by Vanderbilt University Medical Center Blood Bank (Nashville, Tennessee). Abbreviation: LIS, laboratory information system.*

demonstrated that the expected rate of inappropriate ordering, as based on each service's volume, was significantly different from the observed rate of inappropriate orders ($P < .001$). Most inappropriate samples were from adult patients, comprising 3688 samples (94%).

Query of the online incident reporting system demonstrated 54 cases of delayed blood delivery. In 8 cases (15%), blood delivery was delayed owing to lack of a valid TS. In 3 of the cases with no valid TS, the TS had been ordered but the sample was not collected. In 1 case, the TS was ordered and blood was drawn but sent to the wrong laboratory through the pneumatic tube system, leading to a delay in the TS result. In 1 case, the clinical team failed to request a TS extension for an outpatient who had not undergone transfusion. The remaining 3 cases did not have a TS order.

An economic analysis (Table 2) of inappropriate testing demonstrated a total of $80,434 was spent on reagents and technologist time in 2013–2014. A total of $45,469 was also spent on phlebotomy supplies and phlebotomist staffing.

DISCUSSION

Our analysis demonstrates that inappropriate TS ordering is present across our medical institution. We demonstrate that duplicative testing is expensive with regard to reagent use and staffing costs. We also show that, despite the prevalence of overordering, there were several reported cases in which blood delivery was delayed owing to lack of a valid TS, demonstrating that underordering is also problematic.

There are several inherent limitations to our study due to the use of a retrospective study design. Because this study was performed by using an LIS records search, it is possible that not all duplicate samples were captured by our methodology, as paper orders written during computer system downtime may not have been recorded. Our classification system may also have led to an underestimation of the total number of inappropriate duplicate tests, since all TS tests ordered for stem cell and solid organ transplant patients were classified as "appropriate," meaning that any duplicate TS orders beyond the initial requirement of 2 pretransplant samples would not have been designated as "inappropriate" despite lack of clinical utility. Another limitation to our analysis is that there is no evidence-based time point to determine what defines a duplicate sample. We selected 12 hours before expiration as our cutoff point for several reasons. Since our analysis was based on collection time rather than ordering time, we selected our cutoff to reflect nursing schedules rather than when physicians perform rounds. Twelve hours is the maximum length of a nursing shift and would capture daytime phlebotomy, nursing shift handoff, and evening phlebotomy. We avoided setting a time point too close to the midnight sample expiration, as this reflects a time when patients are typically sleeping, so blood draws are performed earlier to avoid disrupting patient sleep. We weighted the inpatient schedule more heavily than outpatient schedule when selecting our time cutoff, as our laboratory allows TS validity to be extended to 14 days for nonpregnant patients who have not undergone transfusion. One population of outpatients with heavy transfusion requirements includes our patients in the sickle cell disease clinic. However, the sickle cell clinic draws blood for laboratory tests the morning of the scheduled transfusion so a current hemoglobin S level can be obtained. This population was found to have very low duplicate testing rates. Our cost analysis also has several limitations. As our institution does not track the percentage of blood draws performed by registered nurses versus those performed by phlebotomists, we calculated cost on the basis of the lower phlebotomist's salary. If blood draws were assumed to be performed by registered nurses, as is the case with many of the inpatients, the calculated cost for inappropriate blood draws would be nearly twice as expensive: $64,627 as compared to $45,469. In addition, our institution has a $24 phlebotomy surcharge, which we do not include in our calculations, as it is waived for most inpatients. However, even with our calculations representing the lowest end of the cost spectrum for individual blood draws at our institution, we show that a substantial amount of money is spent performing tests that have no clinical value.

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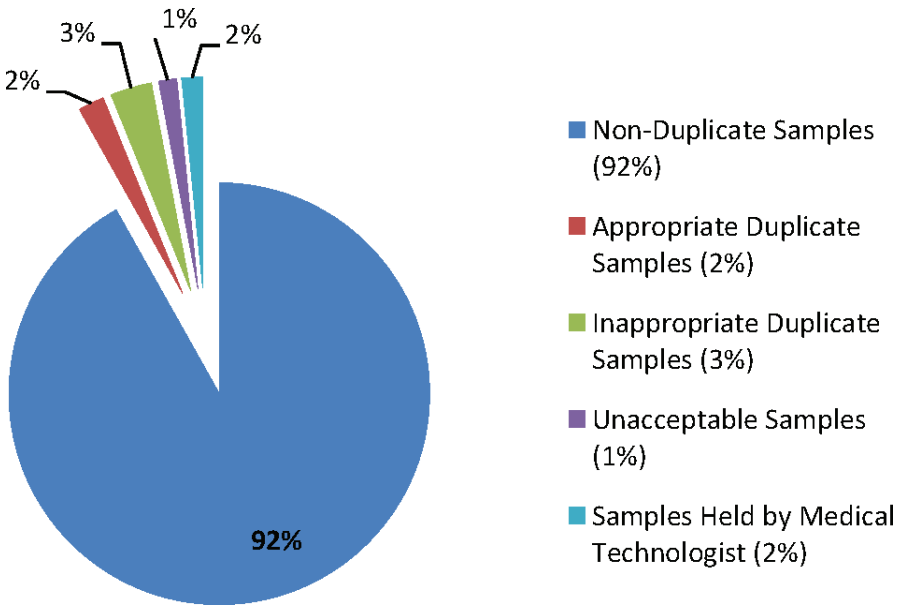

Figure 2. *Classification of specimens received by Vanderbilt University Medical Center Blood Bank (Nashville, Tennessee).*

Despite these limitations, the results of our analysis indicate that duplicative TS ordering is present across multiple inpatient and outpatient services at our institution. The 2016 College of American Pathologists (CAP) Q-Probes study[20] found that, among tests for which blood had been drawn but that were cancelled in the preanalytic phase, the most frequent reason for test cancellation was duplicate ordering. Our study builds upon these results by demonstrating that, despite well-established criteria for timing of repeated TS testing, inappropriate duplicate testing still remains a problem, as does underordering.

At our institution, order entry may be performed by multiple individuals, including nursing or other clinic support staff, nurse practitioners, physician assistants, and house staff at various levels of training. However, our LIS system only tracks the attending provider's name, so it is not possible to determine if the same individual places the duplicate order. Although, because of the study design, we cannot comment on specific causative factors that lead to higher rates of duplicate testing among specific clinical services, the variation between clinical services is an intriguing finding and suggests an area for future studies. The inpatient surgical services, including surgical intensive care units (ICUs), were identified as an outlier with regard to high rates of inappropriate testing. The surgical ICUs had significantly higher rates of TS testing and duplicate testing than the medical ICUs. Failure to complete TS testing before surgery may result in problems from both a financial and patient safety perspective, owing to surgical delays and inability to find appropriate blood for patients with alloantibodies.[21,22] However, there are several available methods that have been found to reduce the number of patients sent to surgery without appropriate presurgical testing. Extension of TS expiration dates in outpatients who have not undergone transfusion significantly reduces the number of elective surgery patients going to the operating

Table 2. Cost for Type and Screen Assay

Cost of Phlebotomy Supplies Per Test	Staffing Time For Phlebotomist/RN	Cost of Laboratory Reagents Per Test	Staffing Time for Laboratory Technologist
Phlebotomy charge: $24 (optional) Needle: $1.30 Lavender tube: $0.06 Tourniquet: $0.18 Alcohol: $0.01 Gauze: $0.01 Gloves: $0.10 Biohazard bag: $0.03	Access pending laboratory orders: 1 min Collect supplies: 1 min Identify patient room and perform hand hygiene: 2 min Perform positive patient identification and counsel patient: 5 min Disinfect site and perform phlebotomy: 5 min Print labels and label tubes at bedside: 2 min Dispose of materials and perform hand hygiene: 1 min	Anti-A: $0.08 Anti-B: $0.08 Anti-D series 4: $0.09 Anti-D series 5: $0.09 Monoclonal control: $0.05 A1 cells: $0.03 B cells: $0.03 Plates: $0.59 Screening cells: $7.51 Low-ionic-strength saline: $0.48 Indicator cells: $0.23	Accessioning of sample and ordering of test: 3 min Setting up strips or plates: 3 min Add reagents: 3 min Loading and unloading centrifuge: 1 min Load automated machine and verify sample position: 3 min Review, export, and verify results: 10 min
Total: $1.69 without optional phlebotomy charge	Total: 17 min ($8.62 in phlebotomist staffing costs or $18.39 in RN staffing costs)	Total: $9.26	Total: 23 min ($11.16 in technologist staffing costs)

Abbreviation: RN, registered nurse.

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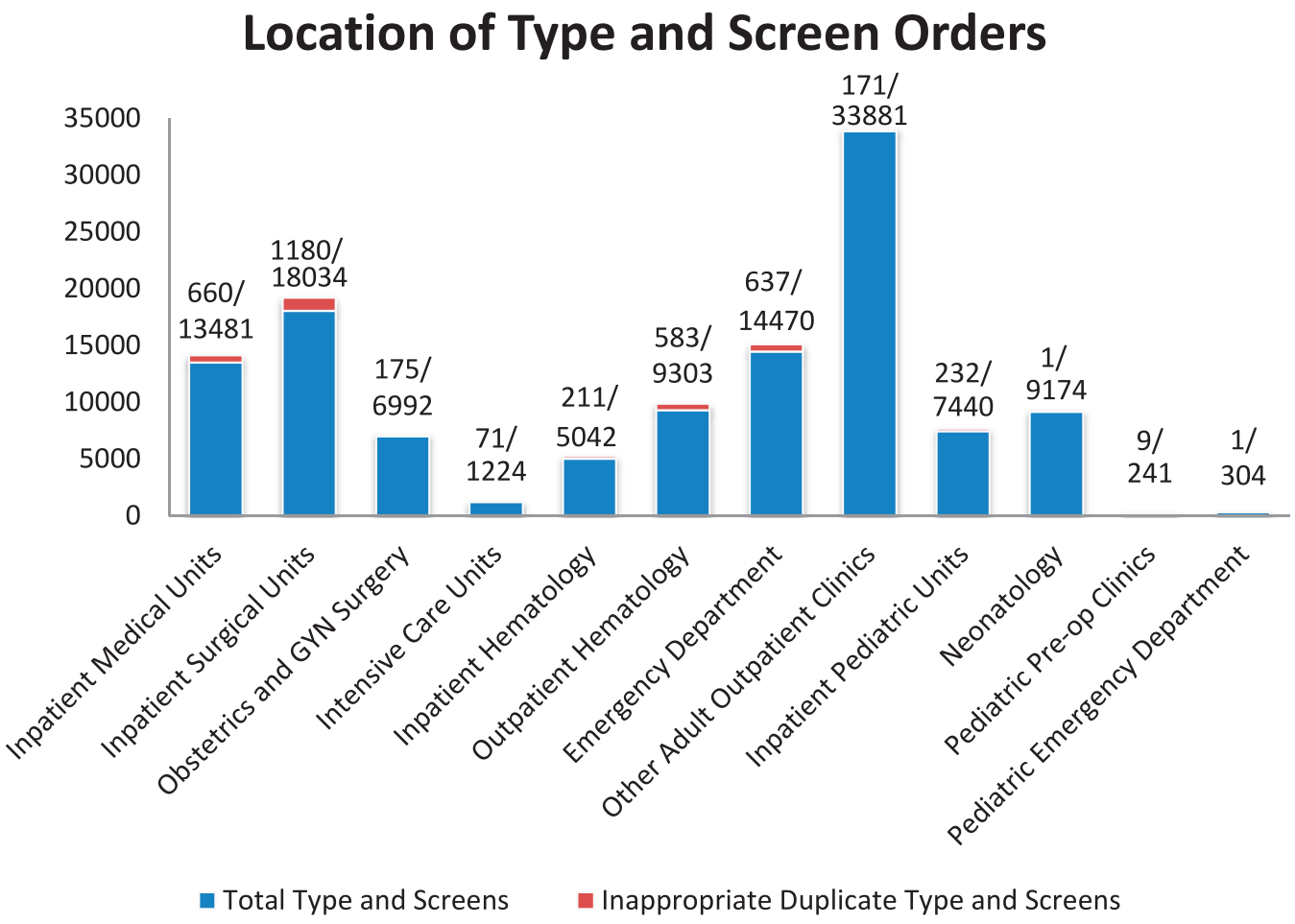

Figure 3. *Overall test volume and number of inappropriate type and screen orders categorized by clinical service. Abbreviations: GYN, gynecologic; Pre-op, preoperative.*

room without a valid TS.[23] Computerized decision support systems[24] and involvement of the anesthesiology team in presurgical planning[25] have also been shown to be beneficial in providing evidence-based presurgical testing.

As well as studying services with high rates of inappropriate duplicate testing, it may also be beneficial to examine why some services have lower rates of inappropriate orders. Although these services did not represent statistically significant outliers, the rate of inappropriate testing for all pediatric services was skewed below the mean. The pediatric residency program at our institution does not have a formal educational program to reduce inappropriate testing in children, but there has been an initiative to reduce overall daily laboratory ordering in the pediatric inpatient population, which has also been successfully expanded to the adult inpatient population.[26] Not only is it more difficult to perform phlebotomy on small children, but multiple studies[27–29] have also documented the negative effects of iatrogenic blood loss on pediatric patients. These factors may have led to increased awareness and efforts among ordering providers to reduce unnecessary testing in this population. Analyzing utilization patterns of the electronic medical record (EMR) system may also be helpful in elucidating ordering practices. Our current EMR (StarPanel, Vanderbilt University Medical Center, Nashville, Tennessee) reports the date and time of sample collection, but not the expiration date of the TS. The screen for order entry and information about sample collection times are located in different sections of the EMR, so it is not easy to access expiration information on patients with a current TS.

There are several possible methods for reducing inappropriate test orders. In some laboratories, standard operating procedures are written so that technologists may cancel duplicate procedures. In the CAP Q-Probes study,[20] 90.4% of preanalytic test cancellations were performed by laboratory personnel. However, within the blood bank, there are several valid clinical scenarios for performing duplicate TS testing (Table 1), and laboratory cancellation in these situations could potentially delay patient care. Moreover, although laboratory cancellation by a technologist eliminates some of the wasted reagent cost and technologist time, there is still a cost associated with the supplies and staffing time for the nurse or phlebotomist to draw the blood and the time spent by laboratory personnel accessioning the specimen. Furthermore, if the test is cancelled at the laboratory stage, the patient still would have been subjected to an unnecessary blood draw. For the above reasons, the onus for identifying inappropriate versus appropriate orders should be with the ordering provider, rather than the laboratory staff.

The optimal system for reducing inappropriate TS orders would be able to perform the following functions: (1) alert providers to the presence of a duplicate sample, (2) alert providers regarding impending TS expiration, (3) ensure the

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presence of a second sample for type verification for patients who have not had previous blood bank testing, and (4) allow for specimen tracking from the patient to the laboratory to avoid unnecessary redraws or samples directed to the wrong laboratory. Additional potential functions include educating providers about evidence-based testing practices and tracking provider performance data with regard to test ordering. Several authors have shown that modifying the computerized physician order entry system is effective in both reducing unnecessary blood transfusions[8,9] and decreasing non–evidence-based laboratory testing.[30] Another potential solution would be use of an electronic positive patient identification system during specimen collection, which would alert the caregivers to the presence of a duplicate sample before drawing the patient's blood. Identification of a potential duplicate order at the time of blood draw is not ideal, as it represents investment of the phlebotomist's time and necessitates seeking out the ordering provider to assess the appropriateness of the order. However, it allows a second layer of safety to avoid unnecessary iatrogenic blood loss, and also can ensure the presence of a sample for type verification, confirm patient identity, and enforce correct labeling practices. Technologic solutions warrant further investigation, as an electronic system for tracking sample collection and an optimized interface for physician order entry not only have the potential to avoid inappropriate ordering, but also may improve patient safety.

Multiple studies have demonstrated high levels of medical waste in the clinical laboratory, but we are the first to demonstrate this from the perspective of TS testing, an assay with well-established guidelines for timing of repeated testing. We also calculate that inappropriate ordering consumes substantial clinical and laboratory resources, yet underordering also may cause delays in blood product delivery. We propose that educational efforts, in combination with technologic solutions, may reduce costs and improve patient safety by decreasing inappropriate orders.

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