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TRANSFUSION COMPLICATIONS

TRANSFUSION

Trend in ABO-incompatible RBC transfusion-related fatalities reported to the FDA, 2000-2019

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Abstract

Background: ABO-incompatible red blood cell (RBC) transfusions and acute hemolytic reactions occur infrequently, yet resultant fatalities are reported to the US Food and Drug Administration (FDA) every year. We describe a 20-year retrospective study of reported mistransfusion cases to identify temporal trends, common causes, and corrective actions taken to prevent recurrence.

Study Design and Methods: ABO-incompatible RBC transfusion-related fatalities reported to the FDA in 2000-2019 were reviewed for patient demographics, primary attributed cause, contributing factors, and corrective actions.

Results: Eighty reported deaths after ABO-incompatible RBC transfusion occurred in the 20-year period. A decrease in the number of cases after 2008 was sustained through 2019 (mean 6 cases/y, 2000-2009 vs 2 cases/y, 2010-2019). The estimated rate of reported mistransfusion fatalities was 1 per 2 million RBC units transfused in 2000-2009 and 1 per 7.14 million RBC units in 2010-2019 ($P < .0001$). Administration errors (wrong patient or wrong unit transfused) and sample collection errors (wrong blood in tube [WBIT]) significantly decreased over time but remained the most common causes. In all WBIT cases, verification of patients' ABO type with a second sample or historical type was not performed before transfusion; 16 of 19 (84%) institutions that reported corrective actions subsequently instituted this requirement. In the other categories, 22 of 58 (38%) facilities reported plans for technological process improvements, such as electronic patient identification.

Conclusions: The rate of reported fatalities from ABO-incompatible RBC transfusion has significantly decreased in the past decade. Still, about two cases are reported each year, highlighting gaps in best practices and areas for improvement.

KEYWORDS

RBC transfusion, transfusion complications–noninfectious, transfusion practices (adult)

1 | INTRODUCTION

Transfusions of ABO-incompatible red blood cells (RBCs) have long been considered preventable errors that should never occur, yet resultant acute hemolytic transfusion

Abbreviations: CAP, College of American Pathologists; CBER, Center for Biologics Evaluation and Research; FDA, US Food and Drug Administration; JC, Joint Commission; NBCUS, National Blood Collection and Utilization Survey; SHOT, Serious Hazards of Transfusion; WBIT, wrong blood in tube.

reactions continue to cause significant transfusion-related morbidity and mortality.[1] Historical benchmark data from 1976 to 1985 in the United States showed that 158 (51%) of 355 transfusion-related fatalities reported to the FDA were from acute hemolysis. Of these 158 cases, 124 (78%) were due to ABO-incompatible RBC transfusion, or about 1 to 2 per million RBCs transfused. This study identified that the nature of the error in many instances was "management system errors," evidenced by the lack of quality systems, the absence of written procedures and/or staff training for preparing and administering blood transfusions, and the lack of clear delineation of responsibilities throughout the transfusion process. In New York state between 1990 and 1999, mistransfusion accounted for 1 in every 19 000 transfused RBC units, or 1 in 14 000 transfused RBC units after adjustment for underreporting and undetectable ABO-compatible but erroneous transfusions.[2] During this period, the authors reported a frequency of fatal reactions resulting from errors in administration of 1 in 1.8 million units of RBCs transfused. As acknowledged at the time, the true incidence likely far exceeded those cases that are recognized and reported.[3]

In 1999, the Institute of Medicine's publication "To Err Is Human: Building a Safer Health System" estimated the magnitude of preventable medical errors and provided recommendations for health care quality system improvements.[4] The Joint Commission (JC), the College of American Pathologists (CAP), and AABB have focused on reducing the risk of patient misidentification and ABO-incompatible RBC transfusion. In 1999, the JC, which accredits health care organizations in the United States, published their first sentinel alert on blood transfusion errors, identifying patient identification error as a primary root cause. From 2002 to the present day, the JC has targeted the accuracy of patient identification as its number one patient safety goal for both hospital and laboratory accreditation programs.[5] More specifically with respect to transfusion practices, the JC, CAP, and AABB promulgate accreditation standards and requirements for written procedures, trained staff, and the use of two patient identifiers and two-person or electronic verification processes when collecting and labeling blood samples and issuing and administering blood components.[6,7] Since 1993, AABB has required two determinations of the patient's ABO group to reduce the risk of misidentification during pretransfusion testing. The two determinations are either from retesting the same sample or testing a second current sample by comparison with previous records. Similarly, CAP first introduced in 1996 the requirement for two separate determinations of the transfusion recipient's ABO group, which was updated in 2001 to specify verification as either retesting the same or a second sample or comparison with historical laboratory records. Notably, testing a second sample or performing a historical check not only reduces the risk of laboratory error but also identifies wrong blood in tube (WBIT) errors that would not be detected by retesting the same sample. Recently, both CAP (in 2019) and AABB (in 2016) stipulated that repeat testing of the same sample requires use of technology or methods for ensuring positive identification (eg, electronic patient identification)[8,9]

Transfusion services are required to report transfusion-related fatalities to the FDA.[10] Since 2005, FDA has provided summary information on reported cases in an annual report on their website.[11] While cases are likely underreported, and the risk underestimated, these data serve as a gauge of the magnitude of the problem and changes over time. In this study, we review all ABO-incompatible RBC transfusion-related fatalities reported to the FDA in a 20-year period (2000-2019), to determine whether the risk and attributed causes of ABO mistransfusion deaths have changed over time. While quality system deficits and manual collection errors accounted for most cases in past years, the types of errors may have changed over time with the increasing use of electronic systems and automated processes for patient identification and laboratory testing. We describe the causes identified in the reported mistransfusion fatalities and corrective actions taken to prevent their recurrence.

2 | METHODS

The transfusion service (ie, the facility that performed the compatibility tests) in the United States must report fatal complications from blood transfusion to the Center for Biologics Evaluation and Research (CBER), FDA (21 CFR 606.170).[10–13] The CBER reviews and analyzes all reported cases and releases an annual report that describes the types and numbers of transfusion-related fatalities each year.[11] The annual report combines the total number of fatalities after hemolytic transfusion reactions from major incompatibility to RBCs or minor incompatibility to plasma or platelets, in the calendar year that the case was reported.[11] We limited the current review to ABO-incompatible RBC transfusion fatalities in 2000-2019 and analyzed individual case files to provide a more detailed description of the cases, with regard to patient demographics, type and number of RBCs transfused, date of death, primary location of incident, reported causes and corrective actions. National Blood Collection and Utilization Survey (NBCUS) data were used to estimate the number of allogeneic RBC transfusions (excluding autologous and directed transfusions, and in some years pediatric-equivalent transfusions)

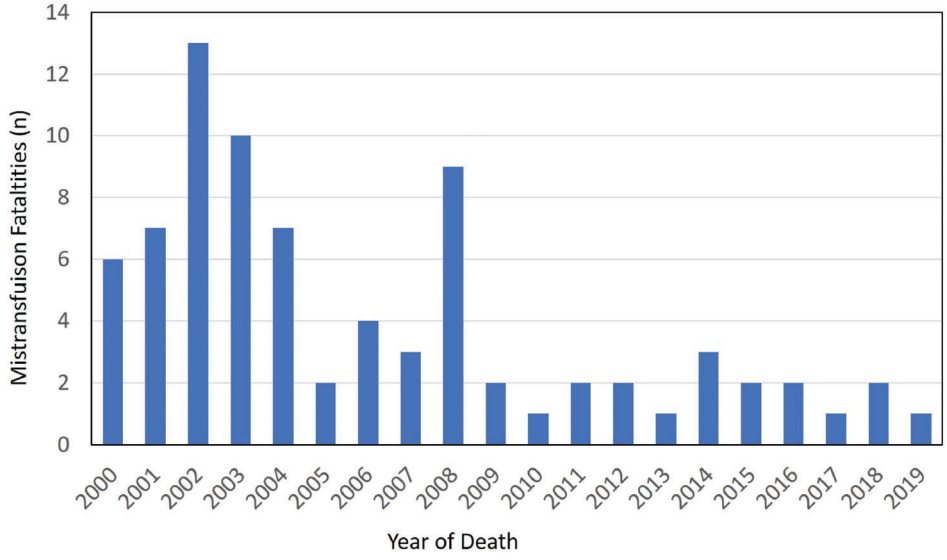
during this time period, providing an estimated denominator to calculate rates. Directed and pediatric equivalent transfusions were excluded because of the relatively small number that these categories contribute to the denominator and the variable reporting in NBCUS of pediatric transfusions in different years of the survey. Reported fatalities involving only ABO-incompatible plasma and/or platelet transfusion were excluded from the analysis. Cases were recorded in the year the death occurred rather than the year that they were reported, as in the annual reports. Reported errors were classified by primary cause into four general categories—sample collection, pretransfusion laboratory testing, issuing, and administration—and stratified by location. Descriptive statistics for patient demographics were computed with percentages, frequencies, means, medians, and ranges, as indicated. Chi-square analysis for categorical variables and two-sample Wilcoxon rank-sum (Mann-Whitney) test for comparisons of continuous variables in the two time periods were calculated using computer software (STATA15; StataCorp LLC, College Station, Texas).

This study is a public health surveillance activity conducted and authorized by a public health authority and necessary to allow the FDA to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance under 45 CFR 46.102(k) and 46.102(l)(2).

3 | RESULTS

From 2000 through 2019, the FDA received 80 fatality reports after ABO-incompatible RBC transfusion from 79 institutions. An apparent decrease in the number of

A



B

Time period	Year	RBC transfusions (number in thousands)*	Reported mistransfusion fatality rate per million RBC transfusions	Calculated average mistransfusion fatality rate per million RBC transfusions
2001-2009	2001	13,361	0.52	0.50 (1 per 2.0 million)
	2004	13,720	0.58	
	2006	13,978	0.29	
	2008	14,782	0.60	
2010-2019	2011	13,684	0.14	0.14 (1 per 7.14 million)
	2013	13,093	0.07	
	2015	11,264	0.27	
	2017	10,527	0.09	

*From National Blood Collection and Utilization Surveys (14, 15)

FIGURE 1 ABO-incompatible RBC mistransfusion fatalities reported to FDA, 2000-2019 [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 1 Patient demographics and ABO-incompatible RBC transfusions

Description		Total	2000-2009	2010-2019	*P* value
Fatalities reported to FDA,[a] n (mean cases per year, SD)		80 (4-3.4)	63 (6.3-3.59)	17 (1.7-0.67)	$P < .0001$
Patient age, mean (SD), median (range)		64.2 (17.9), 68 (21-92)	64.1 (18.0), 66.5 (21-92)	64.7 (17.7), 75 (29-82)	$P = .80$
Patient sex, n (%)	Male	43	32 (51)	11 (65)	$P = .34$
	Female	36	30 (48)	6 (35)	
Patient ABO type, n (%)	O	68	55 (87.3)	13 (76.5)	$P = .56$
	A	4	2 (3.2)	2 (11.8)	
	A2	1	1 (1.6)	0	
	B	6	4 (6.3)	2 (11.8)	
Number of ABO incompatible units transfused median (range)		1 (.16-39)	1 (.16-25)	1 (0.5-39)	$P = .72$
Interval between transfusion and death (d), median (range)		0.9 (.003-168)	1 (.003-168)	0.3 (.003-32)	$P = .06$
Patient/RBC unit ABO mismatch	O/A	54	45	9	$P = .10$
	O/B	11	7	4	
	O/AB	3	3	0	
	A/B	2	2	0	
	A/AB	2	0	2	
	A2/A1	1	1	0	
	B/A	6	4	2	
	Not available	1	1	0	
Clinical location[b]	Inpatient unit	20	19	1	$P = .03$
	Intensive care unit	12	10	2	
	Operating room	11	8	3	
	Emergency department	10	6	4	
	Trauma unit	2	2	0	
	Outpatient dialysis	2	0	2	
	Burn unit	1	1	0	
Reaction reported to blood bank, n (%)		49 (61)	38 (60)	11 (65)	$P = .74$

[a]Missing data (age and sex were not available for one patient; blood type and unit type were not available for one patient).
[b]Reported by clinical location (58 cases) of primary attributed cause leading to mistransfusion (22 cases (not shown) involved the Blood Bank/Laboratory).

mistransfusion cases reported to the FDA after 2009 was sustained through 2019 (mean, 6 cases/y in 2000-2009 vs 2 cases/y in 2010-2019) (Figure 1A). Using the NBCUS data to estimate the number of allogeneic RBC units transfused in these years, the rate of reported mistransfusion fatalities was one death per 2 million RBC units in 2000-2009 and one death per 7.14 million RBC units in 2010-2019 ($P < .0001$) (Figure 1B).[14,15]

The mean patient age was the same in both time periods (64 years; range, 21-92 years), with a slight but nonsignificant male predominance (Table 1). The median number of ABO-incompatible RBC units that were transfused was 1, ranging from less than 1 unit (0.16 unit) to 39 units (Table 1). The median interval between the transfusion and death was 0.9 days (range, 0.003-168 days). Among 79 of 80 (98.8%) patients with blood group data, 61 (77.2%) received group A RBCs, 13 (16.5%) received group B RBCs, and 5 (6.3%) received group AB RBCs ($P < .0001$). The main patient locations included the inpatient unit (20 cases; 25%), the operating room (11 cases; 13.8%), the emergency department (10 cases; 12.5%), and the intensive care unit (12 cases; 15%) (Table 1). About one-third of errors (22 cases; 27.5%) involved both the clinical service and the transfusion service/laboratory.

TABLE 2 Locations and primary cause identified in mistransfusion fatalities

Location	Type	Primary attributed cause	2000-2009 (cases, n)	2010-2019 (cases, n)	Total (cases, n)
Clinical service	Administration[a]	Wrong patient–no transfusion order	8	0	8
		Wrong unit for intended recipient	8	0	8
		Wrong unit from remote storage (OR or Emergency department refrigerator, Hemosafe)	5	2	7
		Wrong unit– 2 patients mixed up	1	3	4
	Sample collection	Wrong blood in tube	17	4	21
	Component issue[a]	Wrong label used to request/issue blood	7	3	10
Subtotal			46	12	58
Blood Bank/transfusion service/laboratory	Laboratory testing	Wrong tube tested–manual process	6	1	7
		Mislabeled samples–manual process	4	0	4
		Technical error–incorrect type (manual process)	2	2	4
		Clerical error– manual process during automated downtime	1	1	2
	Component issue[a]	Wrong unit issued from blood bank	4	1	5
Subtotal			17	5	22
Total			63	17	80

[a]In all cases, final bedside check of patient identification, RBC unit(s), and transfusion order were not performed for all RBC units.

Forty-nine of 80 (61%) cases were recognized at the time of transfusion and reported to the transfusion service/laboratory (Table 1). The remainder were discovered days or even weeks later in some cases, by subsequent ABO typing discrepancies, by recognition of hemolysis in posttransfusion specimens, when additional RBC units were requested for the patient, or on subsequent chart review.

The cases were characterized by location (clinical service or transfusion service/laboratory), according to the first reported error or primary attributed cause in the transfusion process. The majority of the errors (58 cases; 72.5%) occurred in clinical locations (Table 2). Administration errors (eg, unit transfused to wrong patient or wrong unit for intended recipient) (27 cases) accounted for about one-third of the cases in both time periods, but markedly decreased over time, with 22 cases (34.9%) in 2000-2009 and five cases (29.4%) in 2010-2019. Similarly, the total number of WBIT cases decreased in 2010-2019, but accounted for a similar proportion of errors in the two time periods, with 17 (27%) in 2000-2009, compared to four (24%) in 2010-2019 (Table 2). While WBIT errors cannot be detected by the final bedside check before transfusion, almost all cases in the other categories involved multiple errors, including a final point of failure in verifying proper patient identification against the transfusion order and blood component at the bedside before transfusion of every RBC unit.

3.1 | Cases involving the transfusion service/laboratory

Among the 22 cases involving the transfusion service/laboratory, 17 occurred in 2000-2009 compared to 5 in 2010-2019, with decreased numbers of cases in each category over time (Table 2).

The most common causes in 2000-2009 were attributed to wrong tube tested (six cases), wrong unit issued (four cases), or mislabeled samples (four cases) compared to only one case of wrong tube tested and, one case of wrong unit issued in 2010-2019 (Table 2).

Nearly all of the 22 cases identified manual process failures. This most often resulted from a failure of the laboratory technician to ensure proper sample identification prior to performing testing and to verify that the name on the specimen matched the patient's requisition. Two cases involved clerical errors as a result of manual processing when the automated blood grouping system was down. Five cases occurred as a result of issuing the wrong unit from the blood bank, most often reflecting a failure to reconcile the requisition form with the blood units and correctly document the information. In four cases, the error resulted from mislabeled samples; in some of these instances, the sample was repeatedly mislabeled by different technicians.

Technical errors in ABO typing occurred in four cases and were attributed to the following causes: (a) immediate spin was not performed as a final check of

ABO compatibility; (b) anti-A1 was not detected after massive transfusion, (c) reverse B-cell reaction was misread as the forward B typing in an icteric sample, and (d) mistyping of a group O patient as group B on a massive transfusion protocol. The fourth case has been described in detail in a recent publication.[16] Briefly, a trauma patient received a massive transfusion of more than 20 group O uncrossmatched units and was switched after pretransfusion testing was completed to group B RBC units, AB plasma, and A and B platelets. Seven group B RBC units were transfused, based on weak agglutination (1+) in forward-type B reactions, with anti-A detected but not anti-B in the reverse-type reactions, confirmed by two blood bank technologists. ABO typing on Day 4 was again determined as group B. A new crossmatch on Day 8 revealed that the patient in fact was group O in the forward type, with anti-A and weak anti-B reactions in the reverse type, and identified that the previous transfusions were ABO incompatible. The authors noted that their long-standing policy to use weak reactivity in the forward type for ABO interpretation was implemented to detect early engraftment after ABO-nonidentical bone marrow transplantation. The policy had not been associated with prior incidents but became a concern after this reported transfusion-related fatality. The authors made several changes to their massive transfusion protocol, which included obtaining the initial sample for ABO typing early in the course of treatment when the massive transfusion protocol is activated, using group O RBCs throughout the resuscitation, and requiring review by the transfusion service physician before switching massively transfused patients to type-specific RBCs.

3.2 | Receipt of multiple ABO-incompatible RBC units and interval to death

About one-half (45 patients, 56%) received 1 ABO-incompatible RBC unit or less, with as little as 0.2 units (~50 mL) in 5 cases. In 44% of cases (35 cases) the patient received more than one ABO-incompatible RBC unit (median, 2; range, 1.4-39) (Table 3). Twenty of the cases (57%) involving multiple ABO-incompatible RBC units were WBIT (11 cases) or laboratory testing (9 cases) errors, neither of which can be detected at the bedside before the transfusion. The remaining 15 cases (43%) were potentially detectable but collectively received a total of 48 ABO-incompatible RBC units, reflecting repeated failures of the final bedside check of each RBC unit before transfusion.

Despite the wide range in exposure to ABO-incompatible RBC units and the total volume received, the median time to death was not statistically different for patients who received 1 ABO-incompatible RBC unit or less, compared to those who received more than 1 unit in the two time periods (Table 3). Among the 45 patients who received 1 ABO-incompatible RBC unit or less, 27 of the 45 (60%) patients died within 1 day. There was no correlation between the number of units transfused and the interval to death (Figure 2).

3.3 | Reported corrective actions

Overall, 71 of 79 (90%) facilities reported various corrective actions after an ABO-incompatible RBC transfusion-related death. All 21 WBIT cases occurred in facilities that did not have procedures in place to require verification of ABO blood group with a second sample or historical check before transfusion. Some commented that the policy for a second sample or historical type was in place on other clinical services in the hospital system but not in the clinical area where the mistransfusion occurred (eg, operating room, emergency department). Among the 19 WBIT cases that described corrective actions, the majority (16; 84%) implemented a requirement for a second (check) sample or historical type to confirm ABO blood group. For the other categories, 52 of 58 facilities reported information about planned corrective actions, which universally included the need for staff retraining or policy revision and often both. In addition, 22 of these 52 (42%) facilities reported plans for systematic

TABLE 3 Interval between ABO-incompatible RBC transfusion and death

	2000-2009		2010-2019		
ABO-incompatible RBC unit(s) transfused	Number of patients (n)	Interval between transfusion and death (d), median (range)	Number of patients (n)	Interval between transfusion and death (d), median (range)	*P* value[a]
≤1 unit, 45 patients	33	0.92 (.003-36)	12	0.26 (.003-6)	$P = .05$
>1 unit, 35 patients	30	3 (.05-168)	5	7 (.021-32)	$P = .96$

[a]Two-sample Wilcoxon rank-sum (Mann-Whitney) test.

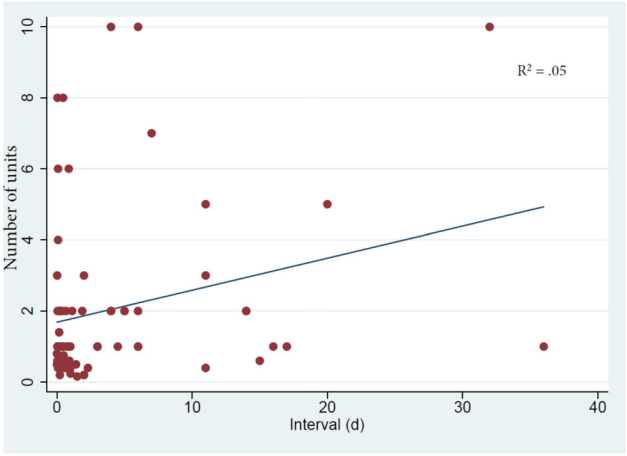


FIGURE 2 Temporal relationship between the ABO-incompatible RBC transfusions and interval to death [Color figure can be viewed at wileyonlinelibrary.com]

technological improvements, such as implementing electronic (eg, bar-coded) patient identification systems. Overall, about one-half (38/79; 48%) of the facilities reported plans for systemic improvement and effective corrective actions. Plans for corrective actions were more often reported to the FDA in later years (2010-2019) and were more likely to involve implementation of electronic patient identification systems.

4 | DISCUSSION

Based on the trend in transfusion-related fatalities reported to the FDA described herein, ABO-incompatible RBC mistransfusions have significantly decreased in the past decade, although cases still occur each year (Figure 1A). The reported rate of ABO-incompatible RBC transfusion-related deaths decreased from 1 per 2 million RBC units transfused in 2000-2009 to 1 per 7.14 million RBC units in 2010-2019 ($P < 0.0001$). On average, two deaths from ABO-incompatible RBC transfusion are reported to the FDA each year. The pronounced decrease in reported cases in clinical locations support a significant improvement in transfusion practices over the past 10 years, which likely reflects advances in patient identification processes for sample collection and unit identification. A decrease was also apparent in the number of reports attributed to errors in the transfusion service or laboratory, although the numbers were small in both time periods.

WBIT and administration errors (ie, wrong RBC unit for intended patient) persisted as the most common causes in both time periods. As in previously published reports, many cases involve multiple points of error. A relatively large percentage of cases in this series (35/80; 44%) involved transfusion of more than 1 ABO-incompatible RBC unit. In 15 of these 35 cases, additional downstream errors represented missed opportunities to detect and prevent transfusion of incompatible units at the final bedside check.

Despite transfusion of multiple ABO-incompatible RBC units in many cases, no correlation was observed between the number of units transfused and the interval between the transfusion and death (Figure 2). This is in contrast to previous reports that have suggested a dose-dependent relationship between number of ABO-incompatible RBC units received and likelihood of death.[17] Our results suggest that adequate supportive care may result in delayed recognition of acute hemolytic transfusion reactions among patients with comorbid conditions. Consistent with this observation, only 61% of the fatal cases were recognized at the time of transfusion and reported to the transfusion service. The remainder were discovered only after the transfusion event, typically when additional samples were drawn for typing or by retrospective investigation after finding discrepancies or hemolysis in posttransfusion specimens or on subsequent chart review.

Although the cases are complex, the study reveals that practice standards and system improvements that can prevent ABO mistransfusion have not been universally adopted or have not been implemented to their full capacity. In the transfusion service/laboratory, almost all reported cases implicated manual processes. Notably, two cases resulted from a manual process when an automated ABO typing procedure was not in use, during a computer downtime. These cases identify the need for having robust backup systems when the automated process is not available. Almost all the facilities that reported WBIT did not routinely perform verification of ABO blood group either by testing another sample, historical check, or verification using an electronic identification system, as currently required by CAP and AABB, but reported their intent to implement such a policy as a corrective action after the sentinel event. Corrective actions were not as completely reported for other categories of errors. Notably, only about one-half of the facilities that reported their intended corrective actions after an ABO-incompatible RBC mistransfusion death included plans for systematic technological improvements, for example, implementing bar-coded patient identification systems. Among the cases in this series, the most complete report of corrective action after a reported mistransfusion was published separately by Hensley and colleagues,[18] who provide a detailed description of implementing bedside bar-code transfusion verification for intraoperative blood transfusion. In contrast, no information about corrective

actions was available in 10% of reported fatalities in this series.

The major limitation of the current study is the underreporting of transfusion-related deaths, which likely reflects the difficulty in recognizing acute hemolytic reactions in patients with complex comorbidities and underlying illness or injuries. Reported fatalities represent only a small fraction of the mistransfusions that occur. Most ABO-incompatible RBC transfusions are not fatal but may be associated with significant complications. In our preliminary analysis of Medicare beneficiaries aged 65 and older, the risk of nonfatal ABO-incompatible RBC transfusions was 1.3 per 100 000 hospital stays with RBC-only transfusions.[19] These data suggest that the actual risk of ABO-incompatible RBC transfusion and the burden on the health care system is at least an order of magnitude higher than estimated by fatality reporting in the United States. Finally, our analysis captured only those corrective actions that facilities reported they planned to implement after the sentinel event but does not reflect any additional actions subsequently taken to prevent recurrence of mistransfusion.

Despite these limitations, the findings are comparable to those of the Serious Hazards of Transfusion (SHOT) in the United Kingdom, which noted a significant contemporary decrease in ABO-incompatible transfusions compared to the prior decade.[20] Between 2010-2019, SHOT reported two deaths after ABO-incompatible RBC transfusion in about 19.2 million RBCs transfusions, or about 1 in 9.6 million RBC transfusions.[21] SHOT first recommended in 2017 and emphasized in 2018 that all available information technology systems to support transfusion practice should be considered for implementation, and electronic blood management systems should be considered in all clinical settings where transfusion takes place.[20,22,23] They concluded, "This is no longer an innovative approach to safe transfusion practice; it is the standard that all should aim for."[20,24] In a recent editorial, Callum and colleagues[25] also declared, "It is time to solve health care's identity crisis and widely implement electronic positive patient identification." Supporting these assertions, several compelling studies from the United States, United Kingdom, and Canada have demonstrated that electronic patient identification systems and other error detection processes significantly decrease the rate of wrong blood transfusions and/or WBIT compared to manual processes.[25–31] Moreover, WBIT is more likely to occur among mislabeled samples, which emphasizes the need for laboratories to reject patient samples with even minor labeling errors to reduce the risk of ABO-incompatible RBC transfusions.[20] Finally, Mistry et al.[32] analyzed laboratory techniques reported in SHOT data from 2004 to 2016, and found that manual intervention was the cause of nearly all (93%) ABO/D typing errors; in contrast, there were no errors when full automation was used. The authors concluded that where manual testing cannot be avoided, results should be confirmed by automated techniques as soon as possible, and a backup process should be available at all times.

In conclusion, the rate of reported ABO-incompatible RBC transfusion-related fatalities in the United States has dramatically decreased in the past decade, representing a clear improvement in patient safety. However, the common causes and contributing factors in these cases largely have not changed over time, with WBIT, lack of electronic systems for patient identification, failure to perform the final bedside check for every RBC unit transfused, and manual laboratory processes implicated as causes in most cases. While the issues that contribute to error are multifactorial and complex, this report underscores that best practices, such as the use of two separate samples to verify ABO blood group, electronic patient identification systems, and automated ABO testing procedures, are not yet universal, highlighting areas for further improvement. This need was recognized by about almost all facilities that reported WBIT, and about one-third of the other facilities after the sentinel event that reported their intended corrective actions included plans to implement systematic technological improvements.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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