Blood Bank Safety Practices

Mislabeled Samples and Wrong Blood in Tube—A Q-Probes Analysis of 122 Clinical Laboratories

Erin Grimm, MD; Richard C. Friedberg, MD, PhD; David S. Wilkinson, MD, PhD; James P. AuBuchon, MD; Rhona J. Souers, MS; Christopher M. Lehman, MD

• ***Context.*—Although a rare occurrence, ABO incompatible transfusions can cause patient morbidity and mortality. Up to 20% of all mistransfusions are traced to patient misidentification and/or sample mislabeling errors that occur before a sample arrives in the laboratory. Laboratories play a significant role in preventing mistransfusion by identifying wrong blood in tube and rejecting mislabeled samples.**

***Objectives.*—To determine the rates of mislabeled samples and wrong blood in tube for samples submitted for ABO typing and to survey patient identification and sample labeling practices and sample acceptance policies for ABO typing samples across a variety of US institutions.**

***Design.*—One hundred twenty-two institutions prospectively reviewed inpatient and outpatient samples submitted for ABO typing for 30 days. Labeling error rates were calculated for each participant and tested for associations with institutional demographic and practice variable information. Wrong-blood-in-tube rates were calculated for the 30-day period and for a retrospective 12-month period. A concurrent survey collected institution-specific sample labeling requirements and institutional policies regarding the fate of mislabeled samples.**

***Results.*—For all institutions combined, the aggregate mislabeled sample rate was 1.12%. The annual and 30-day wrong-blood-in-tube aggregate rates were both 0.04%. Patient first name, last name, and unique identification number were required on the sample by more than 90% of participating institutions; however, other requirements varied more widely.**

***Conclusions.*—The rates of mislabeled samples and wrong blood in tube for US participants in this study were comparable to those reported for most European countries. The survey of patient identification and sample labeling practices and sample acceptance policies for ABO typing samples revealed both practice uniformity and variability as well as significant opportunity for improvement.**

(*Arch Pathol Lab Med.* 2010;134:1108–1115)

Rates of red blood cell (RBC) mistransfusion are surprisingly high (approximately 1 in 14 000), while ABO incompatible transfusions occur at a rate of approximately 1 in 38 000[1] or once every 2 to 3 years for a typical large hospital (>400 beds). Although death due to ABO incompatible transfusion is rare (estimated at 1 in 1.8 million), it can cause significant patient morbidity.[1] Therefore, ABO incompatible transfusion represents a greater risk to patients than the risk of transfusion-acquired infection by hepatitis B virus, hepatitis C virus, or human immunodeficiency virus.[2]

Accepted for publication March 26, 2010.

From the Departments of Pathology (Dr Grimm) and Laboratory Medicine (Dr AuBuchon), University of Washington, Seattle; the Department of Pathology, Baystate Health, Springfield, Massachusetts (Dr Friedberg); the Department of Pathology, Virginia Commonwealth University, Richmond (Dr Wilkinson); Puget Sound Blood Center, Seattle, Washington (Dr AuBuchon); Biostatistics Department, College of American Pathologists, Northfield, Illinois (Ms Souers); and the Department of Pathology, University of Utah, Salt Lake City (Dr Lehman).

The authors have no relevant financial interest in the products or companies described in this article.

Reprints: Christopher M. Lehman, MD, Department of Pathology, Room 2100, University of Utah, 15 N Medical Dr E, Salt Lake City, UT 84112 (e-mail: chris.lehman@hsc.utah.edu).

Patient misidentification resulting in incorrectly administered blood units occurs at 1 of 3 points: during sample collection (phlebotomy), during laboratory testing, or at the time of blood administration. According to a 10-year review of RBC administration in New York State, 56% of errors occur outside the laboratory, and 14% to 20% of these errors occur before the sample arrives at the laboratory.[1]

Samples that do not meet labeling criteria are 40 times more likely to have a blood grouping discrepancy,[3] and therefore, laboratory screening of sample labeling accuracy is a critical patient safety activity. In addition to verifying that the sample tube and requisition form are both adequately labeled and matching, transfusion services are required to compare the current sample blood type against historical records. ''Wrong blood in tube'' (WBIT) occurs when a sample tube is labeled with unique identifiers for one patient, but the blood in the tube was collected from a different patient. Wrong blood in tube is identified by the laboratory when the current ABO typing result disagrees with the historical blood type. This type of delta check does not catch errors when the patient does not have a historical blood type, nor does it identify instances in which 2 patients have the same ABO blood type (ie, silent WBIT). A 2001 multi-institutional, interna-

tional study[4] estimated the median rate of WBIT (corrected for silent WBIT) to be 1 in 1986 samples submitted for ABO testing (uncorrected rate of 1 in 3178 samples or 0.03%), with considerable variation in national rates. Consequently, the authors recommended that nations conduct studies to benchmark current sample mislabeling rates (and WBIT) as a basis for establishing performance standards.

The focus of this study was to establish benchmarks for the rate of mislabeled samples submitted for ABO typing and the uncorrected rate of WBIT primarily for US institutions. This study also documents the patient identification and labeling policies of the participating institutions, correlation of those practices with mislabeling and WBIT rates, and the fate of mislabeled samples.

MATERIALS AND METHODS

Definition of Terms

Mislabeled samples: Samples that do not meet the requirements of the institution's labeling policy.

Rejected samples: Samples that are rejected for ABO testing; a new sample is requested (ie, an ABO type was not performed on a rejected sample).

Historical ABO type: Patient ABO type was performed on a previous sample, and the result was present in the medical record at the time of receipt of the most recent sample submitted for testing.

ABO result discrepancy or uncorrected WBIT: ABO typing result on the current sample disagrees with the historical ABO type.

Study Design

During a 30-day period, participants prospectively reviewed all inpatient and outpatient samples submitted for ABO typing and determined the number received that was incorrectly labeled and the number that was rejected because of mislabeling. In addition, the number of ABO typing samples with a historical ABO type saved in the patient's medical record, the number of ABO discrepancies between the current and historical type, and the number of samples in which the historical ABO type was determined to be correct were recorded. Participants also provided the number of RBC units transfused during the 30-day study period.

For the most recent calendar or fiscal year, for all inpatient and outpatients, participants were asked to provide the total number of RBC units transfused, the total number of samples submitted for ABO testing, the number of discrepancies between the current and historical ABO type, and the number of samples in which the historical ABO type was determined to be correct.

Excluded from the study were all patients (and their associated samples) with a known ABO nonidentical bone marrow, peripheral blood stem cell, or cord blood transplant and all patients (and their associated samples) whose historical ABO type was determined when the patient was younger than 4 months (ie, neonate).

Calculations

The following performance parameters were calculated:

- ABO mislabeled sample rate (%) = (Number of mislabeled samples received for ABO typing ÷ Total number of samples received for ABO typing) × 100
- ABO typing result discrepancy rate (%) = (Number of samples with ABO typing result that disagreed with historical ABO type on record ÷ Total number of ABO samples that had a historical type on record at time of sample receipt) × 100
- Estimated annual rate of ABO typing result discrepancies (%) = [For calendar/fiscal year, number of samples with ABO typing result that disagreed with historical ABO type on record ÷ (No. of samples submitted for ABO typing during calendar year) × (fraction of ABO samples with historical type on record, 30-day study period)] × 100
- Fraction of ABO samples with historical type on record, 30-day study period = (No. of ABO samples with a historical type on record at time of sample receipt during 30-day study period) ÷ (No. of samples received for ABO typing during the 30-day study period)
- Percentage of correct historical ABO types = (Number of historical ABO types that were correct when the most recent ABO type disagreed with the historical ABO type on record ÷ Number of samples with ABO typing result that disagreed with historical ABO type on record) × 100
- Annual percentage of correct historical ABO types (%) = (For calendar/fiscal year, number of historical ABO types that were correct when the most recent ABO type disagreed with the historical ABO type on record ÷ For calendar/fiscal year, number of samples with ABO typing result that disagreed with historical ABO type on record) × 100
- Mislabeled ABO sample rejection rate (%) = (Number of mislabeled samples received for ABO typing that were rejected ÷ Number of mislabeled samples received for ABO typing) × 100

Statistical Analysis

Of 123 participating institutions, 122 submitted complete data and were included in the ABO typing analysis. The data distributions for ABO typing–result discrepancy rate, mislabeled ABO sample rejection rate, and the annual percentage of correct historical ABO types were skewed and were not analyzed. The ABO mislabeled sample rate and the estimated annual rate of ABO typing–result discrepancies were tested for associations with institutional demographic and practice variable information. Both the ABO mislabeled sample rate and the estimated annual rate of ABO typing–result discrepancies had nonnormal distributions.

Individual associations between the 2 indicators and the demographics and practice variables were investigated with the nonparametric Kruskal-Wallis tests for discrete-valued independent variables and regression analysis for continuous independent variables. Both rates were normalized by using a log transformation for the regression analysis. Variables significant at $P = .10$ were introduced into a forward selection multivariate regression model with a cutoff of $P = .05$ for retention in the final model.

Laboratory Characteristics/Participant Characteristics

Most of the 123 participating institutions (95.1%) were located in the United States, with the remaining located in Australia (2), Canada (2), Saudi Arabia (1), and Spain (1). Most participants were private, nonprofit institutions located in urban or suburban neighborhoods with number of occupied beds at no more than 300 (Table 1). Forty-four percent were teaching hospitals and 32.3% had a pathology residency program. Within the past 2 years, 88.5% of the laboratories had been inspected by the College of American Pathologists (CAP) and 34.4% had been inspected by the Joint Commission. The annual number of RBC units transfused at participating institutions ranged from 580 (10th percentile) to 13 757 (90th percentile). The annual number of samples submitted for ABO typing ranged from 1002 (10th percentile) to 28 237 (90th percentile).

RESULTS

Practice Survey Responses

The survey of patient identification and sample labeling and acceptance practices for transfusion medicine samples elucidated both practice uniformity and variability among the study participants. All participants had a policy that specified explicit acceptance criteria for blood bank samples, while only 94.8% had a general policy

Table 1. Institution Demographics		
	No. of Institutions	Percentage of Institutions
Institution type		
Private, nonprofit	52	54.7
State, county or city hospital	13	13.7
Private, profit	9	9.5
University hospital	9	9.5
Governmental, federal	7	7.4
Children's hospital	1	1.0
Other	4	4.2
No. of occupied beds		
0–150	36	38.7
151–300	25	26.9
301–450	12	12.9
451–600	12	12.9
>600	8	8.6
Institution location		
City	48	50.5
Suburban	26	27.4
Rural	17	17.9
Federal installation laboratory	3	3.2
Other	1	1.0
Governmental affiliation		
Nongovernmental	70	73.7
Governmental, nonfederal	18	19.0
Governmental, federal	7	7.4

governing sample labeling and submission. Approximately 94% of participants receive samples collected by nonlaboratory personnel, and roughly 40% have most of their samples collected by nonlaboratory personnel. Ninety percent of institutions provide specific training on sample labeling to nonlaboratory personnel (Table 2).

About one-half of participants stated that they use blood-bank-specific armbands for both inpatient and outpatient transfusions, and 97% of institutions routinely require that an armband be present on the patient before sample collection. About one-half of participants permit removal of an armband during an inpatient admission, and roughly the same fraction have a policy limiting the personnel that can apply an armband. However, 26% do not have a specific policy addressing replacement of armbands that have been removed. Only 8% of participants identify patients by using a system to read bar codes on patient armbands. Sixty percent of participants require 2 ABO typings for patients without a historical type before issuing nonemergent, nongroup O RBCs. Thirty-one percent require the 2 ABO types to be performed on different samples (Tables 2 and 3).

All institutions require verification of patients' first and last names before sample collection. However, not all institutions require verification of a unique identifier before sample collection, and this is more common in the outpatient setting. Sex is used as an identifier relatively uncommonly. Date of birth, one of the recommended identifiers that may be of particular use in the outpatient setting, is verified more commonly for outpatient sample collections, but only by 72% of institutions—probably because of the prevalent use of an armband with a unique identifier for outpatient transfusions. These same trends generally hold true for elements required on the sample label and the test requisition. Additionally, phlebotomist identification (ID) and phlebotomy date are label requirements for greater than 90% of institutions; however, time of phlebotomy is required by only three-quarters of institutions. Required elements for the test requisition differ from the sample in increased frequency of requirement for ward location, sex, and date of birth and less frequent requirements for phlebotomist ID, and phlebotomy date and time (Table 4). Criteria for sample rejection are generally more stringent for identifying information (first and last name and unique identifier) and more lax for other information on the label and requisition. This holds true for both inpatient and outpatient settings with the exception that the requirement for a correct date of birth is more stringent in the outpatient setting. Criteria for sample rejection are also relatively consistent between the sample label and the test requisition, except that the criteria tend to be less stringent for the requisition with the exception of date of birth, sex, and ward/location (Table 5).

A variety of formats are acceptable for labeling samples and filling out test requisitions, with more than 90% of institutions accepting hand-written submissions. A minority (<30%) of institutions use labels prepared directly from the patient armband (Table 6). In addition, more than two-thirds of participants do not have a policy prohibiting production of multiple labels for future sample collections. Ninety-four percent of institutions do not allow correction of first or last name or unique identifier on samples (Table 5), and 75% do not allow any label corrections, with 71% discarding all mislabeled samples (Tables 2 and 3).

Quality Indicators

Participants from 122 institutions reviewed a total of 112 112 samples submitted for ABO typing and identified 1258 mislabeled samples during the 30-day study period. The median number of ABO typing samples reviewed per institution was 610, with a range of 12 to 4779. The median mislabel rate was 0.29%. The highest mislabel rate was 13.7%, and 45 participants reported no mislabeled samples during the study period. For all institutions combined, the aggregate ABO mislabeled sample rate was 1.12% or 1 in 89 samples. The aggregate rate of rejection of mislabeled ABO samples was 81.2%. The aggregate rate of WBIT for all institutions during the 30-day study period was 0.04% (95% confidence interval, 0.02%–0.06%), with the historical ABO type determined to be the correct type in 56.5% of cases (N = 16). The estimated, annual WBIT rate for all institutions was also 0.04%, with the historical ABO type determined to be the correct type in 33.3% of cases (N = 52).

Aspects of Practice and Their Effect on Sample Labeling Errors

Based on univariate testing, the following practice variables were found to be significantly associated with the ABO mislabeled sample rate:

Higher Mislabel Rate

- Nonlaboratory personnel collect and label blood bank samples ($P = .001$)
- Percentage of samples collected and labeled by nonlaboratory personnel ($P = .001$)
- Institution allows clinicians to remove armbands during an inpatient admission ($P = .06$)

Table 2. Laboratory and Hospital Practices Relating to Blood Bank Samples		
Practice	**No. of Institutions**	**Percentage of Institutions**
Is there a written policy with explicit criteria for acceptance/rejection of blood bank samples?		
Yes	123	100.0
If there is a written policy, does the policy permit exceptions to the standard acceptance/rejection criteria under specific circumstances or with permission of the laboratory medical director?		
Yes	72	59.5
No	49	40.5
Do nonlaboratory personnel collect and label blood bank samples?		
Yes	115	93.5
No	8	6.5
Approximately what percentage of blood bank samples are collected and labeled by nonlaboratory personnel?		
<10%	42	36.8
10%–50%	25	21.9
51%–90%	30	26.3
>90%	17	14.9
If nonlaboratory personnel collect and label blood bank samples, is there a hospital-approved standard operating procedure governing sample labeling and submission?		
Yes	109	94.8
No	6	5.2
If nonlaboratory personnel collect and label blood bank samples, do they receive specific training on sample labeling?		
Yes	104	90.4
No	11	9.6
Does your institution use a separate, blood-bank specific armband or patient identifier for *inpatients*?		
Yes	65	52.8
No	58	47.2
Does your institution use a separate, blood-bank specific armband or patient identifier for *outpatients*?		
Yes	67	54.5
No	56	45.5
Do you require submission of a new sample for ABO typing when a patient's name is changed/updated during an admission?		
Yes	62	50.8
No	60	49.2
Do you require 2 ABO typings for patients with no historical ABO type before issuing nongroup O RBCs outside of an emergency situation?		
Yes	74	60.2
No	49	39.8
If you require 2 typings for patients with no historical ABO type before issuing nongroup O RBCs outside of an emergency situation, do you require ABO typing on 2 different samples?		
Yes	23	31.1
No	50	67.6
Not applicable	1	1.4
Do you store and retrieve historical ABO types in a laboratory or hospital computer?		
Yes	114	92.7
No	9	7.3
Does your institution require an armband for outpatient transfusions?		
Yes	110	90.2
No	12	9.8

Abbreviation: RBCs, red blood cells.

Table 3. Other Laboratory and Hospital Practices

Practice	No. of Institutions	Percentage of Institutions
If there is a hospital-approved SOP governing sample labeling, are on-site audits conducted to assure compliance with the policy?		
Yes	73	60.8
No	39	32.5
Not applicable	8	6.7
Does your institution have a specific policy prohibiting the practice of producing and saving labels for sample labeling at a future sample collection?		
Yes	38	31.7
No	82	68.3
In circumstances in which a patient armband is required to be used for patient identification, does your institution have a specific policy requiring an armband to be present on the patient before sample collection can proceed? Exclude any special circumstances for which exceptions to the policy are permitted.		
Yes	119	96.8
No	4	3.2
Does your institution allow clinicians to remove armbands during an inpatient admission (eg, for surgery)?		
Yes	67	54.9
No	55	45.1
Does your institution have a specific policy addressing replacement of armbands that have been removed?		
Yes	89	73.6
No	32	26.4
Does your institution limit who can apply a patient armband (eg, only admitting personnel, only nursing personnel)?		
Yes	63	53.4
No	55	46.6
Does your hospital allow patient name changes during one admission (eg, spelling changes, trauma designation changed to actual name)?		
Yes	116	95.9
No	5	4.1
Do you use a bar code reader to identify patients by their armband at the time of sample collection?		
Yes	10	8.1
No	113	91.9
When a sample does not meet the requirements for sample labeling information, does your institution permit the sample label to be corrected?		
Yes	31	25.2
No	92	74.8
When a sample does not meet the requirements for sample labeling information, is the sample automatically discarded?		
Yes	87	71.3
No	35	28.7
Does your institution require a photo ID to register a patient?		
Yes	56	45.5
No	67	54.5
In the last 12 months, how many times has your laboratory identified a patient who was registered with an incorrect medical record number because the patient intentionally used another person's identifying information when registering for an encounter at your institution?		
0	98	84.5
1	8	6.9
2	7	6.0
5	1	0.9
6	1	0.9
18	1	0.9

Abbreviations: ID, identification; SOP, standard operating procedure.

Table 4. Patient, Requisition, and Sample Identifiers Required for ABO Testing

		Identifiers Required to Be Verified by Phlebotomy Before Collection of ABO Typing Samples		Required Identifiers on Sample Labels for ABO Typing by Laboratory		Required Identifiers on Test Requisition for ABO Typing by Laboratory	
		Yes, No. (%)	No, No. (%)	Required, No. (%)	Not Required, No. (%)	Required, No. (%)	Not Required, No. (%)
Last name	(inpt)	121 (100)	0 (0)	122 (100)	0 (0)	118 (99.2)	1 (0.8)
	(outpt)	123 (100)	0 (0)	123 (100)	0 (0)	121 (10)	0 (0)
First name	(inpt)	122 (100)	0 (0)	122 (100)	0 (0)	118 (99.2)	1 (0.8)
	(outpt)	123 (100)	0 (0)	123 (100)	0 (0)	120 (99.2)	1 (0.8)
Middle initial	(inpt)	28 (23.7)	90 (76.3)	20 (17.4)	95 (82.6)	24 (20.9)	91 (79.1)
	(outpt)	29 (24.4)	90 (75.6)	21 (17.5)	99 (82.5)	25 (21.7)	90 (78.3)
Unique ID	(inpt)	118 (97.5)	3 (2.5)	120 (98.4)	2 (1.6)	116 (97.5)	3 (2.5)
	(outpt)	105 (86.8)	16 (13.2)	113 (91.9)	10 (8.1)	108 (90.0)	12 (10.0)
Ward/location	(inpt)	21 (17.6)	98 (82.4)	15 (12.6)	104 (87.4)	49 (41.9)	68 (58.1)
	(outpt)	16 (13.3)	104 (86.7)	14 (11.7)	106 (88.3)	35 (29.7)	83 (70.3)
Sex	(inpt)	20 (16.8)	99 (83.2)	14 (11.8)	105 (88.2)	43 (37.1)	73 (62.9)
	(outpt)	23 (19.2)	97 (80.8)	13 (10.8)	107 (89.2)	42 (35.6)	76 (64.4)
Date of birth	(inpt)	69 (58.0)	50 (42.0)	41 (34.5)	78 (65.5)	71 (60.7)	46 (39.3)
	(outpt)	88 (72.1)	34 (27.9)	61 (50.8)	59 (49.2)	84 (70.6)	35 (29.4)
Other	(inpt)	30 (26.8)	82 (73.2)	30 (28.3)	76 (71.7)	24 (23.5)	78 (76.5)
	(outpt)	34 (30.1)	79 (69.9)	32 (30.8)	72 (69.2)	25 (24.0)	79 (76.0)
Phlebotomist ID	(inpt)			116 (95.9)	5 (4.1)	77 (66.4)	39 (33.6)
	(outpt)			114 (93.4)	8 (6.6)	75 (64.7)	41 (35.3)
Phlebotomy date	(inpt)			112 (92.6)	9 (7.4)	77 (65.8)	40 (34.2)
	(outpt)			113 (92.6)	9 (7.4)	79 (66.9)	39 (33.1)
Phlebotomy time	(inpt)			93 (76.9)	28 (23.1)	66 (56.4)	51 (43.6)
	(outpt)			93 (76.2)	29 (23.8)	66 (56.4)	51 (43.6)

Abbreviations: ID, identification; inpt, inpatient; outpt, outpatient.

- Institution requires submission of a new sample for ABO typing when a patient's name is changed/updated during an admission ($P = .06$)

Lower Mislabel Rate

- Ward/location must be checked to verify correct patient ID before outpatient collection ($P = .001$)
- Date of birth must be checked to verify correct patient ID before outpatient collection ($P = .05$)
- Ward/location is required on outpatient sample labels ($P = .05$)
- Sex is required on outpatient sample labels ($P = .007$)
- Sex is required on inpatient test requisition ($P = .02$)
- Date of birth is required on outpatient test requisition ($P = .003$)

These variables were introduced into a forward selection multivariate regression model. One practice variable was significantly associated with an increased ABO mislabeled

Table 5. Fate of Samples That Do Not Meet Criteria for Acceptance

		Patient Identifiers Must Be Correct to Avoid Sample Rejection		Patient Identifiers May Be Added or Corrected	
		On Sample Label, No. (%)	On Test Requisition, No. (%)	On Sample Label, No. (%)	On Test Requisition, No. (%)
Last name	(inpt)	113 (94.2)	106 (91.4)	7 (5.8)	10 (8.6)
	(outpt)	114 (94.2)	107 (91.5)	7 (5.8)	10 (8.5)
First name	(inpt)	113 (94.2)	106 (91.4	7 (5.8)	10 (8.6)
	(outpt)	114 (94.2)	106 (91.4)	7 (5.8)	10 (8.6)
Middle initial	(inpt)	44 (45.8)	41 (41.8)	52 (54.2)	57 (58.2)
	(outpt)	45 (45.9)	39 (39.4)	53 (54.1)	60 (60.6)
Unique ID	(inpt)	113 (94.2)	105 (90.5)	7 (5.8)	11 (9.5)
	(outpt)	108 (91.5)	98 (86.7)	10 (8.5)	15 (13.3)
Ward/location	(inpt)	9 (9.7)	10 (10.0)	84 (90.3)	90 (90.0)
	(outpt)	7 (7.4)	8 (8.0)	88 (92.6)	92 (92.0)
Sex	(inpt)	18 (19.4)	28 (28.6)	75 (80.6)	70 (71.4)
	(outpt)	18 (19.4)	26 (26.3)	75 (80.6)	73 (73.7)
Date of birth	(inpt)	49 (49.0)	59 (55.7)	51 (51)	47 (44.3)
	(outpt)	61 (59.2)	65 (60.2)	42 (40.8)	43 (39.8)
Phlebotomist ID	(inpt)	67 (56.8)	42 (39.6)	51 (43.2)	64 (60.4)
	(outpt)	66 (55.0)	42 (39.6)	54 (45.0)	64 (60.4)
Phlebotomy date	(inpt)	59 (49.2)	37 (34.6)	61 (50.8)	70 (65.4)
	(outpt)	60 (49.6)	35 (33.0)	61 (50.4)	71 (67.0)
Phlebotomy time	(inpt)	40 (34.5)	26 (24.8)	76 (65.5)	79 (75.2)
	(outpt)	42 (35.9)	26 (24.8)	75 (64.1)	79 (75.2)
Other	(inpt)	28 (34.6)	19 (22.9)	53 (65.4)	64 (77.1)
	(outpt)	30 (35.3)	18 (21.4)	55 (64.7)	66 (78.6)

Abbreviations: ID, identification; inpt, inpatient; outpt, outpatient.

Table 6. Acceptable Formats for Sample Labels and Test Requisitions Submitted for ABO Typing

	Inpatient Labels, %	Outpatient Labels, %
Acceptable sample label formats for ABO typing[a]	N = 122	N = 120
Hand-written	95.1	95.8
Stamped on label directly from patient armband	29.5	26.7
Printed by computer—eye readable only	64.8	65.8
Printed by computer—eye readable and bar code readable	57.4	58.3
Other	9.0	9.2
Acceptable test requisition formats for ABO typing[a]	N = 118	N = 117
Hand-written	88.1	93.2
Stamped on label or requisition by addressograph	61.0	59.0
Stamped on label directly from patient armband	26.3	24.8
Printed by computer—eye readable only	84.7	80.3
Printed by computer—eye readable and bar code readable	57.6	57.3
Other	5.1	5.1

[a] Multiple responses allowed.

sample rate ($P = .04$). A *higher* rate of ABO mislabeled samples occurred in institutions that require submission of a new sample for ABO typing when a patient's name is changed or updated during an admission.

Based on univariate testing, the following variables were significantly associated with the estimated annual rate of ABO typing–result discrepancies (WBIT):

Higher WBIT

- Nonlaboratory personnel collect and label blood bank samples ($P = .008$)
- Institution has a specific policy addressing replacement of armbands that have been removed ($P = .06$)

Lower WBIT

- Phlebotomist ID is required on inpatient sample labels ($P = .008$)
- Date of birth is required on inpatient test requisition ($P = .05$)

These variables were introduced into a forward selection multivariate regression model, and none were found to be significant at the .05 level. Limiting the multivariate analysis to institutions that reported at least 1 WBIT (N = 63) revealed a trend ($P = .06$) toward a lower rate of WBIT in laboratories that require 2 ABO typings for patients with no historical ABO type before issuing nongroup O RBCs (median rate, 0.03%) versus institutions that do not require a second type (median rate, 0.05%). No significant relationship was found between sample mislabel rate and WBIT.

COMMENT

This Q-Probes study presents the results of (1) a comprehensive survey of patient identification and sample labeling and acceptance practices for transfusion medicine samples, and (2) an analysis of mislabeling rates for samples submitted for testing of ABO blood type at 122 almost exclusively US institutions transfusing a range of 118 to 45 592 RBC units annually. A total of 112 112 sample labels were reviewed and 1258 mislabeled samples were identified for an overall mislabeled sample rate of 1.12% or 1 in 89 samples. This can be compared with the aggregate mislabel rate of 0.75% or 1 in 134 samples observed by Dzik et al[4] in their multinational study. The median mislabel rate for ABO samples for this study was 0.29%, with a broad range of reported mislabel rates varying from 0.0% to 1.80% for the middle 80% of participants. The overall rate of rejection of mislabeled samples submitted for ABO blood typing was 0.9%. This compares with rejection rates of about 0.02% for either hematology or chemistry samples for the combined errors of sample mislabeling and inadequate completion of a test requisition.[5,6] The higher rejection rate for ABO samples most likely reflects the more stringent labeling requirements imposed on transfusion medicine samples. The rate at which mislabeled ABO type samples were rejected was very high, with an overall rejection rate of about 80% and more than three-fourths of institutions rejecting all mislabeled samples.

A number of practice variables were found to correlate by univariate analysis with sample mislabel rate and WBIT. Of note, sample collection by nonlaboratory personnel was associated with both an increased rate of mislabeled samples and WBIT. College of American Pathologists Q-Probes and Q-Tracks studies[7] have demonstrated that nonlaboratory personnel are far more likely to submit unsuitable samples to the laboratory. This represents a clear opportunity for improvement. Increased use of laboratory trained phlebotomists should be encouraged,[8] but laboratories will continue to receive samples collected by clinical personnel (eg, blood draws from indwelling catheters), and therefore, should have hospital-approved standard operating procedures governing sample collection, labeling, and submission. All personnel performing these tasks should be trained and demonstrated competent with the standard operating procedures. Strict adherence (ie, rejection of all samples that can be recollected) to hospital labeling policies by all laboratory sections may decrease the incidence of WBIT,[9] and participation in a longitudinal performance monitoring program, such as the CAP Q-Tracks program, can produce significant performance improvement.[7,10] Ultimately, system improvements (eg, bar coded wrist bands for patient identification) are likely to have the greatest positive impact on patient identification and sample labeling practices.[11] However, our survey indicates that only a small percentage of participating institutions (8.1%) were using a bar code system for patient identification as of 2007, and errors will still occur with identification technologies such as bar coding (eg, incorrect registration and/or misplacement of armbands). Implementation of a requirement for ABO typing of 2 different samples for nongroup O patients who are likely to require transfusion would identify WBIT samples[12] and is correlated with decreased WBIT rates (this study), but would require a significant increase in laboratory resources.[13]

Of the demographic and practice variables tested by multivariate analysis for association with sample-mislabeling rates, a significantly higher rate of mislabeling occurred in institutions that require submission of a new sample for ABO typing when a patient's name is changed

or updated during an admission. This would appear to be a counterintuitive correlation, since name changes represent a significant risk for WBIT. The requirement for a new sample with name change/update may identify institutions with ubiquitous sample labeling or WBIT problems (eg, problems with common names or inconsistent application of changes to patient's records). In addition, this requirement may also identify institutions that are more efficient at identifying ABO mislabeled samples.[14] The increased rate of WBIT at institutions that have implemented a specific policy that addresses replacement of armbands that have been removed may also be attributable to the same 2 explanations.

This study also produced an estimated rate of mislabeled samples and uncorrected WBIT in primarily US institutions. These rates were estimated during a 30-day period as well as during a 12-month period (WBIT only). Both methods of estimating WBIT produced an uncorrected rate of approximately 0.04% or roughly 1 WBIT in 2500 samples submitted for ABO typing. This is a comparable rate to results observed in other studies.[4,15] These rates represent underestimates of the true incidence of WBIT because the check against historical ABO type only identifies WBIT when the 2 patients involved have different blood types. If ABO distribution is known, the true rate of WBIT can be estimated. While we did not collect ABO distribution, our study has demonstrated the feasibility of collecting periodic benchmarking data from a broad spectrum of institutions that could be used to calculate an aggregate national and/or regional WBIT frequency. This frequency could be used to establish minimal performance standards and monitor individual and collective performance improvement, as suggested by Mintz and Dzik.[16]

Several findings from our practice survey are concerning. One-half of participants reported allowing removal of the patient armband during an admission, but only three-fourths reported having a specific policy for replacement of armbands. A minority of institutions prepare labels directly from the patient's armband, and more than two-thirds of participants do not have a policy prohibiting production of multiple labels for future sample collection. Finally, all institutions had written criteria governing acceptance/rejection of pretransfusion testing samples. However, 60% of participants permit exceptions to their policy, and 25% of participants allow relabeling of these samples. Given the potential for deleterious outcomes secondary to ABO incompatible transfusions, institutions should conduct a risk assessment of their patient identification and sample labeling processes and sample acceptance policies to identify opportunities to avoid WBIT occurrences. Incorrect patient registration, misplacement of armbands on patients, lack of a policy governing replacement of armbands after removal (eg, during surgery), failure to require an armband or similar identifier on the patient at the time of phlebotomy, failure to follow the patient identification policy at the time of phlebotomy or blood product administration, name changes during one admission, and accumulation of unused sample labels represent significant risks for patient misidentification and an opportunity for WBIT. Policies that address each of these should be implemented, trained, and monitored for effectiveness. When practical, the laboratory should consider implementing a policy requiring 2 ABO types on 2 different samples before releasing blood for nonemergent transfusions to maximize identification of WBIT collections. Finally, 15.5% of reporting hospitals noted at least 1 annual occurrence of incorrect registration of a patient owing to the use by the registering patient of another person's identifying information. Laboratories should be cognizant of the fact that in 50% to 70% of the WBIT cases, the historical ABO type was not the correct type for the patient in hand.

References

1. Linden JV, Wagner K, Voytovich AE, Sheehan J. Transfusion errors in New York State: an analysis of 10 years' experience. *Transfusion*. 2000;40(10):1207–1213.
2. Luban, NL. Transfusion safety: where are we today? *Ann N Y Acad Sci*. 2005;1054:325–341.
3. Lumadue JA, Boyd JS, Ness PM. Adherence to a strict specimen-labeling policy decreases the incidence of erroneous blood grouping of blood bank specimens. *Transfusion*. 1997;37(11–12):1169–1172.
4. Dzik WH, Murphy MF, Andreu G, et al. An international study of the performance of blood sample collection. *Vox Sanguinis*. 2003;85(1):40–47.
5. Jones BA, Calam RR, Howanitz PJ. Chemistry specimen collection: a College of American Pathologists Q-probes study of 453 laboratories. *Arch Pathol Lab Med*. 1997;121(1):19–26.
6. Jones BA, Meier F, Howanitz PJ. Complete blood count specimen acceptability: a College of American Pathologists Q-Probes study of 703 laboratories. *Arch Pathol Lab Med*. 1995;119(3):203–208.
7. Zarbo RJ, Jones BS, Friedberg RC, et al. Q-Tracks: a College of American Pathologists program of continuous laboratory monitoring and longitudinal performance tracking. *Arch Pathol Lab Med*. 2002;126(9):1036–1044.
8. Wagar EA, Tamashiro L, Bushra Y, Lilborne, L, Bruckner DA. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. *Arch Pathol Lab Med*. 2006;130(11):1662–1668.
9. O'Neill E, Richardson-Weber L, McCormack G, et al. Strict adherence to a blood bank specimen labeling policy by all clinical laboratories significantly reduces the incidence of ''Wrong Blood in Tube.'' *Am J Clin Pathol*. 2009;132(2):164–168.
10. Wagar EA, Stankovic AK, Raab S, Nakhleh RE, Walsh MK. Specimen labeling errors: a Q-Probes analysis of 147 clinical laboratories. *Arch Pathol Lab Med*. 2008;132(10):1617–1622.
11. Valenstein PN, Sirota RL. Identification errors in pathology and laboratory medicine. *Clin Lab Med*. 2004;24(4):979–996.
12. Figueroa PI, Ziman A, Wheeler C, et al. Nearly two decades using the check-type to prevent ABO-incompatible transfusions. *Am J Clin Pathol*. 2006;126(3):422–426.
13. Goodnough LT, Viele M, Fontaine MJ, et al. Implementation of a two-specimen requirement for verification of ABO/Rh for blood transfusion. *Transfusion*. 2009;49(7):1321–1328.
14. Valenstein PN, Raab SS, Walsh MK. Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions. *Arch Pathol Lab Med*. 2006;130(8):1106–1113.
15. Murphy MF, Stearn BE, Dzik WH. Current performance of patient sample collection in the UK. *Transfus Med*. 2004;14(2):113–121.
16. Mintz PD, Dzik WH. Double standard for double ABO grouping? *Transfusion*. 2009;49(7):1282–1285.