Incorrectly labeled patient blood specimens create opportunities for laboratory testing personnel to mistake one patient’s specimen for a specimen from a different patient. Transfusion of blood that is typed on specimens that are mislabeled can result in acute hemolytic transfusion reactions. Clerical errors such as specimen misidentification may lead to acute hemolytic transfusion reactions, resulting in serious morbidity and death.1–3

To reduce the risk of error, American Association of Blood Banks standards require that patient blood sample tubes have affixed to them labels bearing at least 2 unique patient identifiers and the dates on which specimens were collected.4 Further, several studies have demonstrated that bar coding patient specimens reduces specimen misidentification.5–9

Since 1989, the College of American Pathologists Q-Probes studies have determined a broad range of performance benchmarks in anatomic pathology and laboratory medicine.10–12 Participants in these studies, representing the entire spectrum of practice settings worldwide, have been able to compare their performances with those of their peers, and to share among their peers laboratory practices associated with superior performance.

A previous Q-Probes study of 122 blood bank laboratories performed in 2007 determined normative rates of mislabeled specimens submitted to blood banks and the rates of instances in which specimen tubes contained blood belonging to another patient (so-called wrong blood in tube [WBIT]), and examined laboratory and hospital practices that the study designers thought might influence those rates.13

In this Q-Probes study, we again reassessed the normative rates of mislabeled blood bank specimens and WBIT to determine whether or not this rate has diminished, and again examined practices, in particular the use of bar coding, that we thought might contribute to diminished rates.

METHODS

Laboratories enrolled in the College of American Pathologists Q-Probes program for the first quarter of 2015 participated in this
| No. | %  |
|-----|----|
| Does your hospital have a written policy with explicit criteria for acceptance/rejection of blood bank specimens? |
| Yes | 30 | 100.0 |
| No  | 0  | 0.0  |
| If you have 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 | 18 | 60.0 |
| No  | 12 | 40.0 |
| Do nonlaboratory personnel collect and label blood bank specimens? |
| Yes | 26 | 86.7 |
| No  | 4  | 13.3 |
| Approximately what percentage of your blood bank specimens are collected and labeled by nonlaboratory personnel? |
| Less than 10 | 7  | 26.9 |
| 10–50  | 9  | 34.6 |
| 51–90  | 6  | 23.1 |
| Greater than 90 | 4  | 15.4 |
| If nonlaboratory personnel collect and label blood bank specimens, is there a hospital-approved SOP governing specimen labeling and submission? |
| Yes | 25 | 96.2 |
| No  | 1  | 3.8  |
| If nonlaboratory personnel collect and label blood bank specimens, do they receive specific training on specimen labeling? |
| Yes | 24 | 92.3 |
| No  | 2  | 7.7  |
| If there is a hospital-approved SOP governing specimen labeling, are on-site audits conducted to assure compliance with the policy? |
| Yes | 16 | 61.5 |
| No  | 6  | 23.1 |
| Does your institution have a specific policy prohibiting the practice of producing and saving labels for specimen labeling at a future specimen collection? |
| Yes | 16 | 53.3 |
| No  | 14 | 46.7 |
| In circumstances where 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 specimen collection can proceed? (This measure excluded special circumstances where exceptions to the policy are permitted, for example, patients in the burn unit or newborn intensive care patients.) |
| Yes | 29 | 100.0 |
| No  | 0  | 0.0  |
| Does your institution use a separate, blood bank–specific armband or patient identifier for inpatients? |
| Yes | 13 | 43.3 |
| No  | 17 | 56.7 |
| Does your institution allow clinicians to remove armbands during an inpatient admission (eg, for surgery)? |
| Yes | 11 | 39.3 |
| No  | 17 | 60.7 |
| Does your institution have a specific policy addressing replacement of armbands that have been removed? |
| Yes | 20 | 71.4 |
| No  | 8  | 28.6 |
| Does your institution limit who can apply a patient armband (eg, only admitting personnel, only nursing personnel)? |
| Yes | 18 | 62.1 |
| No  | 11 | 37.9 |
| Does your institution allow patient name changes during one admission (eg, spelling changes, trauma designation changed to actual name)? |
| Yes | 29 | 96.7 |
| No  | 1  | 3.3  |
| Do you require submission of a new specimen for ABO typing when a patient’s name is changed/updated during an admission? |
| Yes | 17 | 56.7 |
| No  | 13 | 43.3 |
| Do you require 2 ABO typings on patients with no historical ABO type before issuing non–group O RBCs outside of an emergency situation? |
| Yes | 27 | 90.0 |
| No  | 3  | 10.0 |
| If you require 2 typings, do you require ABO typing on 2 different specimens? |
| Yes | 18 | 66.7 |
| No  | 9  | 33.3 |
The study was conducted and the data were handled in a manner similar to that described previously. Upon their enrollments into the Q-Probes program, participants from each institution submitted certain demographic information including their institutions’ geographic locations, community classifications (urban, suburban, rural), teaching status, residency program status, number of occupied beds, and both hospital and laboratory accreditation status.

The study instructions requested participants to tally both retrospectively during the previous 12 months and prospectively during the next 30 days the number of inpatient and outpatient specimens submitted for ABO typing and the number of those specimens that fulfilled their institution’s definitions of being mislabeled. Our outcome measurement was the number of mislabeled specimens per 1000 specimens submitted for ABO typing.

For those patients whose ABO blood types were archived in blood bank files, we asked participants to tally the number of patients for whom the current specimen’s blood type result differed from that in their records, so-called WBIT. We excluded from the study all specimens submitted from patients who had known ABO discrepancies (eg, history of bone marrow transplantation, stem cell transplants, cord blood transfusions, etc).

We evaluated the effects of various practice characteristics on the rates of misidentification by asking participants to complete detailed questionnaires (see Table 1).

Table 1. Continued

| Question                                                                 | Yes | No |
|-------------------------------------------------------------------------|-----|----|
| Do you store and retrieve historical ABO types in a laboratory or hospital computer? | 28  | 2  |
| Does your computer contain historical blood types performed by other hospitals affiliated with yours? | 7   | 22 |
| Are you served by a centralized transfusion service that may use historical blood types from specimens that were collected at other facilities? | 4   | 26 |
| Do you use a bar code reader to identify patients by their armband at the time of specimen collection? | 11  | 18 |
| Does your institution require an armband for outpatient transfusions? | 28  | 2  |
| When a specimen does not meet the requirements for specimen labeling information, is the specimen automatically discarded? | 18  | 12 |
| When a specimen does not meet the requirements for specimen labeling information, does your institution permit the specimen label to be corrected? | 3   | 9  |
| Does your institution require a photo ID to register a patient? | 22  | 8  |
| In the last 12 months, how many times has your laboratory identified a patient who was registered with an incorrect medical record number (or other unique identifier) because the patient intentionally used another person’s identifying information when registering for an encounter at your institution (eg, presented with another person’s identification card)? | 23  | 1  |

Abbreviation: RBC, red blood cell; SOP, standard operating procedure. * Four institutions responded “not applicable.”

Statistical analysis was performed to determine which demographic and practice characteristics were significantly associated with the performance indicators—ABO mislabeled specimen rate (per 1000 specimens) and WBIT rate (per 1000 specimens). Because of the skewed distributions, the performance indicators were log transformed.

To detect associations between the performance indicators and the discrete-valued demographic/practice variables, we used for univariate analyses both Kruskal-Wallis and Wilcoxon rank sum tests, and for linear regression analysis continuous independent variable testing. We then included variables with significant associations (P < .10) in a forward-selection multivariate regression model. We used a significance level of .05 for this final model.

We evaluated differences between the 2007 and 2015 performance indicator distributions with the Kruskal-Wallis test. All analyses were performed with SAS 9.3 (SAS Institute, Cary, North Carolina).

RESULTS

A total of 30 institutions submitted data for this study, the demographic characteristics of which are shown in Table 2. Most laboratories (19 of 30; 63.3%) were associated with voluntary, nonprofit, nongovernmental hospitals comprising 300 or fewer beds. Slightly more than two-thirds (21 of 30; 70%) of these hospitals were located in urban locations.
and the remaining third (9 of 30; 30%) were located in rural locations. Participants recorded data on 41 333 blood specimens submitted for ABO typing. They identified 306 mislabeled specimens, yielding an aggregate rate of 7.4 mislabeled specimens per 1000 specimens submitted. Archived laboratory records included ABO types for 23 234 of these specimens, 10 of which were identified as having WBIT, yielding an aggregate WBIT rate of 0.43/1000 specimens.

Table 2 shows the percentile distributions of mislabeled blood bank specimens among the 30 participating institutions, and of WBIT specimens in the 29 institutions that provided WBIT data. The top-performing quartile recorded no mislabeled or WBIT specimens. Half the laboratories received slightly more than 4 mislabeled specimens per 1000 and no WBIT specimens. The bottom-performing 10% of laboratories received more than 18 mislabeled and almost 2 WBIT specimens for every 1000 blood bank specimens health care workers submitted to them.

Twenty-one of the 30 participating laboratories (70%) required and 9 (30%) did not require that specimens be labeled with the patients’ birth dates. The median rate of mislabeled specimens among those laboratories requiring birth date labeling was 1.52 per 1000 specimens, compared with 12.61 per 1000 specimens for those that did not (P = .02).

Twenty-nine participants provided information as to whether their institutions used bar code readers to identify patients by their armband at the time of specimen collection. Eleven of 29 (37.9%) did and 18 of 29 (62.1%) did not use bar code readers for this purpose. The specimen mislabeling and WBIT rates were not associated with the use of bar codes or with any of the other practice variables we investigated.

**DISCUSSION**

In this study, we recorded both aggregate and institutional rates of ABO blood specimen mislabeling and instances of WBIT. The aggregate mislabeling rate for 41 333 blood bank specimens examined in 30 participating institutions was 7.4 mislabeled specimens (306) per 1000 specimens submitted. This rate is slightly lower than the rate of 11.2 per 1000 (1258 specimens) tallied in the 2007 study in which 122 institutions examined 112 112 specimens. The rate of WBIT was 0.43 per 1000 specimens (10 of 23 234) and is essentially identical to the WBIT rate of 0.38 per 1000 specimens (23 of 61 305) determined in the 2007 study.

The institutional mislabeling rates provide another perspective. Whereas at least a quarter of participants reported no instances of blood bank specimen mislabeling, at least 75% of participants reported institutional performance that was no better, and if anything a bit worse, than what participants reported in the 2007 study. That institutional performance has not budged may be an accurate assessment of the state of blood bank specimen mislabeling. However, other conclusions must be considered. The results may reflect a statistical consequence of the small sample size of this repeat study. Also, the data may reflect bias inherent in the population of institutions choosing to participate in this Q-Probes study. We do not know how many institutions enrolled in this study precisely because they were having trouble with specimen mislabeling, which, if there were many, might have skewed the results. The anonymity of participation in the Q-Probes studies did not allow us to compare the performance of individual laboratories that may have participated in both this and the 2007 study. Regardless, this Q-Probes study reveals that not all transfusionists routinely adhere to their institutions’ labeling requirements.

In addition to having the ability to compare their performance with that of their peers, participants in the Q-Probes Program seek to discover practices that may improve their performance. In this study, the practice of requiring that all specimens include patients’ birth dates was associated with lower specimen mislabeling rates. None of the other practice variables we tested, including the use of bar coding, were associated with lower mislabeling rates.

---

**Table 2. Institution Demographics**

| Institution Demographic | No. | %  |
|--------------------------|-----|----|
| Institution type (N = 30) |     |    |
| Voluntary, nonprofit hospital | 19  | 63.3 |
| Nongovernmental, university hospital | 4  | 13.3 |
| System/integrated delivery network | 3  | 10.0 |
| County hospital | 1  | 3.3 |
| Proprietary hospital | 1  | 3.3 |
| Public health, nonhospital | 1  | 3.3 |
| Other, governmental, federal | 1  | 3.3 |
| Occupied bed size (N = 29) |     |    |
| 0–150 | 11  | 37.9 |
| 151–300 | 8  | 27.6 |
| 301–450 | 3  | 10.3 |
| 451–600 | 4  | 13.8 |
| >600 | 3  | 10.3 |
| Institution location (N = 30) |     |    |
| City | 12  | 40.0 |
| Suburban | 9  | 30.0 |
| Rural | 9  | 30.0 |
| Government affiliation (N = 30) |     |    |
| Nongovernmental | 27  | 90.0 |
| Governmental, federal | 2  | 6.7 |
| Governmental, nonfederal | 1  | 3.3 |

---

**Table 3. Performance Indicator (Outcome Metric) Distributions**

| Performance Indicator | Study Year | No. of Participants | 10th | 25th | Median | 75th | 90th |
|-----------------------|------------|---------------------|------|------|--------|------|------|
| ABO mislabeled specimen rate (per 1000 specimens) | 2015 | 30 | 0.00 | 0.00 | 4.04 | 12.43 | 18.19 |
|                        | 2007 | 122 | 0.00 | 0.00 | 2.90 | 11.60 | 18.00 |
| WBIT rate (per 1000 specimens) | 2015 | 29 | 0.00 | 0.00 | .23 | 1.82 |
|                        | 2007 | 120 | 0.00 | 0.00 | 0.00 | .80 |

Abbreviation: WBIT, wrong blood in tube.

---

*a* Kruskal-Wallis test; *P* = .94.

*b* Kruskal-Wallis test; *P* = .10.
Slightly less than 38% (11 of 29) of the participants in this study used bar coding to identify patients, almost a 5-fold increase over the 8% (10 of 123) of the 2007 Q-Probes study participants that claimed to be using bar codes. Yet the use of bar coding to identify patients by their armbands at the time of specimen collection was not associated with lower mislabeling rates. Other multi-institutional Q-Probes studies have also failed to correlate the use of bar coding with lower specimen mislabeling rates.24–16 Why is it that single-institutional studies were able to correlate bar coding with lower rates of mislabeling and multi-institutional studies could not? We believe it is logical to assume that the experimental conditions can be more tightly controlled in studies performed in single institutions than they can be in multi-institutional studies. We have no way of knowing whether better-performing institutions that do not bar code specimens compensated by using other practices about which we did not inquire, or whether poorer-performing institutions that did bar-code specimens harbored operational flaws about which we also did not inquire.

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. Quillen K, Murphy K. Quality improvement to decrease specimen mislabeling in transfusion medicine. Arch Pathol Lab Med. 2006;130(8):1196–1198.
3. US Food and Drug Administration. Fatalities Reported to FDA Following Blood Collection and Transfusion. Annual Summary for Fiscal Year 2008: 2008 Food and Drug Administration: Transfusion/Donation Fatalities. Silver Spring, MD. http://www.fda.gov/downloads/BiologicsBloodVaccines/SafetyAvailability/BloodSafety/UCM113904.pdf. Accessed August 13, 2016.
4. Ouley PW, ed. Standards for Blood Banks and Transfusion Services. 30th ed. Bethesda, MD: AABB; 2015.
5. Haylen RT, Patterson DJ, Jay DW, et al. Computer-assisted bar-coding system significantly reduces clinical laboratory specimen identification errors in a pediatric oncology hospital. J Pediatr. 2008;152(2):219–224.
6. Davies A1, Staves J, Kay J, Casbard A, Murphy MF. End-to-end electronic control of the hospital transfusion process to increase the safety of blood transfusion: strengths and weaknesses. Transfusion. 2006;46(3):352–364.
7. Snyder SR, Favoreto AM, Derzon JH, et al. Effectiveness of barcoding for reducing patient specimen and laboratory testing identification errors: a laboratory medicine best practices systematic review and meta-analysis. Clin Biochem. 2012;45(13–14):988–998.
8. Brown JE, Smith N, Sherly BR. Decreasing mislabeled laboratory specimens using barcode technology and bedside printers. J Nurs Care Qual. 2011;26(1):13–21.
9. Nichols JH, Bartholomew C, Brunton M, et al. Reducing medical errors through barcoding at the point of care. Clin Leadersh Manag Rev. 2004;18(6):328–334.
10. Howanitz PJ. Quality assurance measurements in departments of pathology and laboratory medicine. Arch Pathol Lab Med. 1996;114(11):1131–1135.
11. Lawson NS, Howanitz PJ. The College of American Pathologists, 1946–1996: quality assurance service. Arch Pathol Lab Med. 1997;121(9):1000–1008.
12. Tworek JA, Volmar KE, McCall SJ, Bashleben CP, Howanitz PJ. Q-Probes studies in anatomic pathology: quality improvement through targeted benchmarking. Arch Pathol Lab Med. 2014;138(9):1156–1166.
13. Grimm E, Friedberg RC, Wilkinson DS, AuBuchon JP, Souers RJ, Lehman CM. Blood bank safety practices: mislabeled samples and wrong blood in tube—a Q-Probes analysis of 122 clinical laboratories. Arch Pathol Lab Med. 2010;134(8):1106–1115.
14. Nakhlé RE, Idouwu MO, Souers RF, Meier FA, Bekeris LG. Mislabelling of cases, specimens, blocks, and slides: a College of American Pathologists study of 136 institutions. Arch Pathol Lab Med. 2011;135(8):969–974.
15. Wagår EA, Stankovic AK, Raab S, Nakhlé, Walsh MK. Specimen labeling errors: a Q-Probes analysis of 147 laboratories. Arch Pathol Lab Med. 2008;132(10):1617–1622.
16. 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.